Final AMP Rule: Industry Implications

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The Centers for Medicare & Medicaid Services (CMS) published the Medicaid Program Covered Outpatient Drugs final rule in the Federal Register on February 1. This publication ended a 10-year regulatory odyssey that began in 2006. The regulatory odyssey included the following:

- February 2006 — The Deficit Reduction Act of 2005 changed the federal upper limit (FUL) methodology from a WAC-based (wholesale acquisition cost) algorithm to 250% of the lowest average manufacturing price (AMP).
- December 2006 — CMS published the proposed rule changing the FUL calculation. The final rule was published in July 2007 and kept the 250% of the lowest AMP calculation.
- November 2007 — The National Association of Chain Drug Stores (NACDS) and National Community Pharmacists Association (NCPA) filed a lawsuit against CMS. A study was conducted at the time that concluded that an estimated 10,000 to 12,000 pharmacies would close if the proposed FUL methodology using AMPs was implemented. A preliminary injunction was granted in December 2007 preventing this implementation.
- March 2010 — The Patient Protection and Affordable Care Act (PPACA) was enacted, changing the FUL methodology to not less than 175% of weighted-average AMP.
- January 2012 — Proposed regulations were published implementing AMP provisions of the PPACA.
- February 2016 — The final rule was published, implementing the AMP FUL methodology.

The final AMP rule implemented changes to the Medicaid Drug Rebate Program (MDRP) under PPACA that:

- Changed the AMP calculation submitted by pharmaceutical manufacturers.
- Implemented AMP-based FUL for state Medicaid fee-for-service programs.
- Required state Medicaid programs to implement actual acquisition cost (AAC) based pharmacy reimbursement.

These regulatory changes will be reviewed in the following sections.

Pharmaceutical Manufacturer Impact

The final rule updated the definition of AMP to mean the average price paid by wholesalers or retail pharmacies to manufacturers for drugs distributed to retail community pharmacies. AMP does not include:

- Customary prompt-pay discounts extended to wholesalers.
- Bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies.
- Reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods. This includes reimbursement for the cost of the goods and any reimbursement of costs associated with return-goods processing.

- Rebates or discounts provided to pharmacy benefit managers, 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.

Retail community pharmacy (RCP) is defined as pharmacies that dispense medications to the general public at retail prices and includes independent, chain, supermarket, and mass merchandiser pharmacies. RCP *excludes* mail, specialty, nursing home, long-term care, hospital, and clinic pharmacies.

CMS did include an exception for the RCP definition. Manufacturer sales to specialty, home infusion, and home health pharmacies should be *included* in the AMP calculation *if* pharmacies actually meet the statutory definition of a "retail community pharmacy."

This is an interesting caveat, as how would a manufacturer treat sales of a specialty drug that is sold to a chain's specialty pharmacy, but is dispensed at a retail location based on a patient's request? How would the manufacturer have any insight into this situation, since it deals with purchase data and not dispensing data? CMS provides a statement for the manufacturer to follow. If these pharmacies do not dispense medications to the general public, or if they provide medications to patients primarily through the mail, sales to these pharmacies would be *excluded* from the AMP calculation.

Bona Fide Service Fees

The final rule excludes from the AMP calculation "bona fide service fees" that are paid by the manufacturer. Examples of bona fide service fees paid by the manufacturer to the wholesaler or retail community pharmacy include:

- Inventory management fees.
- Product stocking allowances.
- Fees associated with administrative service agreements.
- Patient care programs (e.g., adherence programs, patient education initiatives) where the total benefit of the program is realized by the patient. If the wholesaler or pharmacy benefits from the program, the entire program cost must be included in the AMP calculation.

The pharmaceutical manufacturer must apply a four-part test to determine whether the fee is for a bona fide service. If a fee meets the following four criteria, it is deemed bona fide and excluded from the AMP.

1. It represents fair market value.
2. Itemized services are actually performed on behalf of the manufacturer.
3. The manufacturer would otherwise perform or contract for in the absence of the service agreement.
4. It is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Pharmaceutical manufacturers have created processes to document their testing of service fee agreements to support their decision to include or exclude them from their AMP calculation.

Retail Community Pharmacy Impacts

The changes that were made from the initial Deficit Reduction Act of 2005 that are included in the final AMP rule have addressed the concerns expressed by the retail pharmacy community. The definition of RCP has been narrowed, and discounts have been excluded from the pharmaceutical manufacturer's AMP calculations that are not available to RCPs.

AMP Market Use

AMP was originally defined in the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) legislation for use in the Medicaid drug rebate program. The new definition of AMP has led to use of the AMP as a reimbursement metric for both the FUL price and the drug rebate calculation. AMP pricing was confidential from 1990 through August 2011. Beginning in September 2011, CMS began publishing draft AMP-based FULs on its website to solicit industry feedback on the proposed FUL prices. The publication of FUL prices enabled the industry to reverse-engineer and calculate the AMP unit price.

CMS FUL Definition

The final rule established the following criteria to establish the FUL price:

- FUL is set at 175% of the weighted average AMP; the national average drug acquisition cost (NADAC) unit price is used if it is higher than the AMP-based FUL. The NADAC is based on a monthly voluntary survey of invoice prices from RCPs.

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- There must be three therapeutically equivalent products, including brands, authorized generics, and abbreviated new drug application (ANDA) generics.
- State Medicaid programs must pay no more than the CMS FUL on an aggregate basis in order to receive federal matching funds. Over 40 states have created their own state MAC prices, and these are allowed under the final rule.

AMPs have the following characteristics:

- They are based on transaction prices between pharmaceutical manufacturers and wholesalers or RCPs that purchase directly.
- Manufacturers must sign an OBRA '90 rebate agreement to have their products covered by fee-for-service Medicaid.
- They are available for all products covered under the Medicaid program.
- They are updated and published monthly.

Publication of these draft FUL prices has led to erosion in generic profitability for pharmacies, as payers were able to evaluate market prices and use that information when establishing MAC prices.

Professional Dispensing Fee

The final rule introduces the term "professional dispensing fee," which should reimburse pharmacies the costs, in excess of ingredient cost, each time a covered outpatient drug is dispensed. Examples of these costs are:

- Reasonable costs for the pharmacist's time checking computer information about an individual's coverage.
- Performing DURs.
- Preferred drug list review activities.
- Measurement or mixing the covered drug.
- Filling the container.
- Beneficiary counseling.
- Physically providing the completed prescription to the Medicaid beneficiary.
- Overhead, including maintaining the facility and equipment.

The professional dispensing fee is expected to be higher than the current dispensing fee used in the fee-for-service Medicaid programs.

Next Steps

State Medicaid programs must submit state plan amendments to CMS by June 2017 to implement the AAC-based pharmacy reimbursement methodologies. The new plan amendment must include studies that support establishing the professional dispensing fee in their state. CMS has stated it will review the pharmacy reimbursement in totality, i.e., FUL/acquisition cost plus the professional dispensing fee, and will withhold approval until it is satisfied that retail pharmacy is not disadvantaged by the proposed AAC/FUL reimbursement.

The retail pharmacy community was able to delay implementation of the AMP-based FUL pricing, have CMS revise the AMP methodology, and implement a professional dispensing fee to keep the reimbursement rates equitable. This regulatory odyssey has proven beneficial for retail pharmacy, and the final rule addressed the industry's objections and issues. **CT**

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