Submitter : Dr. Samuel Shelton **Date:** 02/20/2007

Organization : H & S Pharmacy #1

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1335-Attach-1.PDF

1335

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

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

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

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

Submitter : Mr. DAVID BONFIGLIO **Date:** 02/20/2007

Organization : BONFIGLIO DRUG

Category : Pharmacist

Issue Areas/Comments

Background

Background

I AM A PHARMACIST AND I OWN BONFIGLIO DRUG IN OAK CREEK, CO, A TOWN OF 900 PEOPLE. I SERVE THE TOWNS OF OAK CREEK, PHIPPSBURG, YAMPA, TOPONAS AND THE STAGECOACH AREA. THE POPULATION I SERVE IS APPROXIMATELY 1500. IT IS ABOUT 20 MILES FROM OAK CREEK AND 35 FROM YAMPA TO THE NEXT TOWN WITH A PHARMACY - STEAMBOAT SPRINGS. THIS IS THROUGH A WINDING CANYON AND A LONG DRIVE ESPECIALLY IN THE WINTER.
OVER 30 PERCENT OF MY BUSINESS IS COLORADO MEDICAID AND EVEN A 1% DROP IN REIMBURSEMENT WILL FORCE ME TO REVIEW WHETHER I CAN STAY IN THE PROGRAM OR NOT. MANY MEDICAID PATIENTS DON'T HAVE A JOB, HAVE YOUNG CHILDREN AND DON'T HAVE VEHICLES. MANY ARE SENIORS WHO TAKE THE BUS TO THE CLINIC IN OAK CREEK, THE SENIOR LUNCH IN OAK CREEK AND HERE TO THE PHARMACY - MOST DON'T HAVE ANY OTHER TRANSPORTATION.
I WORK 6 DAYS PER WEEK MYSELF AS THE ONLY PHARMACIST, NOT BECAUSE I LOVE TO BE HERE SO MUCH BUT BECAUSE I CAN'T AFFORD TO PAY A PHARMACIST'S SALARY TO HIRE A RELIEF PHARMACIST. I GET LETTERS FROM THE CHAINS ASKING IF I WANT TO SELL - BUT I KNOW THEY WOULD ONLY SHUT DOWN MY STORE AND GIVE ME A JOB IN ANOTHER TOWN OR CITY. THIS WOULD SERVE ME BUT NOT MY PATIENTS WHO RELY ON ME FOR SO MUCH MORE THAN JUST THEIR PRESCRIPTION IN A BOTTLE. OUR CLINIC IS OPEN 3 DAYS PER WEEK SO I ALSO FILL THE ROLE OF TRIAGE AND IF OR WHEN THEY SHOULD SEE THE DOCTOR. I HELP THEM TREAT MINOR INJURIES, COLDS AND OTHER MALADIES. I SERVED ON THE CLINIC BOARD FOR 10 YEARS AND AM PAST PRESIDENT AND CURRENT MEMBER OF OUR SOUTH ROUTT ECONOMIC DEVELOPEMENT COUNCIL AS WELL AS BEING ACTIVE IN MY CHURCH AND LOCAL SCHOOLS. I SAY THIS ONLY TO STRESS THE ROLE AN INDEPENDENT PHARMACIST PLAYS IN A SMALL TOWN. I ALSO EMPLOY 13 PEOPLE IN PART OR FULL TIME ROLES IN MY STORE.
THE GAO REPORT SHOWS A LOSS OF 21 TO 65% OFF COST FOR OUR GENERICS AND SINCE I CAN'T BUY LIKE THE CHAINS AND HAVE AN OVERHEAD COST OF APPROXIMATELY $8.50 PER PRESCRIPTION I WOULD HAVE A LOSS BIGGER THAN THAT. IF I CAN'T COVER MY COSTS OF BEING IN BUSINESS, I CAN'T STAY IN BUSINESS. PLEASE DON'T PUT ME IN A POSITION WHERE I MUST DECIDE TO DROP MEDICAID AND LOSE 30% OF MY BUSINESS OR STAY IN THE PROGRAM AND LOSE 30-40% ON EACH GENERIC PRESCRIPTION.
INDEPENDENT PHARMACY SURVIVES ON A 2-3% MARGIN (I HAVE HAD A PROFIT ONLY A FEW OF THE 11 YEARS I HAVE HAD THIS STORE) YET I READ ABOUT THE 18% PROFITS THE DRUG COMPANIES ARE MAKING AND THE DOUBLE DIGIT PROFITS THE PBMS ARE REPORTING (AND MILLION DOLLAR BONUSES) YET I DON'T SEE THEM CONTRIBUTING TO THIS DEBT REDUCTION.
THE KEY FACTORS ARE THAT MOST INDEPENDENT PHARMACIES ARE IN TOWNS WITH LESS THAN 20,000 PEOPLE (MANY LIKE MINE MUCH SMALLER), A STUDY LAST YEAR BY THE COALITION FOR COMMUNITY PHARMACY ACTION FOUND IT COSTS AN AVERAGE OF $10.50 PLUS THE COST OF THE MEDICATION TO FILL A PRESCRIPTION AND THE GAO REPORT WHICH SHOWS THE LOSS THAT PHARMACY (ESPECIALLY INDEPENDENT PHARMACY) IS BEING ASKED TO CARRY. IF YOU ADD THIS PROPOSED LOSS TO THE LOW AND SLOW REIMBURSEMENT I AM RECEIVING FROM THE MEDICARE-D PROGRAM (A 30% LOSS LAST YEAR) AND THE FACT THAT PRESCRIPTION SALES MAKE UP ABOUT 80% OF MY SALES YOU CAN SEE THAT I CAN'T TAKE MANY MORE ATTACKS AND STAY IN THIS BUSINESS. THE BOTTOM LINE IS I WOULD LIKE TO THINK THAT I DIDN'T GO TO 5 YEARS OF COLLEGE AND BUILD A BUSINESS TAKING CARE OF A LOT OF PEOPLE IN MY SMALL TOWN AREA ONLY TO BE PUT OUT OF BUSINESS BY MY GOVERNMENT. PLEASE CONTACT ME AT 970-736-2377 OR BONDRUG@CMN.NET WITH QUESTIONS.
THANK YOU FOR YOUR TIME.
DAVID R. BONFIGLIO, R.PH. PRESIDENT

Submitter : Dr. Scott Denaburg **Date:** 02/20/2007

Organization : Target Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1337-Attach-1.PDF

CMS-2238-P-1337-Attach-2.PDF

Submitter : Mrs. Debbie Garza **Date:** 02/20/2007

Organization : Director, Government and Community Relations

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1338-Attach-1.DOC

Attach # 1338

Government and Community Relations Department

February 20, 2007

VIA ELECTRONIC SUBMISSION

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

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

Dear Sir or Madam:

Walgreen Co. ("Walgreens") appreciates the opportunity to comment on Proposed Rule CMS-2238-P published in the *Federal Register* on December 22, 2006, which concerns the definition and use of "Average Manufacturers Price" ("AMP"), as well as the new federal upper limits (FUL) program for generic drugs in the Medicaid program pursuant to changes mandated by the Deficit Reduction Act of 2005 ("DRA"). Walgreens is the nation's leading community pharmacy, with more than 5,600 pharmacies in the 48 contiguous states and the Commonwealth of Puerto Rico. We employ more than 200,000 people, including more than 20,000 pharmacists, and we fill in excess of 529 million prescriptions each year. Walgreens participates in the Medicaid programs in each state in which we operate, providing critical access to pharmacy services to millions of Medicaid beneficiaries, many who live in medically underserved areas.

Walgreens is a proud member of the National Association of Chain Drug Stores ("NACDS") and we join, in their entirety and without reservation, their detailed comments submitted on this topic. We are writing separately to reiterate and amplify their comments.

We ask that CMS address the following critical issues for our industry, both through modifications to the proposed regulation, as well as through changes to the proposed timeline for the release and use of AMP data.

SUMMARY

Public Release and All Use of AMP Data Should be Delayed

CMS should not post any AMP data on a public website before CMS finalizes its regulation with a clear, validated definition of AMP that accurately reflects the prices paid to manufacturers by wholesalers for drugs sold to traditional retail pharmacies.

CMS acknowledges that present AMP data are flawed, yet CMS indicates it will publish these data on a public website this spring. Release of flawed AMP data will adversely affect community retail pharmacies if Medicaid programs and the commercial market use these data for reimbursement purposes. Because of its inherent flaws, CMS has already delayed release of this data, and we urge continued delay in the release of AMP data until a final definition of AMP has been promulgated and data collected and verified pursuant to it.

Moreover, CMS has already released existing, flawed AMP data to Medicaid programs and indicated its intent to recalculate federal upper limits ("FULs") using this data in the spring. It is imperative that CMS not use this flawed data to recalculate FULs and that CMS instruct state Medicaid programs not to use this flawed AMP data for purposes of determining pharmacy reimbursement.

AMP data should not be publicly released or used at all as a pharmacy reimbursement metric until CMS has (1) promulgated a final rule that appropriately defines AMP to reflect retail pharmacy purchasing costs and (2) collected and verified data submitted by pharmaceutical manufacturers according to that rule.

AMP Definition Should be Revised to Reflect Retail Pharmacy Purchasing Costs

CMS's proposed regulatory definition of AMP is problematic because it would result in AMP values that would not reflect the approximate prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs distributed to traditional community retail pharmacies should be included in the AMP definition.

Most troublingly, the proposed definition of AMP provides for the inclusion of PBM rebates and discounts in the calculation of AMP. Because retail pharmacies do not benefit from these rebates and discounts -- indeed such amounts are passed on to the PBM's clients, if to anyone, and in no way accrue to the benefit of retail pharmacies -- AMPs calculated with these amounts included will not approximate the drug acquisition costs of traditional retail pharmacies. Accordingly, the proposed definition of AMP should be revised to exclude PBM discounts and rebates.

The proposed rule also includes in the definition of AMP sales to mail order pharmacies, nursing home pharmacies, hospital outpatient facilities, and clinics, as well as manufacturers' coupons sales. Traditional retail pharmacies do not have access to the special prices offered to these classes of trade. Accordingly, because these are not sales within the retail class of trade, they should be excluded from the calculation of AMP.

CMS must also address how to account for the potential lag between the time the manufacturer calculates the AMP data and the time it is posted on a website or provided to states. Without an adjustment to AMP, the posted AMPs may be outdated and may not reflect the existing prices at which retail pharmacies purchase medications.

FULs Should Be Calculated on the Basis of the Weighted Average of Reported AMPs for a Particular Drug Entity

CMS's proposal to use the lowest reported AMP for a particular drug entity in setting the federal upper limit (FUL) for that drug entity is not required by the DRA. A recent report from the Government Accountability Office ("GAO") found that pharmacies would be reimbursed, on average, 36% less for generics than their acquisition costs under the AMP-based FUL system proposed by CMS. Such a reimbursement system will threaten the viability of the network of pharmacies that service Medicaid patients.

In place of the lowest reported AMP, we believe that in determining FULs CMS should use a weighted average of the 11-digit AMPs for generic products that are: (1) AB-rated in the FDA Orange Book, (2) widely and nationally available to pharmacies for purchase from the three major national wholesalers in adequate and consistent supplies, and (3) sold in package sizes of 100s (or the most commonly dispensed package size). In addition, CMS must include an appeals mechanism in the final regulation which would allow providers, manufacturers and states an opportunity to seek removal or modification of an FUL which is not consistent with rapidly-changing market conditions.

States Need to Increase Pharmacy Professional Dispensing Fees

CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset anticipated losses on generic drug reimbursement. Pharmacists are on the front line of the nation's health care delivery system, and the professional counseling services that they provide can often make the difference between a completely successful treatment and a less than optimal outcome. According, pharmacy dispensing fees should be increased to cover a pharmacy's true cost of dispensing, including these critical professional services and a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies will have reduced incentives to dispense lower-cost generic drugs.

DETAILED COMMENTS

Background

I. Calculation and Reporting of AMP

In order for AMPs properly to be used as a metric for determining retail pharmacy reimbursement they must reliably reflect pharmacy drug acquisition costs actually realized by retail pharmacies. The proposed rule fails to accomplish this goal by including in the calculation of AMP certain rebate payments, price concessions and class of trade pricing that are not

available to or realized by retail pharmacies. Prior to using AMP data as a reimbursement metric we urge CMS to correct these deficiencies.

Specifically, § 447.504(g)(6), § 447.504(g)(9) and § 447.504(g)(10) would, respectively, allow manufacturers to deduct "rebates, discounts or other price concessions to PBMs associated with the sales for drugs provided to the retail pharmacy class of trade;" "sales to mail order pharmacies;" and "rebates, discounts, or other price concessions...associated with sales of drugs provided to the retail class of trade." Stated simply and directly -- there is no basis in the statute, nor in the congressional discussion surrounding its enactment, to have manufacturers include these amounts in the calculation of AMP. Had Congress wanted to do so, it would have expressly provided for these items to be included in AMP, as it had done in establishing the Average-Selling Price-based reimbursement system for Medicare Part B drugs.

Moreover, there is a significant difference between requiring manufacturers to deduct rebates and price concessions that are realized by the retail pharmacy class of trade as compared to those that are associated with the retail class of trade. Many of the manufacturer price concessions that may be associated with the retail class of trade are not realized in any way by the retail class of trade, *i.e.*, traditional community retail pharmacies. Therefore, CMS has proposed to adopt an overly expansive definition of the retail class of trade and the amounts that should be included when calculating an AMP for the retail class of trade. Finally, because AMP is calculated based on prices paid to manufacturers by wholesalers, and none of these rebates and price reductions are part of the payments made by wholesalers to manufacturers, they cannot be included in the calculation of AMP.

a. Rebates Paid by Manufacturers to PBMs Must be Excluded from the Calculation of AMP

There is wide documentation in government agency reports (by both the Department of Health and Human Services Office of Inspector General ("OIG") and the GAO) that manufacturers have not been consistent in how they have handled PBM rebates in the calculation of AMPs since they were created as the basis for manufacturer rebates under the Omnibus Budget Reconciliation Act of 1990. According to these reports, some have included, excluded or only partially included rebates paid by them to PBMs and health plans. *See* GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States, 2005 (GAO-05-102). In response to this confusion, CMS issued a Medicaid drug rebate program labeler release in April 1997 that attempted to clarify how these PBM rebates should be handled both in the calculation of a drug's "best price" as well as it's AMP. CMS Manufacturer Labeler Release # 28, April 1997. In that release, CMS stated that: "Drug prices to PBMs have no effect on the AMP calculation unless the PBM is acting as a wholesaler."

The proposed regulation would suddenly change this policy by requiring that drug prices to PBMs, which heretofore have only been included where the PBM was acting as a wholesaler, be included in the calculation of the AMP. In addition, and most disturbing, is the proposed inclusion of "discounts, rebates or other price concessions to PBMs associated with the sales for drugs provided to the retail pharmacy class of trade." Proposed § 447.504(g)(6).

Today most prescriptions are paid for through a third party entity -- such as a PBM -- that receives rebates and other payments from pharmaceutical companies. These rebates and other payments, which include payments such as market share movement payments and formulary placement discounts, are not available to traditional retail pharmacies. These payments and discounts are either retained by the PBM or passed through, in whole or part, by the PBM to the payer -- the PBM's client. Manufacturers should not deduct these amounts when calculating AMPs because retail pharmacies do not receive these payments or discounts nor do they benefit from them in any way.

Including PBM rebates and payments unfairly lowers the AMP, making it unreflective of sales to retail pharmacies. This fact was confirmed by a recent Congressional Budget Office ("CBO") report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies." CBO Paper, Prescription Drug Pricing in the Private Sector, Congressional Budget Office, 2007 (Publication No. 2703). The report also said that "conventional retail outlets generally do not receive rebates for single source drugs." Therefore, including these rebates would lower the AMP for traditional retail pharmacies below their approximate acquisition costs. It is immaterial whether the PBM that receives the rebates passes through some or all of these rebates to the plan sponsor. These rebates ultimately do not affect the prices paid by retail pharmacies for prescription medications.

b. <u>Sales to Mail Order Pharmacies and Nursing Homes Must be Excluded from the Calculation of AMP</u>

We believe that CMS has made the correct decision in the proposed regulation to remove "sales to nursing facilities, including long term care pharmacies" from the calculation of AMP. Sales to these entities are not sales to the retail class of trade. Proposed § 447.504(h)(6). However, CMS has improvidently proposed that manufacturers should include sales of pharmaceuticals to mail order pharmacies (and sales to wholesalers that are eventually sold to mail order pharmacies) in the calculation of AMP. Proposed §§ 447.504(g)(1) & (9). Sales to and for mail order pharmacies should be excluded from the calculation of AMP for the same reasons that sales to or for nursing homes are excluded – they are not sales to the retail class of trade.

In justifying its decision to excluded nursing home sales, CMS correctly indicates that long term care pharmacies do not generally dispense prescriptions to the general public. Because their sales are limited to patients of their facilities, sales to nursing homes should be excluded from the calculation of the AMP. However, CMS concludes that it considers mail order "simply another form of how drugs enter into the retail pharmacy class of trade". This is simply wrong. The same logic used to exclude nursing home sales applies with equal force to mail order pharmacies. Mail order pharmacies are <u>not</u> generally "open to the public" like most traditional retail pharmacies. Individuals cannot "walk into" a mail order pharmacy to obtain a prescription, and there is limited ability for patients to obtain a prescription from a mail order pharmacy unless they belong to a health care plan that includes mail order as part of its benefit design. Moreover, given that there is extremely limited distribution of prescription drugs to Medicaid recipients

through the mail, it is not reasonable to include these prices, or associated rebates, in the calculation of AMP.

CMS indicates in the proposed rule that, in directing manufacturers in the calculation of AMP, it "considered limiting mail order pharmacy prices to only those prices that are offered to all pharmacies under the same terms and conditions." 71 Fed. Reg. at 77179. Through this statement, CMS explicitly recognizes that there are different prices available to different purchasers in the marketplace. And, in fact, the discounts for brand name drugs provided to mail order pharmacies generally are not available to retail pharmacies.

Indeed, CMS recognizes that retail pharmacies may be disadvantaged by inclusion of these sales in the calculation of AMP when its states that "retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for manufacturer price concessions". 71 Fed. Reg. at 77178. Thus, CMS itself makes the argument as to why sales to mail order pharmacies should be excluded from the calculation of the AMP: Inclusion of these sales and rebates -- which are not available to traditional retail pharmacies -- would result in an AMP that is not reflective of the prices paid by traditional retail pharmacies.

c. AMP Must Include Only Sales, Rebates, Discounts and Price Concessions Actually Realized by Retail Pharmacies

Since 1990, federal law has defined AMP, with respect to a covered outpatient drug, as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1). A change made by DRA, requires manufacturers to calculate AMP without regard to customary prompt pay discounts extended to wholesalers beginning on January 1, 2007. The proposed rule fails properly to implement each of these requirements. Specifically, it (1) fails properly to define the "retail class of trade," (2) fails properly to define sales "to" the retail class of trade, and (3) fails properly to define amounts paid by "wholesalers".

i. Proposed Rule Fails Properly to Define Retail Class of Trade

In proposed § 447.504(e), CMS attempts to define the retail class of trade. In the proposed regulation, CMS has adopted an overly expansive definition of "retail class of trade". The definition proposes to include "any outlet that purchases or arranges for the purchase of drugs from a manufacturer, wholesalers, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public". Overall, the proposed regulatory definition of AMP does not achieve the goal of giving Medicaid and other payers a benchmark that accurately reflects the "true market price for prescription drugs" paid for by retail pharmacies.

CMS itself indicates that "while there is no requirement that States use AMPs to set payment amounts, we believe that Congress intended that States have drug pricing data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices to the retail pharmacy class of trade". 71 Fed. Reg. 77178 (emphasis added). State Medicaid programs pay traditional retail pharmacies for the overwhelming majority of drugs provided to Medicaid recipients. Therefore, it stands to reason that providing states with

"drug pricing data based on actual prices" would logically require AMPs based on prices paid by traditional retail pharmacies.

With respect to the retail class of trade, only manufacturers' sales to wholesalers for products that are ultimately sold to traditional community retail pharmacies – traditional chain pharmacies, independent pharmacies, mass merchandise pharmacies, and supermarket pharmacies – should be included in the calculation of AMP. These are the only entities that should be considered to be the "retail class of trade".

This approach would be consistent with congressional intent when AMP was developed in the Omnibus Budget Reconciliation Act (OBRA) 90. It would also be consistent with the intent of DRA to make AMP an approximation of the prices that retail pharmacies pay for medications so that it could be used as another potential reimbursement benchmark. The pharmaceutical market has changed significantly since 1990, but the fact still remains that AMP was created to approximate the revenues received by manufacturers for drugs dispensed to Medicaid recipients so that a basis could be established for the calculation of rebates. Given that almost all fee-for-service Medicaid prescriptions are dispensed by retail pharmacies, it makes sense that the AMP reflect the revenues received by manufacturers from wholesalers for drugs sold to retail pharmacies.

CMS's definition of retail pharmacy in this proposed regulation is inconsistent with that used in the Medicare Part D final rule. In the final rule implementing the Medicare Part D prescription drug benefit program, the agency defines "retail pharmacy" as "any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy". 42 CFR § 423.100. Thus, it would be consistent with CMS's current Part D definition of "retail pharmacy" for the agency to indicate that only sales to true retail pharmacies represent the "retail class of trade" for the purpose of calculating the AMP.

Moreover, as early as 1997, in studies of drug acquisition costs the Department of Health and Human Services—Office of Inspector General ("OIG") considered the retail pharmacy class of trade as only independent and chain pharmacies that sold drugs directly to the public. *See* OIG, Medicaid Pharmacy: Actual Acquisition Cost of Generic Prescription Drug Products, 1997 (A-06-97-00011); OIG, Medicaid Pharmacy: Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs, 1997 (A-06-97-00030). More recently, the OIG has recommended that CMS ask the manufacturer to exclude from the calculation of AMP transactions that the OIG determined were to non-retail entities such as mail order pharmacies, nursing home pharmacies, independent practice associations, and clinics. *See* Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States; February 2005. It is clear that the OIG has recognized that the definition of retail class of trade should not be as expansive as recommended by CMS.

ii. Proposed Rule Fails Properly to Define Sales "To" the Retail Class of Trade

Sales to Other Outpatient Channels. Sales to hospitals and outpatient clinics should be omitted from the calculation of AMP because these entities do not fall within the definition of a traditional retail pharmacy. Direct sales to patients through entities such as specialty pharmacies should also not be included in AMP because the entities that arrange for these sales do not conform to a traditional definition of wholesaler. Only sales to wholesalers for drugs distributed to traditional retail pharmacies can be included in the definition.

Patient Assistance Programs. The proposed regulation would include in the AMP "manufacturer coupons redeemed by any entity other than the consumer that are associated with sales of drugs provided to the retail class of trade." These coupons might refer to manufacturer promotional programs where the manufacturer provides a certain discount off the price of the medication to a patient. If the coupon is used by the patient but redeemed by the pharmacy, CMS would appear to require manufacturers to include those sales in AMP.

Similarly, there are many patient assistance programs where the pharmacy fills a prescription based on a coupon that the manufacturer provides to the physician, where the patient redeems these coupons at the pharmacy. The manufacturer reimburses the pharmacy for the drug that was dispensed, so in theory the manufacturer receives no revenue from the sales of those drugs. Deducting these sales from the AMP (essentially recording a $0 sales for these drugs), but including the units sold in the AMP, would further lower the per-unit amount received by the manufacturer.

However including these sales has nothing to do with the price paid by the wholesaler or the pharmacy, and would inappropriately lower the AMP. For this reason, drugs provided to patients through manufacturer assistance programs should not be included in the AMP. These items cannot by law be included in the AMP because they do not reflect prices paid by wholesalers to manufacturers for drugs distributed to the retail class of trade.

Medicare and Related Programs. Proposed § 447.504(g)(12) would require manufacturers to include sales and associated rebates, discounts and other price concessions under the Medicare Part D, Medicare Advantage Prescription Drug Program, SCHIP program, SPAP programs and Medicaid programs, other then rebates provided under Section 1927. Manufacturers do not sell drugs to these programs directly. They sell drugs to wholesalers who sell to retail pharmacies that dispense these drugs to enrollees of these programs. Retail pharmacies are then paid by these entities for the drugs they dispense.

Thus, manufacturers' sales of drugs to wholesalers that are sold to retail pharmacies would already include drugs that are dispensed to enrollees of these programs. However, including the rebates and discounts manufacturers provide to these programs would be inappropriate because retail pharmacies do not benefit from these discounts and rebates. Moreover, there are several different types of MA-PD programs including staff model HMOs and regional PPOs. Including sales of drugs to HMOs is explicitly proposed to be excluded from the calculation of AMP under proposed § 447.504(h)(5).

iii. Proposed Rule Fails Properly to Define Wholesaler

Proposed § 447.504(f) attempts to define wholesaler. Wholesaler is defined as "any entity (including a pharmacy, chain of pharmacies, or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug". The proposed definition of wholesaler is overly broad and inconsistent with other Federal and state statutes that define wholesalers.

We note initially that pharmacies, chains of pharmacies and PBMs are inappropriately included in the definition of wholesaler. Pharmacies -- both chains and independents -- are licensed by states as retail pharmacies, not as wholesalers. And PBMs, if they are licensed at all, are regulated by state insurance departments. Drug "wholesaler" does exist as a state licensure category, but it simply does not, and should not, apply to pharmacies and PBMs as those entities do not carry out the functions of wholesalers.

For example, according to the National Association of Boards of Pharmacy ("NABP"), "Wholesale Distribution":

" means the Distribution of Prescription Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer of Prescription Drugs by a Pharmacy to another Pharmacy if the value of the goods transferred exceeds five percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12)-month period. "

NABP goes on to say that "Wholesale Distribution" does not include:

- The sale, purchase, or trade of a Prescription Drug or Device, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Prescription Drug or Device pursuant to a Prescription;
- The sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device for Emergency Medical Reasons;
- Intracompany Transactions, unless in violation of own use provisions;
- The sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device among hospitals, Chain Pharmacy Warehouses, Pharmacies, or other health care entities that are under common control;
- The sale, purchase, or trade of a Prescription Drug or Device or the offer to sell, purchase, or trade a Prescription Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Prescription Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;
- The transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement;
- The sale, purchase, or trade of blood and blood components intended for transfusion;

- The return of recalled, expired, damaged, or otherwise non-salable Prescription Drugs, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations; or
- The sale, transfer, merger, or consolidation of all or part of the business of a retail Pharmacy or Pharmacies from or with another retail Pharmacy or Pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board's regulations.

Based on this NABP definition, it is clear that wholesale services are distinct from any services offered by retail pharmacies or PBMs. Accordingly, those entities should be excluded from the definition of "wholesaler" in the final rule.

Indeed, it is especially clear that PBMs do not perform any wholesaling functions. In fact, most PBMs are not entities that handle drugs in any way -- they are administrative service organizations that contract with health plans and other entities to provide prescription drug benefits. PBMs that own mail order operations may obtain their drugs from wholesalers or may obtain them directly from manufacturers, but they do not perform traditional wholesaling functions in either case. Thus, PBMs should be excluded from the definition of "wholesaler."

We urge CMS to adopt an appropriately limited and realistic definition of pharmaceutical wholesaler that is more consistent with the intent of the law by drawing on existing Federal and state definitions of wholesaler:

- The Federal Food, Drug and Cosmetic Act defines wholesale distributor as any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.
- Under the PDMA regulations, wholesale distributor means any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.[1]

To the extent that chain pharmacy distribution centers are licensed as wholesalers in the states in which they are located, such locations may appropriately be included in the definition of "wholesaler". *See* Note 1. Chain pharmacy distribution centers typically are eligible for the same customary prompt payment discounts as traditional pharmaceutical wholesalers. We urge CMS to clarify that customary prompt payment discounts that apply to sales to chain pharmacy distribution centers be excluded from the definition of AMP, consistent with the statutory requirement that all prompt pay discounts are excluded from such calculation.

[1] We do not object that warehousing pharmacy chains, mass merchants and supermarkets be treated as wholesalers only with respect to, and to the extent of, direct sales of drugs to specific locations owned by such entities that are licensed as wholesalers. We do object, however, to the inclusion of individual pharmacies of any sort within the definition of "wholesaler."

d. Other Issues Concerning Calculation of AMP.

i. AMP Data Should be Smoothed

CMS should require manufacturers to "smooth" any discounts or rebates that are passed through to retail pharmacies over a rolling 12-month period. This will help reduce the potential for any significant fluctuations in AMP from quarterly and monthly calculations, and maintain some consistency in reimbursement levels. Such a process was developed by CMS for manufacturer's calculation of the Average Selling Price ("ASP"), which is used as the basis for Medicare Part B drug reimbursement. Without such smoothing, it is very possible that upper limits for generics could be based on AMPs that simply are not reflective of the current market prices for drugs, further reducing generic dispensing incentives.

A recent GAO report confirmed that AMPs for generic drugs can fluctuate widely from quarter to quarter. GAO, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, 2006 (GAO-07-239R). The study calls into question the credibility and reliability of AMP as a benchmark for generic reimbursement. These conclusions are based on the fact that GAO found that 66 of the 77 drugs examined (almost 85%) had significant variation in their lowest AMP between the first and second quarters of 2006. For example, 30 of the 77 drugs -- or almost 40% of the drugs -- had a decrease in their lowest AMP, averaging 33%. Fluctuations in AMP are concerning to pharmacies because their reimbursement would similarly fluctuate, which may not reflect similar variation in their own acquisition costs.

In the proposed rule, CMS is allowing manufacturers to "estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period". 71 Fed. Reg. at 77186. We believe that a much better process would be to require manufacturers to calculate the impact of these discounts based on a rolling 12-month average, rather than allowing manufacturers to simply estimate what these discounts might be in order to make its monthly AMP calculation. The process described in the regulation seems arbitrary as compared to the smoothing process used by manufacturers to determine the impact of their discounts when calculating ASP.

ii. Clarify Terms Relative to Sales, Rebates Discounts and Other Price Concessions Excluded from the Calculation of the AMP

Bona Fide Service Fees: We strongly support the proposal that bona fide service fees should be excluded from the calculation of AMP, especially where those fees are not ultimately passed through to the product's ultimate purchaser. A bona fide service fee pays for a bona fide service, so it does not reduce its cost of purchasing the drug. Accordingly, they are appropriately excluded from the calculation of AMP.

We do not support any attempt to list specific bona fide service fees in the final regulation. This will allow for future flexibility and innovations to occur in a highly competitive marketplace. Manufacturers rely on wholesalers and others to perform various functions to allow

their products to come to market in a safe and effective manner. A significant number of new biological products are likely to come to market over the next few years. For that reason, it is unclear as to what types of new services will be needed to be performed by wholesalers and chain pharmacy warehouses on behalf of manufacturers to assure that their products get to the ultimate purchaser for dispensing or administration to the ultimate user.

Having said this, we believe that the preamble to the final rule should provide examples of the types of bona fide service fee payments that would be acceptable for exclusion from the AMP calculation at this time. For example, as example of bona fide service fees, payments made by manufacturers to entities such as wholesalers and pharmacies acting as wholesalers for inventory management agreements or distribution service agreements should not be deducted from a manufacturer's sales when calculating AMP. These payments do not lower the cost of purchasing prescription drugs. Moreover, not all purchasers are able to participate in these agreements, so deducting them when calculating ASP would be unfair to some smaller purchasers.

In addition, pharmacies sometimes receive payments from manufacturers for performing certain patient care programs, such as patient education and compliance and persistency programs. These payments should be omitted from the AMP calculation because they do not reflect prices paid by wholesalers for drug products. These services provide valuable benefits to patients and the health care system because they improve patients' understanding of their medications and enhance patient compliance. They do not reduce the retail pharmacy's cost of purchasing the drugs.

If these payments are included in AMP, pharmacies would not have incentives to conduct these programs because it would reduce the value of the AMP, thus potentially reducing reimbursement. This could make it appear that the pharmacy's acquisition cost for the drug is lower than it actually is. Moreover, since not all pharmacies participate in these programs, it would be unfair to include these payments in the AMP.

Definition of Return Goods. Proposed § 447.504(h)(13) would allow manufacturers to omit from the AMP "returned goods when returned in good faith." Although we applaud CMS's willingness to exclude returned goods from the calculation of AMP when returned in good faith, the additional condition that the return must be made "pursuant to manufacturer policies" does not take into consideration that negotiated return goods policies exist between manufacturers and retail pharmacies.

We urge that the return goods exclusion be interpreted in such as manner as to exclude from the AMP calculation amounts based on "a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, which is designed to reimburse pharmacies for the replacement cost of product as well as the associated return related expenses and not designed to manipulate or artificially inflate or deflate the AMP".

These negotiated return goods policies take into consideration the unique burdens which retail pharmacies must absorb in order to effectuate the efficient return of expired pharmaceutical

products to manufacturers. By mandating that only returns made pursuant to manufacturers' policies be excluded from the calculation of AMP, CMS is voiding by default these negotiated return goods policies (which were negotiated in good faith between manufacturers and retailers) and could be forcing retailers to accept manufacturers' policies and their inherent deficiencies.

Such action ignores the fact that retailers absorb considerable cost through replacement value of returns, inventory carrying cost, reverse logistics cost, and administrative expense. In order to remedy this imbalance, returned goods made in good faith and pursuant to a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, must also be excluded from the calculation of AMP.

Definition of Manufacturer: We recommend that the definition of manufacturer, found at proposed § 447.502, be narrowed such that entities that repackage drugs simply for distribution to retail pharmacies – also known as retail pharmacy service repackagers – not be considered manufacturers. These entities should not be responsible for signing rebate agreements with the Secretary of HHS, or paying the rebates to Medicaid because these repackagers simply perform a function for thousands of retail pharmacies, *i.e.* preparing dispensing quantities in a highly efficient manner, that would otherwise have to be performed individually by retail pharmacies.

Requiring that these entities act like manufacturers, obtain NDC numbers, and sign rebate agreements would likely result in their elimination. That is because these repackagers are low-margin businesses, who could not afford to pay the rebates. Thus, the proposed definition of manufacturer should be revised to reflect an exemption for "retail pharmacy service repackagers" who purchase drugs from the manufacturer solely for the purpose of repackaging in unit of use quantities for dispensing by community retail pharmacies.

iii. Prohibit Restatements of Monthly AMP

The proposed rule at § 447.510(d) implements DRA requirements relating to new monthly reporting of AMP by manufacturers. Specifically, manufacturers must report AMP not later than 30 days after each month, including an estimate of rebates or other price concessions that should be included in that month's AMP calculation. In calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary. We support the prohibition on the ability of manufacturers to restate monthly AMP data, but are concerned that incorrect estimates of potential liabilities, *e.g.*, chargebacks, rebates, could inappropriately reduce AMP.

Under proposed § 447.510(b), "a manufacturer must report to CMS revisions to AMP... for a period not to exceed 12 quarters from the quarter in which the data were due." We understand that the regulation would continue to require that manufacturers calculate AMPs on a quarterly basis for rebate purposes, and that these retroactive adjustments only apply to quarterly AMPs reported for rebate purposes, not monthly AMPs. Monthly AMPs will be used for reimbursement purposes.

We are concerned about whether a manufacturer's restatement of AMP could affect the reimbursement amounts already paid to pharmacies by Medicaid. If an AMP value is

recalculated by a manufacturer after the time that it is reported to the states by CMS, these restatements should not be used as the basis for reducing the reimbursements already paid. Restating AMPs could cause significant disruption to pharmacies, as recoupment activities are generally extremely time consuming, labor intensive, and frankly unfair. We believe that CMS should only allow restatements for quarterly-reported AMPs rather than monthly-reported AMPs. This appears to be the case, given that the proposed rule at § 447.510(d)(3) indicates that "in calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary". We request explicit clarification of this point in the final rule.

We are concerned that proposed § 447.510(d)(2) would allow manufacturers, when calculating monthly AMPs, to "estimate the impact of its end of quarter discounts and allocate these discounts in the monthly AMPs reported to CMS". This seems like an arbitrary way for manufacturers to calculate its monthly AMPs, and could be subject to manipulation. Manufacturers have a vested interested in maintaining low AMPs, while retail pharmacies want these AMPs to approximate pharmacy acquisition costs.

Moreover, this approach would not appear to be as auditable as a process that would require that the manufacturers smooth their data in a 12-month rolling average of all discounts and rebates given. This approach is similar to that used for Medicare Part B ASP calculation, although it is done on a quarterly basis for ASP. Nevertheless, the proposed rule seems to develop an arbitrary manner for manufacturers to determine the amount of rebates and discounts that should be deducted from their monthly AMPs, given that there exist other more credible and auditable approaches that would result in potentially more accurate AMPs.

iv. Adjust AMPs to Reflect Lag in Data Reported

We are concerned that, even though AMPs will be reported monthly by manufacturers, the AMPs will still be inaccurate compared to current retail pharmacy purchasing costs because of the reporting delay. Manufacturers have 30 days after the end of each month to report their AMPs. Currently, changes in AWP and WAC -- the existing reimbursement benchmarks -- are passed through from the manufacturer to the ultimate payer within 24 hours, as a result of electronic feeds that re-adjust all pricing when a manufacturer price increase occurs. This assures that pharmacies are being paid consistent with their current purchasing costs for medications.

Under the proposed rule, the monthly AMP reported to CMS is already 30 days old, and this AMP must then still be reported by CMS to States and posted on a public web site. Thus, by the time AMP is posted publicly and available to be used for reimbursement purposes, it will be outdated by at least 60 days. This is of particular concern when manufacturer price changes are announced and implemented immediately. There may be various ways to try to mitigate this impact, such as building in a cushion for price increases and inflation generally, since the impact on a drug-by-drug basis could be significant.

We are concerned that this timing issue has not yet been addressed or even sufficiently recognized and appreciated, and believe that CMS should address it directly and in detail before states and others are encouraged to use AMP as a reimbursement benchmark. One way to do this

is to compare the AMPs for brand name drugs to the WACs, given that this published benchmark does approximate retail pharmacy acquisition costs for brand name drugs.

This was recently confirmed by a CBO study that said "...for single source brand name drugs, WAC approximates what retail pharmacies pay wholesalers." CMS should not publish any AMPs that do not approximate the WAC for a brand name drug.

v. Clarify that Sales to Puerto Rico are Excluded from AMP

Required pharmaceutical pricing under certain public health programs within the Commonwealth of Puerto Rico creates a form of price control that results in certain pharmaceutical sales significantly below market prices obtained in the 50 states. Including sales within Puerto Rico would, as a result, deflate AMP so that it would not accurately effect acquisition costs for retail pharmacies serving the various state Medicaid programs. We request the CMS clarify that sales within Puerto Rico are excluded from the calculation of AMP.

vi. Authorized Generic Drugs

Proposed § 447.506 describes new DRA requirements relating to authorized generics. Specifically, proposed § 447.506(b) would require a manufacturer holding title to the original NDA of the authorized generic to include the direct and indirect sales of this drug in its AMP. The inclusion of the AMP of the authorized generic in the calculation of the originator manufacturer's AMP may be required under DRA. However, manufacturers should be required to report separate AMPs for the originator product and the authorized generic version, and these are the AMPs that should be posted on the public website.

If the AMP for the originator brand name product and authorized generic are averaged together, the AMP value for the originator brand product may be lower than the pharmacy's acquisition cost for the product. While CMS may allow the manufacturer of the originator drug to pay its rebate based on the blended AMP, it is not fair to use this blended AMP to potentially underpay pharmacies for the dispensing of the originator drug when prescribed by the physician.

II. Release and Use of AMP Data

a. Continue to Delay Public Release of the AMP Data

The preamble to the proposed regulation indicates that CMS will release AMP data sometime this spring. CMS should not post any AMP data on a public website until such time as a final AMP definition reflects the approximate prices paid to manufacturers by wholesalers for drugs sold to traditional retail pharmacies, and that these prices have been validated to be accurate. The release and use of flawed AMP data will have a negative impact on patient access, if the resulting reimbursement rates are so inadequate that pharmacies simply may not be able to afford participation in Medicaid or other programs. It is in the interests of all relevant parties – patients, payers and providers – to postpone use and disclosure of AMPs until such time as CMS finalizes a regulatory definition of AMPs, and that definition approximate retail pharmacies purchasing costs.

Previously, CMS prudently recognized that AMPs should not be disclosed until they are properly defined. In announcing that CMS would postpone the AMP website last May, CMS Administrator McClellan stated that "CMS will not publicly release the current AMP figures. They just aren't the right numbers to use." The Administrator added that: "Instead, we are focusing our efforts on developing a proposed regulation that will assure an accurate and effective AMP calculation ahead of implementation of the drug payment reforms." Remarks of Mark B. McClellan, NCPA 38th Legislation and Government Conference (May 22, 2006)(emphasis added). CMS should not now reverse course and use AMPs before they are properly defined and determined to be accurate.

The AMP data that CMS would propose to release this spring are no better than the AMP data that CMS refused to release last year. While DRA made some modest changes to the calculation of the AMP, there would still be wide-ranging documented inconsistencies in the data which would render them useless to states and potentially damaging to retail pharmacies. For example, the OIG has repeatedly concluded that AMPs, as currently calculated, are flawed. GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid To States, 2005 (GAO-05-102) (reviewing several OIG reports on the limitations of current AMP).

The OIG recently reported to CMS that "existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent". The OIG added that "because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors". OIG, Determining Average Manufacturer Prices For Prescription Drugs Under The Deficit Reduction Act of 2005, 2006 (A-06-06-00063). We concur with the OIG's findings.

CMS should not underestimate the impact that faulty AMP data could have on the generic marketplace and the pharmaceutical marketplace in general. FULs act as a price control on generics. Given that dollar margins on generics are slim, inappropriately low FULs may force generic manufacturers to exit the market, resulting in less competition and ultimately higher prices. Such an outcome would have dramatic consequences for the entire marketplace. Disclosing current AMPs could also create confusion with respect to the negotiated prices that Part D plans publish on the CMS website, as well as the prices that cash-paying consumers pay for drugs.

b. Release Only Weighted Average AMPs for Generic Drugs

With respect to generic drugs, CMS should only release, both on the public website and to states, an AMP value for a particular dosage form and strength of a generic drug that represents the weighted average of all the manufacturers' 100-count retail package sizes of that particular dosage form and strength (or the size that is most commonly dispensed by retail pharmacies). This would eliminate the need to report potentially dozens of AMP values for the same dosage form and strength of a particular generic drug. Publication of all these data could

create confusion in the market and lead states and others to set reimbursement rates that would not be reflective of widely-available market prices. Reporting this "average" AMP number -- rather than individual AMP numbers -- would also limit the extent to which manufacturers' individual proprietary pricing information is introduced into the marketplace, which could limit competition and reduce incentives for pharmacies to negotiate for lower generic prices.

c. Prohibit Use of AMP as a Pharmacy Reimbursement Metric Unit Until Final Rule Defining Calculation of AMP is Promulgated and Verified

We believe that any use of AMP for purposes of pharmacy reimbursement, including, but not limited to, the calculation of FULs, be suspended until Congress is given the chance to revisit the use of AMP as a benchmark to set these FULs. Suspension of the FULs would be consistent with a "Dear Colleague" letter that then House Speaker Dennis Hastert sent to Members of the House in February 2006. In that letter, he indicates that a DRA technical corrections bill would include a provision that would "permit the Secretary of HHS to delay the implementation of the new payment rates if the Secretary determines, based on information in the new GAO report, that the new payment rates do not reflect pharmacy acquisition costs". And, in fact, as discussed in Section III, that GAO report found that for a select market basket of high expenditure, high volume multiple source drugs, using 250% of the lowest AMP to set the upper limits would significantly underpay pharmacies.

In no event, however, should AMP data be used as a pharmacy reimbursement metric until a final rule defining the calculation of AMP that reflects the drug acquisition costs of retail pharmacies has been promulgated and verified.

d. Only Publish Last Month's Data for the Quarter on Public Website

In the preamble to the proposed regulation, CMS indicates that it will publish both monthly and quarterly AMP data on the public website because "the statute does not specify that this exception applies only to monthly AMP; therefore we also propose to make the quarterly AMP publicly available." CMS goes on to say further that "we note that the quarterly AMP data would not necessarily be identical to the monthly AMP data due to the differences in AMP from one timeframe to the next." 71 Fed. Reg. 77186.

Publishing both the monthly AMP data and the quarterly AMP data will add more confusion to what is undoubtedly already going to be a confusing situation. The DRA requires that CMS update the public website on a quarterly basis. The final rule must clarify the following questions:

- Does CMS intend to publish on the website the AMP values for the last month of the quarter or each month of the quarter that just ended?
- Does CMS intend to publish each monthly AMP value for a quarter as well as the quarterly AMP, or just the last monthly AMP for the quarter and the quarterly AMP?

- The quarterly AMP is likely to be lower than the monthly AMP, so how will CMS (and providers) explain to the public why these AMP values differ?

The most direct way to deal with each of these questions would seem to us to provide that reporting the last month's AMP data for the quarter is sufficient.

Finally, CMS must include special disclaimers and instructions on this website so that individuals viewing this website clearly know how to interpret these data. We believe that release of inaccurate AMP data or AMP data that do not reflect retail pharmacy purchasing costs could cause irreparable harm to community retail pharmacies.

III. Calculation of FULs Using AMP

Proposed § 447.514(b) would specify how CMS would set the FULs for multiple source drugs. The FULs are proposed to be set by applying for each drug entity 250% of the average manufacturers' price...for the least costly therapeutic agent." However, DRA does not specify that the FUL must be set at 250% of the lowest AMP, as the rule would propose. DRA merely changes a section of the current regulation -- found at section 42 C.F.R. § 447.332(b) – by stating that in that regulation "250 % of the average manufacturers price (as computed without regard to customary prompt pay discounts extended to wholesalers)" shall be substituted for "150 % of the published price."

Because Congress did not expressly state that the FUL had to be set based on the lowest AMP, we encourage CMS to base the FUL on 250% of the weighted average 11-digit AMPs for all the 100 package sizes (or most commonly dispensed package size by retail pharmacies) of all the nationally and widely available therapeutically equivalent products, weighted by sales.

This is particularly important given that a recent GAO report found that using the lowest AMP would underpay pharmacies on average for generic drugs by 36%. See GAO, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, 2006 (GAO-07-239R). Even when GAO examined AMP-based FUL rates for the lowest AMP which had the highest value among several quarters of AMP data, it found that reimbursement rates were lower than pharmacy acquisition costs. This argues for an approach that would use, at a minimum, 250% of the weighted average AMPs (based on 11-digit NDCs) for the 100 package sizes or the package sizes most frequently dispensed by community retail pharmacies.

In fact, that GAO report found that for a select market basket of high expenditure, high volume multiple source drugs, using 250% of the lowest AMP to set the upper limits would significantly underpay pharmacies. Under this new formula, the GAO report found that retail pharmacies will be reimbursed on average 36% lower than their costs to purchase these generic medications. This analysis provides credible, independent evidence that DRA changes to pharmacy reimbursement will be inadequate to cover the pharmacy's costs of purchasing generic medications. The GAO study, which compared the new AMP-based FULs for 77 generic drugs compared to retail pharmacies' average acquisition costs for these drugs during the first quarter

of 2006, found:

- Pharmacies acquisition costs for 59 of the 77 (76%) generic drugs in study were higher as compared to the new FULs.
- For the 26 of the 27 high expenditure Medicaid generic drugs studied, the FULs were on average 65% lower than the average retail pharmacy's acquisition costs.
- For the 17 of the 27 drugs that are frequently used Medicaid generic drugs, the FULs were on average 15% lower than retail pharmacies' acquisition costs.
- For the 16 of the 23 drugs that were both high expenditure and frequently used, the FULs were on average 28% lower than the average pharmacy's acquisition costs. For 11 of these drugs, the FULs were below the lowest acquisition cost available to retail pharmacies.

Another report to the Minnesota Medicaid program found that, under the DRA's new definition of multiple source drug, the number of generic drugs with FULs will increase from about 500 to 3,000 products. In addition, the DRA will reduce payment for generics by approximately 35 % in 2007, 51% in 2008 and 67% less in 2009 to 2011. *See* Implementation of Pharmacy Payment Reform in the Minnesota Medicaid Program, January 15, 2007, prepared by the University of Minnesota PRIME Institute.

Generic drug dispensing by pharmacies is helping to reduce the rate of growth of Medicaid drug spending. It makes no sense to underpay pharmacies for dispensing generic drugs – essentially forcing them to dispense these prescriptions at significantly reduced margins – when multiple source drugs are helping to keep Medicaid drug spending growth in check.

a. Identification of Drug Entities Subject to a FUL

Proposed § 447.514(a) would describe the criteria by which CMS would determine whether a multiple source drug product must have a FUL. The DRA did change the definition of multiple source drug from a covered outpatient drug for which there is at least two other drug products that are AB rated in the Orange Book to a covered outpatient drug for which there is at least one other drug product that is AB rated in the Orange Book. In this regard, CMS proposes that two criteria have to be met before a FUL can be established. First, at least two or more AB rated products have to be listed in the Orange Book. Second, at least two suppliers list the drug in the nationally-available pricing compendia.

If a particular product is on the market and is available from two different brand name manufacturers under two different trade names, it may not necessarily be the case that these products are AB rated to each other. Generic manufacturers may conduct bioequivalence studies using one or the other branded product as the reference product. In these cases, CMS cannot establish a FUL for all the drugs in these categories by considering all these drugs bioequivalent to each other. It should establish subcategories of these products according to the products that are determined to be bioequivalent to each other, and then apply the criteria above to determine whether a FUL should be set.

b. Identification of AMP to be Used to Determine FUL

As previously discussed, we strongly urge CMS, for generic products, to publish only the weighted average of AMPs for individual drug entities and use such weighted averages in calculating FULs for individual drug entities. However, if CMS does not use a weighted average of AMPs to calculate the FUL, we urge that the agency publish in its listing of drugs subject to a FUL, the identity of the manufacturer whose product was used to set the FUL. This would be known as the reference product. Publication of the reference product would provide an important "check and balance" in the setting of the FULs, and help assure the integrity of the process used to set the FULs. Identifying the reference product would help pharmacies and generic manufacturers identify for CMS cases in which the reference product used to set the FUL may not be appropriate because it is in short supply or is no longer being produced and distributed.

c. Use 11-Digit NDC Rather than 9-Digit NDC

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit NDC should be used, but then rejects its own arguments by saying that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." As CMS knows, there are many items that Congress fails to specify in passing legislation, leaving the particulars to the implementing agency to develop the best possible approach. There is no evidence that Congress did not intend that the AMPs be calculated at the 11-digit level for generic drugs in order to determine the FULs.[2]

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, not the 9-digit weighted average AMP for the product. FULs are being set for generic drugs dispensed by retail pharmacies. Thus, 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. There is no legislative history to suggest that Congress intended to change this methodology in the existing regulation.

In fact, had Congress intended to change this, it would have required an amendment to the existing regulation through statute as it did to change the basis on which the FUL is calculated. Including the prices paid by other purchasers in a weighted average AMP, some of

[2] Indeed, OBRA 90, which originally established AMPs, did not specify what level NDC was to be used in calculating AMPs. 42 U.S.C. § 1396r-8(b)(3). Thus, it is a bootstrap argument, at best, to suggest that Congress's failure to specify use of the 11-digit NDC in the DRA is evidence of its intent to retain the current practice. Considered in the light of the fact that under the DRA AMPs would be used for both rebate and reimbursement calculation, it is reasonable to expect that Congress intended that the AMP calculation be adjusted so that the appropriate NDC level be used. CMS's own explanation indicates that this is the 11-digit NDC and we urge its adoption.

which may buy in volumes larger than the traditional retail pharmacy can buy, can drive down the AMP below the prices traditionally available to retail pharmacies. According to a recent GAO report, the current AMPs are already well below retail pharmacies' acquisition costs for generic drugs. CMS needs to do all it can to assure that the basis of the AMP is high enough to assure that pharmacies will continue to encourage the use of generic drugs in Medicaid.

d. Base the Reference AMP on Nationally-Available Products Only

In proposed § 447.514(c) CMS attempts to ensure that only drugs that are available for sale nationally are used to determine FULs. In order to encourage continued generic drug dispensing in Medicaid, it is critical that FULs be based on prices for products that are currently nationally and widely available in the marketplace.

We believe that only generic products that are AB-rated in the FDA Orange Book, and are widely and nationally available to pharmacies for purchase from the three major national wholesalers in adequate and consistent supplies, should be used in the calculation of the weighted average AMP (or, if CMS rejects this approach, only such products should be eligible to be designated the reference AMP). Unit dose products, larger bulk package sizes (such as drum sizes, which are generally custom packed for a few select customers), and products that are limited and in short supply, should be excluded from the weighted average AMP calculation used to set the FUL. CMS has an obligation to proactively determine whether products are in fact nationally available and in consistent supplies by contacting the manufacturers of these products on a regular basis, or the national wholesalers that stock them.

We also concur with the agency's proposal to not use a terminated NDC to set the FUL beginning with the first day of the month after the actual termination date is reported to the manufacturer by CMS. The terminated NDC issue needs to be further clarified as drugs can remain on the market for years after a manufacturer ships their last lot. The "termination date" must be based on the last shipment date and not the expiration date of the product as community pharmacy will dispense the product long after the final shipment into the market as wholesalers and retailers deplete their stock. It would be inappropriate to set the FUL based on a product that is no longer being distributed in the marketplace.

As CMS notes in its proposed regulation, eliminating AMPs that are outliers would also reduce the chance that FULs would not be set based on products that are not widely and nationally available. CMS goes to great lengths to describe a process that would eliminate an outlier AMP that is 70% lower than the second highest AMP. This outlier AMP would not be used to set the FUL, even though it might be the lowest. It also discusses the option of eliminating an AMP that is 60% lower. It asks for comment on whether these percentages are appropriate to use.

CMS should have offered AMP data to entities to make informed judgments about what appropriate outlier policy might be. However, CMS did not do that, so it is difficult for any entity to offer a percentage within this so-called "outlier" policy that makes sense in the context of the current AMP data. In fact, CMS itself offers no data to suggest why it chose these percentages. Given that CMS is one of the few entities that has access to and can analyze AMP data across

generic drugs, it is in the best position to offer a reasonable percentage that might eliminate outliers.

However, to minimize the possibility that a FUL would be set based on a product that is in limited or in short supply, the use of a percentage relationship between AMPs to determine outlier policies seems arbitrary. We believe that "outlier" policies could be avoided if CMS assures that the product used to set the FUL is nationally and widely available in the marketplace, and that the monthly AMP data for multiple source drugs are subject to a 12-month rolling average smoothing process. Without this smoothing process, there is no way to know whether the so-called "outlier" AMP is actually the AMP of a widely available product whose AMP just happens to be artificially low in that month. That is because all or many of the rebates and discounts provided for that drug might just happen to be reported in a particular monthly AMP calculation period.

Finally, we believe that a process that allows a manufacturer to estimate a certain amount of discounts and rebates for a month and subtract them from their AMP calculation for the month is an arbitrary way of determining AMP. CMS should not be inconsistent and require manufacturers to calculate a reimbursement metric in one manner under one CMS-administered program -- that is the Medicare Part B ASP program -- and specify that it be done in another manner for a different CMS administered program. AMP calculations should be subject to the same 12-month rolling average smoothing process as are ASP calculations. We urge that CMS rethink this issue of an outlier AMP in favor of a more rational approach to determining the reference AMP used to set the FUL.

e. Provide Appeal Mechanism for Published FULs

Providers should have a formal mechanism to appeal (and expeditiously receive a response from CMS) on a questionable FUL established for a particular product. CMS has generally been responsive to cases in which pharmacies have identified problems or issues with a FUL. However, we believe that there should be a formal appeals process for a FUL if one of the following situations exist: (1) the product does not meet the criteria for a FUL because the product is in short supply or there are no longer an adequate number of suppliers to meet the criteria for a FUL, (2) there have been price changes in the market due to raw ingredient shortages or market consolidation, or (3) the product is generally unavailable at the AMP used to generate the FUL.

IV. States Must Be Required to Set Professional Dispensing Fees that Cover All Pharmacy Costs and Provide Reasonable Return

Proposed § 447.512(b) specifies that the state agency establishes a "reasonable" dispensing fee that would be paid to pharmacies for dispensing Medicaid prescriptions. We believe that CMS should give states additional guidance in the final regulation on how to determine the professional fees that are paid to pharmacies for providing Medicaid prescriptions. That is, the states should be required to set the fees such that they cover all pharmacy's costs of dispensing. It is well documented that one of the major congressional goals of Medicaid

pharmacy payment reform was to pay pharmacies more accurately for the cost of the drug they dispense as well as more accurately for their cost of dispensing.

For example in his May 12th letter to Secretary Leavitt, then Senate Finance Chairman Grassley said that, "CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid particularly for generic drugs." Similarly, we reference the strong statements that Chairman Grassley made in a November 3, 2005, colloquy with Senator Reed when the Senate was considering the DRA.

In that colloquy, Senator Grassley said "states will need to review and increase the fees that they pay pharmacies for dispensing Medicaid prescriptions." *See* Congressional Record, Senate, November 3, 2005, p. S12326. Former CMS Administrator Mark McClellan, in remarks made at the NCPA conference on May 22nd, indicated that: "If states do not maintain the right incentives for generic utilization, any savings will be lost due to higher brand name utilization! ... CMS guidance encourages states to align incentives for generic utilization and consider paying pharmacies more in dispensing fees to support state savings from greater use of generics."

The need to increase pharmacy fees was discussed in the context of paying pharmacies more accurately for their drug product acquisition costs by former House Energy and Commerce Committee Chairman Barton. In his opening statement at a December 2004 hearing, Chairman Barton said, "I believe we should pay providers fairly for their services. I have got absolutely no problem with increasing dispensing fees if that is what we need to do." Hearing of the House Energy and Commerce Committee Subcommittee on Oversight and Investigations, December 4, 2004.

When new FULs are phased in this spring, many states are likely to realize significant savings from reduced payments for generic drug products. As Senator Grassley further stated in his colloquy regarding the Medicaid section of the DRA: "The overall assumption made in the bill is that states will increase their fees to account for the fact that states would probably be paying pharmacists a lower amount for the drug product that more accurately reflects the cost of the drug product being dispensed." Congressional Record, Senate, November 3, 2005, p. S12326. Yet, CMS gives little guidance to states about their obligations, consistent with Congressional intent, to increase their dispensing fees.

Today, Medicaid pharmacy dispensing fee payments are lower than the average pharmacy's cost to dispense a prescription. Recent state-specific studies have shown that the average cost of dispensing a Medicaid prescription is anywhere from $9 to $11, while the average current dispensing fee is only about $4.25. A recent national cost of dispensing study conducted by Grant Thornton and released on January 31 found that the average cost to dispense a prescription, weighted by prescriptions, is about $10.50. *See* Grant Thornton LLP, "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies" (January 2007) (the full report can be obtained from the Coalition for Community Pharmacy Action (CCPA) at www.rxaction.org). This amount is higher when weighted by stores. These amounts vary by state. Therefore, while the Medicaid program will be paying pharmacies less for the generic drug ingredient cost when these new FULs take effect, we believe that CMS should mandate states to make sure that the dispensing fee is adequate and accurate for all pharmacies. This would be consistent with congressional intent.

Submitter : Mr. Charles Sewell **Date:** 02/20/2007

Organization : National Community Pharmacists Association

Category : Other Association

Issue Areas/Comments

Background

Background

See attached comments

Collection of Information Requirements

Collection of Information Requirements

See attached comments

GENERAL

GENERAL

SUBMITTED VIA CMS WEBSITE / HAND DELIVERED TO CMS WASHINGTON, DC OFFICE (G. Hubert H. Humphrey Building, Room 445, 200 Independence Avenue, SW., Washington, DC 20201.)

February 20, 2007

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

Dear Acting Administrator Norwalk:

The National Community Pharmacists Association (NCPA) represents the interests of pharmacist owners, managers, and employees of more than 24,500 independent community pharmacies. These independents employ over 55,000 licensed pharmacists and over 300,000 additional employees across the United States. Independent pharmacists and pharmacies dispense approximately 42% of the nation's retail prescription drugs, with some 92% of our annual revenue coming from prescription medicines.

Many Medicaid recipients, particularly in rural and urban areas, depend on their local community pharmacies to provide them with needed medication; and CMS asked for comments regarding the significant impact the proposed rule would have on community pharmacies, NCPA respectfully submits the enclosed comments regarding CMS-2238-P.

Medicaid comprises approximately 23% of the average community pharmacy s business. The program covers more than 50 million poor and disabled persons, over half of whom are under 18. More than half of NCPA members are located in communities of less than 20,000 persons areas where there are fewer provider choices.

Results from a January 2007 NCPA survey show that 86% of pharmacies will seriously consider dropping out of the Medicaid program if the CMS-proposed formula goes into effect. This proposed reimbursement scheme is certain to lead to pharmacy closures, decreased patient access, poorer health and increased health care costs. If pharmacies are forced to close as a result of inadequate reimbursements, all patients not just Medicaid patients will suffer.

For these reasons, NCPA believes that CMS should exercise the discretion granted the Secretary in the Deficit Reduction Act of 2005 (DRA, PL 109-171) to publish a final rule that docs not harm patient access to community pharmacy.

We appreciate the opportunity to submit the enclosed comments on behalf of our membership and if you have any questions, please do not hesitate to contact NCPA via telephone at 703-683-8200 or via email at: Charlie.Sewell@ncpanet.org.

Sincerely,
Charles B. Sewell
Senior Vice President, Government Affairs

Enclosure

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attached comments

Regulatory Impact Analysis

Regulatory Impact Analysis

See attached comments

Response to Comments

Response to Comments

See attached comments

CMS-2238-P-1339-Attach-1.DOC

Attach #1339

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

Comments of the National Community Pharmacists Association
Centers for Medicare & Medicaid Services
42 CFR Part 447
[CMS-2238-P]
RIN 0938-A020
Medicaid Program; Prescription Drugs implementing the Medicaid Prescription Drug provisions of the Deficit Reduction Act of 2005 (DRA)

SECTION ONE – INTRODUCTION (General Comments)

The Deficit Reduction Act of 2005 (DRA) gives CMS great responsibility and latitude to define metrics that will set Medicaid reimbursements to pharmacy. CMS still has the opportunity to issue a final rule that will fairly address community pharmacy and, more importantly, will serve the interests of beneficiaries and the general public.

NCPA believes that implementation of the proposed rule would create additional long-term costs to the government which will more than offset any initial budgetary savings. The additional costs would result from pharmacy closures due to inadequate reimbursements arising from the proposed rule, which would lead to decreased timely and safe access to prescription drugs. This change will result in additional costs incurred due to more doctor visits, emergency room care, hospital stays and long term care. It is NCPA's hope that the following comments and recommendations will assist CMS in addressing beneficiary health and access issues.

If CMS does not adopt these recommendations, NCPA believes that the implemented rule will ultimately cost the government and taxpayers money, and lead to a large number of community pharmacy closures in rural America and in urban centers -- where the heaviest concentrations of Medicaid patients exist -- and significantly decrease access and the quality of health care for Medicaid patients.

It would be difficult to underestimate the negative impact of this newly proposed rule. CBO estimated that when implemented, new Federal Upper Limit (FUL) reimbursements to pharmacies based on a newly constructed Average Manufacturer Price (AMP) could reduce total Medicaid spending for prescription drugs by $3.6 billion from 2007 to 2010 and by about $11.8 billion from 2007 to 2015.[1] Including the State match, those figures worked out to some $6.3 billion from 2007-2010 and over $28 billion 2007 – 2015.[2] (The $8.4 billion in state and federal savings from 2007 to 2011 now touted by CMS includes some $4.8 billion in federal savings alone).[3] The Medicaid cuts to pharmacy reimbursements are thus heavily back loaded. Because the cuts are expected to increase in size, it is important to correctly define the metrics at this time.

In addition, the proposed cuts that community pharmacy will sustain under the DRA must be considered. In looking at just the first four years of implementation of the DRA:

- The DRA cuts federal spending by $39 billion over the first 5 (actually 4) years
- 10% of the total deficit reduction in the DRA ($3.9 billion of $39 billion) were cuts to Medicaid
- 91% of these pharmacy cuts are for Medicaid generic drugs, ($3.6 billion of $3.9 billion) though pharmacy services represent only 2% of Medicaid spending. Brand name drugs were not

[1] Congressional Budget Office Cost Estimate, S. 1932, Deficit Reduction Act of 2005, January 27, 2006, at p. 37.
[2] Id. at p. 35.
[3] Id. at 3 and at CMS Fact Sheet: Medicaid Drug Pricing Regulation Proposed, December 15, 2006, found at http://www.cms.hhs.gov/apps/media/press/factsheet.asp .

affected, even though it is more cost-effective to encourage the dispensement of relatively cheap generic drugs.

- Including the State Match, the cuts equal at least $6.3 billion over the 4 years covered by the DRA (CMS now says $8.4 billion for 2007 – 2011)
- This equals an average cost of over $30,500/year per pharmacy in these first several years – but those with a large percentage of business devoted to Medicaid patients (approximately 23% is the current average for independent pharmacy) will be more dramatically affected.

NCPA requests that the proposed rule, including: (1) CMS's concerns with potentially affecting manufacturing rebate liability to the states; and (2) CMS's choice not to lessen the impact of reducing community pharmacy reimbursement rates -- and thus patient access to Medicaid drugs -- be considered in the context of the miniscule cut to the federal budget created by this section of the DRA. This relatively small cut must be viewed in juxtaposition to the substantial harm that implementing the proposed rule would create.

SECTION TWO – KEY NCPA COMMENTS

I. Fundamental Problem of CMS's Formulation of AMP as a Measure for Reimbursement

(under II. Provisions of the Proposed Regulations – *Definition of Average Manufacturers Price – Section 447.504 at p. 21of the CMS website version of the proposed rule and p. 77177 of the Federal Register version)*

AMP is now set to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement and 2) as an index for manufacturer rebates paid to states. **AMP was never intended to serve as a baseline for pharmacy reimbursement,** and may not have been an effective measure for manufacturer rebates as outlined in the Government Accountability Office (GAO) report, "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States" (GAO-05-102, February 5, 2005).

CMS indicates it is trying to reconcile the use of a measurement for manufacturers rebates with using that instrument as a measure for pharmacy reimbursements. This dichotomy is a strain upon an effective use of the measure that can only be resolved, in part, if CMS effectively addresses the opportunity for manufacturers to underreport AMP prices. If the CMS definition of AMP is to even come close to serving both purposes, CMS MUST define AMP to reflect only those prices available to community pharmacy, excluding all rebates and price concessions not available to pharmacy. All rebates and price concessions are appropriately included in "Best Price" but should not be included in the CMS definition of AMP.

An accurate definition of AMP and Best Price will not only lead to larger rebates to state Medicaid agencies, but will also set a more accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care and access.

If left unchanged, the end result of the proposed definition would create a perverse disincentive to dispense generic drugs. Congress assigned CMS the responsibility of defining metrics that would ensure adequate reimbursements, thus ensuring beneficiary access to community pharmacy.

To accomplish these two goals of increasing rebates to the states and encouraging the use of affordable generics through setting an accurate baseline for reimbursement rates, CMS must first define AMP so that it reflects community pharmacy acquisition costs – including accurately defining retail pharmacy class of trade and incorporating only those elements in the CMS definition of AMP that reflect pharmacy acquisition costs.

A. Retail Pharmacy Class of Trade

(II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP at p. 25 and p. 77178 and p. 34 and p. 77179).*

NCPA requests that CMS change its proposed definition of retail pharmacy class of trade, proposed 42 CFR Sec. 447.504(e) at p. 130 as follows:

(e) Retail pharmacy class of trade means any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, traditional chain pharmacy – including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy.

This definition currently encompasses over 55,000 retail pharmacy locations.

In order to be included in the definition of retail pharmacy class of trade, the prices used should be prices available to community pharmacy and the prescriptions should be "publicly accessible."

Under this definition, sales to mail order facilities should not be included in AMP. Mail order facilities are wholly owned and operated almost exclusively by PBMs, and as such they do not meet the above mentioned two criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.

CMS's definition of retail pharmacy in this proposed regulation is inconsistent with that used in the Medicare Part D prescription drug program final rule. (*See* 42 CFR 423.100). In the final rule implementing the Medicare Part D prescription drug benefit program, the agency defines "retail pharmacy" as "any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy." Thus, it would be consistent with CMS' current Part D definition of "retail pharmacy" for the agency to indicate that only sales to true retail community pharmacies represent the "retail class of trade" for the purpose of calculating the AMP.

B. Workable definition of AMP

(II. Provisions of the Proposed Regulations – *Definition of Average Manufacturers Price – Section 4447.504 at p. and p. 77177)*

In passing the DRA, Congress gave CMS the task of creating a workable definition of AMP. CMS still has the opportunity to meet this challenge.

NCPA requests that CMS adjust its definition of AMP, proposed 44 CFR Sec. 447.504(a) as follows:

(a) AMP means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)) for a calendar month, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include community pharmacy sales only (chain and independent) and only adjustments that reduce the actual price paid by community pharmacy.

NCPA recommends that the following elements, which community pharmacy does not receive, be excluded from the calculation of AMP:

- State supplemental, state only and SPAP prices
- FFS/depot
- Non-contingent free goods
- Discounts, rebates and price concessions to PBMs
- Prices extended to Mail Order
- Patient care programs

- Administrative Service Agreements
  - Inventory management fees
  - FFS agreements to wholesalers
- Price adjustments that do not affect the actual price paid by community pharmacy
- Other new classes of trade which receive prices not available to community pharmacy

Appropriate calculation of the AMP depends upon an accurate definition of the retail class of trade, an accurate identification of manufacturers' prices paid by wholesalers for drugs distributed to retail pharmacies, and an appropriate definition of wholesaler. CMS proposed definition has problems in all three areas.

The law clearly limits AMP calculations to prices paid by wholesalers and discounts received by wholesalers. However, CMS proposes to require that manufacturers include in the AMP calculation prices that are not paid by wholesalers, as well as discounts on drugs that are not received by wholesalers. Only payments to manufacturers by wholesalers, for drugs that are subsequently distributed to the retail class trade, can by law be included in the AMP. Any other payments must be as a matter of law, excluded from the calculation of AMP.

CMS does not follow its prior practices regarding this issue. In the preamble to the proposed rule, CMS acknowledges that for years "our position has been that PBMs have no affect on the AMP calculations unless the PBM is acting as a wholesaler...." 71 Fed. Reg. at 77179. CMS now proposes to change this current position and instead include "any" price adjustments or discounts provided by manufacturers, regardless of whether those price adjustments or discounts have anything to do with the prices paid by wholesalers. This is a complete reversal of CMS' longstanding interpretation of the statute, which clearly defines AMP as the prices paid by wholesalers.

CMS also does not follow language of the statute by including payments by non-wholesalers in calculations of AMP. CMS says "we recognize that the statute defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade...." Id. However, CMS goes on to state that "in light of congressional intent, we believe that the definition is meant to capture discounts and other price adjustments, regardless of whether such adjustments are provided directly or indirectly by the manufacturer." This version of "Congressional intent" is not reflected in statute, and is inconsistent with CMS's longstanding interpretation of the statute.

Negotiated returned goods should also be excluded from the calculation of AMP. We recommend that CMS adopt the following policy regarding returned goods in the calculation of the AMP: "a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, which is designed to reimburse pharmacies for the replacement cost of products as well as the associated return related expenses and not designed to manipulate or artificially inflate or deflate the AMP"

These negotiated return goods policies take into consideration the unique burdens which retail pharmacies must absorb in order to effectuate the efficient return of expired pharmaceutical products to manufacturers. By mandating that only returns made pursuant to manufacturers' policies be excluded from the calculation of AMP, CMS could be voiding these negotiated return goods policies (which were negotiated in good faith between manufacturers and retailers) and are forcing retailers to accept manufacturers' policies and their inherent deficiencies.

Such action ignores that retailers absorb considerable cost through: replacement value of returns, inventory carrying cost, reverse logistics cost, and administrative expense. In order to remedy this inequity, returned goods made in good faith and pursuant to a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, must also be excluded from the calculation of AMP.

*1. **Rationale against CMS redefining AMP to instead become lowest manufacturer price***

(II. Provisions of the Proposed Regulations – *Definition of Average Manufacturers Price – Section 447.504 at p. and p. 77177)*

CMS's proposed rule is unworkable and unrealistic in that it fails to take into account community pharmacy's actual acquisition costs.

The CMS defined AMP and the resulting FUL impact not only government Medicaid programs, but now have the far reaching effect of substantially impacting the entire private market. Therefore it is essential that the FUL determination represents an accurate determination of pharmacy actual acquisition cost. Former CMS administrator McClellan already backed away from posting incorrect AMP data, stating,

> They just aren't the right numbers to use. . . We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a reference point for setting pharmacy reimbursement.[4]

In light of a recent GAO report (*GAO-07-239 Medicaid Federal Upper Limits, December 22, 2006, hereinafter "GAO report")*, it appears that CMS' initial guess at a proper FUL, based on its newly proposed definition of AMP, falls significantly short of an accurate mark. In that report, dated December 22, 2006 but not made available to the public (including NCPA) until a full month later, on January 22, 2007, the GAO issued a strong rebuttal to CMS's contention that community pharmacy could mitigate the effects of AMP-based FULs as a reimbursement measure.

The GAO report found that on average, FUL, defined as a ceiling of 250% of the lowest AMP for the chemical compound, was still on average 36% below the acquisition cost to pharmacies. Although CMS notes that rebates were not included in the GAO analysis, generally speaking community pharmacy does not receive manufacturer rebates. In the limited instances where community pharmacy does receive rebates, the amount is minimal.

Wholesalers and buying groups can choose to give – or choose not to give – pharmacies performance standard purchasing rebates out of the incentive amounts that they receive from manufacturers for purchasing drugs in patterns that benefit the manufacturer. In any case, as will be discussed in SECTION TWO, I.B.2.b., infra, any of these performance standard purchasing rebates that wholesalers choose to pass along to pharmacies do not begin to offset the average reimbursement shortfall of 36% below acquisition cost as found in the GAO report. In the case of generic drugs, community pharmacy will not even be reimbursed for the cost of the drug, let alone the cost of dispensing the prescription. The dispensing fee received from the states does not offset the considerable difference below acquisition costs reported in the GAO report.

What CMS fails to address in its response to the GAO report is the issue of generic drug availability, and how it renders CMS' scheme of lowest manufacturer's price in lieu of AMP unworkable. Smaller generic manufacturers seeking to capture additional market share are willing to enter the market with a discounted price of 20 - 30% in an effort to force pharmacies to buy their product. **The problem is manufacturing capacity**. Smaller generic manufacturers do not have the product inventories to serve more than just a percentage of the Medicaid population.

The implementation of the proposed FUL scheduled for July 1, 2007 would have a devastating impact on community pharmacies regardless if they elect to participate in the Medicaid program or not. A government defined price index that misrepresents pharmacy acquisition costs will create pricing misperceptions in the marketplace which will cause serious harm to independent pharmacies. We request that in the final rule an AMP definition that truly reflects at least real pharmacy acquisition costs be utilized in the calculation of FUL.

CMS is seeking to create a lowest manufacturing price metric to replace AMP by, for example, proposing "to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug." (p. 81). CMS asks for comment on the 30 percent rule, but to do so thoughtfully would require CMS

[4] Administrator Mark B. McClellan before NCPA's 38th Annual Legislation and Government Affairs Conference on May 22, 2006.

to reveal the additional criteria on how it proposes to implement the proposed rule. We assume, for example, that when CMS states, "We propose to adopt additional criteria to ensure that the FUL will be set at an adequate price to ensure that a drug is available for sale nationally as presently provided in our regulations." (p. 81) that CMS is referring to 42 CFR 447.332. That regulation requires that at least three suppliers list the FDA category "A" drug for it to be eligible for inclusion on the FUL list for multiple source drugs.

2. Inadequacy of FUL – proposed 42 CFR Sec. 447.514
(II. Provisions of the Proposed Regulations – *Upper Limits for Multiple Source Drugs, pgs. 73 – 83 and pgs. 77186 – 77188)*

a. FUL is a ceiling of up to 250% of the lowest AMP

In its discussion of the type of NDC code information it will require from manufacturers reporting AMP, on p. 79 – 80 of the proposed rule, CMS makes the following statement:

> Furthermore, we expect that because the CMS defined AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased, and that to the extent it does have an impact, it would encourage pharmacies to buy the most economical package size. *(p. 79 – 80).*

That statement is simply incorrect in terms of its assertion that the new FUL ceiling is sufficient to reimburse pharmacies. (It also incorrectly implies that pharmacies are currently not motivated to buy economical packaging, a point that will be refuted in the more detailed comments in SECTION TWO, at IX, infra).

First, it is important to note that FUL is now based on a ceiling of a new measurement -- 250% of the lowest CMS defined AMP, as opposed to the previous reimbursement measure of 150% of the lowest published price of the therapeutically equivalent versions – which states typically measure through an adjustment to AWP, MAC or Best Price (BP) as set by First Databank. Prior to January 1, 2007, FUL was established for multiple-source drugs for which there are at least three therapeutically equivalent products. Since the beginning of this year, FUL is to be established for multiple-source drugs that had two or more therapeutically equivalent products.

To a lay person, a reimbursement up to 250% of an "average" metric that sounds like a retail purchasing price appears to be more than adequate. CMS must understand that a FUL ceiling of up to 250% of AMP does NOT mean that pharmacies will be reimbursed at two-and-a-half times their costs. The 250% of AMP also begs the question, "how is AMP determined?" If AMPs are numbers far below pharmacy acquisition costs, taking 250% of these numbers will not even come close to covering community pharmacy's costs for their prescriptions.

Calling the 250% a "markup" is a blatant misrepresentation of the facts. Multiplying by 250% of a low number that does not accurately reflect retail acquisition costs is a calculation in a vacuum designed only to force community pharmacy from serving their Medicaid patients.

b. 'CMS' measurement of FUL is inadequate
(II. Provisions of the Proposed Regulations – *Upper Limits for Multiple Source Drugs, pgs. 73 – 83 and pgs. 77186 – 77188)*

NCPA is compelled to strongly dispute CMS' contention that the new FUL under this newly proposed definition of AMP will adequately reimburse community pharmacists. Under the DRA, the FUL is to be a ceiling of 250% of the AMP for the class of generic drug at issue. *Sec. 6001 (a) of P.L. 109-171.* CMS, however, is making the FUL a ceiling of the lowest CMS defined AMP of the class of generics. In addition, not only will that actual payment typically be below the FUL, but as will be discussed in the following section c., supra, CMS is allowing the lowest AMP to be as low as only 30% of the amount of the second lowest AMP (see pgs. 81-82).

In their December report, the GAO has issued a strong rebuttal to CMS's contention that community pharmacy could mitigate the effects of AMP-based FULs as a reimbursement measure. The GAO did so by pointing out that estimated AMP-based FULs in its sample "fell below the lowest acquisition cost available to retail pharmacies." *GAO-07-239 Medicaid Federal Upper Limits at p. 16.*

The paragraph from which the above quote is taken reads as follows:

> CMS also pointed out that our study did not include an analysis of how retail pharmacies could mitigate the effects of AMP-based FULs by filing more Medicaid prescriptions with lower cost versions of multiple-source outpatient prescription drugs. However, as part of our analysis, we compared estimated AMP-based FULs to the lowest available acquisition cost for each of the multiple-source outpatient prescription drugs in our sample. As we reported in our draft, for most [sic] the drugs in our sample—43 of 77 [56%]—the estimated AMP-based FUL fell below the lowest acquisition cost available to retail pharmacies. *Id.*

In addition: (1) 59 of the 77 drugs (77%) in GAO's sample were found to be lower than average community pharmacy acquisition costs; and (2) for the entire 77 drug sample, the estimated AMP-based FULs were, on average, 36 percent lower than average community pharmacy acquisition costs for the first quarter of 2006. *Id. at 4.*

That paragraph reads, in its entirety:

> The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs [77%] in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006. *Id.*

Two criticisms by CMS of GAO's draft report merit discussion and refutation. First, CMS incorrectly claims that community pharmacy receives rebates from manufacturers. What community pharmacies can potentially earn are purchasing rebates from wholesalers providing the pharmacy meets or exceeds certain defined performance standards.

Community pharmacy is dependent on the wholesalers choosing to reward pharmacies with some savings that the wholesalers arrange with manufacturers over the drugs due to their volume of purchases. Such performance standards might include: (1) Total dollar volume of all prescription purchases during a defined period of time; (2) total dollar volume of generics purchased during the defined period; (3) frequency of pharmacy invoice payments to the wholesalers; and (4) credit performance/history of the pharmacy. When a community pharmacy has the ability in its market to comply with purchase performance standards and receive these rebates, they are approximately 5%, if indeed any are received at all. Also *see previous discussion at SECTION TWO I.B.1. at p.6, supra.*

Perhaps even more importantly, whatever can possibly reach community pharmacies in the purchasing system in no way comes close to approaching the 36% gap that GAO found between the maximum reimbursement that pharmacies can receive under a fully utilized FUL ceiling and actual costs to acquire prescription drugs.

Second, CMS' criticism of the GAO's inclusion of outliers in calculating AMPs is a weak and inconsequential criticism of the GAO report. The footnote at the bottom of page 9 of the GAO report states that "Excluding statistical outliers from our analysis resulted in a less than 1 percent change in the average percent difference between average retail pharmacy acquisition costs and estimate[d] AMP-based FULs." *Id. at 9.* A one percent change is insignificant, and would have little bearing on the overall calculation of average community pharmacy acquisition costs.

The lowest AMP that CMS is proposing to include in the AMP calculation is also disturbing in that it creates a lowest manufacturing price metric to replace AMP. CMS proposes "to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug." (p. 81). We recommend that an 80 percent level is a much more realistic measuring point.

CMS asks for comment on the 30 percent rule, but to do so thoughtfully would require CMS to reveal the additional criteria on how it proposes to implement the proposed rule. We assume, for example, that when CMS states, "We propose to adopt additional criteria to ensure that the FUL will be set at an adequate price to ensure that a drug is available for sale nationally as presently provided in our regulations." (p. 81) that CMS is referring to 42 CFR 447.332. That regulation requires that at least three suppliers list the FDA category "A" drug for it to be eligible for inclusion on the FUL list for multiple source drugs. Many smaller generic manufacturers should be able to meet these criteria. This problem is also exacerbated by the problem of shortages of drugs, discussed earlier in SECTION TWO – I.B.1., supra.

Finally, CMS must provide an appeals mechanism to allow providers and states an opportunity to seek removal or modification of an FUL which is not consistent with changing market conditions.

NCPA has been unable to find anyone in the industry that believes that the new FUL metric will be sufficient to adequately reimburse community retail pharmacists for their drug costs. While CMS incorrectly claims that the new FUL will sufficiently cover acquisition costs, CMS makes it clear that states are free to pay pharmacies more than what the federal government will give to the states. CMS acknowledges that the states need to make up the difference between this new metric and what pharmacists have received in the past from state Medicaid programs. Where are the states supposed to find this new funding? This amounts to another unfunded mandate being handed to the states.

c. **CMS is setting an unrealistic threshold for Outlier Prices in the FUL calculation**

(II. Provisions of the Proposed Regulations – *Upper Limits for Multiple Source Drugs, at pgs. 81 – 83 and pgs. 77187 – 77188)*

CMS proposes to set the FUL based on the lowest AMP, as long as that AMP is not more than 70 percent below the second lowest AMP for that drug. (p. 81). CMS somehow reasons that this standard will "further safeguard to ensure" that "a very low AMP is not used by us to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs." Id. In other words, CMS will only exclude the lowest "outlier" AMPs that are more than 70% lower than the second lowest AMP for the drug – so a lowest AMP as low as $3 could serve as the AMP used to calculate FUL if the next lowest AMP was up to $10.[5]

[5] CMS thought it was worth criticizing GAO for excluding outliers in its estimated calculation of AMP-based FULs. GAO responded to the criticism by concluding that based on the numbers provided by CMS, excluding outliers from the analysis

CMS is therefore proposing to create a FUL based on possible situations where a solitary manufacturer's AMP could very well become the AMP used in the calculation of the FUL for a particular drug, even though a vast majority of the manufacturers for that drug have set an AMP that is over three times the value of the lowest AMP of a manufacturer of the drug.

It is not logical to set an exclusion of outliers at an AMP that is so much less (70%) than the next lowest AMP. A 20% figure is a more acceptable threshold level (so as low that an $8 AMP could serve as the basis for FUL if the next lowest AMP was $10).

Finally, as nominal pricing will be included in the calculation of AMP (p.131), CMS needs to explain how that decision does not in effect make the outlier price discussion moot for nominal pricing based drugs.

II. CMS has not provided drug pricing data on a confidential basis to the affected parties and thus our response to the proposed rule is based on the new GAO study and on communications with industry sources as to what AMP prices will be. This severely handicaps NCPA's ability to fully comment on the proposed rule.

(I. Background – *Changes Made by the Deficit Reduction At of 2005 at p.8, p. 77175)*

CMS has never, despite repeated requests from pharmacists and many sectors of the pharmaceutical industry, distributed on a confidential basis AMP data. The GAO Report states it simply, and perhaps best: "Because these data are not publicly available, retail pharmacies cannot determine what the relationship will be between AMP-based FULs and the prices the pharmacies pay to acquire these drugs." *GAO-07-239R Medicaid Federal Upper Limits* at p. 2. (Footnote omitted).

CMS is asking for specific examples of the "significant impact" of the proposed rule upon community pharmacy (see pgs. 108 – 109, p. 77192 under **V. Regulatory Impact Analysis**. B.3. Impact on Retail Pharmacies) despite choosing not to provide even limited AMP data. It is nearly impossible to accurately comment on the effect of the proposed definition of AMP and to provide CMS with real examples of the impact of the proposed rule without the use of actual AMP numbers. NCPA looks forward to CMS providing AMP data so that it can in turn provide CMS with the price-based specific examples that it is seeking. In the meantime, the GAO study is by far the best information available to the public. **Based on an extrapolation of the GAO findings, the CMS definition of AMP approximates only 25% of pharmacy acquisition costs.**

III. CMS's Costs Savings Estimates Ignore Increased Costs
(V. Regulatory Impact Analysis, p. 93, p. 77190)

The estimated $8.4 billion over five years - $8 billion of which would be borne by community pharmacy – does not take into account the very real potential additional costs to the government (taxpayers) through additional payment through disincentives to dispense generics. Before the implementation of Medicare Part D began, published numbers from generic manufacturers indicated that for every additional 1% of brand name drug use under Medicaid that moved to generics, some $475 million in savings would be realized.[6] Now that the dual eligibles are captured under Part D, that figure is not as large, but still quite significant. The new figure is estimated to be well over $300 million.

Considering the level of generic drug use as a percentage of all drugs under Medicaid in 2005 varied between some 42% - 61% among the states, there are potentially large monetary losses that will be incurred by creating disincentives to prescription generic drug use – and corresponding large potential savings that could be

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resulted in a less than 1 percent change in the average percent difference between average retail pharmacy acquisition costs and estimate AMP-based FULs.

[6] http://www.gphaonline.org/AM/Template.cfm

realized by incentivizing generic drug use. Unfortunately, the proposed rule penalizes generic dispensing and rewards brand dispensing.

In addition, pharmacy closures, or the suspension of Medicaid program participation caused by inadequate Medicaid reimbursements could lead to decreased timely and safe access to prescription drugs. This will also lead to additional costs of more doctor visits, emergency room care, hospital stays and long term care. Patients who do not have access to their community pharmacy will often go without their medications until their health deteriorates and they are forced to seek out much higher cost health care options.

IV. According to the CBO, CMS's Costs Savings Assume that States Will Increase Their Dispensing Fee. If the States do not do so, then pharmacy reimbursements will be so inadequate that most pharmacies will not be able to participate in the Medicaid Program.

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176 and **V. Regulatory Impact Analysis.** F. Conclusions at p. 119, p. 77195*)*

From *Congressional Budget Office Cost Estimate, January 27, 2006, S. 1932 Deficit Reduction Act of 2005 Conference agreement, as amended and passed by the Senate on December 21, 2005*:

Based on administrative data on AMPs and prescription drug spending by Medicaid, CBO estimates that those provisions would reduce Medicaid spending by $3.6 billion over the 2006-2010 period and $11.8 billion over the 2006-2015 periods. **Those savings reflect CBO's expectation that states would raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies and preserve the widespread participation of pharmacies in Medicaid.** The estimate also accounts for lower rebates from drug manufacturers resulting from increased use of cheaper generic drugs. *p. 37 (emphasis added).*

CBO does not reveal to what degree it "expects" states to raise dispensing fees when it calculates its numbers. Even if states were to double their dispensing fees – which is improbable -- the total reimbursement to community pharmacy would be far below their acquisition costs and their cost to dispense. Finally, for community pharmacies to stay in business, the reimbursements must include at least a small profit margin.

A study recently completed by one of the 4 largest world-wide accounting firms, Grant Thornton, has found that the average cost to dispense in the nation was $10.50.[7] Grant Thornton is a respected accounting firm that used industry-accepted accounting standards and methods. The study was based on responses from over 23,000 pharmacies and the response size was large enough that separate cost-to-dispense measurements were computed for 46 states. As the current average cost to dispense fee among the states is only $4.50, states will be highly challenged to provide an adequate reimbursement to pharmacies, consistent with the documented cost.

V. Retail Pharmacy Class of Trade should be defined as only retail pharmacies. The definition should not include PBM mail order operations, which dispense almost no Medicaid prescriptions.

(II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP at p. 25 and p. 77178 and p. 34 and p. 77179).*

The Omnibus Reconciliation Act of 1990 through amended Section 1927 of the Social Security Act (the Act), created the Medicaid Drug Rebate Program. The rebate legislation became effective on January 1, 1991. **CMS states that the program affords state Medicaid programs the opportunity to pay for drugs at discounted prices similar to those offered by pharmaceutical manufacturers to other large purchasers.**

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[7] *Grant Thornton LLP: National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies, January 26, 2007 (hereinafter "Grant Thornton Study"). This figure is independent of the ingredient cost of the drug. Conducted by the accounting firm Grant Thornton, LLP, the study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.*

The rebate agreement attaches to single-source drugs (new, under patent with no generic equivalents) and innovator multiple-source drugs (drugs that have new-drug FDA approval for which generic equivalents exist). **This rebate agreement includes non-innovator multiple-source drugs. (FDA approved new drug generics)** The basic rebate formula for new drug generics is 11% of AMP.[8]

Since it has been repeatedly stated by CMS that AMP should reflect and look like what large purchasers in the private market pay for drugs, then retail AMP should not include price concessions, and rebates to PBMs and mail order pharmacies for which the rebate is designed to offset. No entity in the private market place receives a rebate off of the rebated price. The result would be a short change to the government by receiving manufacturer rebates based on deflated AMP values which including private sector rebates. This erroneous result was clearly never contemplated by Congress.

Mail order pharmacies are operated as closed model systems that are not available to the general public, and are presently excluded from the retail pharmacy class of trade. Since a large number of Medicaid beneficiaries are children, there is more of a need for acute medication, e.g., antibiotics and pain medicine, so the mail order pharmacy model has not been found to be an efficient one and therefore has not been adopted by the majority of state Medicaid programs. Since generally speaking mail order pharmacies do not service this population, they should not be included in the definition of retail pharmacy class of trade.

Moreover, given that there is relatively no distribution of Medicaid prescriptions through mail order, including these sales and rebates would create a benchmark that would be of little use to state Medicaid directors to set reimbursement rates for retail pharmacies.

For all these reasons, NCPA asks CMS to not include PBM price concessions and mail order pharmacies in the retail pharmacy class of trade definition.

VI. PBM Transparency

(II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP at p. 34 and p. 77179)*

CMS writes at pages 30:

> One of the most difficult issues with PBM discounts, rebates, or other price concessions is that *manufacturers contend that they do not know what part of these discounts, rebates, or other price concessions is kept by the PBM* for the cost of its activities and profit, what part is passed on to the health insurer or other insurer or other entity with which the PBM contracts, *and what part, if any, that entity passes on to pharmacies*. Despite the *difficulties* of including certain PBM rebates, discounts or other price concessions in AMP, excluding all of these price concessions could result in an artificial inflation of AMP. For this reason, we propose to include PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP; however, we invite comments on whether this proposal is operationally feasible. (emphasis added).

The major problem with these assertions is that community pharmacy simply does not have access to these PBM rebates, discounts or other price concessions. Not only is CMS's proposal not operationally feasible, the premise behind the reasoning is flawed and inapplicable to what actually happens in the marketplace. To rectify the situation, CMS should require transparency from PBMs. In the absence of such transparency, CMS should not include these undisclosed elements in AMP.

[8] For innovator (brand) drugs, the rebate is the larger of 15.1% of the AMP per unit or the difference between the AMP and the best price per u it and adjusted by the CPI-U based on launch date and current quarter AMP. http://www.cms.hhs.gov/MedicaidDrugRebateProgram/.

Defining retail pharmacy class of trade as the sector of the drug marketplace which dispenses drugs to the general public and which includes all price concessions related to such goods and services, and including in the CMS definition of AMP mail order and the prices of sales and discounts to mail order pharmacies, is an approach that does not recognize what happens in mail order.

While there is a relatively small mail order component in some of the biggest chain pharmacies, the most important characteristics of mail order is that PBMs run their own mail order companies. PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore, to include the rebates, discounts, or other price concessions given the current state of non-regulation, is not warranted. Specifically, to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate.

CMS requested comments on the operational difficulties of tracking said rebates, discounts or charge backs. The difficulty begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.

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

Only with PBM transparency can CMS accurately ascertain whether CMS's intention to "...include PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade of the purpose of determining AMP" is "operationally feasible" (p. 31) – a question for which CMS seeks comments.

VII. Definition of "Dispensing Fee" Needs to be Wholly Inclusive of the True costs to pharmacists/pharmacies to dispense Medicaid drugs.

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176*)*

An adequate Dispensing Fee definition includes the true costs of: 1) valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling: communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and 2) other real costs such as rent, utilities and mortgage payments. Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Perhaps most importantly, they provide important health, safety and counseling services by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

NCPA accordingly recommends that the dispensing fee definition section of the final rule be written as follows:

42 CFR Sec. 447.502 Definitions.

Dispensing fee means the fee which--

(1) [as CMS has written]

(2) Includes pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to any reasonable costs associated with:

Staffing costs: (a) Salaries for pharmacists and technicians, and compensation to other employees such as managers and cashiers; (b) Licensure/continuing education for pharmacists and technicians.
Store operations and overhead: (a) Rent or mortgage; (b) Cleaning, repairs, and security; (c) Utilities; (d) Computer systems, software ,and maintenance; (e) Marketing and advertising; (f) Accounting, legal and professional fees; (g) Insurance, taxes, and licenses; (h) Interest paid on pharmacy-related debt; (i) Depreciation; (j) Complying with federal and state regulations; and (k) Corporate overhead.
Preparing and dispensing prescriptions: (a) prescription dispensing materials (packages, labels, pill counters, etc.); (b) compounding the Rx when necessary; (c) special packaging (unit dose, blister packs, bingo cards and special supplies (syringes, inhalers).
Assuring appropriate use of medication: (a) drug use review; (b) consumer/patient counseling; (c) consulting with prescribers, (d) disease management, and (e) education/training.
A reasonable profit margin to ensure business viability

VIII. The Dispensing Fee is inadequate

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176*)*

The dispensing fee is the amount that state Medicaid programs add to the reimbursement formulas (typically AWP, WAC or BP) to try to total an adequate reimbursement amount for pharmacies. Currently that amount is approximately $4.50 per dispensed prescription with some states providing a slightly higher dispensing fee for generics to encourage the use of these lower priced medicines.

The Grant Thornton comprehensive study found that the average cost to dispense a Medicaid prescription in the United Sates is $10.55. CMS' definition of dispensing fee, discussed in SECTION TWO, VII, supra, must therefore be adjusted as proposed by NCPA in order to avoid (1) creating a perverse disincentive to dispense relatively inexpensive generics, and (2) increasing the likelihood that a pharmacy will no longer be able to participate in the Medicaid program because reimbursements will not fully cover the cost of the drug, pharmacy operations costs, and the opportunity to secure a reasonable profit.

IX. NCPA supports the use of NDC 11-digit codes for reimbursement purposes

(II. Provisions of the Proposed Regulations – *Definitions – Section 447.502 – National drug code at p. 19, p. 77177 and Upper Limits for Multiple Source Drugs – Section 447.514 at pgs. 81 – 83 and pgs. 77187 – 77188)*

CMS states that the "National drug code (NDC) would be defined as it is used by the FDA and based on the definition used in the national rebate agreement. For the purpose of this subpart, it would mean the 11-digit code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in the regulation as being without respect to package size (9-digit numerical code)" (p. 19, p. 77177).

NCPA agrees with the need for requiring an 11-digit, product size specific NDC when reporting/acquiring AMP data. Identifying package size for reimbursement purposes should lead to more accurate measurement of acquisition costs – i.e. the cost to pharmacy to purchase the medications.

CMS mischaracterizes community pharmacy's perspective on the 9 v. 11 digit NDC issue

(II. Provisions of the Proposed Regulations - *Upper Limits for Multiple Source Drugs – Section 447.514 at pgs. 81 – 83 and pgs. 77187 – 77188)*

CMS made the following statement regarding "encouraging" pharmacies to buy economical package sizes:

> Furthermore, we expect that because the CMS defined AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased, and that to the extent it does have an impact, it

would encourage pharmacies to buy the most economical package size. (pgs. 79 – 80, p. 77187).

NCPA wishes to make clear that community pharmacies are already motivated by both the desire to obtain appropriate package sizes that will best allow the pharmacist to help beneficiaries and also by economy of scale concerns. Community pharmacists operate under tight margins, so they constantly pursue the most economical purchasing options.

Pharmacies already do look to switch to purchasing lower cost drugs to save their patients money and will continue to do so where the lower price drugs are not outdated (less effective and less safe) and are appropriate for use by their patients.

For example, a community pharmacy would like to buy drugs in 1000-pill package sizes in order to take advantage of whatever economies of scale that exist with the larger package size. Certain pharmacies, however, might need to buy 100-pill package sizes of a certain medicine as they simply might not have the sales in a particular market to justify a high volume purchase. A pharmacist that bought the 1000-pill size for such a medication might have to destroy significant amounts of unsold medications. In these situations, switching to an 11-digit NDC would fairly reflect the purchasing situation of certain pharmacies. Simply put, the most economical decision in such cases is to purchase the smaller size.

In reality, the economies of scale for many medications often do not vary between 100 and 1000 pill size containers. However, some dramatic differences in price can be found between, e.g. a 15 ml. and 5 ml. size container of eye drops, and for topical products.

Finally, it must be remembered that the dosage of the medication is dictated by the doctor-chosen prescription.

It should be clear that the issue for independent community pharmacists is adequate compensation, as opposed to motivating them to do something that CMS incorrectly assumes they otherwise would not have done. NCPA therefore favors utilization of the 11 digit NDC in order to obtain price accuracy resulting from package size specificity.

X. Reporting period should be at least Weekly, and NCPA advocates implementation of smoothing/rolling of data

(II. Provisions of the Proposed Regulations – *Requirements for Manufacturers – Section 447.510 at pgs. 65 – 73, pgs. 77185 - 77186)*

There are frequent, sudden changes in drug prices that are not accurately captured by the currently contemplated reporting period. Indeed, prices change on a daily basis, reflecting market palace availability and the number of manufacturers supplying the product in question.

CMS, however, proposes at p. 69 (p 77185) that manufacturers must submit monthly AMP to CMS by 30 days after each month, and it requires AMP, best price, and customary prompt pay discounts on a quarterly basis (presumably within 30 days of the end of each quarter). In addition, CMS states that manufacturers can rely on estimates regarding the impact of their end-of-quarter rebates or other price concessions and allocate these to their monthly AMP.

Under monthly pricing, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoicing to community pharmacy, however, continues to change daily. **NCPA requests that CMS eliminate this lengthy reporting lag period to accurately reflect the prices pharmacies must pay.**

Because of dramatic, frequent changes in drug prices, corresponding changes in AMP could negatively impact community pharmacists. Purchase prices could turn out to be significantly higher than reimbursements that are received after purchase and filling of the prescription. To lessen this unfair outcome, "smoothing" of AMP data is necessary because failure to average out AMP data could result in significant fluctuations in AMP data from month to month. CMS does not propose to develop a smoothing process for AMP data as it has for the reporting of Part B data. NCPA recommends that CMS develop a smoothing process for AMP data. A "rolling" average of AMP based on prices over the preceding 12 months is the best method to smooth out the price spikes and valleys. Spikes and valleys in AMP prices can vary significantly amongst quarters, so a 12 month average smoothing rolling period, as is done in the Medicare Part B Average Sales Price (ASP) program, is appropriate.

CMS should require manufacturers to "smooth" any discounts or rebates that are passed through by wholesalers to retail pharmacies over a rolling 12-month period. This action will reduce the potential for any significant fluctuations in AMP from quarterly and monthly calculations, and maintain some consistency in reimbursement levels. This process was developed by CMS for manufacturers' calculations of the Average Selling Price (ASP), which is used as the basis for Medicare Part B drug reimbursement. Without the smoothing process, it is very possible that upper limits for generics could be based on AMPs that are not reflective of the approximate current market prices for drugs, further reducing generic dispensing incentives.

XI. Cuts to pharmacy are much greater than CMS' characterization of a "1% loss of drug revenues" (V. Regulatory Impact Analysis – 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

CMS misleadingly, and erroneously, claims that the effect of implementation of the rule will be less than "1 percent" of prescription drug revenues.

> 3. Effects on Retail Pharmacies
> ... The savings to the Medicaid program would largely be realized through lower payments to pharmacies. As shown earlier in this analysis, the annual effect of lower FULs and related changes will likely reduce pharmacy revenues by about $800 million in 2007, increasing to a $2 billion reduction annually by 2011. These reductions, while large in absolute terms, represent only a small fraction of overall pharmacy revenues. According to recent data summarized by the National Association of Chain Drug Stores (http://www.nacds.org/wmspage.cfm?parm1=507), total retail prescription sales in the United States, including chain drug stores, independent drug stores, supermarket, and mail order, totaled about $230 billion in 2005. Assuming, conservatively, that sales will rise at only five percent a year, 2007 sales would be over $250 billion and 2011 sales well over $300 billion. Thus, the effect of this proposed rule would be to reduce retail prescription drug revenues by less than one percent, on average. Actual revenue losses would be even smaller for two reasons. First, almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as prescription drug sales. Second, pharmacies have the ability to mitigate the effects of the proposed rule by changing purchasing practices. The 250 percent FUL will typically be lower than the prices available to pharmacies only when one or more very low cost generic drugs are included in the calculation. Pharmacies will often be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs. *pgs. 108 – 109, pgs. 77192 - 77193 (emphasis added).*

NCPA respectfully rebuts CMS' assertions on these pages for the following reasons:

First, for independent pharmacies, some 92% of sales consist of monies from prescription drug sales. The effect on independent pharmacies, which are disproportionately, located in the rural and urban areas that will most be affected by implementation of the proposed rule, will be tremendous and will not be abated by the small amount of non-pharmaceutical sales that occur at these pharmacies.

Second, the 1% looks at gross revenue sales figures for all of community pharmacy (chain and independent), and does not look at the Medicaid market of those pharmacies. Medicaid makes up 23% of the average independent pharmacies' business. To receive Medicaid reimbursements that are on average 36% less than acquisition costs means that many independent pharmacies will have to suspend their participation in the Medicaid program or close their doors, thus decreasing patient access, increasing health care costs, and causing the deterioration of beneficiary/patient health.

XII. NCPA requests that CMS provide AMPs on a confidential basis for the 77 multi-source medications provided to the GAO. (I. Background – *Changes Made by the Deficit Reduction At of 2005 at p.8, p. 77175)* NCPA further requests that CMS extend the comment period for an additional 60 days so our comments may reflect actual AMP data. (p. 1, p. 77174)

CMS will undoubtedly receive comments that will inform it of the nature of concerns of both community pharmacy and everyone else affected by the proposed rule. For CMS to receive at least some of the specific examples that it claims that it needs to adequately form a final rule, however, it needs to provide community pharmacy with actual AMP prices so that community pharmacy can speak with specificity as to the costs that it will bear under the proposed definition. CMS said repeatedly in CMS-2238-P that faced with uncertainty regarding the effect of a policy decision, CMS has shown concern about the potential impact on manufacturer rebate liability "precedent" in the national manufacturer rebate agreements regarding AMP when it was used as a rebate measure, and inclusion of measurement metrics in AMP. (*See, e.g., pgs. 25, 28, 32, 33, 79, 106, 107, 110, 116-118*). The same concerns regarding potential impact of the rule should be extended to community pharmacy. The entire tone and specific policy choices in CMS-2238-P suggest that CMS would not consider making any substantive changes to the proposed rule unless it is provided specific examples that are totally dependent upon having AMP data.

Receiving the proposed rule earlier would have made it easier for all concerned parties to meet the deadlines mandated in the DRA, but CMS still has adequate time to extend the comment period and issue a final rule in time to meet the July 1, 2007 deadline.

In the proposed rule and in the March 31, 2006 CMS Roadmap to Medicaid Reform, CMS repeatedly said that access to community pharmacy, particularly in remote areas, should be preserved and that the states are free to increase dispensing fees so that community pharmacy may continue to serve their local communities.

XIII. Impact Analysis

(V. Regulatory Impact Analysis – pgs. 93 – 110, pgs. 77190 – 77193, particularly 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

The negative impacts of this rule upon independent pharmacies, Medicaid beneficiaries, and the communities they serve – particularly in rural areas – will be far greater than the impact of the implementation of the prescription drug sections of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (P.L. 108-173, MMA).

Significant Impact

CMS is conceding there will be a significant impact upon smaller independent community pharmacies, but it is still claiming that there will only be a 1% impact upon community pharmacy revenues.

This contradictory position stems from CMS analyzing community pharmacy as a whole. CMS is not quantifying the impact upon small, independent pharmacies, especially rural independents. Independents serve a disproportionate percentage of lower income (Medicaid) beneficiaries, and will thus be disproportionately impacted by the proposed rule. NCPA believes that CMS is apparently claiming that there are only Regulatory Flexibility Act (RFA) implications for small pharmacies, but it does not analyze or quantify this impact.

Offsets

There are no offsets to the negative impacts upon community pharmacy and beneficiaries. In contrast, in its RFA analysis of the MMA, CMS conceded that the shift in treatment of the prescription needs of dual eligibles from Medicaid to Medicare Part D would cause a 1 percent negative impact, but also said that the impact would be offset by overall increase in revenues due to increased prescription drug use by senior citizens.

CMS' RFA analysis that addresses the impact of implementation of Medicare Part D upon retail pharmacies, is found at pages 4498 – 4513 of Federal Register, Vol. 70 #18, January 28, 2005. The SBA's May 3, 2002 comments to CMS regarding CMS-4027-P, the SBA Office of Advocacy's comments to the proposed Part D regulations, which can be found at: http://www.sba.gov/advo/laws/comments/cms02_0503.html

The January 28, 2005 CMS document that CMS justified its conclusion that Part D would not have a "significant impact" because it projected revenue increases from projected increased drug use would offset losses.

There are no projected offsets in the proposed rule to implement the Medicaid provisions of the Deficit Reduction Act of 2005. CMS and CBO clearly state that over 90% of the revenue savings to the federal government in DRA Medicaid cuts are due to reduced reimbursements to pharmacies. CMS does not, however, offer any offsets to address the cost to taxpayers due to the negative impact upon community pharmacies and harm to beneficiary access and health. CMS has not, in other words, first even defined the projected losses. CMS also fails to make an "internal offset" of scheduled losses to pharmacy by at least directing a reasonable shouldering of the burden by manufacturers.

Independent pharmacy is disproportionately impacted

The DRA grants CMS great regulatory responsibility and discretion to make many different policy choices that will make the AMP-based rebate and reimbursement system work. It does so by, perhaps most importantly, directing CMS to create the appropriate definitions of retail pharmacy class of trade and to define the elements of AMP. By continually choosing to benefit manufacturers over community pharmacists and beneficiaries, CMS is hurting those that are least able to soften these draconian cuts yet are also the most responsible for patient health care in the Medicaid drug system.

CMS' analysis fails to consider that approximately 23% of the average independent retail community pharmacy's business is devoted to serving their Medicaid patients and that 92% of their entire business consists of prescription drug sales. The program covers more than 50 million poor and disabled persons, over half of whom are under 18. More than half of NCPA members are located in communities of less than 20,000 persons where there are fewer provider choices. Results from a January 2007 NCPA survey show that 86% of pharmacies say they are seriously considering dropping out of the Medicaid program if the CMS-proposed formula goes into effect. This proposed reimbursement scheme is certain to lead to pharmacy closures, decreased patient access, poorer health, and increased health care costs. If pharmacies are forced to close as a result of inadequate reimbursements, all patients – not just Medicaid patients -- will suffer. For these reasons, NCPA respectfully believes that CMS should exercise the discretion granted to the Secretary in the Deficit Reduction Act of 2005 (DRA, PL 109-171) to publish a final rule that does not harm patient access to community pharmacy.

It would be difficult to underestimate the impact of this newly proposed rule. CBO estimated that when implemented, setting new Federal Upper Limit (FUL) reimbursements to pharmacies based on a newly constructed AMP could reduce total Medicaid spending for prescription drugs by $3.6 billion from 2007 to 2010

and by about $11.8 billion from 2007 to 2015.[9] Including the State match, those figures worked out to some $6.3 billion from 2007-2010 and over $28 billion 2007 – 2015.[10] (The $8.4 billion in state and federal savings from 2007 to 2011 touted by CMS includes some $4.8 billion in federal savings alone).[11] The Medicaid cuts to pharmacy reimbursements are thus heavily back loaded. Because the cuts are expected to increase in size, it is important to correctly define the metrics at this time, so that manufacturers are also included in deficit reduction.

Overall Impact

According to CMS analysis, about 18,000 independent pharmacies have revenues less than $6.5 million. This classifies the majority (73%) of independent pharmacies as small businesses.[12]

As pointed out by CMS in the proposed rule, the calculation of AMP as proposed by CMS will have a "significant impact" on some small, independent pharmacies. (p. 110). However, NCPA concludes that it will have a significant impact on the entire independent pharmacy sector. Consequently, independent pharmacies have a large stake in the findings of the final small business regulatory flexibility analysis (RFA).

Anticipated Effects

We believe that they agency's initial impact analysis is flawed based on incomplete information and inaccurate assessments of pharmacy marketplace realities. Throughout our comments, NCPA has provided mitigating information to assist the agency with the final small business regulatory flexibility analysis.

Most notably, the agency's flawed analysis does not consider that independent pharmacies service a significantly higher percentage of Medicaid patients than traditional chain, grocery store and mass merchant pharmacies.

We reiterate that the agency's reasoning for potential offsets in decreased revenue in small business does not apply for the majority of independent pharmacies. First, losses due to the CMS proposed AMP definition would not be offset in front end sales because only 8% on average of total sales are non-prescription products in independent pharmacies. Second, independent pharmacies already seek the best pricing they can obtain while still maintaining quality standards. The proposed strategy to change purchasing practices when presented with a 250% of AMP benchmark that is on average 36% below acquisition costs[13] is not realistic in today's marketplace and is frankly inconsistent with quality patient care. Is CMS suggesting that a Medicaid patient wait to receive a life saving medication such as an antibiotic or heart medication until a pharmacy receives a generic in stock which has an AMP greater than acquisition cost?

The proposed definition by CMS of AMP and retail pharmacy class of trade in CMS-2738-P would have a devastating impact on the already slim operating margin in independent pharmacies. This is further heightened by that fact that independent pharmacies disproportionately serve Medicaid patients and will bear the impact of the flawed AMP definition more profoundly that traditional chain, grocery store and mass merchant pharmacies.

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[9] Congressional Budget Office Cost Estimate, S. 1932, Deficit Reduction Act of 2005, January 27, 2006, at p. 37.
[10] Id. at p. 35.
[11] Id. at 3 and at CMS Fact Sheet: Medicaid Drug Pricing Regulation Proposed, December 15, 2006, found at http://www.cms.hhs.gov/apps/media/press/factsheet.
[12] The *2006 NCPA-Pfizer Digest,* a marketplace survey of independent pharmacy both demographic and financial, places the number of independent pharmacies with annual revenues of less than $6 million at 19,600 (80%). Regardless of the figure is used; the overwhelming majority of independent pharmacies are small businesses.

[13] GAO-07-239.

XIV. Possible Exemptions of Community Pharmacy

(V. Regulatory Impact Analysis – pgs. 93 – 110, pgs. 77190 – 77193, particularly 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

CMS on pages 98 – 105 discusses its obligations under the Regulatory Flexibility Act and on pages 108 – 110, the effects on retail pharmacies. As approximately 23% of the average independent pharmacy's business is devoted to Medicaid patients (beneficiaries), implementation of the proposed rule will have a dramatic impact upon patient access and health through the suspension in participation in the Medicaid program by, or closure of, independent pharmacies caused by reimbursements that fall significantly below costs to acquire the medications needed to fill Medicaid prescriptions.

An option for reducing this impact would be to exempt community pharmacies under certain criteria. The criteria should include: 1) the SBA definition for small business based on gross dollar of business – $6.5 million annual; or 2) pharmacies that have a 10% or higher volume of Medicaid business. Those pharmacies exempt under this criteria should instead be reimbursed based on a formula that accurately reflects independent community pharmacies.

SECTION THREE – SPECIFIC COMMENTS

Rebate period (p. 20, p. 77178, under **II. Provisions of the Proposed Regulation** - *Definitions – Section 447.502*)

CMS states that because it did not find Congressional intent that the definition of rebate period would be changed from monthly to quarterly; CMS is not changing that definition. As AMP data is reported monthly for purposes of calculating the FUL and for release to States, NCPA does not find a compelling reason for leaving the rebate period as a quarterly measure. Congress did not explicitly prevent this change, and the rule is more unified if CMS makes the change.

Past policy under AMP as a rebate measure

(pgs. 27 – 28, pgs. 77178, **II. Provisions of the Proposed Regulation** - *Definitions – Section 447.502-Definition of Retail Pharmacy Class of Trade and Determination of AMP*)

CMS wrote on pgs 27 - 28 (p. 77178) of the proposed rule:

> The exclusion of prices to mail order pharmacies, nursing home facilities (long-term care facilities), and PBMs would substantially reduce the number of transactions included in the CMS definition of AMP. In addition, removal of these prices would address differing interpretations of CMS policy identified by the OIG and the Government Accountability Office (GAO) due to the lack of a clear definition of AMP or specific guidance regarding which retail prices should be included in AMP. However, such a removal would not be consistent with past policy, as specified in manufacturer Releases 28 and 29 (http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp#TopOfPage), would likely result in a higher AMP, and would result in an increase in drug manufacturers' rebate liabilities.

The sole reasons offered by CMS, therefore, for including mail order in the AMP calculation is that its removal would not be consistent with "past policy" and that it would result in "an increase in drug manufacturers' rebate liabilities."

Congress, however, has deemed that AMP will now also serve a new purpose – as a measure for reimbursement. For CMS to choose to make the measure fit merely the old purpose is to reject Congressional

intent in making AMP a measuring unit for a new purpose. "Past policy" therefore does not apply to this new use of AMP. In addition, if the purpose of the Deficit Reduction Act was to reduce budgetary costs to the federal government, it is inconsistent with the DRA for CMS to be so concerned with potential increases in manufacturers' rebate payments to the states that it reduces AMP, thus negatively impacting reimbursements to pharmacies.

Administrative and Service Fees (p. 39, p. 77180, **II. Provisions of the Proposed Regulation -** *Definitions – Section 447.502*)

This is yet another area that exists as part of AMP because of its legacy as a measure of rebates. CMS concedes that "Some believe that these fees should not be included in AMP because the manufacturer does not know if the fees act to reduce the price paid by the end purchasers." (p. 39, p. 77180). Unless there is transparency by PBMs, there is strong reason to believe that these fees do not in fact reduce the price paid by the end purchasers. Certainly retail pharmacists do not receive administrative and service fees, so NCPA's position is that they are not provided to, and should not be included in the definition of, retail pharmacy class of trade.

Direct Patient Sales (pgs. 40 – 41, pgs. 77180 – 77181, **II. Provisions of the Proposed Regulation -** *Definitions – Section 447.502*)

These are special deals in which community pharmacy does not participate, and as such, should not be included in the calculation of AMP.

Manufacturer Coupons (p. 42, p. 77181, **II. Provisions of the Proposed Regulation -** *Definitions – Section 447.502*)

CMS again shows sensitivity to an area that has been "problematic for CMS as well as some manufacturers" (p.42, p. 77181) without adequate understanding of what happens to community pharmacy. Later in the same page, CMS writes, "In this proposed rule, we propose to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of AMP", thus including "coupons redeemed by any entity other than the consumer in the calculation of AMP."

NCPA believes that if consumer-redeemed coupons are not included in the retail pharmacy class of trade, then there is no reason to exclude those redeemed by the pharmacist, for in such cases the pharmacist is merely a pass-through entity – the pharmacist does not realize any monetary gain. As the pharmacist does not receive monetary benefit when it redeems a coupon, pharmacist-redeemed coupons should also be excluded from the calculation of AMP.

Similarly, patient assistance programs should also not be included in the calculation of AMP, as these sales have nothing to do with the price paid by the wholesaler or the pharmacy, and would inappropriately lower the AMP. For this reason, drugs provided to patients through manufacturer assistance programs should not be included in the AMP. These items cannot by law be included in the AMP because they do not reflect prices paid by wholesalers to manufacturers for drugs distributed to the retail class of trade.

Future Clarifications of AMP (p. 43, p. 77181, **II. Provisions of the Proposed Regulation -** *Definitions – Section 447.502*)

CMS intends to "address future clarifications of AMP through the issuance of program releases and by posting the clarifications on the CMS website as needed." Some areas of clarification will likely reflect policy choices, as opposed to being technical clarifications. For those more substantive areas, NCPA advocates using a regulatory, due process method of proposing and receiving comment on proposed rulemaking.

Determination of Best Price – Section 447.505 (p. 44, pgs. 77181- 77182, **II. Provisions of the Proposed Regulation)**

To obtain Medicaid coverage of their products, drug manufacturers must enter into a rebate agreement with CMS. The basic rebate formula for generics (non-innovator multisource drugs) is 11% of AMP.[14]

Pharmacists do not receive or give these rebates – the manufacturers provide them to Medicaid. CMS goes to great lengths to exercise its authority and discretion to clarify the requirements for best price. This choice stands in stark contrast to the authority and discretion which it consistently declines to exercise in several key areas of this proposed rule on areas which need clarification regarding the definition of retail pharmacy class of trade and AMP. Those refusals to exercise discretion and maintain the status quo despite clear indications of the true state of the perverse disincentive to dispense generic drugs created by the proposed rule will, if not rectified, lead to injury to patient access to Medicaid medications.

Any discussion of best price, therefore, must first note this dichotomy between CMS's treatment of best price on the one hand, and AMP and the definition of the retail pharmacy class of trade on the other.

Issues regarding best price, including the nominal price aspect of best price, are of more concern to manufacturers than to community pharmacy as the best price metric affects the levels of manufacturer rebates. CMS does, however, include nominal price in the calculation of AMP (p. 131, p. 77198), which is illogical as nominal price is a best price concept. NCPA also notes, that in the proposed rule, CMS was careful to repeatedly express concern about the potential effects on manufacturer liability when it rejected at several points defining AMP in a way that would increase pharmacy reimbursements. In contrast, the discussion of nominal pricing, CMS expresses an opposite concern on a matter that does not directly affect reimbursements: "Additionally, we believe that adding other entities or facilities would have an undesirable effect on the best price by expanding the entities for which manufacturers can receive the best price exclusion beyond those specifically mandated by the DRA and lowering manufacturer rebates to the Medicaid Program." p. 64., p. 77184.

Finally, the inclusion of nominal price in the CMS definition of AMP appears to override the purpose of including outliers up to 30% of the next lowest AMP into the AMP calculation. CMS must clarify how it is treating these two measurements.

Electronic Submissions - *Requirements for Manufacturers – Section 447.510* **(p.** 72, 77186, **II. Provisions of the Proposed Regulation** - *Definitions – Section 447.502)*

CMS proposes requiring that all product and pricing data (monthly and quarterly) be submitted to CMS in an electronic format. NCPA supports this CMS proposal. In a related issue, NCPA hopes that CMS will impose the same standard to NCPA's efforts to obtain EFT reimbursement payment from PBMs for Part D claims submitted by EFT by pharmacists.

SECTION FOUR – CONCLUSION

In order to reduce the negative impact upon patient access that will result from implementation of the Medicaid provisions of the Deficit Reduction Act of 2005 (DRA), CMS must significantly alter key provisions of CMS-2238-P. As discussed in these comments, CMS must make changes in the following areas:

1. **Proposed Definitions must be significantly changed**

[14] For innovator (brand) drugs, the rebate is the larger of 15.1% of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP. http://www.cms.hhs.gov/MedicaidDrugRebateProgram/.

(under II. Provisions of the Proposed Regulations – *Definition of Average Manufacturers Price – Section 447.504 at p. 21of the CMS website version of the proposed rule and p. 77177 of the Federal Register version)*

Congress gave CMS considerable regulatory authority and responsibility to create REGULATORY definitions that would adequately address the point that AMP now serves two purposes. CMS' intention to side with manufacturer interests at the expense of community pharmacy participation in the Medicaid program -- and in the pharmacy business itself – will hurt patient access and increase health care costs, thus defeating the purpose of deficit reduction. Creating an inadequate AMP-based FUL will lead to these results.

The retail pharmacy class of trade must not include PBMs and sales to Mail order facilities, and must not include elements to which community pharmacy does not have access. The elements of AMP must be restricted so that CMS does not create a lowest manufacturer price instead of an AVERAGE manufacturers price.

2. CMS must provide drug pricing data on a confidential basis to community pharmacy

Without the data, no one (except, of course, for CMS, manufacturers and state Medicaid directors) can provide CMS with the specific examples and information regarding "significant impact" that it seeks. Extrapolating from the GAO report – which utilizes data CMS provided to it - shows that the CMS defined AMP to only approximate 25% of pharmacy acquisition costs.

3. Both the costs savings estimates and the Regulatory Flexibility Act assessments must be changed as they fail to recognize the impact upon community pharmacy and the increased health care costs of Medicaid beneficiaries that implementation of the rule would cause.

(I. Background – *Changes Made by the Deficit Reduction Act of 2005 at p.8, p. 77175, and* **V. Regulatory Impact Analysis**. *3. Effects on Retail Pharmacy at pgs. 108 – 110, pgs. 77192 -77193)*

4. CBO said that CMS's Costs Savings assume that states will increase their dispensing fees – If the states do not do so, then pharmacy reimbursements will be even lower. States are not required to increase dispensing fees. **Even if they increase them to meet the Grant-Thornton calculated average dispensing fee cost of $10.50, community pharmacies will not receive adequate reimbursements because of the artificially low AMP contemplated in the proposed rule. CMS should reveal what levels of increased state dispensing fees it gave as a basis for CBO's analysis.**

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176 and **V. Regulatory Impact Analysis.** F. Conclusions at p. 119, p. 77195*)*

5. We emphasize again that retail pharmacy class of trade should be defined as only retail pharmacies. The definition should not include PBM mail order operations, which dispense almost no Medicaid prescriptions.

(II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP at p. 25 and p. 77178 and p. 34 and p. 77179).*

6. CMS "invite[s] comment as to whether [the following] proposal is operationally feasible": to "include PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP". **Community pharmacy knows that it does not receive these rebates, discounts or other price concessions. Requiring PBM transparency will provide solid proof.**

(II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP at p. 34 and p. 77179)*

7. **The Definition of "Dispensing Fee" Needs to be wholly inclusive of the true costs to pharmacists/pharmacies to dispense Medicaid drugs.**

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176 and **V. Regulatory Impact Analysis.** F. Conclusions at p. 119, p. 77195*)*

8. CMS needs to strongly encourage the states to increase their inadequate dispensing fees, consistent with the policy it stated in its March 31, 2006 Roadmap to Reform.

(II. Provisions of the Proposed Regulations – Definitions – Section 447.502 – Dispensing fee at p.15, p. 77176 and **V. Regulatory Impact Analysis.** F. Conclusions at p. 119, p. 77195*)*

9. NCPA supports the use of NDC 11-digit codes for reimbursement purposes, which CMS appears to state is logical, but then backs away from implementing. Independent pharmacies are generally small businesses that have to be careful to buy the most economical packaging balanced with sensitivity to patient needs.

(II. Provisions of the Proposed Regulations – *Definitions – Section 447.502 – National drug code at p. 19, p. 77177 and Upper Limits for Multiple Source Drugs – Section 447.514 at pgs. 81 – 83 and pgs. 77187 – 77188)*

10. The reporting period should be at least weekly and NCPA advocates implementation of smoothing/rolling of data.

(II. Provisions of the Proposed Regulations – *Requirements for Manufacturers – Section 447.510 at pgs. 65 – 73, pgs. 77185 - 77186)*

11. Cuts to pharmacy are much greater than CMS' characterization of a "1% loss of drug revenues". CMS contradicts this assertion by stating that there will be a "significant impact" upon small pharmacies. CMS must place greater weight on the RFA impact upon these pharmacies. NCPA estimates that the impact of this rule on independent pharmacies and their Medicaid patients will be devastating.

(V. Regulatory Impact Analysis – 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

12. NCPA requests that CMS provide AMPs for the 77 multi-source medications provided to the GAO. NCPA further requests that CMS leave open the comment period for another 60 days so our comments may reflect actual AMP data.

(I. Background – *Changes Made by the Deficit Reduction At of 2005 at p.8, p. 77175,* and p. 1, p. 77174**)**

13. CMS must consider, ascertain and fulfill its RFA obligations regarding the impacts of the proposed rule upon community pharmacy.

(V. Regulatory Impact Analysis – pgs. 93 – 110, pgs. 77190 – 77193, particularly 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

14. CMS should implement the following exemptions for community pharmacies based on the following criteria: 1) SBA definition of small business based on gross volume of business; or 2) pharmacies that have a 10% or more volume of Medicaid business. Those pharmacies exempt under this criteria should instead be reimbursed based on a formula that accurately reflects independent community pharmacies.

(V. Regulatory Impact Analysis – pgs. 93 – 110, pgs. 77190 – 77193, particularly 3. Effects on Retail Pharmacies at pgs. 108 – 110, pgs. 77192 – 77193)

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

Organization : Uptown Drug & Gift Shop

Category : Pharmacist

Issue Areas/Comments

Background

Background

See Attached

Collection of Information Requirements

Collection of Information Requirements

See Attached

GENERAL

GENERAL

See Attached

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attached

Regulatory Impact Analysis

Regulatory Impact Analysis

See Attached

Response to Comments

Response to Comments

See Attached

CMS-2238-P-1340-Attach-1.DOC

Attach # 1340

February 20, 2007

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

File code: CMS-2238-P
(42 CFR Part 447)

To Whom It May Concern:

Uptown Drug & Gift Shop is a family run business established in 1945. For the past twenty-seven years the store has been located in the Mid-Wilshire area. Uptown Drug & Gift Shop is dedicated to helping patients receive the best possible medical care as it relates to pharmacy services. First and foremost, we are prescription specialists.

Medicaid patients comprise approximately 95% of Uptown Drug & Gift Shop's pharmacy business. The implementation of the proposed rule by CMS would severely impact our ability to serve patients in the Medicaid program. As such, I respectfully submit the enclosed comments regarding CMS-2238-P.

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.

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 customers 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. ***PBM's operate mail order facilities in the U.S.A. and they earn certain rebates, discounts and other price concessions that are <u>not</u> 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 independent pharmacies.***

5. ***PBM's 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. PBM's "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 independent retail pharmacy are not, in any fashion, shared with the pharmacy.***

6. ***PBM's are <u>not</u> 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.

<u>Conclusion:</u>

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

<u>Treatment of Medicaid Sales.</u>

In the proposed regulation CMS states that rebates paid to the States under the Medicaid Drug Rebate Program should be excluded from AMP calculations, but the price concessions associated with the sales of drugs in the retail class of trade which are provided to Medicaid patients should be included.

<u>Comments:</u>

Kindly review the examples under the impact analysis section of this document. States require multi-source generic manufactures to "register" their products prior to acceptance on the states Medicaid formulary. Pharmacies are not permitted to dispense a multi-source generic products (to Medicaid patients) of manufacturers who are not approved. Approved manufacturers pay rebates to the state (estimated at 15% - 16%) for products dispensed to Medicaid patients. No portion of these rebates are shared with the retail pharmacy community and therefore are not a component of pharmacy acquisition cost.

<u>Determination of Best Price.</u>

CMS proposes that best price be calculated for single source or innovator multiple source drugs to include all sales, discounts, and other price concessions provided by the manufacturer for covered outpatient drugs to any entity unless the manufacturer can demonstrate that the sale, discount, or other price concession is specifically excluded by statute or is provided to an entity not included in the rebate calculation. To the extent that an entity is not included in the best price calculation, both sales and associated discounts or other price concessions provided to such an entity should be excluded from the calculation.

OIG recommended that CMS clarify the treatment of all PBM rebates. The document states that manufacturers do not know what part of these discounts are kept by the PBM and what part is passed on to the insurer or other entity and what part that PBM entity passes on to pharmacies. Additionally CMS states that PBM's have assumed a significant role in drug distribution.

Comment:

No PBM rebates or other price concessions or discounts are shared with Uptown Drug & Gift Shop. Therefore, these discounts must be excluded from any calculation of Best Price or require the PBM's to relinquish their rebates to retail pharmacy.

Exclusion From Best Price of certain sales at a Nominal Price (section 447.508).

The national rebate agreements permit manufacturers to exclude from their Best Price calculation outpatient drug prices below 10% of the AMP. CMS is proposing to define Nominal Price as prices at less than 10% of the AMP in the same quarter only when certain safety net providers are the purchasers. These safety net providers include: federally qualified health centers, (340B); certain family planning projects; HIV / AIDS programs, black lung clinics, hemophilia centers, Native Hawaiian Health Centers, urban Indian organizations, sexually transmitted disease treatments, TB, and mental retardation (ICF /MR) programs.

CMS recognizes that Nominal Price exclusion will continue to be used as a marketing tool. Historically, patients frequently remain on the same drug regimen following discharge from a hospital (or safety net provider).

Comments:

Nominal Priced products should be excluded from Best Price calculations because these prices are not in any way representative of the acquisition costs available to retail pharmacies.

Aggregate Upper Limits of Payment (aka: FUL) – Section 447.512.

Upper Limits for Multiple Source Drugs
Section 447.514

Upper Limits for Multi-Source (M.S.).

The DRA (effective January 1, 2007) states that a FUL must be established for each Multi-Source drug for which the FDA has rated two or more products as therapeutically equivalent.

Currently CMS selects the lowest price (AWP, WAC or direct cost) from among the A rated formulations and drugs not proven to be therapeutically equivalent (B rated drugs) and applies the formula described in 447.332 (150% of published price) to determine the FUL for the drug.

Effective January 1, 2007 the FUL for Multi-Source drugs shall be established at 250% of the AMP for the least costly therapeutic equivalent. Calculation of AMP will be at the nine-digit NDC thereby combining all package sizes of the drug into the same computation.

CMS believes that computing the AMP at the 11-digit NDC would not be significantly more than computing the AMP at the 9-digit level. State Medicaid payments are computed at the 11-digit NDC.

CMS believes that computing FUL at AMP times 250% is sufficient pharmacy reimbursement for the drug regardless of the package size the pharmacy purchases.

Comments.

1. ***If pharmacies purchase the most economical package size, the return on investment decreases if the drug is not a high volume***

product. Also its chance for out-dating increases yielding a net loss to the pharmacy.

2. *The inclusion of B rated multi-source drugs means that CMS is sanctioning the practice of dispensing generic drugs which are <u>not</u> proven to be therapeutically equivalent. FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" defines A & B rating. If CMS chooses to include "B" rated drugs then CMS must indemnify retail pharmacies from all adverse patient reactions and/or negative outcomes. Further, some Medicaid programs will only reimburse A rated equivalents causing a conflict in this area.*
3. *The DRA changed a requirement whereby an FUL must be established for each multiple source drug for which the FDA has rated two or more products as therapeutically equivalent. If the FUL is to be calculated at the limitation of two products then the regulation must insure that these products are readily available for purchase by all retail pharmacies.*

Example: Independent pharmacies purchase their multi-source drugs from national wholesalers. If wholesaler A does not inventory the lowest priced multi-source generic the pharmacy will not be able to purchase the product from Wholesaler B. Wholesale B may have the product, but the pharmacy will not be able to purchase it. Wholesalers sell to independents under contractual agreements which are not readily transferable. Independent retail pharmacies are not able to 'cherry pick' or price shop between wholesalers on a product by product basis. Therefore it is essential that the FUL be based only on pricing of products readily available at all major wholesalers.

<u>The Regulatory Flexibility Act. (aka: RFA)</u>

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small businesses if a proposed or final rule would have a "significant impact on a substantive number of small entities." Small retail pharmacies are one of the three small business entities potentially affected by this regulation.

According to the SBA's size standards, a retail pharmacy is a small business if it has revenues of $6.5 million or less per year. (<u>www.sba.gov/size/sizetable2002.html</u>)

Small pharmacies will be negatively affected by these regulations resulting in lower <u>FUL's</u> for most drugs subject to the limits, thus reducing Medicaid payments to pharmacies.

CMS concludes that the proposed rule would reduce retail prescription sales by less than 1%, on average. CMS also concludes that <u>all</u> of these stores sell goods other than prescriptions drugs and that pharmacies have the ability to mitigate the effects of the proposed rule by changing purchasing practices.

<u>Comments:</u>

1. *More than 92% of the total sales in Independent pharmacies is from prescription drugs. Therefore there is little opportunity to profit from*

other sales as defined by CMS. Additionally 55% to 70% of the dispensed prescriptions are for multi-source generic drugs which represent approximately 22% of the sales (in dollars) and 70% of the gross profit. These gross profit margins are necessary to pay for the rent, utilities, wages, taxes and insurance and other costs of the business. If all of the price concessions described in this document are included in the calculation of AMP then the resulting FUL will decrease the profit margins on multi-source generic prescription as much as 50% thereby forcing many pharmacies to close their doors. In effect, CMS is requiring the independent pharmacy to cut by half 70% of the gross profit dollars coming into the pharmacy. That is an unbearable burden for any small business to weather.

2. *CMS also proposes to include in the calculation of AMP manufacturer rebates paid:*
   For Medicare Part D Sales
   To State Pharmaceutical Assistant Programs (SPAP)
   To PBM's (who operate the country's mail order facilities)
   To Medicaid programs

   CMS also proposes to include all administrative and service fees, except those for bona fide services paid by manufacturer, to be included in the calculation of AMP.

3. *CMS proposes to include manufacturer coupons redeemed at retail pharmacies.*

   Independent retail pharmacies <u>do not</u> share in any of the above listed manufacturer price concessions. Utilization of these concessions to reduce the AMP (and subsequent calculation of FUL) will subject pharmacies to receive reimbursements that do not reflect a realistic net acquisition cost experienced by the pharmacy and thus will severely jeopardize the financial viability of independent pharmacies.

<u>Impact Analysis.</u>

It is not possible to calculate the financial impact of the CMS AMP calculation due to the fact that AMP's are not available to the retail community. Only manufacturers and CMS have access to these numbers at this time. Following is a hypothetical scenario of the financial impact of AMP on independent community pharmacy utilizing CMS' proposed rules.

Example #1.

Drug A with a CMS calculated AMP of $0.10 per tablet.

FUL = $0.10 x 250%
= $0.25 per tablet

Pharmacy reimbursement for prescription for 30 tablets of Drug A utilizing current Medicare Part D or Medicaid reimbursement formula's and AMP.

30 tablets x $.25	=	$7.50
Current average Medicaid dispensing fee	=	<u>$4.15</u>
Total payment to pharmacy		$11.65

Independent pharmacies net cost of Drug A utilizing the proposed CMS rule.

Manufacturer invoice price to a wholesaler	=	$0.10
Plus value of PBM rebates	=	5% - 15%
Plus value of Medicaid/rebates	=	15% - 16%
Plus value of SPAP rebates	=	unknown
Plus value of Medicare rebates	=	unknown

(the marketplace does not divulge the value of Medicare or SPAP rebates so for argument sake we will select a factor

of 50% which is conservative)		$0.10
	+ 50%	$0.05
		$0.15
Wholesaler markup to cover inventory and distribution costs to independent pharmacies. (15% - 25%)		
	+ 20%	$0.03
Net Cost to pharmacy		$0.18

Profitability to independent pharmacy:

Total Payment	=	$11.65
Less product cost (0.18 x 30)	=	$5.40
Gross Profit		$6.25

Example #2

Many states are utilizing the Managed Medicaid model for provision of prescription and medical services to Medicaid eligible patients. The average dispensing fee paid in this model is $2.00. If a Medicaid prescription is dispensed under the typical managed reimbursement model the financial impact on independent pharmacy is devastating.

30 tablets x $.25	=	$7.50
Current average Medicaid dispensing fee	=	$2.00
Total payment to pharmacy		$ 9.50

Independent pharmacies net cost of Drug A utilizing the proposed CMS rule.

Manufacturer invoice price to a wholesaler	=	$0.10
Plus value of PBM rebates	=	5% - 15%
Plus value of Medicaid/rebates	=	15% - 16%
Plus value of SPAP rebates	=	unknown
Plus value of Medicare rebates	=	unknown

(the marketplace does not divulge the value of Medicare or SPAP rebates so for argument sake we will select a factor of 50% which is conservative)

		$0.10
	+ 50%	$0.05
		$0.15
Wholesaler markup to cover inventory and distribution costs to independent pharmacies. (15% - 25%)		
	+ 20%	$0.03
Net Cost to pharmacy		$0.18

Profitability to independent pharmacy:

Total Payment	=	$ 9.50
Less product cost (0.18 x 30)	=	$5.40
Gross Profit		$4.10

According to a national study released on February 1, 2007 by the Coalition for Community Pharmacy Action (CCPA) the national average cost of dispensing medication is $10.50 per prescription which is in addition to the ingredient cost of the drug. In order to remain profitable and to deliver prescription services to millions of American citizens Medicaid reimbursement must be adequate to permit the continuation of this service. Currently independent pharmacies dispense multi-source generic prescriptions at a rate of 55% to 70% of all prescriptions. In other words, up to seven out of ten prescriptions are generics. Implementation of the proposed CMS AMP rule will devastate the financial viability of independent community pharmacy.

Conclusion.

1. ***The inclusion of manufacturer rebates and price concessions in the calculation of AMP clearly benefits manufacturer and disadvantages independent pharmacies because these price reductions are not shared with independents yet they are added into the cost of multi-source drugs paid by independent pharmacies.***

2. ***Independent pharmacies serve nearly 40% of the marketplace for their prescription needs. We are unique in our level of patient service where satisfaction levels are the highest in the entire health care industry. We are also the only prescription provider in rural America and in the majority of urban population centers.***

3. ***Independent pharmacies purchase their drugs from wholesalers under contractual agreements that link a pharmacy to a wholesaler for 90-95% of their purchases. Independent pharmacies do not have the ability to move their purchasing to another wholesaler or supplier if one of these entities has a "lower" priced generic.***

   Availability of the lowest price Generic drugs must be universal or the AMP pricing rule will place independent pharmacy at a competitive disadvantage. Availability must also mean that "stock is on hand", not just listed in a data base as available.

4. ***CMS proposes to include FDA "B" rated drugs in the calculation. With this inclusion the Department of Health and Human Services must indemnify retail pharmacies from any harmful affects resulting from the utilization of these FDA declared substandard drugs.***

5. ***If CMS is unwilling to modify the inclusion of rebates and price concessions in their calculation of AMP then CMS should include a Minimum Margin for low cost generic drugs for independent pharmacies. The minimum margin must, at the very least, cover the cost of dispensing.***

6. ***CMS suggests, without mandate, that states should amend their dispensing fees to modify the AMP impact. This is unlikely due to federal payment reductions to state Medicaid programs and budget constraints at the state level.***

   Additionally many states have implemented a managed care model for Medicaid patients. Prescriptions dispensed under this model will utilize AMP, but will not modify dispensing fees due to the capitated agreements.

The majority of managed Medicaid programs are administered by PBMs under the proposed rules discussed in this document. CMS is rewarding the PBM's and their mail order businesses because of their access to rebates and other manufacturer price concessions.

Respectfully Submitted,

Gerald Shapiro, P.D.
Owner
Uptown Drug & Gift Shoppe
444 S Flower St Ste 100
Los Angeles, CA 90071

Submitter : Dr. Bob Phillips **Date:** 02/20/2007

Organization : H & S Pharmacy #2

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1341-Attach-1.PDF

#1341

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

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

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

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

Submitter :

Organization : **Planned Parenthood of Central Oklahoma**

Category : **Other Health Care Provider**

Date: **02/20/2007**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-2238-P-1342-Attach-1.DOC

Attach# 1342

COMMENT FROM
PLANNED PARENTHOOD of CENTRAL OKLAHOMA

I am the CEO of Planned Parenthood of Central Oklahoma, a non-profit healthcare organization operating five outpatient clinics in Oklahoma City, Norman, Edmond and Midwest City, Oklahoma and that provides critical health services to uninsured and underinsured women. Planned Parenthood of Central Oklahoma serves over 8,400 patients, many of whom could not otherwise afford the health services -- particularly oral contraceptives -- that Planned Parenthood of Central Oklahoma provides.

For more than 70 years, Planned Parenthood of Central Oklahoma has served a vulnerable population of women who cannot normally afford contraception by providing them access to oral contraceptive pills at prices far lower than what is available in the retail market. Planned Parenthood of Central Oklahoma has been able to serve this underprivileged community because it could purchase oral contraceptive drugs from drug manufacturers willing to provide them at nominal prices. The very existence and fiscal viability of Planned Parenthood of Central Oklahoma turns on its 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 provide the low-cost outlet for poor women that they so desperately need, and that we very much 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 Central Oklahoma's sister health centers across the country are Title X clinics, and therefore 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured. Planned Parenthood of Central Oklahoma, however, is not federally funded. Planned Parenthood of Central Oklahoma is not a 340B covered entity eligible under the terms of the proposed rule for nominal prices.

Planned Parenthood of Central Oklahoma, 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 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 plight of Planned Parenthood of Central Oklahoma and other similarly situated non-profit outpatient 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 Planned Parenthood of Central Oklahoma 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.

Moreover, we have been told by several manufacturers who have historically sold to us at nominal prices that we may have to pay full prices 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 Planned Parenthood of Central Oklahoma and entities like it from the nominal price exception will not effect best price at all -- the only consequence of this policy will be to preclude manufacturers from charitably helping safety net providers like Planned Parenthood of Central Oklahoma to serve our patients.

In conclusion, Planned Parenthood of Central Oklahoma is a non-profit outpatient health care facility that serves a critical function in the health and well being of more than 8,400 uninsured and underinsured women in central Oklahoma. Planned Parenthood of Central Oklahoma 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 more than 70 years. Carving safety net providers like Planned Parenthood of Central Oklahoma out of the nominal pricing exception would be devastating to our mission and to our operations. Planned Parenthood of Central Oklahoma urges CMS very strongly to reconsider its position and apply the safety net provider exception as provided in the DRA.

Submitter : Dr. Franklin Crigger **Date:** 02/20/2007

Organization : H & S Pharmacy #2

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1343-Attach-1.PDF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Tim Hammonds **Date:** 02/20/2007

Organization : Food Marketing Institute

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

Please use this submission in lieu of the documents filed earlier this afternoon by courier and electronically. the earlier documents both contained significant typographical errors. Thank you.

CMS-2238-P-1344-Attach-1.PDF

1344

Your Neighborhood Supermarkets

February 20, 2007

Via Courier

Leslie Norwalk, Esq.
Acting Administrator
The Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Proposed Rule To Implement Provisions of DRA Pertaining to Prescription Drugs under the Medicaid Program; (Docket No. CMS--2238--P)

Dear Administrator Norwalk:

The Food Marketing Institute (FMI) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid program. 71 Fed. Reg. 77174 (Dec. 22, 2006). FMI is highly concerned about the impact of the proposed rule on its supermarket pharmacy members. As CMS notes in the proposed rule, the use of Average Manufacturer Price (AMP) as a benchmark for pharmacy reimbursement represents a departure from the previous role of AMP in the Medicaid rebate calculation. Understanding the difficulties that the agency faces in reconciling these conflicting roles for AMP, we believe that several of the decisions CMS has proposed would unduly reduce AMP. Our comments and recommendations are discussed more fully below and in the attached Appendix A, which translates our comments into regulatory language for your consideration.

FMI conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies - food retailers and wholesalers - in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion - three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

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FMI's retail members also operate more than 10,000 in-store pharmacy departments. We estimate that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs dispensed in the United States. Based on current industry trends toward larger store formats and the convenience of one-stop shopping, we anticipate that the number of pharmacies located in supermarkets will continue to increase in the coming years as will the number of prescriptions that are dispensed on an outpatient basis from these community settings.

A. Executive Summary

FMI urges CMS to take the steps necessary to ensure that pharmacies are adequately reimbursed for serving Medicaid patients. Recent studies suggest that Federal Upper Limits (FULs) based on AMP may result in ingredient cost reimbursement that is below pharmacy acquisition cost.[1] While FMI is not certain that this situation can be fully addressed in regulations, we believe that CMS should take the following steps to mitigate this problem:

- Restrict the scope of discounts included in the "retail class of trade" to reflect only those prices that are provided to wholesalers for drugs distributed to retail pharmacies;
- Define "wholesaler" in a manner that better reflects current law and practice;
- Remove from the proposed rule's definition of AMP sales to PBMs, outpatient hospitals, clinics and mail-order pharmacies that fall clearly outside of the statutory definition of AMP;
- Remove from AMP those prices that Congress excluded from "best price" to allow for deep discounts that could otherwise artificially deflate AMP;
- Set FULs based on the average AMP of various therapeutic alternatives, rather than the lowest cost alternative;
- Exercise discretion to delay publication of AMP information to ensure that the consequences of publishing this information are fully understood;
- Reduce the potential for volatility in the AMP-based reimbursement system by removing a larger number of outliers when establishing FULs;
- Base FULs on the AMPs of those products that are nationally available and in sufficient supply to meet the needs of pharmacies over time;
- Revise the regulatory definition of "dispensing fee" to ensure that all pharmacy costs are identified; and
- Require states to update their Medicaid dispensing fees to be sure that these fees are adequate in light of newly implemented DRA policies, particularly to ensure appropriate utilization of generic drugs.

The remainder of this letter provides more details on each of these issues as well as proposed regulatory language in Appendix A.

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[1] Government Accountability Office "Medicaid Outpatient Prescription Drugs: Estimated 2007 Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs", Letter to Rep. Joe Barton (R-TX) (December 22, 2006).

B. Policy Context

Supermarket pharmacy profit margins are generally only a very small percent of total revenue, far lower than most other businesses. In this context, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. FMI and its members are particularly concerned about the impact of the DRA's FUL policies on retail pharmacies. According to the GAO's comparison of AMP-based FULs to pharmacy acquisition costs, AMP-based FULs were 36% lower than average pharmacy acquisition costs when calculated using information from the first quarter of 2006. To the extent that FULs are below pharmacy acquisition costs for generic drugs, our members may find it increasingly difficult to serve Medicaid patients. This situation is exacerbated by dispensing fee amounts at the state level that are far below the costs our members incur to dispense prescription drugs to Medicaid patients.

FMI is aware that the use of AMP in setting FULs is dictated by the DRA, and of the difficulty facing the agency in balancing between the use of AMP for reimbursement and its use in the calculation of manufacturer rebates to the Medicaid program. Along with others in the pharmacy community, FMI is involved in efforts to address this problem legislatively. However, as we discuss in the balance of this letter, we believe that CMS has significant discretion to mitigate the severity of the problem, discretion that the agency has not fully exercised. We urge CMS to emphasize the role of AMP as a reimbursement benchmark in the final rule to ensure that our member pharmacies can continue to serve Medicaid patients.

C. Analysis of Issues

1. Revise Proposed AMP Definition To Exclude Sales to Mail Order and PBMs That Are Outside the Statutory Definition of AMP.

While FMI recognizes the difficulties that the DRA has imposed on CMS by requiring AMP to be used for a very distinct new purpose, we believe that CMS errs in the proposed rule by defining AMP as encompassing a variety of sales that are outside of the statutory definition of AMP. The statute is clear: AMP is the *average* price paid to the manufacturer for the drug in the United States *by wholesalers* for drugs *distributed to the retail pharmacy class of trade*.[2] In contrast, CMS proposes to include price structures that are beyond the statutory definition either because they do not reflect prices paid by true wholesalers or because they do not reflect discounts and concessions that are ultimately realized by the retail class of trade. Accordingly, and as explained more fully below, CMS has proposed a regulatory definition for AMP that is neither adequately supported by the statute nor an effective benchmark for pharmacy reimbursement.[3]

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[2] §1927(k)(1) of the Social Security Act (42 U.S.C. 1396r-8(k)(1).

[3] As noted, FMI does not believe that AMP – even as defined by the statute – can be an effective benchmark for pharmacy reimbursement under the Medicaid program. Nonetheless, given the enactment of the DRA, we recognize that Congress has made a determination in this regard, and CMS is obligated to implement that legislative decision.

a. Exclude Discounts Given to PBMs and Mail Order Pharmacies Because These Businesses are Outside the Retail Class of Trade.

FMI's primary concerns with the proposed definition of AMP are the overly broad view of retail class of trade and the definition of wholesaler. Section 1927(k)(1) of the Social Security Act defines AMP in relevant part as "the average price paid to the manufacturer for the drug in the United States by *wholesalers* for drugs distributed to *the retail pharmacy class of trade*." We believe that this definition in fact counsels that AMP "should only reflect prices of sales to those pharmacies which dispense drugs to the general public", an option that CMS chose to reject as inconsistent with "past policy."[4] We would note, however, that the "past policy" to which CMS refers was implemented at a time when AMP was not being used for pharmacy reimbursement purposes, but only for the purpose of calculating rebates owed by manufacturers to CMS and the states. Accordingly, CMS is not bound by its past policy, nor should the agency feel constrained to operate within it. Rather, given the new task imposed on CMS by the DRA, CMS should establish a new policy reflective of the multiple purposes that AMP must now serve.

Indeed, reading the statutory definition of AMP in light of its new use as a reimbursement benchmark counsels for excluding sales to PBMs, mail-order pharmacies and other entities that are outside the retail class of trade. The inclusion of PBM discounts and mail order prices that are clearly not accessible to retail pharmacies artificially deflates AMP, potentially impeding the convenient access of Medicaid beneficiaries to supermarket pharmacies if these retail outlets cannot receive adequate reimbursement for their pharmaceutical acquisition costs for generic drugs.

In addition, it is our understanding that some manufacturers consider both mail order pharmacies and PBMs to be separate and distinct from the retail class of trade. Indeed, it is difficult to describe PBMs as falling within the retail class of trade, as their pharmacy benefit management functions are not directly involved in the supply chain for pharmaceuticals. Only in their role as mail order pharmacies do PBMs typically participate directly in the purchase and delivery of prescription drugs, an activity which is also outside the retail class of trade. Mail order pharmacies take title and deliver products to patients but are a separate and distinct option for consumers in contrast to the supermarket and community pharmacies that are typically considered "retail". Indeed, in its rule implementing the Medicare Modernization Act, CMS explicitly excludes mail order pharmacies from its definition of "retail pharmacy."[5]

b. Discounts Given to PBMs and Mail Order Pharmacies – Entities Typically Outside of the Wholesaler Distribution System – Cannot Be Included in AMP

Not only does the statute limit the data to be used to calculate AMP to prices paid for drugs distributed within the retail class of trade, the statute expressly defines AMP as the

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4 71 Fed. Reg. at 77178.

5 70 Fed. Reg. 4493, 4535 (January 28, 2005).

price *paid by wholesalers*. Therefore, although discounts to PBMs and mail order pharmacies may affect the "net price realized by manufacturers," as asserted by CMS, the statute requires the use of wholesaler pricing in the determination of AMP. Indeed, many of the sales to PBMs and mail order do not flow through wholesalers at all, so the discounts received by PBMs and mail order generally do not affect the price paid by "wholesalers," as this term is typically defined.

Specifically, CMS proposes to define "wholesaler," as follows:

> Any entity (including a pharmacy, chain of pharmacies or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drugs.

Proposed 42 CFR 477.504(f). The proposed regulatory definition, which includes retail outlets, overreaches common and statutory wholesaler definitions resulting in a situation that is contrary to state licensing practices and conflicts with related federal statutes.

First, treating pharmacies as wholesalers is inappropriate and could unduly burden FMI's members with new licensing requirements at the state level. Supermarket pharmacies are licensed as pharmacies – not wholesalers, to which different licensing and regulatory requirements apply. Accordingly, supermarket pharmacies are not properly considered wholesalers.

Moreover, the distribution functions typically performed by wholesalers are far different from the administrative functions performed by PBMs. Section 510(g) of the Federal Food, Drug, and Cosmetic Act defines "wholesale distributor" as an entity "who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user."[6] As discussed, PBMs generally do not take title to prescription drugs except in limited instances, and then generally because they are operating as mail order pharmacies and not in their traditional functions as PBMs. Therefore, CMS should not include PBMs within the regulatory "wholesaler" definition either.

c. AMP Should Not Include Discounts that Fall Outside the Medicaid Program

Many of the discounts that CMS seeks to include within the definition of AMP are given by manufacturers to entities that are able to increase the market share of particular products through therapeutic switching and other mechanisms. Under the Medicaid program, which prohibits formularies and a variety of other cost containment tools, pharmacies cannot engage in these practices and are, therefore, ineligible for many of the discounts predicated on these practices. Consequently, it is inappropriate to apply these discounts to AMP when it will be used as a Medicaid pharmaceutical reimbursement benchmark.

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[6] 21 U.S.C. 360.

For these reasons, FMI believes that CMS has erred in its proposed definition of AMP. We urge CMS to promulgate a final regulatory definition of AMP consistent with the recommendations in Appendix A of our comments that omits pricing given to PBMs and mail order pharmacies from the definition and, therefore, will better reflect the retail class of trade and wholesaler elements of the statutory definition.

2. Revise Proposed AMP Definition To Exclude Sales Excluded from Medicaid's "Best Price"

CMS proposes to include within the definition of AMP certain sales, notably sales to Part D plans and State Pharmacy Assistance Program (S-PAPs), that are excluded from Medicaid's "best price". These sales are excluded from "best price" to provide deeper discounts to S-PAPs and Part D plans. Indeed, the Congressional Budget Office specifically scored the exemption from "best price" for sales to Part D plans as producing savings because it "gives those plans more leeway to negotiate steeper price discounts from manufacturers since those manufacturers will not have to pass on the same discount to Medicaid."[7]

The "best price" exclusion reflects the policy judgment of Congress that deeper discounts should be available for particular classes of sales than are typically available to the retail marketplace. The exclusion has been available for many years for various government sales and was extended to prescription drug plans under Medicare Part D in the Medicare Modernization Act.

In contrast to S-PAPs and Part D plans, sales to retail pharmacists are not exempt from best price, and pharmacists are unlikely to receive the level of discounts available to those entities. Thus, including sales that are exempt from "best price" in AMP will artificially lower AMP as a reimbursement benchmark by including discounts in AMP to which pharmacists do not have access. FMI therefore urges CMS to exclude from the definition of AMP those sales that are exempt from "best price" under §1927(c)(1)(C)(i) of the Social Security Act.

3. Statute Requires CMS To Use Weighted Average of AMPs to Set FULs, Not Lowest Cost Therapeutic Alternative

CMS proposes to set AMP-based FULs at 250% of the AMP of the lowest cost therapeutic alternative. While the DRA requires FULs to be set at 250% of AMP, the statute itself does not reference the lowest therapeutic alternative – that benchmark was defined in previous CMS regulations.

Thus, CMS retains the discretion to improve pharmacy reimbursement by using a weighted average of all therapeutic alternatives of a particular prescription drug and should, in

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[7] "A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit." (July 2004). http://www.cbo.gov/ftpdocs/56xx/doc5668/07-21-Medicare.pdf

fact, do so to reflect the standard set by the statute properly. Particularly in light of the GAO's findings that AMP-based FULs are below pharmacy acquisition costs, FMI believes that the use of a weighted average could mitigate the number of instances where pharmacies are to be reimbursed below their acquisition costs and urges CMS to change to a weighted average FUL calculation in the final rule.

4. CMS Should Exercise Its Discretion To Delay Publication of AMP Data

FMI believes that the publication of AMP data has the potential to distort the marketplace for generic drugs, with potentially serious anti-competitive effects. Publishing AMP data could create a floor on the price discounts that generic manufacturers are willing to offer, reducing the level of competition between generic manufacturers with potentially significant negative effects on the Medicaid program.

If AMP data are published, manufacturers may find it difficult to offer discounts to some customers and not to others, as most customers will be unwilling to pay more than the average price. In this scenario, manufacturers will be more likely to sell to all buyers at the same rates, eliminating the benefits of competition that could otherwise accrue to the marketplace. In the case of Medicaid, the government will bear most of the consequences of this reduced competition -- the prices paid prices paid to manufacturers on average will increase, driving AMP-based reimbursement up also.

FMI and others are exploring legislation to ensure that AMP data remain confidential. In the interim, we believe that CMS has the discretion to delay publication of this information and we urge the agency to exercise this discretion.

5. CMS Should Reduce Volatility by Excluding Outlier Prices Less than 10 Percent of Next Highest AMP, Implementing Smoothing Mechanisms Similar to ASP

FMI is concerned about the potential for volatility in the drug reimbursement system, particularly in light of the CMS decision to rely on monthly AMP reports in setting FUL rates. We believe that relying on monthly AMP reports to set FULs and seeking to update FULs on a monthly basis could create significant volatility in the system, along with an undue burden on states seeking to administer FUL rates. We understand that Average Sales Price (ASP) based rates for certain products reimbursed under Medicare Part B have been highly volatile – even though ASP rates are calculated quarterly – and we believe that smoothing mechanisms will also be needed for AMP-based rates.

a. Possible Range Between AMP of Lowest Therapeutic Alternative and Next Highest AMP Should be Reduced

To avoid setting FULs based on "very low" AMPs, CMS proposes to set each FUL based on the lowest AMP "that is not less than 30 percent of the next highest AMP for that

drug."[8] However, as the competition between generic therapeutic alternatives tends to reduce differences between competing products to very small levels, the proposed 70 percent range would still capture and incorporate a wide range of outliers in AMP-based FULs.

Thus, to reduce volatility and ensure a nationally available AMP, we encourage CMS to exclude "outlier" percentages that are more than 10 percent below the next highest AMP. A wider gap between therapeutic alternatives would likely be indicative of problems in AMP data or temporary spikes that would not actually reflect prices nationally available in the marketplace. Using a small percentage range will also improve the ability of pharmacists to purchase prescription drugs at prices below the FUL and better serve the agency's stated purpose of ensuring that drugs are "nationally available at the FUL price."[9]

b. AMP Should Employ "Smoothing" Mechanisms Similar to Those Used in the ASP Reporting System Under Medicare Part B.

In Medicare Part B, CMS created various mechanisms for "smoothing" ASP reporting to limit volatility. For example, manufacturers must calculate "lagged discounts" using a percentage methodology that reduces the potential for these discounts to be over-stated or understated in a particular quarter. The proposed rule for AMP does not employ such a smoothing methodology, which could contribute to volatility in Medicaid reimbursement for generic drugs. FMI urges CMS to require manufacturers to "smooth" those discounts that are included in AMP.

c. CMS Must Ensure That FULs Are Based on Nationally Available Prices.

Finally, CMS should ensure that no FUL is based on an AMP for a generic pharmaceutical produced by a manufacturer that does not make the product nationally available. It is common for generic manufacturers to work directly with select pharmacy chains and wholesalers to meet market share goals in a manner that may not provide national access to their products. Consistent with others in the industry, FMI believes that AMP should only be calculated based on generic products that are AB-rated in the FDA *Orange Book* and are consistently available from the three major national wholesalers in supplies adequate to afford national distribution. Products that are erratically available or that are available only in limited supplies should be excluded from the weighted average AMP calculation. We are particularly concerned that a FUL could be set by a manufacturer undercutting the market, but without enough supply to meet market demands for an extended period of time. Particularly if CMS does not move to a FUL based on weighted average AMP, we would urge the agency to take steps to ensure that each AMP used to represent a FUL reflects a product that continues to be available to all retail pharmacies.

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8 71 Fed. Reg. at 77188.

9 *Id.*

6. CMS Should Take All Necessary Measures To Ensure Adequacy of State Dispensing Fees

In order to protect convenient access to prescription drugs for Medicaid beneficiaries, CMS must ensure that the final regulatory definition of "dispensing fee" captures all of the applicable pharmacy operating costs. Specifically, the definition of dispensing fee in the proposed rule should be amended to include medication therapy management services and a reasonable return for pharmacies. As Medicaid may no longer adequately reimburse pharmacies for the ingredient costs of generic drugs, setting dispensing fees adequate to cover pharmacy costs in delivering pharmaceuticals to Medicaid beneficiaries is absolutely essential. (Suggested regulatory language for CMS's consideration in this regard is included in Appendix A.)

According to various sources, the current average dispensing fee at the state level is approximately $4.50. Recent studies of the actual costs to pharmacists to dispense prescription drugs have placed those dispensing costs at between $9 and $14 per prescription, depending on the state, with a national average of more than $10.[10] Thus, dispensing fees at the state level are clearly inadequate to cover pharmacy costs.

Accordingly, CMS should take an active role in informing the states about the need to adjust dispensing fees, especially in light of the DRA FUL policy. CMS should require each state to make a specific finding that the existing dispensing fee structure is not only adequate to cover pharmacy costs (including a reasonable return), but also that these fees provide adequate incentives for generic usage in light of the revised FUL policy. CMS should direct states to increase dispensing fees that will not allow for adequate generic usage.

These suggestions reflect Congressional intent in enacting the DRA. Specifically, during the DRA debate, Senator Grassley stated that "states will need to review and increase the fees that they pay pharmacies for dispensing Medicaid prescriptions" in response to the revised FUL policy.[11] Without significant changes in state dispensing fees, pharmacy incentives to encourage generic utilization will be significantly reduced, with the corresponding potential to reduce greatly the savings that the DRA's imposition of AMP-based FULs was intended to provide. Given that brand name prescriptions cost an average $120 while generic drugs average $12 per prescription, the impact of reduced generic utilization could be significant indeed. State dispensing fees should be set in a manner that provides adequate incentives for the use of generic drugs and protects the convenient access of Medicaid beneficiaries to retail supermarket pharmacies.

D. Conclusion

FMI appreciates the opportunity to offer these comments on the impact that CMS's proposed regulation will have on supermarket pharmacies. We respectfully request that you

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[10] "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies", Grant Thorton LLP (January 2007). Also, C. Mullins and A. Davidoff, et al, "Analysis of Cost of Prescription Drug Dispensing in Maryland" (December 2006).

[11] See Congressional Record, Senate, November 3, 2005, p. S12326 (Colloquy between Senators Grassley and Reed).

consider our comments fully on the record and that you utilize the regulatory changes proposed in Appendix A of our comments.

We look forward to working with CMS on these issues in the future. Please feel free to call me or Deborah White, FMI's Associate General Counsel and Vice President of Regulatory Affairs at 202-220-0614, with any questions you might have.

Sincerely,

Tim Hammonds

Tim Hammonds
President and CEO

APPENDIX A:

Specific Regulatory Proposals

§447.502 Definitions

Amend paragraph 2 of the definition of "dispensing fee" as follows:

Dispensing fee means the fee which – …

"(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling (including medication therapy management services), physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy (including a reasonable profit); and".

S447.504 Determination of AMP

(e) *Retail pharmacy class of* trade means any independent pharmacy, chain pharmacy, ~~mail order pharmacy, pharmacy benefit manager (PBM),~~ or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

(f) *Wholesaler* means any entity ~~(including a pharmacy, chain of pharmacies or PBM)~~ to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug that is licensed in a state as a wholesale distributor of pharamaceuticals.

Amend subsection (g) by striking paragraphs 3, 6, 7, 8, 9 and 12 and re-designating paragraph numbers accordingly.

Amend subsection (h) by inserting a new paragraph after paragraph 3 (and re-designating paragraph numbers accordingly) that reads as follows: "Sales exempt from best price (as defined by §447.505)."

Amend subsection (i)(1) by striking "PBM price concessions,".

§447.514 Upper Limits for multiple source drugs

(b) *Specific upper limits*. The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the weighted average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for ~~the least costly therapeutic equivalent~~ all therapeutic equivalents for sale nationally (as described in subsection (c).

Amend subsection (c) by:

(1) striking "30" in paragraph 2 and replacing it with "90"; and
(2) inserting a new paragraph as follows:

"(4) Any product that is not consistently available from the three largest wholesalers in amounts reasonably adequate to supply the retail pharmacy sector will be excluded from the FUL group."

§447.518 State plan requirements, findings and assurances

Amend subsection (b)(1) by:

(1) in clause (i) by striking at the end "and";
(2) in clause (ii) striking the period at the end and inserting in lieu thereof "; and";
and
(3) inserting the following new clause:

"(iii) In the aggregate, the dispensing fees paid to pharmacies cover the costs described in §447.502 and are designed to encourage the utilization of multiple source drugs where appropriate."

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

Organization : Keith's Drive-In Drugs Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

As a local independent retail pharmacist I am concerned by the proposed AMP calculations of prescription pricing for medicaid recipients. Not only will the proposed figures negatively impact my pharmacy, but they will also negatively impact my medicaid propulation. I currently serve approximately 25% Nebraska medicaid recipients at my 2 locations. With the propsed figures I will not be able to continue to serve these patients. The propsed figures appear to represent costs which are not available to the retail pahrmacy sector. Retail pharmacy in the United States fills the vast majority of the medicaid prescriptions dispensed. To allow an arbitrary figure such as AMP to reflect reimbursement only makes sense if the actual cost of dispensing the medication is also included in the reimbursement of the medication. The cost of product is only 1 part of the entire cost of dispensing prescriptions. Pharmacy must be reimbursed for the entire cost of dispensing; including, salaries, utilities, vials and labels, business services and insurance, not just the cost of medication. Please ask your local pharmacist what all he does each time a prescription is filled. Contrary to popular belief he or she doesn't just count pills. Don't shortchange your medicaid population or the pharmacies that fill all of those prescriptions that save millions of dollars in lost wages, hospitalizations and ER visits daily. Thank You!!