

Report to the Office of Legislative Fiscal Analyst

Reimbursement Options for Pharmaceutical Drugs: Replacing Average Wholesale Price

in compliance with HB 2 Intent Language

Prepared by the Division of Medicaid and Health Financing

October 1, 2010



EXECUTIVE SUMMARY

Average wholesale price (AWP) has been the basis of calculating pharmaceutical pricing and reimbursement for many years. Lawsuits filed, beginning in 2003, have challenged the use of AWP as an inflated benchmark costing government and insurance health plans millions. A final ruling in 2008 ended litigation and mandated a five percent rollback in the basis of AWP, and national pricing compendia agreed to cease publishing AWP in September 2011.

Until recently, the search for a suitable replacement for AWP has largely centered around academic discussions of the merits of the various other pricing benchmarks that are in common use within the industry. In late 2009 and early 2010, the National Association of State Medicaid Directors (NASMD) along with the American Medicaid Pharmacy Administrators Association (AMPAA) began dialogue with the states to produce a white paper focused on this issue. The purpose of the white paper can be viewed as three-fold:

1. Provide an understanding to major stakeholders of the issues involved with pharmaceutical pricing
2. Emphasize the need for CMS to adopt a leading role in the effort to identify and advocate a suitable, nationwide pricing metric for pharmaceutical pricing
3. Raise the awareness of all stakeholders to the problems facing them in the absence of a single, nationally viable AWP replacement

The white paper was submitted to the Centers for Medicare and Medicaid Services (CMS) in July of 2010. In the wake of this submission, two states, Alabama and Oregon, submitted state plans to CMS outlining differing approaches for identifying an Actual Acquisition Cost (AAC) and the cost of dispensing, through the use of survey tools. CMS has approved the Alabama plan, but is cautious about all 50 states undertaking similar measures since provisions in the Medicaid laws and the Affordable Care Act (ACA) provide for retail pricing surveys by CMS.

The intent language of H.B. 2 directs that the Department of Health:

...report on ...reimbursement options for pharmaceutical drugs that would give the State more control over inflationary increases and/or move away from a reimbursement based on Average Wholesale Price...

The main issue surrounding AWP is the unknown and inconsistent margins built into the price. This particular issue is believed to be the concern and focus of the information sought. Accordingly, this report will focus on efforts to replace AWP as a basis for Medicaid reimbursement.

Introduction

State and federal agencies have struggled for years over appropriate levels of reimbursement for pharmaceutical products purchased by their respective programs. Indeed, the current Medicaid program involving rebates from manufacturers came as a result of those concerns. Even with these efforts, however, a pricing system based on transparent pricing has eluded all attempts at transparency. There are simply too many purchasers and purchaser types, too many discounts and discount types, and too many negotiable and negotiated scenarios for a manufacturer to have a single price for all business transaction types. Attempts to limit pricing benchmarks to certain types of sales have only resulted in multiple benchmarks, thus raising confusion and ending in frustrated systems. After years of experimentation with different manipulations of the various benchmarks, litigation over the use of AWP leaves all stakeholders facing the same inevitable conclusion: AWP must be replaced. It also leaves all stakeholders facing the same question: What to replace it with and how?

Replacing AWP - options

Left in the wake of a discarded AWP are approximately seven or more different pricing benchmarks including:

- Average Sales Price (ASP)
- Average Manufacturer Price (AMP)
- Best Price (BP)
- Wholesale Acquisition Cost (WAC)
- Nominal Pricing (NP)
- 340b
- Federal Upper Limit pricing (FUL)

Except for FULs, these benchmarks are all manufacturer derived and reported to CMS. Each has a role in some federal regulation. Each also has potential application as well as unique problems. Their definitions, merits, faults, and differences however are not within the scope of this report. These, for the most part, are treated exceptionally well in the NASMD white paper, and the reader is referred to Attachment 1 for that information.

State Plans and pricing methodology

In addition to pricing benchmarks, other pricing tools have resulted as a direct result of the manipulations previously mentioned. Some are the result of regulation. Others from dissatisfaction with available tools. Among these are:

- Estimated Acquisition Cost (EAC)
- Actual Acquisition Cost (AAC)
- Maximum Allowable Cost (MAC)

In contrast to the benchmarks mentioned above, these tools are within the scope of state regulation and except for AAC, have their relationship and application defined in some way by those general benchmarks.

State Plans are required by federal regulation to stipulate the methodology a state uses to determine reimbursement. Federal regulation (42 CFR 447.512) requires that a state base its reimbursement on EAC and allows each state the leeway to derive EAC, but it must be described in the State Plan (42 CFR 447.518). Historically, states have begun with AWP as the starting point for EAC derivations. Any change in the methodology requires the state to file a State Plan Amendment (SPA) with CMS, which then must be approved by CMS for the change to qualify for federal financial participation.

Pricing methodologies are scrutinized by CMS to ensure they satisfy federal requirements that reimbursements are adequate to guarantee access and scope of coverage. Reimbursement methodologies that result in too many providers choosing not to participate limit access to coverage for beneficiaries. On the other hand, methodologies that result in excessive payments, as determined by CMS, are not acceptable either. Speaking at the Western Medicaid Pharmacy Administrators (WMPAA) conference on September 28, 2010 CMS officials stated that any SPAs changing the basis for pharmacy reimbursement methodology from EAC to AAC would be carefully reviewed, and more specifically any such SPA would have to include a new, validated cost-of-dispensing survey upon which dispensing fees are based. The reasoning given for this position is rooted in the fact that most payers' dispensing fees have historically been artificially low due to the hidden margins provided by the use of AWP as a pricing benchmark. CMS is committed to corrections in both pricing methodology and dispensing fees in light of the call to eliminate AWP. Changes proposed through SPAs must be carefully approached.

State efforts to replace AWP

State Medicaid Agencies have been reluctant to rush into pricing methodology changes for their Medicaid programs because of the national white paper effort. CMS accepted the NASMD white paper and agrees that it would not be in the best interest of the states or the federal program to have multiple pricing metrics in use. This is especially true since, as the white paper establishes, a reliable alternative is not obvious. The various state Medicaid agencies would be best served if a single basis were established for use by all. This is underscored by requirements in the Medicaid laws (SSA 1927(f)) and the ACA that provide for retail pricing surveys. CMS has stated these surveys are in process. The intent of CMS is to provide pricing information on a monthly basis (Joe Fine, CMS, 9/28/2010).

In spite of the white paper initiative, two states - Alabama and Oregon, have initiated SPAs to switch their pricing methodology from an AWP-based reimbursement (EAC) to an AAC-based method. The SPA from Alabama has been approved and goes into effect October 1, 2010. Alabama initiated an ambitious effort to involve all pharmacy groups and associations as well as other providers and manufacturers in the process. In the end, pharmacies volunteered to provide invoice pricing to the state agency survey vendor every 6 months. Alabama also conducted through the same vendor an extensive cost-of-dispensing survey that resulted in an increase in its dispensing fee from \$5.40 to \$10.64.

Oregon has undergone a similar process of stakeholder involvement and SPA submission. The difference in the Oregon plan, however, is a plan for a tiered dispensing fee based on pharmacy prescription volume. The tiers will range from \$10.14 to \$15.00, and pharmacies not participating in the surveys will automatically receive the lowest dispensing fee (current dispensing fee is \$3.50). The Oregon SPA has yet to be approved. Both states have been working since the beginning of this year to implement their respective programs.

From confidential information shared by states that have contracts with the vendor involved with both of the Alabama and the Oregon surveys as well as information from Alabama and Oregon, vendor services for survey and maintenance operations can cost from \$170,000 to \$360,000 per year depending on the package of services provided in the contract.

Summary

The call for the elimination of AWP as a pricing meter for Medicaid pharmacy programs is escalating, aided by the cessation of its publication by national pricing compendia in 2011. The lack of a suitable alternative, as well as CMS interest in state activities over replacement methodologies suggest, that a cautious approach be adopted in the pursuit of establishing an appropriate replacement to AWP. While a measure of urgency is acknowledged, the state is not without groundwork in identifying and implementing a change in Medicaid pricing methodology.

Recommendation

Adopt a price benchmark based on actual average acquisition cost data. This, as noted in the NASMD White Paper (emphasis added):

...most clearly fulfills legal and practical requirements... However, obtaining a valid source of acquisition cost information will require strict definitions, legal reporting obligations, and the identification of a data gathering and reporting process – Using true average cost data complies most literally with federal law and, with a reasonable dispensing fee, is both equitable and legally defensible. **Its development, however, may require: changes in state and federal law, the imposition of reporting obligations on wholesalers, pharmacies, or manufacturers;** Medicaid State Plan Amendments; and a revised process for price reporting, ideally one that was coordinated among groups of states if not all states.