

NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

VIA Electronic Submission

October 4, 2010

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-2238-P2  
P.O. Box 8016  
Baltimore, MD 21244-8016

**Subject: CMS-2238-P2; RIN 0938-AP67, Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs**

The National Association of Chain Drugs Stores (NACDS) is pleased to submit our comments to the Centers for Medicare and Medicaid Services (CMS) proposed regulation published on September 3, 2010 in the *Federal Register* (hereafter AMP proposed rule). The proposed rule would withdraw two provisions of the “Medicaid Program; Prescription Drugs” final rule (hereafter AMP final rule) published in the *Federal Register* on July 17, 2007; the provision pertaining to the definition of Average Manufacturer Price (AMP), and the provision pertaining to the calculation of Federal Upper Limits (FULs) for multiple source drugs. The proposed rule also proposes to withdraw the “Medicaid Program; Multiple Source Drug Definition” final rule published in the October 7, 2008 *Federal Register* (hereafter Multiple Source Drug rule).

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NACDS represents 140 companies – traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate 39,000 pharmacies, and employ more than 2.7 million employees, including 118,000 pharmacists. They fill nearly 2.6 billion prescriptions annually, including the majority of Medicaid prescriptions.

NACDS commends CMS for issuing the AMP proposed rule. NACDS strongly believes the AMP final rule was fundamentally flawed, and implemented the Medicaid pharmacy reimbursement provisions of the Deficit Reduction Act of 2005 (DRA) in a manner that was inconsistent with congressional intent. NACDS and the National Community Pharmacists Association (NCPA) challenged the AMP final rule in a lawsuit in November 2007. A federal court identified several legal problems with the AMP final rule, and as a result the court halted implementation of the AMP final rule for the purposes of Medicaid reimbursement to pharmacies. Rather than continuing efforts to implement the flawed AMP final rule, we applaud the Agency for moving forward with withdrawing the provisions of the AMP final rule, as well as the Multiple Source Drug rule.

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We are committed to working with CMS on the implementing regulations pertaining to the Medicaid pharmacy reimbursement provisions of the Patient Protection and Affordable Care Act (PPACA), as amended by the Health Care and Education Reconciliation Act, and the FAA Air Transportation Modernization and Safety Act. We offer these comments in the hopes of establishing a strong, collaborative partnership with the Agency, and the implementation of a Medicaid pharmacy reimbursement policy for multiple source drugs that maintains the strong link between community pharmacies and Medicaid patients.

**Definition of Average Manufacturer Price, Retail Community Pharmacy, and Wholesaler**

Federal law defines AMP as “with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies; and retail community pharmacies that purchase drugs directly from the manufacturer.” In addition to the definition of AMP, accurate definitions of retail community pharmacy, wholesaler, and multiple source drug are also critical to implementation of these provisions in a manner consistent with congressional intent.

PPACA, as amended by the Health Care and Education Reconciliation Act, provide CMS with clear guidance on the definition of AMP. Specifically:

AMP calculations should include only prices paid by wholesalers to the original manufacturers only for drug products the wholesalers distribute to retail community pharmacies, and prices paid by retail community pharmacies for direct sales by the original manufacturer. AMP calculations should not include prices paid by entities other than the original manufacturer, such as repackagers.

CMS should issue a new rule that defines “retail community pharmacy” in order to accurately implement PPACA’s definition of retail community pharmacy. For example, in the AMP final rule, “retail pharmacy” was defined to include mail order pharmacies. Inclusion of mail order pharmacies would result in the inclusion of sales and rebates which are not available to retail pharmacies. It is also inconsistent with the definition of retail pharmacy in other programs, such as the Medicare Part D program, which 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.” PPACA clearly excludes mail order, long term care, and other providers, defining retail community pharmacy as “an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices.”

CMS should also issue a new rule that defines “wholesaler” consistent with PPACA. In the AMP final rule, wholesaler is defined as “any entity (including a pharmacy, chain of pharmacies, or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, that does not relabel or repackage the covered

outpatient drug.” The definition of wholesaler is overly broad and inconsistent with federal and state statutes that define wholesalers as entities that are licensed by states as wholesalers and engage in “wholesale distribution.”

We urge CMS to adopt a more limited, realistic definition of wholesaler, and one that is consistent with PPACA as well as the Food Drug and Cosmetics Act. In future rulemaking to implement PPACA, an entity should be considered a wholesaler only if it is required to be licensed as a wholesaler, and is engaging in wholesale distribution when it purchases the drugs. Both the 340B and ADAP programs include this licensure requirement. In the case of chain pharmacy distribution centers, they are generally licensed as wholesalers in the states in which they are located.

Furthermore, future rulemaking should also make clear that the prices paid to the original manufacturer by repackagers and other entities listed in the definition of wholesaler should only be included in AMP calculations to the extent those entities distribute the drugs directly to retail community pharmacies.

PPACA, as amended by the Health Care and Education Reconciliation Act, specifically excludes certain transactions from AMP calculations.

- i. Prompt pay discounts.
- ii. Bona fide service fees, including but not limited to:
  - a. Distribution service fees
  - b. Inventory management fees
  - c. Product stocking allowances
  - d. Fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs).
- iii. Reimbursement for returned goods and associated costs.
- iv. Transactions with PBMs, MCOs, HMOs, insurers, long term care providers, etc.
- v. Manufacturer discounts provided in the Medicare Coverage Gap Discount program (section 1860D-14A of the Social Security Act).

NACDS strongly supports the policy that bona fide service fees be excluded from the calculation of AMP. A bona fide service fee pays for a bona fide service, so it does not reduce the cost of purchasing a drug. We do not believe the list of bona fide service fees in PPACA is exhaustive, nor do we support an attempt to list all specific bona fide service fees in the final regulation. This will allow for future flexibility and innovations to occur in a highly competitive marketplace. Manufacturers rely on wholesalers and others to perform various functions to allow their products to come to market in a safe and effective manner. It is unclear what types of services will be needed from wholesalers and pharmacies on behalf of manufacturers in the future. CMS should withdraw the definition of bona fide service fees in section 447.502 of the AMP final rule, as it is inconsistent with PPACA. Future rulemaking will be required in this area.

In addition, unlike section 477.504(g) of the AMP final rule which CMS has proposed to withdraw, in a new AMP rule CMS should ensure that the following transactions are not included in AMP calculations:

- i. Sales to patients.
- ii. Sales to physicians.
- iii. Sales to hospital pharmacies, clinics and affiliated entities.
- iv. Sales to other manufacturers not acting and licensed as wholesalers.
- v. Sales to surgical centers.
- vi. Sales to ambulatory care centers.
- vii. Sales to clinics.
- viii. Sales to dialysis centers.
- ix. Sales to other mental health centers.
- x. Sales to other medical outpatient facilities.
- xi. Sales to home infusion providers.
- xii. Sales to specialty pharmacies.
- xiii. Sales to home health providers.
- xiv. Sales to mail order pharmacies.
- xv. Sales and rebates to pharmacy benefit managers (PBMs)
- xvi. Fees paid to group purchasing organizations (GPOs).
- xvii. Nominal price sales to “any entity”.
- xviii. Rebates and discounts “associated with” these sales.
- xix. Sales reimbursed by certain third parties.
- xx. Sales to patient assistance programs.
- xxi. Sales to all other closed door pharmacies.

#### **AMPs for Drugs Not Generally Dispensed by Retail Community Pharmacies**

In addition to the changes in AMP calculations made by PPACA and the Health Care Education and Reconciliation Act, Section 202 of the FAA Air Transportation Modernization and Safety Act made further changes to the calculation of AMPs for certain prescription medications.

Under the changes made by PPACA, manufacturers can only include prices for drugs distributed to retail community pharmacies when calculating AMPs. However, Section 202 requires manufacturers to exclude non-retail community pharmacy prices from the calculation of AMP “...unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.”

We understand that the purpose of Section 202 is to ensure that AMPs can still be calculated for certain drugs for the purpose of state rebate collections. However, AMP now has two purposes – use as a benchmark for rebate collection as well as a benchmark for pharmacy reimbursement. The inclusion of non retail community pharmacy sales in AMP calculations will result in the inclusion of discounts and rebates not available to retail community pharmacies, and will lower AMPs. These

lowered AMPs could result in the setting of FULs that will underpay retail community pharmacies for multiple source drugs.

There are several alternatives available to CMS to ensure the calculation of AMPs for these drugs do not result in the below cost reimbursement for retail community pharmacies. First, it is critical for CMS to clearly define when these prescription medications are “not generally dispensed through a retail community pharmacy.” Lack of clear guidance from CMS will result in an inconsistent policy, as each manufacturer will make its own interpretation.

NACDS believes a drug is not generally dispensed through a retail community pharmacy when 90 percent or more of unit sales are to entities other than retail community pharmacies. Therefore, if 10 percent or more of a manufacturer’s unit sales are to retail pharmacies, then the drug is generally dispensed through a retail pharmacy and non-retail sales and discounts should not be included in AMP calculations. CMS should provide a definition of “not generally dispensed through a retail community pharmacy” in future rulemaking or other regulatory guidance, rather than leaving this determination to each manufacturer.

In addition to clear guidance from the Agency on the calculations of AMPs for these drugs, how and if these calculations are used in setting FULs is equally important. NACDS strongly believes that the FULs should be determined using prices paid by retail community pharmacies. Congressional intent in this matter is clear – the colloquy between the Senators that drafted the provision is attached. Therefore, when AMPs are calculated for certain drugs – such as inhalation or infused medications – and these drugs are not generally dispensed through a retail community pharmacy – then these calculations should not be used to determine FULs. The AMPs will be available for the determination of rebates, which we understand and support. However, since these AMPs will not be reflective of the prices paid by retail community pharmacies, they should not be used to determine pharmacy reimbursement. FULs are to be calculated when three or more therapeutically and pharmaceutically equivalent multiple source drug products are available for purchase by retail community pharmacies on a nationwide basis (PPACA §2503(a)(1)(B)). Since these drugs would clearly not be available in this manner, their AMPs should not be used to set FULs under the requirements of PPACA.

The ability of manufacturers to include non-retail sales in AMP calculations is limited to those drugs listed in Section 202 - inhalation, infusion, instilled, implanted, or injectable drugs. Whether a drug is not generally dispensed through a retail community pharmacy is not a consideration in the calculation of AMPs for drugs that do not fall into these classifications. CMS should provide clear guidance to manufacturers on this matter.

Finally, in providing clear guidance to drug manufacturers on the calculation of AMPs, we believe it is important to reverse the “adequate documentation” provision of the AMP final rule. See 72 Fed. Reg. 39142 (July 17, 2007). The provision states

that manufacturers should include all sales in the calculation of AMPs unless they have adequate documentation proving the sales should be excluded. PPACA clearly sets forth sales that should not be included in AMP calculations. Including this adequate documentation provision in rulemaking or other regulatory guidance would be in conflict with the intent of Congress in passing PPACA and inconsistent with current law. Instead, CMS should provide guidance to manufacturers that sales and discounts should be excluded from AMP calculations unless the manufacturers have adequate documentation to show that the sales and discounts fit the statute's definition of AMP.

#### **When to Calculate Federal Upper Limits (FULs)**

Since CMS also proposes to withdraw the sections of the AMP final rule pertaining to the calculation of FULs, additional rulemaking will be required to establish a process consistent with PPACA to determine federal upper limits. In the interim, NACDS believes CMS lacks regulatory processes that are necessary to make updates to the current FULs, such as a smoothing process and a process for determining nationwide availability of drug products. Any updates to federal upper limits should be suspended until CMS issues rulemaking on the calculation of FULs. In particular, AMP-based FULs should not be put into place until a new AMP rule has been finalized by CMS.

In order to be consistent with PPACA, future rulemaking should provide that FULs should be calculated only when three or more therapeutically and pharmaceutically equivalent multiple source drug products – rather than two or more, as required by the DRA - are available for purchase by retail community pharmacies on a nationwide basis.

PPACA is clear in this regard. CMS can only calculate a FUL if these minimum three products are available for purchase by retail community pharmacies on a nationwide basis. If only two equivalent products are available on a nationwide basis, then a FUL cannot be calculated. Similarly, after a FUL is set, if a drug shortage, product recall or other issue results in less than three products being available for purchase by retail community pharmacies on a nationwide basis, the FUL should be lifted. NACDS believes a drug product should be considered to be available on a nationwide basis if they are readily available for purchase by retail community pharmacies across the nation in sufficient quantities to supply the needs of the nation's retail community pharmacies. Products that are in short supply, or are marketed or sold by regional or niche manufacturers or suppliers should not be considered to be nationally available.

Furthermore, it is critical that CMS first issue a rule that creates a process for CMS to determine whether products are available on a nationwide basis. Consistent with PPACA, CMS should not just assume that all products are available nationwide and then place the burden of this determination on pharmacies, states, manufacturers, or others. In determining nationwide availability, a possible test may be whether the products are stocked by two of the three national wholesalers in sufficient quantities to supply most retail community pharmacies.

The AMP final rule's determination of what is "therapeutically and pharmaceutically equivalent" must also be revised. The FDA *Orange Book* refers to drugs that are equivalent as "A-rated" drug products. In contrast, drug products that the FDA "considers not to be therapeutically equivalent" are referred to as "B-rated" drug products. Nevertheless, the AMP final rule stated the CMS would apply FULs to "B-rated" drug products that are not equivalent to the drug products that were used to set the Federal Upper Limit; "we proposed that the FUL will be established, as per section 1927(e)(4) of the Act, only using an "A" rated drug. However, we proposed to continue our current practice of applying the FUL to all drug formulations, including those drug versions not proven to be therapeutically equivalent, (for example, B-rated drugs)." AMP Rule Preamble, 72 Fed. Reg. at 39155.

FULs are to be calculated based on three or more therapeutically and pharmaceutically equivalent multiple source drugs available for purchase by retail community pharmacies on a nationwide basis. After a FUL is set, it should be used to determine the reimbursement for A-rated drug products. Drugs that are B-rated are not therapeutically equivalent, and therefore should not be subject to the FUL.

#### **Amount of Federal Upper Limit**

In order to be consistent with the requirements of PPACA, future rulemaking should indicate that the FUL for each multiple source drug be calculated at no less than 175% of weighted AMP based on national sales utilization for all the nationally-available equivalent multiple source drug products.

We also recommend a smoothing process similar to that adopted for the calculation of ASP for lagged discounts. A smoothing process will help prevent a sudden reduction in a manufacturer's AMP from month to month for a particular multiple source drug if a large amount of discounts are paid in a particular month, but have been earned over a period of time. Before reporting the AMP, the manufacturer should determine a percentage based on the most recent 12-month rolling average of legitimate lagged discounts for a particular multiple source drug. The percentage amount should be applied to the AMP calculated for that quarter.

The "no less than 175%" language of PPACA provides clear authorization to CMS to use a higher multiplier to determine FULs in all cases, or in specific instances. NACDS believes this is critical in ensuring pharmacies are not reimbursed at a level below their costs to purchase prescription drugs. As AMP has never been used as a benchmark for pharmacy reimbursement, it remains to be seen how often a higher multiplier may be needed. We do believe a method for determining when to exceed 175% should be established in future rulemaking. For example, even if AMP was smoothed using a 12-month rolling average of lagged discounts, we would expect reported AMPs to move sharply from month to month, particularly for generic drugs. In situations where AMPs plummet from month to month as a result of discounts being applied or other issues, CMS should use its authority to go above 175%.

A multiplier higher than 175% may also be needed in the case of the inhalation, infusion, instilled, implanted, or injectable drugs identified in Section 202 of the FAA Air Transportation Modernization and Safety Act. Again, NACDS strongly believes that any AMPs associated with these drugs should not be used in the calculation of FULs as they are not available for purchase on a nationwide basis by retail community pharmacies. However, if CMS would elect to include these AMPs in the calculation of FULs, this would provide a clear instance in which a higher multiplier would be necessary.

We also encourage CMS to have a formal mechanism to appeal FULs in certain cases, such as if the product does not meet the criteria for a FUL because the product is in short supply or there are no longer an adequate number of equivalent products to meet the criteria for a FUL, there are price changes in the market due to raw ingredient shortages or market consolidation, or if the product is generally unavailable at the AMP used to generate the FUL. In these cases the FUL should be updated more frequently than monthly.

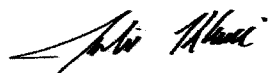
#### **Multiple Source Drug Rule**

We appreciate the decision by CMS to propose to withdraw the Multiple Source Drug rule, as well as the provisions of the AMP final rule. In determining the availability of a multiple source drug to retail community pharmacies, the rule inaccurately indicated a drug would only need to be available “in a State” rather than “in the United States.” CMS should issue a new Multiple Source Drug rule that is consistent with the requirements of PPACA.

#### **Conclusion**

Thank you for the opportunity to share our views. On behalf of NACDS and its membership, thank you for the proposed rule to withdraw the provisions of the AMP final rule and the Multiple Source Drug rule. As you move forward with additional rulemaking, we look forward to working with you.

Sincerely,



Julie Helm Khani  
Vice President, Public Policy



S6766

CONGRESSIONAL RECORD—SENATE

August 5, 2010

MEDICAID PHARMACY REIMBURSEMENT

Mrs. LINCOLN. I ask to engage in a brief colloquy with the distinguished Senate majority leader and Senator MURRAY as it relates to the intent of a provision in this legislation regarding average manufacturer price—or AMP.

Do I understand that the provision in section 203 of this bill is solely intended to ensure that Medicaid rebates are collected from the manufacturers of the particular drugs specified in the bill, that is inhalation, infusion, in-stilled, implanted, or injectable drugs not generally sold at retail pharmacies?

Mr. REID. Yes, the intention of this provision is to ensure that rebate dollars are collected for those particular drugs. Drug rebate dollars have long helped support state Medicaid programs and the provision will ensure an accurate calculation of AMP for the purposes of these drug rebates.

Mrs. MURRAY. I thank the Senator for engaging in a colloquy with Senator LINCOLN and me and would also like to clarify that this provision is in no way intended to impact reimbursement to retail pharmacies participating in the Medicaid Program. Is that the Senator's understanding?

Mr. REID. The Senator is correct. The Secretary should direct drug manufacturers to calculate AMPs for these drugs to allow States to collect rebates. In order to maintain pharmacy reimbursement at appropriate levels for these drugs, the Secretary should use the discretion that is provided under the Patient Protection and Accountable Care Act to calculate a Federal upper limit, FUL, at an amount that is at least 175 percent of the weighted average AMP for those covered outpatient drugs.

Mrs. LINCOLN. We would like to thank the leader for his clarification and shared goal of protecting access to critical drug therapies for vulnerable populations at retail pharmacies.

Mr. REID. I agree with the Senators on the importance of protecting beneficiaries' access to these drug therapies and the retail pharmacies that faithfully serve them. I thank the Senators for their shared commitment to this goal.

The PRESIDING OFFICER. The Senator from Illinois.

Mr. DURBIN. Madam President, I ask for the yeas on the motion to concur in the House amendment to the Senate amendment to H.R. 1586 with amendment No. 4575.

The PRESIDING OFFICER. Is there a sufficient second? There appears to be a sufficient second.

Amendment No. 4576 is withdrawn. The question is on agreeing to the motion to concur in the House amendment to H.R. 1586, with amendment No. 4575.

The clerk will call the roll.  
 The legislative clerk called the roll.  
 The result was announced—yeas 61, nays 39, as follows:

[Rollcall Vote No. 228 Leg.]

YEAS—61

Akaka	Gillibrand	Nelson (NE)
Baucus	Goodwin	Nelson (FL)
Bayh	Hagan	Pryor
Bayh (OH)	Harkin	Reid
Bennet	Inouye	Raid
Bingaman	Johnson	Rockefeller
Boxer	Kaufman	Sanders
Brown (OR)	Kerry	Schumer
Burr	Klobuchar	Shaheen
Cantwell	Kohl	Snowe
Cardin	Leahy	Specter
Carpenter	Leahy (NH)	Stabenow
Caspey	Leahy (VT)	Ticker
Collins	Leahy (VT)	Udall (CO)
Cortez	Lieberman	Udall (NM)
Dodd	Lincoln	Warner
Dotson	McCaskill	Waxman
Durbin	Menendez	Webb
Feinstein	Merkley	Whitehouse
Franken	Mikulski	Wyden
	Murray	

NAYS—39

Alexander	Orapo	LeMieux
Barraso	DeMint	Lugar
Bennett	Ensign	McCaain
Bond	Evans	McConnell
Brown (MA)	Graham	Markowski
Brownback	Grassley	Niich
Bunning	Gregg	Roberts
Burr	Hatch	Schiff
Chambliss	Hatch	Shelby
Coburn	Hatch	Thune
Cochran	Isakson	Vitter
Corker	Johanns	Waltovich
Cornyn	Kyl	Wicker

Mrs. MURRAY. Madam President, I move to reconsider the vote, and I move to lay that motion on the table. The motion to lay on the table was agreed to.

Mr. BERNETT. Madam President, today I was proud to vote for final passage of the amendment offered by Senators MURRAY, HARKIN, SCHUMER and REID to the FAA authorization bill. This amendment brings long overdue good news to teachers and kids in Colorado and those worried about losing access to the health care they need. I was elated to see the Senate break through the usual gridlock and pass this important legislation.

The package will save thousands of jobs and protect health services for kids and vulnerable populations across Colorado and the country. During this savage economy that is hurting families all over our state and our country, as we work to get our ship righted, our kids and our schools should be at the top of our list of priorities.

If we are going to ensure that we leave more opportunity for our kids than we ourselves have had then we must remain committed to education—to set the table for our kids' futures; to prepare them for the competitive world that awaits them; and to enrich their lives with a better education than the one that was offered to us.

I have tried to be a leader in the fight for the Medicaid Federal Medical Assistance Percentage, FMAP, funding and saving teachers' jobs. I was an original cosponsor of the Keep Our Educators Working Act of 2010, introduced by Senator TOM HARKIN. In February, I also led a group of 43 of my Senate colleagues in submitting a letter urging the majority leader to provide States with an additional 6-month FMAP extension.

The Medicaid FMAP extension passed today by the Senate was crucial in the effort to keep public servants at work across the country. Without it, States would be forced to layoff tens of thousands of more teachers and other public employees, cut education funding even further, and further reduce payments to health care providers. More than 900,000 public and private sector jobs could be lost.

Colorado alone would lose more than \$200 million if the FMAP extension fell victim to Washington politics. Cuts could include eliminating state aid for full-day kindergarten for 35,000 children, eliminating preschool aid for 21,000 children, and increasing overcrowding in juvenile detention facilities, according to the Center on Budget and Policy Priorities. The education jobs funding would prevent the loss of between 2,000 and 3,000 teacher jobs in Colorado alone.

I am glad to see this package is paid for. However, I was very concerned about the House package which paid for teacher jobs in part by cutting education reform programs. I joined 15 of my colleagues in signing a letter requesting that we find other offsets to pay for this important measure. I am very pleased that we were able to avert the cuts to critical education programs and save teachers' jobs—all without raising the deficit.

Additionally, while I strongly support the measure, in no small part because it is completely paid for and does not add one dime to our deficit, I would like to raise a strong concern with one of the pay-fors in this package. A rescission of \$1.5 billion from the Department of Energy's, DOE, renewable energy loan guarantee program was used to help offset this amendment.

In Colorado this important program has helped foster tremendous growth in the clean energy economy. Just last month, President Obama announced a conditional loan guarantee for a solar manufacturing facility in my home state and there are dozens of job creating renewable energy projects across the country waiting for approval from DOE.

This rescission places \$15 to \$20 billion of private investment in clean energy investment in jeopardy. While I am constantly reminded that the Senate needs to make tough choices as we strive to be fiscally responsible, I am compelled to raise my objection to this offset. It is my sincere hope that, in the future, this Chamber, the House of Representatives and the administration will avoid tapping into what are already scarce clean energy investments to pay for what are admittedly important recession-stopping items such as the ones we approved today.

Mr. NELSON of Nebraska. Madam President, earlier today, I voted in favor of two motions designed to extend the 2001 and 2003 tax cuts. Let me be clear, I strongly support extending individual income tax rates. While I voted in favor of these motions to show





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Print Comments Reprint

## Changes in Medicaid Reimbursement: Implications for Generic Manufacturers and Pharmacies

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6/20/2011

*US Pharm.* 2011;36(6)(Generic suppl):12-20.

According to the most recent data, the Medicaid program pays for the prescription drugs of approximately 44 million Medicaid fee-for-service patients.<sup>1</sup> By the second quarter of 2010, Medicaid had paid for more than 266 million prescriptions, with these prescription drug costs totaling about \$20 billion dollars (**TABLE 1**).<sup>1</sup> Medicaid is expected to expand in 2014 as a result of the new health care reform law. About 16 million more people, primarily adults, are expected to be added to the program, significantly increasing the number of prescriptions paid for by Medicaid.<sup>2</sup> This will have an impact on generic drug manufacturers as well as pharmacies. Thus, Medicaid pharmacy reimbursement policies are critical to pharmacies, wholesalers, and generic-drug manufacturers.

**Table 1. Medicaid Generic Utilization (2009 Q3-2010 Q2)**

	<b>Total Rx</b>	<b>Brand Rx</b>	<b>Generic Rx</b>
Number of Rxs	266 million	80 million	186 million
Total spending	\$19.8 billion	\$16.1 billion	\$3.7 billion
Total Rxs (%)	100	31	69
Total \$ (%)	100	82	18
Average price	NA	\$201	\$20

NA: not applicable; Q: quarter; Rx: prescription.  
 Source: Reference 1.

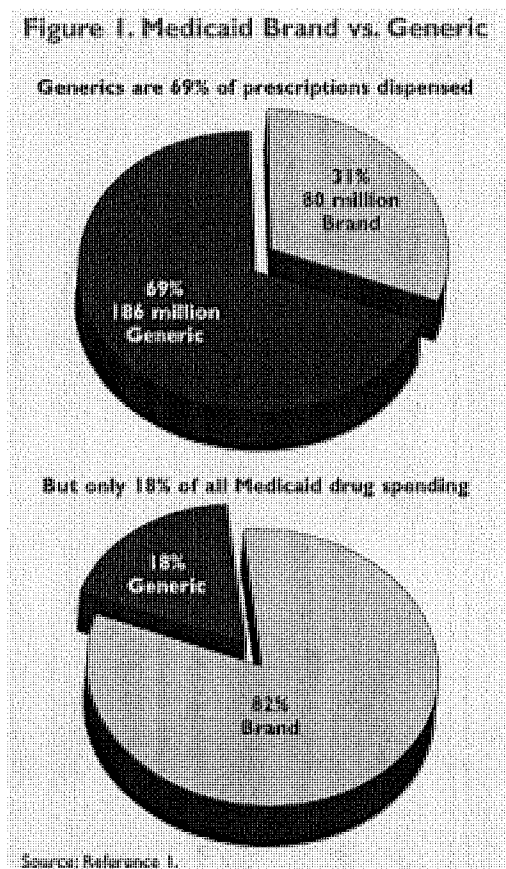
### Generic Use Helps Medicaid Save Billions



The Medicaid program—at both the federal and the state level—can save billions of dollars by increasing the use of high-quality, low-cost generic medications. As the Congress and state lawmakers debate ways to improve the Medicaid program, lawmakers should consider policies to promote the use of cost-saving generic medications.

- About 69% of all Medicaid prescriptions are dispensed with generic medications, but those prescriptions represent only about 20% of total Medicaid drug-program spending. The remaining 31% dispensed with higher-cost brands make up 80% of Medicaid drug-program spending (**FIGURE 1**).<sup>1</sup>
- The average brand prescription costs Medicaid about \$200, which is 10 times more than the average generic prescription cost of \$20 (**FIGURE 2**).<sup>1</sup>
- If generic medication use was increased by just 1%, Medicaid would save \$682 million in one year. If generic use was increased by 5%, \$3.4 billion would be saved (**FIGURE 3**).<sup>1</sup>
- Many states have Medicaid generic dispensing rates that are less than the national average of 69%. If states increased these rates just to the national average, the states and the federal government would save hundreds of millions of dollars.<sup>1</sup>

Reimbursement policies are a key driver in determining generic dispensing rates. Lower generic-drug reimbursement may reduce incentives for pharmacies to dispense generics.



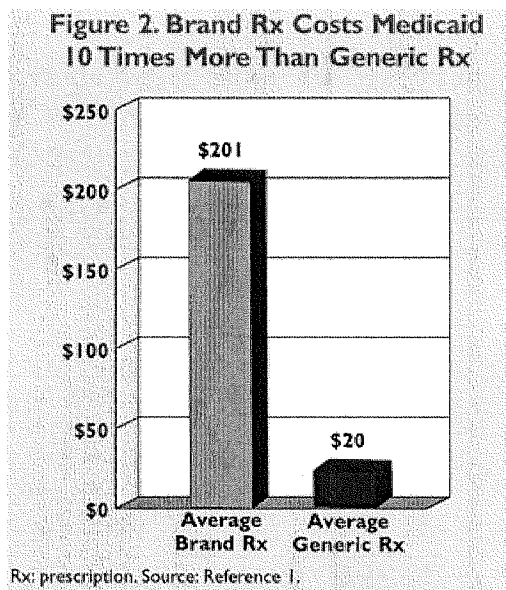
Currently, most states still base reimbursement to pharmacies for brand-name drugs on the average wholesale price (AWP) or the wholesale acquisition cost (WAC), while generic reimbursement is based on federal upper limits (FULs), which are set by the Centers for Medicare and Medicaid Services (CMS) or state-based maximum allowable costs (MACs), which are usually lower than the FULs. States can apply their MACs to more drugs than just those with FULs. States also pay a dispensing fee for each prescription, although the fees are usually lower than pharmacies' actual cost of dispensing, which remains in the range of about \$11 per prescription.<sup>3</sup>

Some states, such as Alabama and Oregon, have moved to a reimbursement system based on actual acquisition cost (AAC) for drug product reimbursement. The AAC amounts are determined based on surveys of pharmacy purchasing invoices. The dispensing fees in these situations are usually higher than average, approximating the pharmacy's cost of



dispensing, because there is no “margin” for the pharmacy on acquisition cost–based reimbursement. For example, in Oregon the pharmacy dispensing fee is tiered but averages \$10.65, while in Alabama it averages \$10.64 per prescription.<sup>3</sup>

More changes are in store for Medicaid pharmacy reimbursement. The new Patient Protection and Affordable Care Act (PPACA) of 2010 included changes to Medicaid reimbursement policies that were originally enacted in the Deficit Reduction Act (DRA) of 2005.<sup>4,5</sup> The 2005 law moved Medicaid pharmacy reimbursement—specifically the setting of the FULs—to an average manufacturer price (AMP)–based reimbursement system for generic medications. Previously, FULs were based on the AWP or WAC, which policy makers believed did not reflect pharmacies’ costs of purchasing these drugs. These 2005 changes were never implemented, however, because of a court injunction that has since been lifted, but it is likely that AMP-based reimbursement will be coming soon to Medicaid programs.<sup>4,5</sup>



## What Is AMP?

AMP was originally created in a federal law known as *OBRA 90* (Omnibus Budget Reconciliation Act of 1990) as a benchmark for manufacturers to determine the basis of rebates that they would have to pay to states for drugs dispensed to Medicaid patients.<sup>6</sup> The rebate program, still in effect today, is supposed to reduce the cost of drugs for Medicaid programs. Quarterly rebates are paid by brand and generic companies based on their utilization in the state Medicaid program, although brand drugs pay a higher amount than generic drugs.

AMP did not exist before 1990. It was created because it was generally recognized that the AWP was not really a transaction price, and that it would be unfair to base manufacturer rebates to states on a price that did not accurately reflect market transactions and the actual revenues received by manufacturers.

AMP was supposed to reflect prices paid by retail community pharmacies for prescription drugs, because almost all Medicaid drugs are provided through such pharmacies. Thus, manufacturers would pay back a percentage of the revenues they actually received on sales of drugs to Medicaid through community retail pharmacies.

Even though the law mandated changes in Medicaid pharmacy reimbursement in 2005, CMS never published a final regulatory definition of AMP until 2007.<sup>4,5</sup> Under the 2005 law, reimbursement for a particular multiple-source drug, as reflected by the FULs, was to be changed from 150% of the lowest published price (WAC or AWP) to 250% of the lowest AMP.<sup>4,5</sup> This change was expected to reduce pharmacy reimbursement by billions of dollars, creating concerns among the pharmacy community that many pharmacies with a significant number of Medicaid patients, such as small pharmacies in urban and rural areas, would be hardest hit by these reductions.

In fact, various government reports after the 2005 law was enacted suggested that this new benchmark would not cover





pharmacies costs of purchasing generic drugs.<sup>4,5</sup> Making matters worse, states could even further reduce the FULs for reimbursement purposes. This fact exacerbated concerns among the pharmacy supply chain that generic-drug reimbursement would be squeezed down hard, with the result that generic-drug dispensing would be reduced.

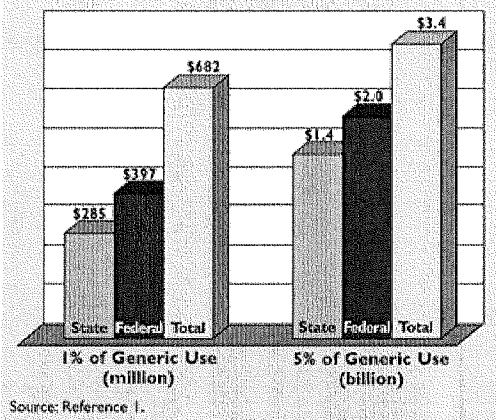
In fact, two Government Accountability Office (GAO) studies found that use of 250% of the lowest published AMP to set FULs would have underpaid pharmacies by 36%.<sup>4,5</sup> The AMP-based reimbursements could have averaged about 78% below what pharmacies were getting paid. An economic analysis of this Medicaid FUL reimbursement policy found that 11,000 pharmacies would have closed had the policy been implemented.<sup>7</sup> That means about 20% of all pharmacies could have closed. Such an outcome could have devastated the community pharmacy infrastructure that is relied on by millions of Medicaid, Medicare, and other patients every day to obtain their pharmacy services.

Community pharmacy believed that the July 2007 CMS regulation implementing the 2005 changes had several flaws that did not follow the intent of Congress. The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) filed suit in federal court against CMS and won an injunction in December 2007, staying certain parts of the regulation relating to pharmacy reimbursement and the public posting of AMP data.<sup>4,5</sup>

According to the retail pharmacies, the AMP definition finalized in 2007 did not reflect the statutory intent of Congress that the AMP should only include retail pharmacy prices. To their consternation, CMS required manufacturers to include in the AMP any price for a drug dispensed in an outpatient setting, including hospitals, mail order, pharmacy benefit managers (PBMs), physician offices, and others.

Pharmacies believed that this would result in an AMP that would not reflect their costs of purchasing—especially for brands—and they won an injunction on the regulation. As of December 15, 2010, the NCPA and NACDS reached an agreement with CMS to dismiss the Medicaid AMP lawsuit.<sup>8</sup> This was made possible by CMS's withdrawal of the last remaining provisions of the AMP rule that had been blocked by a preliminary injunction following the litigation. This injunction has helped to avert billions of dollars in Medicaid generic-drug reimbursement reductions to community pharmacies.

Figure 3. Medicaid Savings From Increased Generic Use Could Top \$3 Billion



## How Did the Health Care Reform Law Change Medicaid Pharmacy Reimbursement?

The PPACA of 2010 made significant changes to the original Medicaid pharmacy reimbursement changes in the 2005 DRA law.<sup>9</sup> These changes were made in response to concerns that the original DRA law excessively reduced Medicaid generic pharmacy reimbursement and that CMS did not correctly implement the law as originally intended by Congress.

Provisions in the health care reform law, which went into effect as of October 1, 2010, reversed some of the reductions in generic reimbursement by modifying the definition of AMP so that it includes only manufacturers' sales to retail



community pharmacies, increasing the AMP. When calculating AMP, manufacturers are required by law to *exclude* the following<sup>9</sup>:

- Customary prompt pay discounts extended to wholesalers
- Bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)
- Reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods
- Payments received from, and rebates or discounts provided to, PBMs, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail-order pharmacies, long-term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy
- Discounts provided by manufacturers under the Medicare coverage gap discount program.

When calculating AMP, manufacturers should *include* the following<sup>9</sup>:

- Notwithstanding the listed exclusions, any discounts, rebates, payments, or financial transactions that are received by, paid by, or passed through to, retail community pharmacies.

Taken together, this list of inclusions and exclusions means that manufacturers should be calculating an AMP that more closely reflects pharmacy acquisition costs than would have occurred under the original regulation.

The new law also directs CMS to set Medicaid FULs for reimbursement of generics at a rate of “no less than 175 percent of the utilization-weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis.”<sup>9</sup> This replaced the 2005 DRA requirement that FULs be set at 250% of the lowest AMP for a multiple-source drug.<sup>4</sup> These factors combined should help ameliorate some of the reduction that would have taken place had the original law gone into effect. In addition, the NCPA secured report language that encourages the CMS secretary to increase the reimbursement even higher for small independent community pharmacies.

The lifting of the 2007 injunction clears the way for CMS to eventually release new FULs based on 175% of the weighted-average AMP. CMS has not released an update to the FUL list in almost 2 years. When the list is next updated, only AB-rated (bioequivalent) drugs that are available by three sources of supply will be included. However, this list could be released at any time, given that the new law allows CMS to implement the new FULs without final regulations.<sup>9</sup>

A December 2010 GAO report validates that the new PPACA FUL reimbursement policy is more reasonable.<sup>8</sup> For example, the GAO found that for most of the drugs in their sample, using AMP and other data from 2008, FULs based on the new FUL formula were higher than the average retail pharmacy acquisition costs. In the aggregate, the sum of the FULs based on the PPACA’s formula for all the drugs in the sample was 35% higher than the sum total of the pharmacy acquisition costs for these drugs.<sup>8</sup>

Thus, for the market basket of generic drugs studied by GAO, pharmacies would not have to take a loss on average on the ingredient cost component of these Medicaid generic prescriptions.<sup>8</sup> However, it does not mean that pharmacies are being overpaid. Studies based on percentages do not give a sense of how much dollar revenues pharmacies are making on these prescriptions. Generics tend to have a lower dollar cost basis, so even if the FULs are 35% percent on aggregate higher than acquisition costs, it does not mean that pharmacies are being over paid. It could mean pennies in terms of the actual difference between the AAC and the FUL.

The 2010 law also changed which data CMS would publish on a public Web site. The original DRA law called for CMS to publish individual AMPs for brand and generic medications. The goal was to give the marketplace additional data in addition to the AWP and WAC that could be used to determine pharmacy reimbursement. However, concerns were raised about how such individual AMP data would be used and whether the publication of all these data could actually reduce competition and lead to an increase in prices for some purchasers. As a result, the 2010 law only requires that CMS publish weighted-average AMPs for multiple-source drugs.<sup>9</sup>



## The Future of AMP and Other Key Issues

Pharmacies and generic-drug companies have expressed concerns to CMS that without a formal AMP regulation or guidance, there could be significant variance among manufacturers in the calculation of AMP, and that could affect pharmacy reimbursement under the new FUL for generics. Manufacturers have been reporting monthly AMPs to CMS since November 2010 (for the month of October), given that the changes to the AMP took effect October 1, 2010, even though a regulation has not been published to date.<sup>8,9</sup>

While the new PPACA law does provide more direction to manufacturers on how to calculate AMP, many questions remain that can likely only be addressed through more detailed direction from the agency, including, for example, the definition of bona fide service fees. However, the proposed regulation also needs to address other important implementation issues for both generic manufacturers and pharmacies.

**How to Calculate AMP for the Five “I” Drugs:** Manufacturers that sell infusion, injection, inhalation, implantable, and instilled drugs (the five “I” drugs) can include nonretail pharmacy sales in their AMPs for these drugs if they are not generally dispensed through retail pharmacies. However, CMS has not indicated how it will interpret this phrase. Manufacturers may be making different assumptions about the cases in which a product is “not generally dispensed through a retail community pharmacy.”<sup>8,9</sup> This is also important to pharmacies, as the AMPs for these drugs will likely be lower, meaning that reimbursement even at 175% of the weighted-average AMP could be lower than the acquisition costs.

**Reimbursement at Greater than 175%:** How will CMS interpret Congressional intent to set FULs “at least 175% of the weighted-average AMP” for a particular multiple-source drug?<sup>8,9</sup> Even if CMS sets FULs higher than 175%, nothing stops states from lowering them even further. Will CMS apply a higher multiplier to particular drugs or particular pharmacies, such as small rural pharmacies? The law also requires that only “nationally available” multiple-source drugs be used to set FULs. How will CMS determine if a particular drug meets this definition?

**Posting of Weighted-Average AMP Data:** CMS will be publicly posting FUL data for 600 to 700 multiple-source drugs at 175% of the weighted-average AMP.<sup>8,9</sup> Thus, it will be relatively easy to determine the weighted-average AMP for a particular multiple source drug. Individual AMPs will not be posted. But one issue relating to posting remains: How will the market react to the posting of weighted-average AMPs? Purchasers above the weighted average will obviously want to get a better price, while those below the weighted average will want to protect their “lower than average” price from price compression or equalization. How will third-party payers use the weighted-average AMPs? They might use them to set their own MACs once they have a better sense of this price point in the marketplace.

**Publication of AAC Data Based on Pharmacy Survey:** CMS has indicated that it intends to publish a file that will include pharmacy acquisition cost data for Medicaid-reimbursed drugs.<sup>8,9</sup> The data would be obtained from surveys of retail pharmacies. It is not clear whether the survey will include weighted-average or individual AACs. Moreover, it is not clear whether CMS has the authority to collect and publish such a file. CMS has said it would not allow states to use AAC-based reimbursement unless they increased the pharmacy dispensing fee.

**State Initiatives to Determine Reimbursement:** Regardless of CMS action, states are already acting to change their reimbursement to an AAC-based system. Both Oregon and Alabama have approved State Plan Amendments that move to AAC for product reimbursement plus a more accurate dispensing fee.<sup>9</sup>

These changes could affect generic-drug dispensing if some of the economic incentives to dispense generics (such as a reduction in margin) are removed from the pharmacy’s reimbursement. CMS appears to be adopting a policy that only allows states to move to the AAC if they also increase the dispensing fee to more accurately reflect the pharmacies’ costs of dispensing prescriptions.

## Conclusion

Adequate Medicaid pharmacy reimbursement for generic drugs is critical to assuring that Medicaid maintains—and eventually increases—its generic dispensing rate. Lower cost generics create a win-win situation for pharmacies, generic manufacturers, and the federal and state Medicaid programs. The implementation of AMP-based reimbursement at 175% of the weighted-average AMP and the posting of weighted-average AMPs as modified in the PPACA of 2010,



while an improvement over the DRA of 2005, could still have a dramatic impact on pharmacies and generic manufacturers. States also need to remember that pharmacies are the Medicaid program's best partners in both promoting the use of generics and helping Medicaid patients manage their often complex drug therapies.

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