



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



Frequently Asked Questions (FAQs)
Lawsuit Filed by NACDS and NCPA Against CMS
Challenging AMP Rule
November 7, 2007

Why has the lawsuit been filed?

The lawsuit was filed to block implementation of a new federal rule known as the AMP rule. As discussed below, the AMP rule violates the plain language of the Social Security Act.

The AMP rule will drastically cut reimbursement payments to community pharmacies that serve disadvantaged Americans in the Medicaid program. The defendants estimated that the AMP rule will reduce Medicaid reimbursement to community pharmacies by more than \$8 billion over five years. Studies by the HHS Office of Inspector General and the Government Accountability Office found that Medicaid reimbursement rates will be cut well below the prices that retail pharmacies pay for drugs.¹

Medicaid reimbursement rates for retail pharmacies were expected to decline as a result of the Deficit Reduction Act of 2005. However, in their zeal to cut retail pharmacy reimbursement rates even further, the Defendants have slashed reimbursement well below the rates called for by Congress. Retail pharmacies will suffer even greater losses than they would if the defendants had faithfully implemented the plain meaning of the statute.

Many community pharmacies, particularly independent pharmacies that serve a large number of Medicaid patients, are expected to be forced to reduce hours and services, forced out of Medicaid, or forced to close their doors altogether. When that happens, many Medicaid patients will lose access to the community pharmacies they depend on for critical pharmacy care.

Who are the plaintiffs and defendants in the lawsuit?

The plaintiffs are the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA). Together, NACDS and NCPA represent virtually all community pharmacies in the United States. An important purpose

¹ See OIG, *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program*, OEI-03-06-00400 (June 2007); GAO, *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*, GAO-07-239R (Dec. 22, 2006).

of both plaintiffs is to protect and advance their members' interests relating to Medicaid and other Federal health programs. Members of NACDS and NCPA participate as providers in the Medicaid program. According to CMS, chain and independent retail pharmacies represented by NACDS and NCPA filled over 294 million prescriptions for Medicaid patients in 2006. These retail pharmacies will be reimbursed for dispensing multiple source drugs to Medicaid patients based on the AMP Rule beginning in 2008.

The defendants are the US Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS). HHS Secretary Michael Leavitt and CMS Acting Administrator Kerry Weems are also named as defendants, but only in their official capacities.

What are the key arguments in the lawsuit?

The AMP rule establishes a procedure for drug manufacturers to calculate and report their "Average Manufacturer Prices" (or "AMPs"). CMS will then use those AMPs to establish Federal Upper Limits (or "FULs") on Medicaid reimbursement rates for pharmacies that dispense "multiple source drugs" to Medicaid patients. Multiple source drugs are commonly referred to as "generic" drugs.

The AMP rule establishes an illegal method of calculating AMPs. The AMP rule also establishes an illegal method of calculating and applying the FULs that limit reimbursement to pharmacies.

The Plaintiffs assert three basic legal claims:

First: The AMP rule does not comply with the Social Security Act's definition of AMP. The statute defines AMP as the prices paid to manufacturers by wholesalers for drugs distributed to retail pharmacies. The AMP rule includes many transactions that have nothing to do with either the prices paid by wholesalers or drugs distributed to retail pharmacies.

For example, the AMP rule includes sales to patients and physicians in calculations of AMP, even though patients and physicians are obviously not drug wholesalers and are obviously not retail pharmacies. Other examples of transactions that are inappropriately included in the AMP rule are sales and discounts to hospitals, surgical centers, dialysis centers, clinics, pharmacy benefit managers (PBMs), mail order pharmacies, and many other transactions that are not prices paid by wholesalers for drugs distributed to retail pharmacies.

Second: The AMP rule does not comply with the Social Security Act's definition of multiple source drugs. The statute limits the definition of "multiple source drugs" to drug products that are generally available to the public in each individual state through retail pharmacies. The AMP rule violates the statute because it will apply the FULs to multiple source drugs without any process for ensuring that the drug products used to establish

those upper limits are generally available to the public through retail pharmacies in each state.

Third: The AMP rule also does not comply with another provision of the Social Security Act's definition of multiple source drugs. The statute further limits the definition of multiple source drugs to "equivalent" drug products. The statute also provides that the defendants may only establish FULs for equivalent multiple source drugs. Nevertheless, the defendants have specifically stated that they will apply the FULs to *non-equivalent* drug products.

What is the time frame for action now that the suit is filed? What happens next?

The next step is to file a motion for preliminary injunction. That motion will ask the court to stop the defendants from implementing the AMP rule. The preliminary injunction motion will also ask the court to stop the defendants from posting on a public website the flawed AMPs that are calculated pursuant to the AMP rule.

What does this do to the Medicaid pharmacy reimbursement cuts scheduled for January 2008 and the anticipated posting of pricing data on the Internet?

Given the strength of our legal arguments, we believe the Court will grant our motion for preliminary injunction and halt implementation of the reimbursement cuts and the AMP website. Ultimately we expect that the defendants must scrap the AMP rule and issue a new rule that complies with the law.

Is there still a need for the U.S. Congress to act to address the Medicaid pharmacy reimbursement cuts, and is there still a need for the states to increase dispensing fees?

Absolutely. Our lawsuit argues that the defendants must comply with existing law. However, the existing law itself is fundamentally flawed and must be replaced.

How will Association members and pharmacy patients be impacted if the AMP rule takes effect?

If implemented, this rule will cost pharmacies providing Medicaid services to the neediest Americans billions of dollars in revenue. Indeed, they would be reimbursed well below their actual cost to purchase and dispense the drug - basically forcing pharmacy to pay for what the federal government will not pay for. Such a situation puts pharmacies in a very difficult position. The economics of the situation could mean that patient access to community pharmacies may be reduced through shorter work hours or fewer pharmacists or may even be eliminated should smaller and independent pharmacies close due to the huge financial burden imposed by this rule.

What will happen if the lawsuit is successful?

If successful, this will require CMS to return to the drawing board to publish a rule that is consistent with Congressional requirements for calculating AMP. Should CMS do so, the economic hardship on pharmacies is expected to be somewhat eased. More importantly, while we are hopeful to have a success in court, it is imperative to encourage Congress to work with community pharmacy to find more appropriate, cost-based models for reimbursement under Medicaid.

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*National Association of Chain Drug
Stores & National Community
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