

Submitter : Mr. Charles Sewell
Organization : National Community Pharmacists Association
Category : Other Association

Date: 02/20/2007

Issue Areas/Comments

Background

Background
See attached comments

Collection of Information Requirements

Collection of Information Requirements
See attached comments

GENERAL

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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 does 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

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>.

Comments of the National Community Pharmacists Association
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42 CFR Part 447
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Medicaid Program; Prescription Drugs implementing the Medicaid Prescription
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- 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. 21 of 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 Act 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

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.**

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 unit 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 States 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 place 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 Act 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 the 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 costs¹³ 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 than traditional chain, grocery store and mass merchant pharmacies.

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. 21 of 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 Act 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
Organization : Uptown Drug & Gift Shop
Category : Pharmacist

Date: 02/20/2007

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

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 not available to retail pharmacies. Inclusion of PBM price concessions in the calculation of AMP places retail pharmacies at a significant price disadvantage because these price concessions are not available to 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 not wholesale distributors therefore there is no method for distributing these lower cost drugs to the retail sector.*

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

Conclusion:

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

Treatment of Medicaid Sales.

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.

Comments:

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.

Determination of Best Price.

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 not 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.

The Regulatory Flexibility Act. (aka: RFA)

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. (www.sba.gov/size/sizetable2002.html)

Small pharmacies will be negatively affected by these regulations resulting in lower FUL's 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 all 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.

Comments:

- 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 do not 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.

Impact Analysis.

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.

$$\begin{aligned} \text{FUL} &= \$0.10 \times 250\% \\ &= \$0.25 \text{ per tablet} \end{aligned}$$

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	=	\$4.15
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%	<u>\$0.05</u>
		\$0.15
Wholesaler markup to cover inventory and distribution costs to independent pharmacies. (15% - 25%)		
	+ 20%	<u>\$0.03</u>
Net Cost to pharmacy		\$0.18
Profitability to independent pharmacy:		
Total Payment	=	\$11.65
Less product cost	=	\$5.40
(0.18 x 30)		
Gross Profit		<u>\$6.25</u>

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	=	<u>\$2.00</u>
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%	<u>\$0.05</u>
		\$0.15

Wholesaler markup to cover inventory and distribution costs to independent pharmacies. (15% - 25%)		
	+ 20%	<u>\$0.03</u>
Net Cost to pharmacy		\$0.18

Profitability to independent pharmacy:		
Total Payment	=	\$9.50
Less product cost	=	\$5.40
(0.18 x 30)		
Gross Profit		<u>\$4.10</u>

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

CMS-2238-P-1341

Submitter : Dr. Bob Phillips
Organization : H & S Pharmacy #2
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

CMS-2238-P-1342

Submitter :

Date: 02/20/2007

Organization : Planned Parenthood of Central Oklahoma

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

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

**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
Organization : H & S Pharmacy #2
Category : Nurse Practitioner

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

1343

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

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

Submitter : Dr. Tim Hammonds
Organization : Food Marketing Institute
Category : Association

Date: 02/20/2007

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



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.

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

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

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.

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

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 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.

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

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

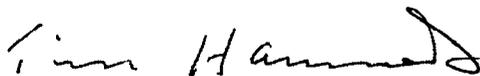
¹¹ See Congressional Record, Senate, November 3, 2005, p. S12326 (Colloquy between Senators Grassley and Reed).

Leslie Norwalk, Esq.
February 20, 2007
Page 10

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,

A handwritten signature in black ink that reads "Tim Hammonds". The signature is written in a cursive style with a large, stylized "H" and a long, sweeping underline.

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 pharmaceuticals.

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 proposed figures I will not be able to continue to serve these patients. The proposed 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!!

Submitter : Ms. Christine Bronson
Organization : Minnesota Department of Human Services
Category : State Government

Date: 02/20/2007

Issue Areas/Comments

Background

Background

Thank you for the opportunity to comment on the proposed regulation. Minnesota supports efforts to ensure appropriate payment for Medicaid services. This has been a challenge in the area of pharmacy services for many years and we look forward to receiving regular updates on Average Manufacturer Prices. We also support the agency's goal of paying appropriately for generic drugs.

For many years, Minnesota has implemented fairly aggressive pricing policies for generic drugs. Currently, many of our Maximum Allowable Cost (MAC) limits are close to 40 to 60 percent below the Federal Upper Limit (FUL) amounts and have been applied to more products than are on the FUL list. We have also implemented MAC price controls for drugs earlier than CMS has included them in the FUL list, routinely implementing MAC pricing when one generic equivalent was widely available.

Minnesota, like many other states, has a significant rural population and must be cognizant of access issues for our Medicaid beneficiaries living in non-urban areas. Therefore, we must continuously balance our efforts to reduce costs with our responsibility to set reimbursement amounts sufficient to ensure that all Medicaid beneficiaries have access to prescription drugs. With that in mind we have the following comments on specific provisions of the proposed regulation.

Collection of Information Requirements

Collection of Information Requirements

Definition of Retail Class of Trade, Determination of Average Manufacturer Price

Mail Order and PBM CMS is proposing to include in the calculation of AMP mail order discounts and pharmacy benefit manager (PBM) rebates, discounts and fees in the calculation of AMP. We are concerned about the inclusion of these discounts and rebates in the AMP calculation when used in conjunction with the FUL process. While we understand that including these discounts in the AMP may be appropriate from a rebate perspective, we are concerned that their inclusion in AMP for purposes of the FUL may affect access.

Direct Sales Please clarify the meaning of direct sales as it will be used in the AMP calculation. Will manufacturer patient assistance programs be considered direct sales?

Bundling We support the inclusion of bundled sales in the determination of AMP.

Rolling Average for AMP We support the use of a rolling average for AMP prices, however, we suggest that CMS specify in the final regulation the precise methodology that will be used. For example, CMS should clarify if it intends to use AMP data from periods prior to the implementation of the new definition of AMP in the post-implementation rolling averages. It would also be helpful to include the entire discussion of rolling averages in both the AMP definition and the FUL sections of the preamble text in the final regulation.

Federal Upper Limits

Nine Digit Level NDC CMS currently uses the 100 count package size in calculating the FULs. Please include a discussion of how using the nine digit level codes, which essentially average the effects of package size, will affect the FUL prices in the final regulation. We are concerned that using large package sizes more commonly used by mail order services rather than retail, would skew the AMP toward a price that is lower than may be available to retail pharmacies.

Rolling Average for AMP As noted above, we support the use of a rolling average for AMP but ask that CMS specify the methodology to be used and include a discussion of it in this section of the final regulation.

Systems Issues MAC and FUL We have already noted our concerns as to the possibility that FUL limits for some drugs could be below pharmacy acquisition cost within some chemically equivalent groups. While we understand the aggregate nature of the FUL limits, we have historically ensured our compliance with the FUL limits by setting our MAC limits using the FUL methodology within the chemically equivalent groupings. If we find that we must adjust a significant number of our MAC rates to account for the FUL being below acquisition costs, we will also have to completely retool our system to recalculate our aggregate FUL limits.

Dispensing Fees In the preamble section of the regulation defining dispensing fees, CMS seems to imply that dispensing fees might be used to cover some of the shortfall in Medicaid payments for drugs where actual acquisition costs are above 250% of the AMP. Yet in the regulatory language section, dispensing fees are clearly defined as being limited to only those costs associated with dispensing the medication. Both the preamble to this regulation and Drug Rebate Program Release #144 contain suggestions that states evaluate their dispensing fees to ensure that the fees are reasonable. We are concerned that some would interpret these statements as encouraging states to increase dispensing fees to offset potential losses on ingredient costs due to the new FUL limits.

GENERAL

GENERAL

See Attached

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Physician-Administered Drugs

Information Required to Claim Rebates There are several pieces of information that will be required in order for states to claim rebate amounts on physician-administered drugs. Because many of the claims will be for services provided to beneficiaries that are eligible for both Medicare and Medicaid, CMS should ensure that Medicare providers or claims processors have processes in place to collect and transmit this information to state Medicaid agencies.

" CMS must ensure that the National Drug Code (NDC) numbers are reported on all Medicare claim forms. States cannot process rebates for multiple source drugs without the NDC information.

" CMS should also ensure that the NDC Quantity, in addition to the HCPCS Quantity is reported on all claims forms.

" CMS should ensure that standard billing instructions are followed for reporting NDC and NDC Quantity.

" States will also need to know the Medicare payment amount for each drug administered. The most common reason manufacturers cite in rebate disputes is that the rebate amount is not proportional to reimbursement. If states do not have ready access to the Medicare paid amount, manufacturers will have no incentive to refrain from disputing the Medicaid rebate requests.

Guidance to CAP Vendors Medicare has recently implemented the Competitive Acquisition Program (CAP) for Part B drugs. We recommend that Medicare issue guidance to or work with CAP vendors to ensure that they collect and transmit to state Medicaid agencies all of the information required for states to cover the Medicaid share of the drug costs and collect the rebate from the manufacturer.

Proportionality of Rebates Collected The proposed rule does not address the proportionality of the rebate to the amount paid by Medicaid for physician-administered drugs. Historical practice has been for states to claim Medicaid rebate on the full amount paid for the drug, rather than Medicaid paid amount. We support continuation of the historical practice of claiming rebates based on the total amount paid by all parties.

CMS-2238-P-1346-Attach-1.PDF



Minnesota Department of Human Services

February 20, 2007

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

Minnesota Department of Human Services Comments:

Docket: CMS-2238-P, DRA Provisions Pertaining to Prescription Drugs

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Leslie V. Norwalk
February 20, 2007
Page 2

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Sincerely,



Christine Bronson
Medicaid Director

CMS-2238-P-1347

Submitter :

Date: 02/20/2007

Organization : Safety Net Hospitals for Pharmaceutical Access

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1347-Attach-1.DOC



Safety Net Hospitals for Pharmaceutical Access

**COMMENTS IN RESPONSE TO NOTICE OF
PROPOSED RULEMAKING OF DECEMBER 22, 2006
TO IMPLEMENT THE DEFICIT REDUCTION ACT OF 2005**

RE: CMS File Code 2238-P

Safety Net Hospitals for Pharmaceutical Access (SNHPA) submits these comments in response to the Notice of Proposed Rulemaking published in the Federal Register on December 22, 2006, regarding regulations to implement the Deficit Reduction Act of 2005 (DRA). SNHPA, formerly known as the Public Hospital Pharmacy Coalition, is a non-profit association of safety-net hospitals that qualify as disproportionate share hospitals (DSH) for purposes of Medicare reimbursement, and participate as covered entities under the federal drug discount program established by Section 340B of the Public Health Service Act (the “340B program”).

SNHPA and its members believe that several aspects of the proposed regulations need to be substantially revised in order to avoid adverse consequences that include: (1) unrealistic requirements and undue burdens in hospital operation and administration, (2) interference with or confusion in program operations administered by the Centers for Medicare and Medicaid Services (CMS), but which are nevertheless the responsibility of the Department of Health and Human Services (HHS), (3) negative impact on delivery of patient care, and (4) ineffective execution of Congressional intent in the governing legislation. As is explained below, certain of the proposed regulatory provisions reflect a failure to take cognizance of significant practical and legal obstacles, or to give adequate consideration to ways in which implementation of policies in the Medicaid program will affect other important HHS programs

I. (Proposed §447.520) – “Physician Administered” Drugs

Of particularly grave concern to SNHPA and its member hospitals is the proposal to require State Medicaid agencies to collect National Drug Code (NDC) information with respect to outpatient drugs administered to patients incident to a physician’s service in physicians’ offices, hospital outpatient clinics and departments, and other outpatient settings. We strongly oppose the proposed application of this requirement to drugs administered in hospital outpatient settings. The proposed requirement threatens to impose a burden on hospitals that is not only significant but severe, and to have serious negative effects on the 340B program and its participating providers. In addition, as applied to hospital outpatient clinics and departments, we believe the proposed requirement is entirely unnecessary and indeed contrary to Congressional intent.

A. Background

Proposed Section 427.520 of the DRA regulations ostensibly implements Section 6002 of the Act, which amended Section 1927(a) of the Social Security Act to require State Medicaid agencies to collect NDC information on so-called “physician administered” drugs, so that manufacturer rebates can subsequently be collected on those drugs. The published rulemaking Notice makes it clear that CMS intends the requirement to apply to drugs administered in hospital outpatient settings, as well as physicians’ offices and other locations where drugs are furnished incident to a physician’s service. In recent months, SNHPA, whose membership includes the majority of hospitals qualified (by virtue of the high percentage of indigent patients they serve) to participate in the federal 340B drug discount program, has received a steady stream of e-mails and telephone calls from member hospitals that are strongly opposed to the proposed rule on “physician administered” drugs.

CMS has indicated that it does not expect the administrative burden imposed by this new requirement to be significant, or for the associated expense to be very great. It has estimated that the cost to providers of reporting NDC numbers on all “physician administered” drugs will be approximately 9 cents per claim, and that an average of 15 seconds of staff time per claim will need to be devoted to manually accomplish reporting of NDC numbers on Medicaid billing submissions. CMS acknowledges that compliance with the requirement will ultimately require an overhaul of most providers’ electronic billing systems, but offers no estimates of the time or expense that would be involved in this eventuality. Yet CMS nevertheless takes the position that reporting NDC numbers will not have a significant impact on providers.

B. The Proposed Requirement Would Place an Unreasonable Burden on Hospitals

According to our member hospitals - and contrary to the assumptions made by CMS - the burden associated with providing NDC numbers in Medicaid billing submissions for drugs administered in hospital outpatient settings would be extraordinary, and the task would be virtually impossible to accomplish with any meaningful degree of accuracy. The 15 second per claim estimate advanced by CMS with respect to manual billing is vastly understated;¹ and, in any event, electronic billing requirements imposed under HIPAA make manual billing procedures an unrealistic solution for anything but the short term. The expense of adapting hospital billing systems to accommodate the new NDC reporting requirement would in fact average in the hundreds of thousands of dollars for each hospital, and this is an expense many hospitals – especially small facilities and institutions already struggling to stretch their resources to serve large indigent populations – can ill-afford.²

¹ Indeed, even from a purely common-sense perspective, the 15 second estimate seems oddly divorced from reality. The NDC number for a drug will be an eleven-digit number that conveys a good deal of information about a drug, including information as to the form and packaging of the product. Just to copy an eleven digit code by hand with any degree of care would normally take something like two-thirds of the 15 second time frame CMS would allocate to the task – leaving virtually no time for the undoubtedly more time consuming demands of finding and verifying the accuracy of the numbers to be copied onto a Medicaid billing form.

² It should be noted that seven years ago, when a similar specter of having to associate NDC numbers with hospital outpatient drugs was raised (and ultimately rejected) in connection with proposed regulations to

The present proposal seems to overlook much of the financial and administrative burden that, as a practical matter, would face hospitals if they were forced to change their current systems and begin using NDC numbers to bill Medicaid. Currently, hospitals use NDC numbers for two purposes: drug purchasing and inventory maintenance. NDC numbers are rarely, if ever, utilized in hospital accounting or billing systems. Instead, the somewhat less specific, HCPCS codes known as "J-codes" are generally utilized to bill outpatient clinic drugs for Medicaid purposes. In order to incorporate NDC data into billing submissions, nearly all practice management systems would need to be re-adapted to accommodate expanded fields and larger databases to display and store thousands of NDC numbers. For these reasons, the billing system changes needed to accommodate association of NDC numbers with hospital outpatient clinic drugs billed to Medicaid would be complex, comprehensive, and extremely costly.

Moreover, not only is the technical and logistical task of recording and reporting NDC numbers on hospital clinic drugs highly problematic, but the accurate determination of those numbers presents equally intransigent difficulties. Because NDC numbers both identify a drug substance and convey information about its dosage, form, and packaging, there are many possible NDC designations that may pertain to the same pharmaceutical product. When drugs are sold directly to patients for self-administration, such as regularly occurs in hospital outpatient pharmacies, this is not ordinarily a problem, because drugs will generally be sold in a form and quantity with which a specific NDC is associated. However, in an outpatient treatment setting, patients will frequently be administered a limited amount or dose of a drug that the hospital purchased in bulk, or at least in larger quantity, and generally not in single-dose packaging. Thus there simply may not be an accurate NDC designation for a given incidence of drug administration in an outpatient clinic.

For example, if a syringe were to be filled with an injectable medication from a vial of liquid medication, but it did not take the entire contents of the vial to fill the syringe, and that vial had been packaged with nine other, similar vials in their original packaging, assigning an accurate NDC number to the drug treatment actually administered to a patient could be difficult or impossible. Hospital staff would have to calculate how much of the vial, from the box of ten vials, was used to treat the patient, and attempt to associate an NDC number with their best approximation of the form and quantity of the drug. But depending upon the exact amount of the drug used, it might be impossible to achieve accuracy, because there might not be a specific NDC number for the drug in the form and quantity actually used.

Where (as is frequently the case with cancer treatments and many other drug therapies administered to patients on an outpatient basis) a patient receives a pharmaceutical "cocktail" of multiple medications through one infusion or other drug treatment modality, the NDC reporting difficulty would be compounded exponentially. Indeed, drugs are often administered in hospital outpatient clinic settings with the use of pre-mixed, infusion "bags"

implement HIPAA, the American Hospital Association's information indicated an average cost of roughly \$200,000 to each hospital subjected to the new requirement. That figure would, of course, be substantially higher in current dollars.

consisting of a combination of various drug substances in various quantities, the precise formulation of which even a prescribing doctor may not be specifically aware when he orders the treatment. Furthermore, hospitals very often purchase the same medications in a variety of package forms and sizes, depending on the hospital's needs and the relative cost and availability of different forms and packaging options at various times. In order to comply with an NDC reporting requirement for Medicaid billing, hospital staff would have to meticulously monitor each package of medication and determine which patient receives precisely what quantity of medication from what type of package, in order to bill Medicaid properly for that patient's treatment.³ Tracking these matters with the requisite level of care and precision in an outpatient hospital treatment setting would be a logistical and administrative nightmare. The burden, in terms of staff time and effort would be enormous, and even with the best of intentions and efforts, a great deal of inaccurate or misleading information would still in all likelihood be communicated to State Medicaid agencies.

There is also legitimate cause for concern that patient care might suffer as a result of NDC reporting requirements being imposed on hospital outpatient clinics and departments. The need for constant vigilance and tracking of drug packaging and use information would be an additional task for physicians and other medical personnel, and the attendant delay and diversion of staff attention and resources could detract from the efficacy of patient care. The magnitude of the additional administrative burden and expense associated with NDC data collection is of especially great concern to the safety net hospitals that SNHPA represents, because the limited resources of these hospitals are already strained by the demands of caring for a patient population that includes a high proportion of uninsured or underinsured individuals unable to pay for their own care.

C. The Proposed Extension of NDC Reporting Requirements to Hospitals Is Unnecessary and Improper

Not only are the administrative difficulties of the proposed new requirement on hospitals prohibitive from a practical standpoint, but there is no need to impose the administrative and financial burdens described above on hospital outpatient clinics at all. Indeed, it would be improper under the law to do so, since the purpose of NDC reporting -- enabling States to collect manufacturer rebates on drugs that are "physician administered" -- does not apply to drugs administered in most, if not all, hospital outpatient clinics. Correctly read, the DRA does not mandate submission of NDC numbers in billing Medicaid for drugs administered incident to physicians' services in hospital outpatient settings; but the numerous factors that support this conclusion appear to have been overlooked by CMS in promulgating its proposed rule.

First, Section 6002 of the DRA amended the rebate provisions of the Medicaid statute to require States to collect drug utilization and coding data "such as NDC numbers *or* J-Codes for drugs that are physician administered." Accordingly, collection of J-Codes with respect to

³ It may be that some similar problems could affect NDC reporting in physicians' offices to some degree as well, but the problems and complexities of tracking and monitoring drug packaging sources and sizes is obviously magnified in the hospital context, because of bulk purchasing and supply issues, as well as the greater possibility of affording drug treatment to patients in need of emergency outpatient care.

drugs administered in hospital outpatient clinics would comply with the letter of law, even assuming drugs administered in that setting were intended to fall within the statutory meaning of “physician administered” drugs. Since virtually all hospital billing systems are now configured to bill for outpatient clinic drugs with the HCPCS codes known as “J-Codes,” compliance with the new law, on its face, does not necessitate the burdensome changes that, as we have explained above, would be involved in submission and collection of NDC numbers.⁴

Second, and more importantly, CMS appears to be misconstruing the “physician administered” drug provision to pertain to hospital outpatient clinic drugs. The purpose of the NDC submission and collection requirement, as expressed by Congress in the words of the statute itself, is to better enable States to collect manufacturer rebates on drugs pursuant to Section 1927 of the Social Security Act.⁵ However, drugs administered on an outpatient basis in most hospital clinic settings have long been exempt from application of the Medicaid rebate laws pursuant to Section 1927(j)(2) of the Medicaid Act. Thus, since as a general rule manufacturer rebate obligations do not apply to hospital outpatient clinic drugs, Congress could not have intended to require NDC number information to be collected by States in order to pursue rebates on those drugs.

D. Accurate Construction of DRA Section 6002

In construing Section 6002, a starting point is the heading on the section as it was enacted by Congress in the DRA. That heading plainly indicates that Congress did not intend the provision to apply to *all* “physician administered drugs,” but rather to some subset described in the DRA as “*certain*” physician administered drugs. It is also extremely important to note that Section 6002 expressly amended Section 1927(a) of the Social Security Act (SSA), but did not purport to amend or repeal any other, pre-existing provision of the Medicaid statute. In particular, the relevant provisions of the DRA made no reference to, and accordingly did not alter the continuing legal force and effect of, Section 1927(j) of the SSA, which expressly exempts drugs used in certain types of outpatient care settings from rebate requirements.

The Conference Report accompanying the bill enacted as the DRA makes the point quite clearly. In a section-by-section analysis of the bill, the Conference Committee prefaced discussion of Section 6002 with a description of “current law,” noting that the law expressly exempts drugs provided through managed care organizations and in certain outpatient hospital settings from manufacturer rebate requirements.⁶ Thus the Conferees acknowledged the existing exemptions from rebate requirements that are established in Section 1927(j) of the Medicaid statute, which provides, in pertinent part, as follows:

⁴ The statute directs the use of NCD numbers unless the Secretary, in his discretion, chooses to instruct that alternative information be utilized. Thus the Secretary plainly has authority to direct that J-Codes, and not NDC’s, continue to be the data reported to Medicaid on clinic administered drugs. This is the case even if clinic administered drugs are regarded as falling within the statutory reference to “physician administered” drugs – which as we explain they should not be.

⁵ Section 1927 of the Social Security Act is codified at 42 U.S.C. §1396r-8.

⁶ See H. R. Rep. No. 109-362, at 262 (2005)

(j) EXEMPTION OF ORGANIZED HEALTH CARE SETTINGS.-

(1) Covered outpatient drugs dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1903(m), are not subject to the requirements of this section.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

The Conferees went on in the Report expressly to distinguish between these statutorily exempt drugs and the drugs to which the new provision was intended to apply, described as “[c]ertain drugs administered by physicians in their offices or in another outpatient setting, such as chemotherapy [that] have often been excluded from the drug rebate program although there is no specific statutory exclusion.”⁷ In other words, the Conference Report confirms that it was only drugs for which “there is no specific statutory exclusion” from rebates, that Congress intended to subject to NDC reporting (and subsequent rebate collection) through the DRA. Accordingly, in the remainder of the discussion of the provision in the Conference Report, it is clear that the references to “physician administered outpatient drugs” (with respect to which Congress intended the new law to require collection of NDC numbers) refer to the drugs that as a practical matter had generally not been subjected to rebate requirements by the States, despite the absence of any applicable statutory exemption.

Given the Conference Report's explicit acknowledgement of exemptions from rebate requirements in current law, the absence of any reference in the text of the DRA to repealing or altering those exemptions can only be construed as a conscious decision to leave the exemptions in place.⁸ The salient inquiry for purposes of determining the impact of DRA Section 6002 on hospital clinic administered drugs, therefore, is whether those drugs fall within the Section 1927(j) exceptions from rebate requirements. This is so because, under basic tenets of statutory construction, statutes must be read as a whole, and each part of a statute is to be construed in the light of the other provisions of the same statute,⁹ so as to reconcile competing

⁷ Id.

⁸Since, as the Conference Report demonstrates, the legislators responsible for enacting the DRA were fully aware of the preexisting provisions at SSA Section 1927(j) creating statutory exemptions from rebate requirements in Medicaid law, their failure to amend or even mention those provisions in Section 6002 itself cannot reasonably be construed as an oversight. If Congress had wanted to repeal or amend these provisions, it most certainly would have said so.

⁹See, e.g., *Dolan v. U.S. Postal Service*, 126 S.Ct. 1252, 1257 (2006) (“The definition of words in isolation, however, is not necessarily controlling in statutory construction. A word in a statute may or may not extend to the outer limits of its definitional possibilities. Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, and consulting any precedents or authorities that inform the analysis.”); *Lexecon v. Millberg Weiss Bershad Hynes*, 118 S.Ct. 956, 962, 523 U.S. 26, 36 (1998)(A central tenet of construction is that a statute is to be considered in all of its parts when construing any one of them).

provisions and, to the extent possible, give all parts of the same statute a harmonious meaning.¹⁰ It follows that whatever drugs fall within the purview of the Section 1927(j) exemptions from the rebate law cannot be regarded as “physician administered drugs” within the meaning of the SSA Section 1927(a), as amended by the DRA, since Congress apparently intended those drugs (unlike those exempt under subsection (j)) to be subject to rebates.

E. Hospital Clinic Administered Drugs are Ordinarily Exempt from Rebates

Clinic administered drugs generally fall within the scope of subsection (j)(2) and are not subject to Medicaid rebates. To reiterate, section 1927(j)(2) excepts from rebate requirements drugs used by :

...a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital’s purchasing costs for covered outpatient drugs (as determined under the State plan).

Drugs administered by medical professionals in hospital outpatient clinic settings are virtually always subject to hospital formulary systems, so this first statutory criterion is easily met by clinic administered medications in most if not all hospitals. Proper application of subsection (j)(2) turns, then, on the meaning of the language describing rebate-exempt hospital outpatient drugs as ones for which the hospital “bills [Medicaid] no more than the hospital’s purchasing costs for covered outpatient drugs (as determined under the State plan).” Consistent with this standard, hospital outpatient clinic drugs are characteristically billed to state Medicaid programs at or below levels defined by Title XIX state plans as the estimated acquisition costs (EACs) for the drugs, plus a reasonable dispensing fee.¹¹

Importantly, hospital “purchasing costs” within the meaning of subsection (j)(2) cannot reasonably be construed to be their actual acquisition costs (AACs) of obtaining the

¹⁰ See, e.g., *Schmitt v. City of Detroit*, 395 F.3d 327, 330 (6th Cir. 2005); *United States v. Stauffer Chemical Co.*, 684 F.2d 1174, 1184 (6th Cir. 1982), aff’d 464 U.S. 165, 104 S. Ct. 575 (1984).

¹¹ Under regulations at 42 C.F.R. 447.331 and 447.332, Medicaid payments to hospitals for most covered outpatient drugs administered to Medicaid beneficiaries are limited to the lower of the provider’s “usual and customary charges to the general public” and the “estimated acquisition costs” (plus reasonable dispensing fees) for the drugs, as established by the State Medicaid agency. Thus, while a hospital’s billing submission to Medicaid for reimbursement of costs of administering outpatient drug treatment to a Medicaid beneficiary may reflect the provider’s “usual and customary” or “chargemaster” charge for the drug utilized, this is in fact the information needed by the State in order to apply the relevant federal regulation and pay the provider at or below a level estimated by the State to represent “acquisition cost” (plus a dispensing fee) for the drug. In effect, then, a hospital’s submission of its chargemaster or “usual and customary” charges to a Medicaid State agency represents its request for payment at the lower of that rate or the EAC that is determined by the State agency and specified in the applicable Medicaid State plan. While the uniform “chargemaster” rate representing the hospitals “usual and customary” charge may appear on the bill sent to Medicaid, what the hospital is seeking is payment at the Medicaid rate of reimbursement, established under the relevant State Plan. A hospital thus “bills” Medicaid for outpatient drug treatments no more than the applicable, state-determined EACs, by providing the requisite billing information to enable the State to make payment at the proper rate (*i.e.*, at the EAC level if it is lower than the provider’s usual and customary charges, or at the usual and customary charge rate in the event it is lower than EAC).

pharmaceutical products administered in outpatient settings, which may be lower or in some instances higher than EAC levels for the same drugs. This is plain on the face of the statute by virtue of Congress' inclusion in (j)(2) of the parenthetical language "as determined under the State plan." If this language is to be ascribed any meaning or effect at all, it must be read to clarify Congressional intent that a "hospital's purchasing costs" as referenced in the statute are not costs that are fixed as a factual matter or by market forces external to Medicaid (*i.e.*, such as the actual prices paid by a provider to obtain drugs), but are rather cost levels specifically determined under the provisions of a reimbursing State's Medicaid plan, such as EACs defined under most states' Title XIX plans as the maximum proper billing and reimbursement rates for hospital outpatient drugs administered to Medicaid beneficiaries. Any other construction renders the parenthetical language in (j)(2) utterly meaningless and completely superfluous, contrary to well-established canons of statutory construction.¹²

That 1927(j)(2) exempts most hospital clinic administered drugs from Medicaid rebate requirements is also a conclusion comports with the structure and internal logic of the Medicaid law. The subsection (j) exemptions address a marketplace reality that is common to both the managed care and hospital outpatient clinic settings for pharmaceutical care, both of which are encompassed by the exemption. Specifically, these are settings in which the drugs that providers utilize are especially likely to have been obtained from drug manufacturers at negotiated prices that are relatively favorable to the purchaser. Health maintenance organizations (HMOs) and other managed care organizations (MCOs) generally are able to negotiate lower prices based on high-volume purchasing, and hospitals utilizing formulary systems can leverage more favorable pricing on drugs through inclusion or exclusion of specific products in developing and maintaining their formularies. Implicit in Section 1927(j) is the Congressional purpose to protect manufacturers from being required, in effect, to afford two separate discounts on the same drugs. If manufacturers were to sell drugs to MCOs at prices lowered by high-volume discounts, and sell outpatient drugs to hospitals at prices discounted so as to gain placement on the hospitals' formulary systems, but then be required to pay Medicaid rebates on the same drugs, the manufacturers would be, in essence, discounting their products twice. The subsection (j) exceptions plainly anticipate and correct for this potential unfairness.

Another point worth noting is that under Section 1927(k)(1) of the statute, AMP is based on the average price paid by wholesalers for a covered outpatient drug distributed to "the retail pharmacy class of trade." AMP calculation does not take into account, in other words, drugs purchased and utilized by HMOs or hospitals for outpatient clinic use, because these settings are not part of the "retail pharmacy class of trade." Pursuant to Section 1927(c) of the Social Security Act, the Medicaid rebate on a covered outpatient drug is calculated according to a formula that is based on the drug's AMP. It would therefore be anomalous for rebates to be calculated for drugs, (such as those dispensed by health maintenance organizations or administered in hospital clinics) that are excluded from the calculation of AMPs due to not

¹² See, e.g., *Cooper Industries, Inc. v. Aviall Services, Inc.*, 125 S.Ct. 577, 584 (2004); *TRW Inc. v. Andrews*, 534 U.S. 19, 122 S. Ct. 441, 449 (2001); *Duncan v. Walker*, 533 U.S. 167, 174, 121 S. Ct. 2120, 2125 (2001).

being dispensed “in the retail class of trade,” and consequently with respect to which there is, in effect, no relevant AMP figure.

Thus, as has been explained above, hospital clinic administered outpatient drugs continue to be exempt from rebate requirements, and DRA Section 6002 could only have been intended to subject “physician administered drugs” in non-hospital settings to NDC reporting and rebate payment requirements. The historical backdrop to enactment of DRA Section 6002 further supports this conclusion. Section 6004 was drafted soon after and in apparent response to issuance of a Report by the Office of Inspector General (OIG) of the HHS, finding that the States were losing millions of dollars in Medicaid funds by their failure to collect rebates on “physician administered drugs.” CMS makes frequent reference to this OIG Report in the Federal Register issuance explaining the proposed DRA regulations, and seems to acknowledge the relationship between the OIG Report and the purpose of Section 6002. In fact, CMS has indicated that cost estimates for savings to be achieved through implementation of the “physician administered drug” rule are based on the cost estimates made by the OIG in connection with its report on the same topic. The subject of this report, however, *was limited to drugs administered to patients in physician offices*; and indeed the report explicitly defined the “physician administered drugs” with which it was concerned as “drugs that a medical professional administers to a patient in a physician’s office.”¹³

This same definition of “physician administered” drugs should also be applied in implementing Section 6002 of the DRA. But even if there are some outpatient treatment settings other than physicians’ offices to which the “physician administered drug” rule should properly apply, it is at least clear that hospital outpatient clinics – which are exempt from rebate requirements under Section 1927(j)(2) of the Medicaid Act – are not among those treatment settings; and the final regulation should be revised to reflect this point.

F. Misapplication of DRA Section 6002 Undermines the 340B Drug Discount Program

Yet another concern raised by misinterpretation and misapplication of the “physician administered” drug provision is the negative impact the proposed rule would have on the 340B drug discount program. The fundamental purpose of the 340B program is to afford deep discounts to qualifying “safety net” health care providers on drug purchases so that these facilities will better be able to stretch their limited resources and care for indigent and uninsured patients. For many 340B covered entities, which by definition are facilities that serve large indigent populations, much of the benefit of 340B program participation derives from savings achieved by purchasing drugs at discounted 340B prices for outpatient clinic use, including use in treating Medicaid beneficiaries.

For many of these entities, the 340B program assists in stretching their resources largely because hospital outpatient drugs are not “rebateable.” If rebates were to be collected on those drugs in the future, 340B providers would lose a substantial part or in some cases virtually all of their 340B savings, which have been an important support to these facilities for

¹³ Office of Inspector General, Department of Health and Human Services., OEI 03-02-00660, *Medicaid Rebates for Physician Administered Drugs* (2004)

more than a decade and on which they have come to rely. This is because the law prohibits subjecting manufacturers to “double discount” obligations. That is, manufacturers may not be both charged Medicaid rebates and required to afford 340B discounts on the same drugs. Consequently, collection of rebates on clinic-administered hospital outpatient drugs would likely force 340B entities to give up the benefit of discounted purchases they make under the 340B program for Medicaid patient treatments.¹⁴ This would represent a sufficiently large part of the 340B benefit to many of our member hospitals that a high percentage of them have indicated they would seriously consider dropping out of the program as a result.

The problem is one particularly likely to have a negative impact on children’s hospitals, which, as Congress provided in the DRA, are now to have access to 340B discounts on drug purchases. Because many children’s hospitals have an exceptionally high percentage of Medicaid patients, and because few of them operate outpatient pharmacies that dispense drugs for self-administration, the loss of potential benefit to those hospitals from discounted 340B purchases of clinic drugs for their Medicaid patients could render 340B participation all but pointless for many of the children’s facilities that have waited so long to gain much-needed support from 340B authorities.

The problems created in the 340B program, moreover, would not be limited to diminishing the number of safety net providers that participate in or benefit from the program. The usual process for avoiding duplicate discounts in the 340B program with respect to drugs bought by Medicaid patients from 340B participating outpatient “retail” pharmacies involves use of an “exclusion file” maintained by the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA). Pharmacies dispensing 340B drugs are listed in the OPA exclusion file, and these pharmacies are identified to State Medicaid agencies as entities whose purchases should not be subjected to rebates, so that duplicate discounts can be avoided. However, clinic administered drugs are sometimes billed by a hospital and sometimes by physicians that staff the hospitals. Consequently, OPA’s exclusion file and its system for transmitting information to States is not capable of recording and identifying the hospital clinic drugs purchased under 340B authorities that would need to be afforded “special handling” by States to avoid the duplicate discount problem if rebates were collected on those drugs. Thus application of the “physician administered drug” rule to hospital outpatient clinics will cause a severe problem for OPA in fulfilling its administrative responsibilities in the 340B program. Furthermore, SNHPA is already hearing that some drug companies, anticipating the fact that OPA will be unable to avoid a double discount effect respecting 340B drugs, have suggested they may respond by simply refusing to sell 340B drugs to hospital outpatient clinics in the future.

Before turning to the next section of these comments, we would like to briefly summarize the above points. First, the explanation provided by CMS for the proposed rule on physician administered drugs fails to accurately quantify or characterize the administrative and financial burdens on hospitals that would be associated with an NDC reporting requirement on clinic administered Medicaid drugs. Second, there is no need to impose the new NDC

¹⁴ This would have to be accomplished either by the providers “carving out” their Medicaid inventories from 340B purchases, and not using 340B drugs for Medicaid patients, or by the State foregoing rebates and reimbursing 340B providers at their 340B discounted drug price levels.

reporting requirement in the hospital outpatient clinic context, because in that setting the law precludes the rebate collection that is the *raison d'être* of the NDC reporting provision in the first place. Lastly, CMS overlooks the significant adverse impact of the proposed rule on operations and administration of the 340B program.

II. Provisions of the Proposed Rule Relating to AMP Calculation and Reporting (Proposed §447.504)

The proposed regulation also should be revised or clarified in other important respects. CMS has not included in its cost estimates any recognition of the fact that the new statutory and regulatory formula for computation of Average Manufacturer Price (AMP) (to the extent it no longer takes prompt pay discounts into account) would tend to drive up drug price ceilings under the 340B program if it were applied in the 340B pricing formula. This would result in significant additional costs to 340B covered entities. That result should not come about because, by application of subsections (b) and (c) of Section 340B,¹⁵ AMP must continue to be calculated as it was prior to passage of the DRA, for purposes of determining the 340B ceiling price of covered outpatient drugs. This needs to be made clear in the issuance of final regulations, however, in order to avoid confusion and the possibility of undue and improper increases in the costs of drugs to safety net healthcare facilities.

The 340B provider community is also deeply distressed by the proposed policy choice of requiring manufacturers to identify drugs for purposes of AMP calculations through NDC numbers that consist of only 9 digits, instead of the 11 digits that fully identify a drug in terms of package size. As CMS expressly acknowledges in its published regulatory proposal, an 11-digit NDC is critical to providing additional pricing transparency in the 340B program,¹⁶ and utilization of a 9-digit AMP sacrifices this much-needed transparency. It is difficult to comprehend the basis for CMS' apparent conclusion that Congress did not intend AMP to be calculated and reported in the expanded form that would enhance transparency in the 340B program.

Any such conclusion seems especially unfounded in light of hearings held before the House Energy and Commerce subcommittee towards the end of 2004, at which the urgent need for greater transparency in 340B pricing was prominently discussed by members of Congress and witnesses from HHS and from its OIG. Furthermore, the part of the Social Security Act to be implemented by these new regulations (Section 1927) is a section of law expressly concerned with the 340B program as well as the Medicaid rebate program. Thus there is no indication of Congressional intent that the less informative 9-digit NDC form be used in AMP calculation; and some indication that Congress intended the utilization of data in a form more conducive to 340B pricing transparency. To the extent Congressional intent is ambiguous on the point of whether a 9-digit or 11-digit NDC number should

¹⁵ Section 340B(b) incorporates by reference the definition of AMP in Section 1927(k) of the Social Security Act. Subsection (c) makes it clear that the reference must be read as one to the un-amended Section 1927(k) effective in November, 1992.

¹⁶ Even though in the future the AMP figures relevant to 340B price calculations will differ from the AMP calculated for Medicaid rebate determination purposes, HRSA will presumably need to calculate 340B ceiling prices based on an AMP figure derived from AMP data provided by manufacturers to CMS. The specificity and accuracy of AMP information therefore remains an important concern of 340B providers, irrespective of the fact that ultimately two AMP figures will need to be calculated for each drug. The publicly reported AMP figures, if computed with appropriate specificity instead of as weighted averages, would still enhance 340B program transparency.

be used, there is no question HHS has authority to construe the AMP reporting to pertain to a package-size specific AMP, and there seems no valid rationale for a policy choice by the HHS that consciously undermines the potential for enhancing compliance and efficient administration of a program for which the Department is responsible, *i.e.*, the 340B drug discount program. In fact, CMS had exercised its discretion specifically to define NCD numbers as 11-digit codes in §447.502 of the proposed regulations; and not to apply this definition to AMP calculation therefore seems all the more anomalous. The various factors cited by CMS in the Federal Register Notice as pertinent to its policy choice on this matter weigh decidedly in favor of utilization of an 11-digit NDC, and consequently this is plainly the direction in which the Secretary should exercise his discretion.

III. Nominal Pricing Provisions (Proposed §447.508)

In addition, the proposed regulations explicitly decline to exercise the HHS Secretary's statutory discretion to identify additional "safety net" providers that may receive nominal pricing on drugs without those prices being included in calculations of "best price." This failure to exercise authority seems to us ill-advised and fundamentally unfair to many providers that are mainstays of our nation's health care safety net, but receive inadequate support and assistance in their service to indigent and uninsured citizens. Many of these health care providers are neither qualified to be covered entities under the 340B program nor otherwise specified in the DRA provision on nominal pricing, but nevertheless play a vitally important role in the care of indigent and vulnerable populations. These providers, whose scarce budgetary resources are strained by rising costs of pharmaceutical products, include childrens' hospitals, psychiatric facilities, critical access hospitals, and a wide range of other providers that do not technically qualify as "DSH" facilities or 340B covered entities, but need and deserve the price "break" on drugs that access to nominal pricing can provide.

The statutory changes defining limits on best-price-exempt nominal pricing have already had a negative effect on manufacturers' willingness to provide such pricing, even to the facilities that continue to be eligible for nominal prices on a best-price-exempt basis. This appears to be a consequence of the fact that permissible nominal pricing is now so limited that manufacturers are inclined to avoid the complexities of administering a nominal pricing program by simply terminating all nominal pricing contracts altogether. Congress clearly intended, in passing the DRA, that providers representing the healthcare safety net for our nation's poor and uninsured would be identified and given access to nominal pricing, beyond those providers expressly specified in the law. The agency's failure to exercise its discretion in this regard gives inadequate recognition to the contributions and the budgetary burdens of numerous facilities that serve large indigent populations. It also has a ripple-effect on even those facilities that are technically eligible to receive nominal pricing, because the shrinking scope of nominal pricing programs previously operated by drug companies is being felt in the entire safety net provider community.

A further issue that needs to be clarified in the regulations relating to nominal pricing is the scope of the best price exemption for which the designated safety net providers qualify. The regulations should clarify, for example, that the best price exemption for nominally priced products sold to a qualified hospital would also apply to nominally priced drugs purchased for inpatient use by the same safety net hospital. The rules should also clarify that eligibility for best-price-exempt nominal pricing may extend to other components of a larger health system of which a 340B entity is a

part. This is especially important because in many cases the larger health systems of which 340B entities are a part serve the same vulnerable and largely indigent patient populations served by the 340B facility. While not technically part of the discrete facility qualified for 340B pricing, they nevertheless comprise a larger safety net entity that should qualify for nominal pricing, consistent with congressional intent in the DRA.

IV. Participation of Children's Hospitals in the 340B Program

Finally, Section 6004 of the DRA expressed clear Congressional intent that children's hospitals serving a high proportion of indigent patients be afforded the discounts on covered outpatient drugs provided to covered entities under the 340B program. The Social Security Act was amended to provide that in order for a manufacturer's drugs to be covered under Medicaid and Medicare Part B, the manufacturer must have an Agreement with the Secretary of HHS to provide 340B discounts to qualifying children's hospitals. In addition, the statute made this new requirement applicable to purchases of outpatient drugs by children's hospitals, effective February 8, 2006. Although the 340B program is administered by HRSA, the DRA provisions regarding discounts for children's hospitals were enacted as amendment, not to the Public Health Service Act, but to the Medicaid statute, which is administered by CMS.

It has now been more than a year since the date when Congress intended qualifying children's hospitals to begin receiving 340B discounts, and yet this expansion of the program has not been implemented in any respect and remains mired in confusion and bureaucratic delay. Given this circumstance, and the clarity of Congressional intent that manufacturers' products should not now be covered by Medicaid or Part B Medicare if children's hospitals are not being given access to 340B discounts on those manufacturers' products, we believe it is incumbent on CMS as well as HRSA to take whatever steps are necessary to assure actual implementation of DRA Section 6004 as promptly as possible. The absence from proposed regulations to implement the DRA of any provisions concerning, or even any reference to, 340B discounts for children's hospitals is thus a serious omission, and should be corrected in the final regulations.

* * * * *

We believe all of the above-mentioned matters need to be addressed and revised or clarified in a final regulatory issuance. We hope that these comments are clear, that they will receive your full and careful consideration in deliberating upon final policies respecting DRA implementation, and that as a result the proposed regulations published on December 22 will be substantially revised in their final form.

William von Oehsen
President and General Counsel

Edith S. Marshall
Special Counsel and Director of Legal
Affairs

Submitter : Dr. Jennifer Barker
Organization : Morehead Clinic Pharmacy
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

1. The formula for AMP-based FULs in the proposed rule will not cover pharmacy costs for multiple-source generic medications. 2. AMP was never intended to serve as a basis for reimbursement. 3. To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by: a.excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy. b.excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. c.reporting AMP at the 11-digit NDC level to ensure accuracy.

Submitter : Ms. Jeanne LaBrecque
Organization : Indiana Office of Medicaid Policy and Planning
Category : State Government

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

Second Submission of Comments. Received error message on 1st attempt.

CMS-2238-P-1349-Attach-1.DOC

February 20th, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Attention: **CMS-2238-P**

Dear Ms. Norwalk:

The State of Indiana's Office of Medicaid Policy and Planning is submitting comments on the proposed rule pertaining to 42 CFR Part 447, Medicaid Program; Prescription Drugs. The Office has a vested interest in ensuring that CMS carefully considers the merits of all comments prior to issuing a final rule. These comments have been provided to CMS to assist CMS in evaluating the best course of action to pursue while meeting the Congressional intent of the legislation. Should questions arise during CMS review of our comments, the Office has provided contact information at the end of the comments document.

Sincerely,

Jeanne M. LaBrecque
Director of Health Policy and Medicaid

States of Indiana
Office of Medicaid Policy and Planning
Agency Comments Related to 42 CFR Part 447
Medicaid Program; Prescription Drugs; Proposed Rule
File Code: CMS-2238-P

I. "Background"

Agency Comments

None

II. "Provisions of the Proposed Regulations"

Definitions—Section 447.502; Page 77176

Dispensing Fee; Page 77176

Agency Comments

The definition of "dispensing fee" specifies that it is a "fee" that is incurred at the point of sale. Even though this facet of pharmacy reimbursement has historically and colloquially been referred to as a "fee", it more correctly is an administrative allowable paid to pharmacies for certain services they provide. The definition specifies, in part, that the dispensing fee is paying "...for costs other than the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed". This wording is problematical in a couple of aspects, the first being that it mentions only pharmacy "costs". CMS needs to advise States as to whether or not it is CMS's intent that some profit to the pharmacy be included in the dispensing fee. Obviously, drug component reimbursement (EAC) is to approximate the agency's best estimate of the pharmacy's actual acquisition cost of the drug, and the dispensing fee is, by the CMS definition, to cover certain "costs" that the pharmacy incurs in dispensing the prescription. This leaves the obvious and significant policy question as to whether or not CMS intends that pharmacies are entitled to "profit" (presumably, through the dispensing fee) and, if so, at what level of profitability. A literal interpretation of the EAC and dispensing fee definitions implies that pharmacies are reimbursed at cost for the drug and dispensing fee. CMS needs to establish clear and unambiguous policy in this regard, incorporate it into this rule, and communicate it to States. Conversely, if CMS's intent is that there is to be no profit to pharmacies for Medicaid dispensations, through the dispensing fee or otherwise, CMS should so-specify through this rule and advise States accordingly.

The second problematical aspect to the referenced wording is that it mentions a dispensing fee as being applicable "*each time a covered outpatient drug is dispensed.*" This wording is too prescriptive and would likely prove costly to the federal government and States. In addition, some States have policies such that pharmacies are NOT entitled to a dispensing fee each time they dispense, an example being both long term care and retail pharmacies that dispense to residents of nursing facilities. Some States have adopted fiscally prudent policies that, while ensuring and preserving recipient access to necessary drugs, limit the payment of dispensing fees in such circumstances to, e.g., one

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dispensing fee per recipient per legend drug order (“prescription”) per month. It is up to the pharmacies and the nursing facilities with which they contract to mutually determine how often the pharmacy dispenses to residents of the facility—daily if they so choose, or otherwise on an agreed-upon lesser frequency that meets the needs of the facility and its patients—and this rule should not inadvertently interfere with that relationship such that pharmacies could claim far more dispensing fees than to which they are currently entitled in such States. Basically, the provision as currently worded could significantly increase States’ dispensing fee expenditures and do so at no benefit whatsoever to the States or beneficiaries.

The CMS definition States that the dispensing fee includes “...*only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. 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, 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...*”. This definition is ambiguous, due to the “not limited to” and “reasonable cost” provisions. In order for States to properly administer the benefit, States will need greater specificity and clarity from CMS regarding CMS’s intent pertaining to “pharmacy costs”, and what CMS considers as “reasonable”. Too, this definition seems to be unduly wordy, yet does not provide the clarity needed by States. The CMS definition specifies that pharmacy costs do NOT include “*administrative costs incurred by the States in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.*” That disclaimer seems unnecessary and confusing, since it should be inherently obvious that the referenced States costs are not those of pharmacy providers. In summary, CMS should craft a definition of “dispensing fee” that is brief, clear, fully descriptive as to what CMS considers as “pharmacy costs” and “reasonable”, and provides States with the necessary policy direction regarding whether or not profit is to be included in the dispensing fee or elsewhere. CMS should be aware that one of the major “pushes” by organized pharmacy since the new FUL methodology was announced is for States to increase their dispensing fees to make up for the revenue that pharmacy providers will lose due to the deficiencies of the new FULs. Unless profitability is behind this “push”, it does not make sense because the advent of the new FULs will in no way increase pharmacies’ dispensing “costs”; rather, the new FULs would be removing some level of profitability that pharmacies currently enjoy, and the dispensing fee (which, according to CMS’s definition, apparently reimburses only “costs”) is the target that pharmacies have focused on as the means by which to make up the lost revenue. This leaves a policy disconnect that CMS should remedy via this rule.

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CMS may want to consider defining the dispensing fee solely in terms of its adequacy in ensuring sufficient provider participation to maintain recipient access which is, of course, a requirement of existing Federal law. That is to say, if a pharmacy chooses to participate even in light of a dispensing fee that may not cover their "costs", there should be nothing binding on the States to preclude that from happening. "Cost to dispense" studies, some quite recent, have invariably shown a "cost to dispense" dollar figure that is a multiple of existing fee-for-service Medicaid dispensing fees. Yet, pharmacy participation in Medicaid remains substantial and far more than adequate, even in light of this fact. Moreover, pharmacies that service Medicaid populations in capitated managed care arrangements accept dispensing fees that are a fraction of the fee-for-service dispensing fee—in instances, one-half or less. In light of the fact that pharmacies are apparently more than willing to accept dispensing fees that are far below their purported "cost to dispense", and do so in such numbers that more than adequate beneficiary access has historically been easily maintained, it would be highly advisable for CMS to consider defining "dispensing fee" solely in terms of what States determine to be an adequate rate to ensure necessary access. Doing so would allow States to take full fiscal advantage of the intensely competitive forces at work in the pharmacy marketplace, and eliminate the need for CMS to try to come up with a holistic, all-inclusive definition that would have to address the complicated matter of provider "costs" and what constitutes "reasonable". It should also be noted that CMS has chosen to define dispensing fee in a similar fashion to how it is defined in the Medicare Part D program in 42 CFR 423.100. It is common knowledge that the Medicare prescription drug plans have dispensing fees that are a fraction of current Medicaid dispensing fees. This can be directly attributed to the competitive forces in the pharmacy marketplace that allow the prescription drug plans to contract with an adequate pharmacy provider network in order for beneficiaries to have uninterrupted access to necessary medications. Simply stated, let States do what they do best—manage their pharmacy benefits (and associated costs) by taking full advantage of the competitive forces of the marketplace, and ensuring that rates paid to providers are sufficient to enlist and maintain necessary access to services by beneficiaries. All this can be accomplished by adopting a simplistic and fundamentally clear and sound definition of "dispensing fee".

Innovator Multiple Source Drug; Page 77176

Agency Comments

CMS should consider adding products approved under Biologic License Applications (BLA's) to this definition. While many of these products, such as vaccines, are not subject to the national rebate agreement, there are several products, such as antihemophilic and coagulation factors, that have traditionally been subjected to the covered outpatient drug requirements and national rebate agreement. This would align with the definition of manufacturer where the term "biological product" is specifically mentioned.

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Multiple Source Drug; Page 77177

Agency Comments

CMS should consider adding products approved under Biologic License Applications (BLA's) to this definition along with the other application types referenced under innovator multiple source drugs and single source drugs. While many of these products, such as vaccines, are not subject to the national rebate agreement, there are several products, such as antihemophilic and coagulation factors, that have traditionally been subjected to the covered outpatient drug requirements and national rebate agreement. This would align with the definition of manufacturer where the term "biological product" is specifically mentioned.

CMS should also consider revising or creating separate definitions for this term. One component of the definition should define this term with respect to the establishment of the FUL since the FUL will be applied to a particular date of service on a pharmacy claim. The Office assumes that the new monthly FUL will apply to a particular date of service span that will be provided by CMS. A second component of the definition should be provided that is applicable to the rebate period.

Single Source Drugs; Page 77177

Agency Comments

CMS should consider adding products approved under Biologic License Applications (BLA's) to this definition. While many of these products, such as vaccines, are not subject to the national rebate agreement, there are several products, such as antihemophilic and coagulation factors, that have traditionally been subjected to the covered outpatient drug requirements and national rebate agreement. This would align with the definition of manufacturer where the term "biological product" is specifically mentioned.

Determination of Average Manufacturer Price—Section 447.504; Page 77177

Definition of Retail Pharmacy Class of Trade and Determination of AMP; Page 77178

Agency Comments

CMS states that "*States might use AMP to calculate pharmacy payment rates.*" The Office strongly recommends that CMS consider removing or revising this statement because AMP is not representative of pharmacy provider acquisition costs and would create additional problems over and above those forthcoming with the AMP derived FUL rates as proposed by CMS. The AMP does not take into account the markup that is applied within the distribution chain between the manufacturer and purchasing pharmacy. The Office strongly recommends that CMS consider other mechanisms to calculate

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pharmacy payments rates. In terms of estimating pharmacy acquisition costs, the Office believes that there is no substitute for pharmacy provider acquisition costs surveys.

Upper Limits for Multiple Source Drugs—Section 447.514; Page 77186-77188

Agency Comments

Since CMS is ultimately accountable for the methodology, oversight, and administration of the FUL program, the Office has the following recommendations and suggestions for CMS:

- CMS should operate and staff an FUL call center. Many States utilize call centers to handle provider concerns relating to their SMAC programs. The CMS call center should be available during normal business hours, excluding holidays, via a toll-free number. This call center will triage and address concerns regarding FUL rates that have been established by CMS. These concerns would include, but not be limited to, drug shortages and lack of national availability at the FUL price. If CMS chooses not to establish a call center for this purpose, CMS, at a minimum, should designate a specific individual at each regional office to triage FUL related issues from pharmacy providers.
- CMS should establish a comprehensive quality assurance process for reviewing FUL rates prior to the rates being released to States. Incorrect FUL rates result in pharmacy claims being processed incorrectly. CMS should describe, in detail, the quality assurance process in the final rule. It is unreasonable and inappropriate for pharmacy providers to be reimbursed via the FUL rate if the FUL rate is not accurate. FUL rates that have not undergone a rigorous review for accuracy should not, in any circumstance, be released to States.
- CMS should allow reasonable timeframes for the implementation of new and revised FUL rates. The Office recommends a minimum of 30 calendar days. Particular attention should be focused on rate decreases since these rates are based on monthly AMPs submitted by manufacturers rather than pharmacy purchasing histories. There will most likely be an inherent lag time between the AMP derived FUL rates and what rates pharmacies actually purchase or have purchased the drug products that subject to the FUL rates. In addition, States need ample time to review the impact of the rates as it pertains to their Preferred Drug Lists. It is not uncommon for a State to designate a multi-source brand name drug as preferred when the supplemental rebate offered by a manufacturer results in the brand name drug being less expensive, in the aggregate, than the A-rated generic equivalent. The monthly release of FULs will require States to re-analyze the expenditures, in the aggregate, thus possible requiring States to cancel or amend supplemental rebate contracts with manufacturers. The Office requests that CMS address this issue in the final rule.
- The Office assumes that CMS will apply FUL rates to the full extent in terms of product depth and breadth of covered outpatient drugs as allowed by the

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legislation. In the past, CMS has not assigned FULs to injectable covered outpatient drugs. The Office requests that CMS address this assumption in the final rule.

- Current CMS methodology states that *“If all formulations of a multiple source drug are not A-rated, there must be at least three A-rated versions of the drug listed in ‘Approved Drug Products with Therapeutic Equivalence Evaluations’ for CMS to establish a FUL for the drug.”* A literal reading of the first part of this sentence entails a situation in which there are no A-rated products, and that is likely not what you intended to convey. Suggested corrective wording here would result in the following: *“If not all formulations of a multiple source drug are A-rated, there must be at least three A-rated versions of the drug...(etc.)”*. This statement would make sense in the given context, and correct the currently existing methodology text.
- In general, the Office supports the use of the 9-digit NDC to calculate the AMP for the reasons specified in the proposed rule. However, the Office disagrees with the idea that the most economical package size is always the one with the lowest per unit cost. In particular, for pharmacies serving smaller populations, the package size with the lowest per unit cost may include many more units than is needed for the patient base. Purchase of this package size would lead to waste if that package size is ordered and units have to be later discarded due to product expiration. The expectation that the lowest per unit cost product is always the most economical for the pharmacy can lead to reimbursement that will not fully cover costs for pharmacies that prudently purchase quantities of drugs appropriate for their patient population. The Office requests that CMS should consider and make exceptions to utilizing only the 9-digit NDC for establishing certain FUL rates. CMS should strongly consider that package sizes for creams, ointments, eye drops and IV solutions are traditionally not consistent on a unit cost basis. These products, in the smaller package sizes, are typically more costly on a unit cost basis for providers to purchase as compared to the larger package sizes of identical drug products. Establishing the FUL utilizing the 9-digit NDC will result in reimbursement below pharmacy acquisition costs when the smaller package size is being dispensed. In these instances, it would be prudent for CMS to incorporate 11-digit NDC’s into the FUL process or establish other mechanisms to ensure that pharmacy providers can purchase the smaller package size at or below the established FUL. It should be noted that prescribers dictate the package sizes that are dispensed when the prescription is written, not retail pharmacies. CMS states *“We are proposing to use the currently reported 9-digit AMP for calculating the FUL.”* The Office would recommend that CMS revise this statement to read *“We are proposing to use the AMP associated with the reported 9-digit NDC for calculating the FUL.”*
- Utilizing the February 2007 AMP rates, our analysis showed that over half of all FULs would reimburse below the average retail acquisition cost pharmacies incur to purchase these drugs. These results represent no change from the previous 2

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iterations that were performed by the Office. The Office will provide the February analysis to CMS outside of the public comments due to concerns related to AMP confidentiality.

- We agree that safeguards are necessary to ensure that a drug is nationally available at the FUL price. However, based on our analysis of the Proposed Rule and the February 2007 AMP data supplied to all states, we strongly disagree that the proposed additional criteria (e.g., carve-out policy) will ensure that a sufficient supply of the drug will be available nationally at or near the FUL price for the following reasons:

The Proposed FULs are Extremely Poor Estimations of Pharmacy Acquisition Cost

- 1) Since 2002, the State of Indiana has been collecting drug acquisition cost data from Indiana retail pharmacies. Based on our extensive database of drug acquisition cost data which is currently updated on a monthly basis, we evaluated the retail pharmacies ingredient costs and the proposed FUL reimbursement for over 1,000 of these widely used drugs. Our analysis revealed a wide variance in underpayments and overpayments that will be made with the proposed FULs.
- 2) FUL Underpayment: We found that for **more than 51%** of drugs subject to a new FUL, the FUL reimbursement would be less than the average acquisition cost incurred by retail pharmacies to acquire the drugs from their suppliers. Among these drugs, many highly utilized drugs had FULs that were **less than 60%** of the average retail acquisition cost. In several cases, the FUL was **less than 10%** of the average retail acquisition cost. Underpayments on this scale would force pharmacies to reconsider participation in the Medicaid program or make States increase other payment to compensate for the insufficient ingredient cost reimbursement.
- 3) FUL Overpayment: On the other hand, for **nearly 49%** of drugs subject to a new FUL, the FUL reimbursement would be greater than the average retail acquisition cost. While this allows providers a margin for profit, in many cases, the profit margin can be much larger than intended if the State does not have a robust SMAC program in place. The range of overpayment extended as high as FULs that were **over 400%** of the average retail acquisition cost. The Office strongly recommends that, for this reason, CMS advise States not to discontinue their SMAC programs in lieu of the proposed FUL implementation.

Limited Supply of Drug at the FUL Price

- 1) Of the 1,454 drugs that meet the eligibility for an FUL, the supplier (5-digit NDCs) with the lowest AMP (after applying the proposed carve-out criterion) on average accounted for only 28% of recent claims made for the drug, which is a proxy for the current Medicaid market demand for the drug. That is to

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say, the lowest cost supplier is currently distributing less than three out of ten units dispensed.

- 2) Of the 1,454 drugs that meet FUL eligibility, there are ninety-three (93) drugs where there is only one 9-digit NDC with a reported AMP that is less than the FUL price. These include highly utilized drugs such as Glyburide, Heparin, Mirtazapine, Oxycodone, Prednisone, and Warfarin. For these 93 drugs, the suppliers (5-digit NDCs) account for an average of 44% of recent claims made for the drug. That is to say, the lowest cost supplier is currently distributing about four out of ten units dispensed.
- 3) Of the 1,454 drugs that meet FUL eligibility, there are two hundred and twenty four (224) drugs where less than 40% of the current suppliers (5-digit NDCs) have reported AMPs that are less than or near the projected FUL. These include highly utilized drugs such as Acyclovir, Ciprofloxacin, Fluoxetine, Gabapentin, Lisinopril, Metformin, Nitroglycerin, and Paroxetine. Also, for these 224 drugs, these low price suppliers account for, on average, 40% of recent Medicaid claims for the drugs.

Increase in Price of Lowest AMP Due to Effects of Supply and Demand and Time Lag Before FUL Reflects Price Changes

- 1) Initially, pharmacies will have a large incentive to purchase drugs from the supplier of the drug with the lowest AMP in order to maximize profits. In the short run; however, manufacturers will not be able to increase capacity the nearly fourfold (in the aggregate, see 1 above) necessary to meet the demand for their drug(s). When demand exceeds supply, the manufacturer with the lowest AMPs will increase its price to distributors who will increase their price to retailers. At that point, it is likely that no supplier will have the drug available at the FUL price due to the time lag inherent in reporting AMPs to CMS and CMS communicating new FUL prices.
- 2) As more pharmacies begin purchasing the drug with the lowest AMP, they will likely purchase these drugs in quantities necessary to meet all their client needs, including Medicare, commercial insurers and walk-ins. This will further reduce supply and cause the price of the lowest AMP to increase.

Regarding the exclusion criterion as proposed by CMS, we understand through discussions with CMS that it is meant to be applied only once for each FUL drug. In other words, if the lowest AMP is less than 30 percent of the second lowest AMP, and the second lowest AMP is less than 30 percent of the third lowest AMP, then the FUL would be established based on the second lowest AMP. Please confirm that you plan to apply the exclusion criteria only once. The Office also recommends that CMS utilize simple examples to illustrate the exclusion criterion as the present wording is confusing.

We applied the exclusion criterion in iterations of 40%, 50%, and 60% to the AMP data to gauge the impact of changing the carve-out percentage. We were discouraged to

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discover that increasing the percentage had little impact on increasing the number of FUL drugs where the FUL rate exceeds the average retail acquisition cost of the drug. In summary, using the proposed 30% carve-out percentage resulted in only 49% of FUL drugs having a price greater than the average retail acquisition cost of the drug. Increasing the carve-out percentage to 60% resulted in a modest increase in the number of FUL drugs having a price greater than the average retail acquisition costs (58%).

Based on our analysis, the proposed carve-out approach is not adequate at any percentage to ensure access to drugs at or near the FUL. Therefore, we do not believe that adjusting the percent threshold for the carve-out policy addresses or corrects deficiencies with the AMP data or the proposed outlier approach. Based on our analysis of the data, we believe other safeguards beyond a carve-out approach, are necessary to ensure that a drug is nationally available at the FUL price.

Based on our analysis, we do not believe that the proposed approach for handling outlier AMPs is adequate to ensure that a drug is available nationally at the FUL price. With the stated goal to ensure that a drug is nationally available at the FUL price, we recommend CMS consideration of utilization data as a proxy for marketplace availability. Three suggested utilization data sources to explore are 1) claims data submitted by State Medicaid programs on a regular basis, 2) NDC-level utilization data collected for the Medicare Part D program, and 3) monthly purchase data submitted to CMS by 3 or 4 national drug wholesalers for all purchases made during the prior month.

In an example of using utilization data to ensure marketplace availability, we used State drug utilization data available from the CMS web site and defined the lowest AMP as the AMP where the cumulative claims for its NDC and those associated with lower AMPs was at least 80% of the current Medicaid drug claims (refer to Table 1 below for illustration). This resulted in slightly more than 80% of all FUL drugs having a price greater than the average retail acquisition cost of the drug. We believe this provides a reasonable balance between access to drugs and incentives to encourage pharmacies to acquire less costly generic drugs.

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Table 1. Assuming all NDCs are within the same FUL group, are generic, A-rated, from rebating manufacturers and non-terminated

NDC	AMP	Diff %	Util*	Cumul. Util.**	Lowest AMP (30% carve out considered)	Lowest AMP (80% util.)
12345-6789-10	1.00	--	10%	100%		
98765-4321-01	0.5	-50%	50%	90%		Lowest (FUL:1.25)
56789-1234-11	0.25	-50%	25%	40%		
78910-2345-00	0.09	-36%	15%	15%	Lowest (FUL:0.225)	

* Utilization. May be utilization measured by claims data obtained from States, utilization data collected through Medicare Part D, or purchase history obtained from national drug wholesalers.

** The Cumulative Utilization increases from lowest AMP to highest since establishing the FUL based on the lowest AMP where at least 80% of utilization is at or below that AMP would result in a FUL that provides cost coverage for all NDCs at or below that AMP price.

FFP: Conditions Relating to Physician-Administered Drugs—Section 447.518; Page 77188

Agency Comments

The Office requests that CMS specifically clarify in the rule that claims for physician administered drugs must meet all covered outpatient drug requirements. Specifically, the NDC must be from a rebating manufacturer, not have a termination date prior to the date of service on the claim and the drug must not have a DESI value of 5 or 6.

The Office requests that CMS specify, in detail, the required file format for submission of claims for physician administered multiple source drugs using NDC numbers for those drugs with the highest dollar volume listed by the Secretary.

The Office requests that CMS require NDCs and NDC quantities on Medicare B claims involving covered outpatient drugs where the beneficiary is dual eligible. This is necessary for provision of services, coordination of benefits and to minimize paper billing of crossover claims to Medicaid where NDCs are not allowed or required by Medicare intermediaries. The paper billing of crossover claims is time consuming, resource intensive and fails to take advantage of the data interchange standards that are available to providers.

The Office requests that CMS provide State Medicaid programs and Medicare intermediaries with a comprehensive list of all HCPCS procedure codes pertinent to covered outpatient drugs. This list should be supplied on a quarterly basis to coincide

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with the release of new HCPCS codes by CMS. This list will ensure consistency across all Medicaid programs as it pertains to the collection of NDC's for physician administered drugs. The Office recognizes the need for collection of NDC's based on wording from CMS in the proposed rule: *"We expect that States will require physicians to submit all claims using NDC numbers, as using multiple billing systems would be burdensome for physicians and States."*

The Office requests that CMS provide State Medicaid programs with a uniform remedy for the collection of NDCs and NDC quantities as it pertains to outpatient hospital claims that will be submitted on the UB-04 claim format. The UB-04 claim format does not accommodate these values and therefore would require each State to develop a non-standard mechanism to collect this information. In particular, this is problematic for providers who work across State lines with multiple State Medicaid programs.

The Office requests that CMS provide State Medicaid programs with a uniform remedy for processing HCPCS claims involving NDCs where the product has been compounded. The Office recommends that CMS only require the NDC and NDC quantity for the NDC that most closely ties the HCPCS narrative description since the various claim forms and electronic data standards do not allow for multiple NDCs to be transmitted for a single HCPCS code. The Office does not consider duplicate submission of a HCPCS coded claim reasonable or efficient for the purposes of collecting NDCs related to secondary ingredients involved in compound claims.

III. "Collection of Information Requirements"

Agency Comments
None

IV. "Response to Comments"

Agency Comments
None

V. "Regulatory Impact Analysis"

Requirements for Manufacturers; Page 77198

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The CMS text is as follows: “(a) *Quarterly reports. A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period.*” Over the past several months, CMS has been “cleaning up” their MDR file, notifying States of NDCs for products that should not have been considered to be “covered outpatient drugs” but were, nonetheless, somehow included on CMS’s MDR file. This erroneous inclusion and subsequent file clean-up has created confusion, as States have been reimbursing for these products and, apparently, invoicing manufacturers for rebates for the products. We anticipate that the initial inclusion of the NDCs/products on CMS’s MDR file occurred because manufacturers erroneously identified the products as “covered outpatient drugs”, but subsequently disputed rebate invoicings for the products and asked that CMS delete the products from CMS’s MDR file. If that is the case, and in order to preclude future confusion such as caused by CMS’s MDR file clean-up, we suggest that wording be added to this cite that clearly places the responsibility on manufacturers to ensure that they report to CMS only those products/NDCs that are truly “covered outpatient drugs”. Further, that CMS be required to coordinate as necessary with FDA or other federal agencies to ensure that products that manufacturers report to CMS as being “covered outpatient drugs” actually are same. Finally, that if products that are reported to CMS by manufacturers as being “covered outpatient drugs” are subsequently determined to not be same, States are not to be held accountable for any expenditures for, or rebates collected for, the products in the interim.

Overall Impact; Page 77190

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It is not clear that the estimated savings accounts for savings already realized through State Maximum Allowable Cost (MAC) programs operated in most States. If this has not been taken into account then the State and Federal Savings is most likely grossly overstated. In many instances, a lower State MAC rate is already in place and pharmacies will continue to be reimbursed at the lower State MAC rate. These lower State MAC rates would negate some or most of the expected additional savings projected in the Proposed Rule. In addition, analysis of the February 2007 AMP rates shows that many FULs would reimburse pharmacies below their average retail acquisition cost for many drugs. States will receive tremendous pressure to increase their dispensing fees to compensate for deficiencies on the ingredient cost reimbursement, which would significantly diminish the projected savings or possibly end up costing the program more in the long term.

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Alternatives Considered; Page 77194

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We are also concerned that a sufficient supply of drugs be available nationally at or near the FUL price and believe an exception is warranted. However, based on our analysis, we do not believe in any way, shape or form that the proposed carve-out policy will ensure that a sufficient supply of the drug will be available nationally at or near the FUL.

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Submitter : Dr. Scott Bergman
Organization : Southern Illinois University Edwardsville
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

I recently moved to Illinois to serve as a faculty member for the new school of pharmacy at Southern Illinois University Edwardsville. I live in Springfield and work with the physicians in the Division of Infectious Diseases at the SIU School of Medicine. I help treat patients with life threatening infections everyday. I also teach about antibiotics, antivirals, antifungals and vaccines. Student pharmacists learn not just about the medications, but how to use these anti-infectives in a cost-effective manner that will benefit patients and the health care system. In their last year of pharmacy school students will come to learn from me at the clinic and hospitals in Springfield. Today, it takes a minimum of six years to earn a Doctor of Pharmacy (PharmD) graduate degree in order to practice pharmacy. I am a clinical pharmacist trained to make medication recommendations to physicians. This is the future of pharmacy practice. Pharmacists work with physicians to develop medication regimens that lead to successful, cost-effective patient outcomes. My wife, Jessie, is a community pharmacist that has experience counseling diabetic patients about their disease as well as their medications. Before we moved to Illinois, we lived in West Virginia where Jessie was able to earn additional reimbursement for the extra time she spent counseling diabetic patients. This practice was based on a successful model shown to lower overall health care expenses in Asheville, NC. If pharmacists are allowed into the health care decision making process earlier in a patient's care, we can save the system money and improve outcomes. Unfortunately, Illinois is not yet progressive enough to reimburse pharmacists for their clinical knowledge and patient counseling skills. Chicago is participating in a 10 city trial to prove once again that paying pharmacists to educate patients can lower overall health care costs. I encourage you to support efforts such as these that provide pharmacists incentives to improve patient outcomes. Medicare Part D has opened a few doors, but there is still a long way to go before pharmacists are recognized for the professional services they provide. At this time, payment is linked only to dispensing a product and does not take into account the value of a professional service. It has come to my attention that the President's deficit reduction act intends to cut reimbursement to pharmacies. The proposed reductions will lower Medicaid payments for generic medications which are the most affordable products available. This seems counter productive to me. The pharmacists I train make every attempt to lower health care expenses by recommending cost-effective therapies. If the government decreases generic medication reimbursements, then pharmacists will actually be punished for using cheaper medications. The proposed budget cuts also plan on basing reimbursement on 'average manufacturer price'. This value is much lower than what most local pharmacies are able to dispense the product for. Pharmacists are the most accessible health care professionals, but these prices are based partially on what mail order pharmacies are able to purchase their medications at. With these reimbursement rates, local pharmacies that actually see patients and make a difference in their lives will not be able to compete with discount mail order warehouses and patient care will suffer. I hope you take the time to consider this matter.

Thanks, Scott

Submitter : Dr. Eric Lee
Organization : Lees Total Health Pharmacy
Category : Individual

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

see attached

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

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