Reimbursement Options for Pharmaceutical Drugs

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Utah Department of Health

Division of Medicaid and Health Financing

Bureau of Coverage and Reimbursement Policy

Executive Summary

"For nearly forty years, a standard pricing benchmark employed for the reimbursement of drugs, for both public and private payers, has been the "Average Wholesale Price" or "AWP," a value based on manufacturer-reported information and compiled by commercial drug pricing compendia. The recent determination of [a] major drug pricing compendia to cease publication of AWP no later than September, 2011 creates a challenge and an opportunity for state Medicaid programs: states [need to] find a new drug pricing standard. [N]ecessary adaptations, in law, regulation and system design, [need to] be accomplished."[1]

After study, and in response to this challenge outlined in the National Association of State Medicaid Directors (NASMD) and the American Medicaid Pharmacy Administrators Association (AMPAA) (collectively referred to hereafter as NASMD) White paper, Utah Medicaid issued a companion report in October 2010[2] detailing replacement reimbursement options facing the state and issued a recommendation for moving to an Actual Acquisition Cost (AAC) reimbursement basis.

This paper seeks to outline State Medicaid Agency activities undertaken in the interim. It lists challenges encountered, and responds to requests for information specific to reimbursement options for pharmaceutical drugs, reasons for annual pharmacy cost increases, and options to address annual increases in pharmacy costs. The following points summarize the detail in the contents:

- CMS is estimating National Average Retail Prices;
- Up to twenty distinct factors influence Pharmaceutical reimbursement;
- Of the twenty, Medicaid can influence nine (see pgs. 4 & 5);
- AWP built in margins are responsible for low dispensing fees;
- CMS requires a validated dispensing fee survey for programs switching to AAC;
- Medicaid does not reimburse at AWP but rather uses "lesser-than logic" comparing EAC (82.6% of AWP), FUL, SMAC, and U&C;
- Lesser-than logic saved Utah Medicaid approximately $126,000,000 over AWP, and approximately $74,000,000 over EAC in CY2011;
- In CY2011, 75 percent of all prescriptions were for generics, 25 percent for brands;
- In CY2011, 26 percent of prescription costs were for generics, 74 percent for brands; this favorable ratio is one of the highest in the nation;
- The average cost of a prescription in CY2011 was $66.91;
- The average cost of a single source brand product was $249.27;

[1] Executive Summary, American Medicaid Pharmacy Administrators Association and the National Association of Medicaid Directors White Paper: "Post AWP Pharmacy Pricing and Reimbursement", November 2009

[2] "Reimbursement Options for Pharmaceutical Drugs: Replacing Average Wholesale Price" (http://health.utah.gov/medicaid/stplan/LegReports/Medicaid%20AWP%20Replacement%20Option%20Report.pdf)

- The average cost of a generic prescription was $23.42;
- Eight factors influence the yearly total cost of pharmaceuticals. Medicaid can exert control over four of those (see pg. 8);
- Drug manufacturers averaged just under two price changes per year for products reimbursed in CY2011;
- The PDL saves costs through supplemental rebates, lower price alternatives, and market shift;
- Rebates (primary) for older brand products frequently approach 100 percent of Utah's cost. Reimbursing for those brands in the PDL provides more value than reimbursing for comparable generics;
- Utah began regular SMAC pricing updates in 2007 by surveying other states;
- In early CY2012, a vendor was contracted to conduct pricing surveys. Provider response to surveys is low. Other states experienced similar results;
- A SMAC program uses AAC-like methods;
- Clawback I and Clawback II (Quarterly Rebate Offset Amounts) are not related. Clawback payments continue and are determined by claim history;
- Several factors lower Medicaid reimbursements:
    - Reduce dispensing fees
    - Lower reimbursement rates
    - Restrict or limit services
    - Expansion of the Preferred Drug List
- CMS wants increased dispensing fees for AAC programs. Implementing AAC and increasing dispensing fees may appear cost neutral;
- Current MMIS system limitations hinder more modern program analysis, research and design opportunities. System replacement is anticipated to enhance these going forward;
- Legislative mandates prohibit limitations (e.g., PDL) on drugs comprising one-third of reimbursements;
- Scientific principles applied to the PDL and DUR process yield savings; and
- A full AAC program effectively represents a 100 percent SMAC program.

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 [business transaction types] 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 [question]: AWP must be replaced, [but with what and how]?"[3]

The NASMD white paper, which was released in early 2010, was an effort on the part of the various state Medicaid Agencies to push for a federal lead in the design and composition of an AWP replacement. Groundwork for Federal involvement in establishing a nationally recognized pricing benchmark was provided in the Omnibus Budget and Reconciliation Act of 1990 (OBRA '90) enabling legislation, but was never implemented. As a result, state agencies have relied upon their own resources in the struggle to provide adequate, fair reimbursement, and not without significant criticism. Since the Center for Medicare and Medicaid Services (CMS) must approve every states' reimbursement methodology, this underscores the need to have at least a federal standard upon which states might rely for a "rationality" test in their quest for a suitable AWP replacement. On July 26, 2012, CMS hosted its first webinar detailing its "Draft Methodology for Estimating National Average Retail Prices (NARP) for Medicaid Covered Outpatient Drugs". This final piece, when completed, will allow states an additional resource, and justifies the recommendation made in the October 2010 report: "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."[4] Indeed, simply replacing AWP is not a simple undertaking.

Ultimately, pharmaceutical reimbursement is a complex issue influenced by the following factors:

1. Base cost – the base pricing metric used as a starting point for all reimbursements. Subject to federal agency approval through the state plan;
2. Average wholesale price (AWP) – currently the base cost used by Utah;
3. Estimated acquisition Cost (EAC) – currently AWP minus 17.4 percent. Subject to federal agency approval through the state plan;

[3] Introduction, "Reimbursement Options for Pharmaceutical Drugs: Replacing Average Wholesale Price", October, 2010
[4] Summary, "Reimbursement Options for Pharmaceutical Drugs: Replacing Average Wholesale Price", October, 2010

4. Dispensing fees – the cost over and above product cost that a provider incurs when dispensing a drug to a patient. Subject to federal approval in the state plan;
5. Federal upper limits (FUL) – an aggregate upper limit of reimbursement for specified products set by the federal agency;
6. State Maximum allowable cost (SMAC) – Ceiling prices for products established by the state through surveys;
7. Federal (primary) rebates – rebates paid by manufacturers to Medicaid agencies in order to qualify their products for reimbursement in the Medicaid program;
8. Supplemental (preferred drug list) rebates – rebates negotiated by the states through a purchasing pool comprised of several states;
9. Preferred drug list (PDL) – Drug categories used for treating the same disease state where certain drugs within those categories are designated as "preferred" or "non-preferred" based first on safety and efficacy profiles, and finally, cost; impact is measured by market share;
10. Usual and customary cost (U&C) – the usual and customary price a provider charges for a product as a loss leader;
11. Lesser-than logic – a policy used by Utah Medicaid wherein the least of prices (e.g., EAC, SMAC, FUL, U&C) is paid as outlined in the State Plan;
12. Dead-net cost (DNC) – the final cost to the state for a product after all factors (e.g., rebates) are taken into consideration;
13. Brand versus generic usage mix – the ratio of brands to generic drugs reimbursed;
14. Drug Utilization Review (DUR) coupled with a Prior Authorization (PA) program;
15. New drug releases – the penetration of newly approved drugs entering the market; more expensive biologics dominate this factor, but new drug releases are more costly without exception;
16. Utilization creep – annual increases in the total number of prescriptions reimbursed;
17. State and Federal match (FMAP) – the percentage share of costs and rebates split between the state and the federal agency. Currently the split averages between 70 – 71 percent federal, 30 – 29 percent state;
18. Drug availability – market shortages affect dispensing options;
19. Client enrollment; and
20. Inflation.

Of the twenty factors listed above, the state Medicaid agency can influence nine of them: numbers 1, 3, 4, 6, 8, 9, 11, 13, and 14.

Dispensing Fees

The case against AWP stems from the fact that within the price itself are built-in margins. These margins have themselves been the object of manipulation. In the course of Calendar Year 2011, as First Data Bank (FDB) prepared to cease publication of its AWP, Utah Medicaid needed to identify a replacement for FDB-AWP to cover the time period between the cessation of AWP

publication and the start-up of a new point-of-sale pharmacy system that would not be utilizing FDB services. During that process, FDB gave Utah part of the logic used to derive AWP. AWP is the product of the Wholesale Acquisition Cost (WAC) and a fixed factor. Where no WAC figure was available, the manufacturer Direct Price (DP) was substituted. FDB and other companies still publish WAC, but the calculation logic is unknown. Other companies, including Utah's current contractor Medi-Span, continue to publish AWP. Manufacturers determine both WAC and DP (for more detail, the reader is referred to the NASMD white paper http://health.utah.gov/medicaid/stplan/LegReports/Rx%20Exec%20Sum%20and%20White%20Paper%20FINAL1.pdf).

Historically, Utah Medicaid discounts AWP when calculating pharmaceutical reimbursement rates. However, because of the margins available to providers even through the use of a discounted AWP (otherwise known as EAC, or estimated acquisition cost), dispensing fees are kept very low, both commercially as well as in federal programs. As a result, "speaking at the Western Medicaid Pharmacy Administrators (WMPAA) conference on September 28, 2010 CMS officials stated that any [state plan amendments] changing the basis for pharmacy reimbursement methodology from EAC to AAC would be carefully reviewed, and more specifically any such [state plan amendments] would have to include a new, validated cost-of-dispensing survey upon which dispensing fees are based."[2]

In other words, AAC eliminates all margins. This means that dispensing fees become the only means to appropriately reimburse providers for services rendered. Setting the correct dispensing fee is important to achieve access and secure provider participation. In anticipation of a potential move to an AAC based reimbursement option, Utah Medicaid commissioned a Dispensing Fee survey through Dan Jones and Associates in November 2011. Some providers offered significant resistance in completing the survey. Dan Jones is now tabulating the final results, and the survey sample lacks information from major chains.

Current Utah Medicaid Dispensing fees for the Utah Medicaid plan are, $3.90 for the four metro counties (Salt Lake, Utah, Weber, and Davis), and $4.40 for providers in all other counties. Over-the-counter (OTC) products, insulin, and birth control receive a $1.00 dispensing fee.

Infusion products requiring special handling have specific differential dispensing fees for limited use only for those products. Prescriptions using these special dispensing fees comprise a minor portion of prescriptions reimbursed. The dispensing fee survey commissioned does not address these fees since they are already tailored to meet the needs of this segment of Medicaid prescriptions.

Pharmaceutical cost increases

As previously stated, EAC is a discounted AWP benchmark. Utah Medicaid does not reimburse at AWP. Instead, Utah Medicaid uses a "lesser-than logic" combination methodology outlined in the State Plan that includes SMAC, FUL, EAC, and U&C. The following illustrates the impact of discounting AWP and including lesser of SMAC, FUL, and U&C to further reduce costs:

Total Prescriptions reimbursed Calendar Year 2011 (CY2011)[5]:	2,686,118
Total actual reimbursement CY2011:	$ 179,720,091
Potential reimbursement CY2011 applying AWP exclusively:	$ 305,958,222
Potential reimbursement CY2011 applying EAC exclusively:	$ 253,493,329

Using "lesser-than logic" saved the state $126,000,000 over AWP and nearly $74,000,000 over EAC alone.

For CY2011, the total number of distinct products reimbursed by Utah Medicaid, as measured by the number of National Drug Codes (NDC) used in paid claims, was 13,185. For these NDCs, there were 22,966 total price changes, an average of 1.74 price changes per NDC per year. Other vital statistics for this claim set are:

Average cost of a prescription:	$66.91
Percentage **brand** utilization- prescriptions:	25%
Average cost of single source brand prescription:	$249.27
Average cost of brand multi-source prescription:	$113.82
Percentage of total costs - **brand** prescriptions:	74%
Percentage **generic** utilization- prescriptions:	75%
Average cost of generic prescription:	$23.42
Percentage of total costs - **generic** prescriptions:	26%

Note that while brand name drugs comprise 25 percent of the total prescriptions, they account for 74 percent of total reimbursement costs. The individual cost of each product, the total number of prescriptions reimbursed for each product, the total number or quantity of units reimbursed per

[5] Implementation of a new pharmacy point-of-sale system in FY2012 makes the use of CY2011 more convenient for extraction of prescription data for these illustrations.

prescription, the ratio of brands to generics paid for, the total number of price increases per item per year, the total rise in price per unit per increase, the reimbursement amount per unit, and the number and cost of new products coming to market all influence the total cost of pharmaceuticals reimbursed each year. Of these eight factors, Medicaid can exert some control over only four:

- Reimbursement amount;
- The ratio of brands to generics;
- The total quantity of units per prescription;
- The total number of prescriptions reimbursed for each product.

Tools available to exert control in these areas include:

- Preferred drug lists;
- Prior authorizations;
- Quantity limitations;
- Maximum allowable cost ceilings.

Federal match is not influenced by any of the forgoing. Rebates are influenced.

As noted, pharmaceutical costs are influenced by an average of almost two price changes per year. As an example, a biologic drug used to treat certain cancers cost Utah Medicaid $149.97 per vial at the beginning of CY2011, and finished the year at $159.92 undergoing four price increases for a total of $9.95. This represents a 6.6 percent increase. Interestingly, this same product took another $8.00 increase (5 percent) in the first 90 days of CY2012. Dosing further magnifies the cost at two vials a day, five days a week for four weeks (for induction therapy) followed by one vial three days a week for 48 weeks. Total cost of therapy: $29,425 at end of CY2011 pricing. (Utah Medicaid reimburses below WAC for this product.)

Preferred Drug List

The Utah PDL saves resources three ways: Supplemental rebates, lower price alternatives, and market share proportions. Supplemental rebates are negotiated by the state with manufacturers desiring preferred preference in the use of their product over other products used for the same treatment. The Pharmacy and Therapeutics Committee (P&T) reviews comparative data on safety and efficacy of drugs in a class and makes recommendations as to which drugs to place on the PDL. These rebates lower the DNC of the preferred drugs, and consequently the overall cost of therapy for the disease state to Utah Medicaid. As market share for these lower costing products increase, overall program costs decrease.

Not all drug categories on the PDL garner supplemental rebates. Some categories consist of entirely (or a majority) generic drugs. In these cases, preferred drugs move market share to the lowest costing alternatives, thus reducing costs.

An important observation is noteworthy at this point. Due to ACA, the way that federal rebates are calculated, and the way brand name drug manufacturers regularly take price increases, primary rebates for many older brand name drugs approach and, in many cases, cover 100 percent of the cost of the product to Utah Medicaid. When this happens, it is vital that Utah Medicaid reimburse for a brand name product. This practice causes concern to pharmacy providers since these brand name products may cost them more to stock than the generic counterparts. Nevertheless, Medicaid reimbursement for the generic in these cases is more costly to Utah Medicaid. This is difficult for providers to accept because they do not see the savings that Medicaid is garnering. The National Community Pharmacists Association (NCPA) in a letter[6] to Governor Gary Herbert in December of 2011 strongly emphasized the advantages of generic usage, a position with which Utah Medicaid has no disagreement. In fact, Utah Medicaid enjoys one of the highest generic usage rates in the nation. However, when viewed in connection with the PDL, it makes sense to take advantage of available savings and conserve resources. Providers, as evidenced by the NCPA letter, don't understand and do not see that potential for the Medicaid program.

Utah SMAC pricing Surveys

In 2007, Utah Medicaid began pursuing more regular updates to SMAC pricing. Staff surveyed other state programs. In CY2011 Utah expanded efforts and began surveying providers. An RFP was also issued for a vendor to manage the surveys and quarterly pricing updates. A contract was awarded and the new vendor is aggressively pursuing SMAC pricing updates. The difficulty with SMAC surveys is provider participation. Surveys are labor intensive for providers, and cooperation with survey efforts is low. The effort and cost required to respond to a survey can only be compensated for in the dispensing fee. Consequently providers feel the return does not merit the effort. Incentivizing providers to participate in pricing surveys remains important to future efforts. In the Oregon and Alabama AAC programs, provider participation is voluntary. They are incentivized by a less frequent survey cycle that has produced mixed results.

As noted earlier, SMAC pricing enhances lower reimbursements where EAC and FUL are deemed more costly. This program lays important groundwork for an eventual AAC replacement of AWP because many SMAC's approach AAC in scope.

[6] "Potential Savings for State Employee Benefit Plans by Increased Utilization of Generic Medications", National Community Pharmacists Association letter dated December 7, 2011 (http://www.ncpanet.org/pdf/leg/jan12/ut_cost_savings_generics.pdf).

Clawback increases

Clawback I is the term given to federal recoupment of costs associated with Medicare's assumption of prescription benefits of dual eligible clients (those eligible for Medicare as well as Medicaid) into the Medicare Part D program. The transfer of dual eligible prescription benefits dramatically reduced Utah Medicaid pharmaceutical costs beginning in January 2006. Utilization creep, increasing recipient enrollment, and inflation have slowly increased program reimbursements back to pre-Part D levels as of FY2012.

Clawback II, otherwise known as Quarterly Rebate Offset Amounts (QROA), refers to the increase in federal rebates due to the Affordable Care Act (ACA) legislation. This legislation increased the minimum federal rebate by two to eight percent, depending on the product and earmarked it as federal share. Depending on the product (for example the line extension drugs) the extent to which the state program utilizes certain drugs, part of what was once state share is now federal share rebate. The state is responsible for collecting and remitting the federal share of all rebates.

Clawback I and Clawback II are not related.

Options to address annual increases in costs

Clearly, annual cost increases will continue. Attenuating the magnitude of those increases is, or should be, the focus. Medicaid reimbursements can ultimately be lowered in several ways:

- Reduce dispensing fees
- Lower reimbursement rates
- Restrict or limit services
- Expansion of the Preferred Drug List

Under an AAC environment, lowering reimbursement rates and reducing dispensing fees cannot be undertaken simultaneously. With a vigorous SMAC program, much of the mechanics to an AAC reimbursement methodology are underway, albeit not entirely with complete provider assent. Provider satisfaction is important to ensure benefit access for clients. In fact, in light of federal pressure for increased dispensing fees in conjunction with an AAC system, implementing those two measures as outlined by CMS takes on the appearance of a cost neutral activity. Other options for addressing cost increases share some of the same issues. For example, disease management and 340B reimbursements have both been investigated in the past with mixed results. 340B is an AAC-type system, and disease management after the likeness of the Utah Hemophilia program uses 340B as a cornerstone. At issue for disease management is the move

to managed care, which ultimately impacts the extent to which disease management can become useful under fee for service.

The PDL restricts which drugs are available without a prior authorization. The drugs are evaluated for safety and efficacy by the Pharmacy and Therapeutics (P&T) Committee and then drugs are selected based on the dead net cost of the drugs.

Prior authorizations, a mechanism for restricting certain drugs, can result in coverage of higher cost drugs (e.g., non-preferred PDL drugs, DUR PAs based on cost). Prior authorization programs also carry federal requirements which tend to expand rather than limit services, yet when carefully crafted they can demonstrate savings.

Eliminating pharmaceutical services is, perhaps, the most drastic means for reducing costs. As such, it is often not considered an option since the cost of other services (e.g., inpatient hospital) are likely to increase and more than offset any anticipated savings in the cost of drugs.

Utah Medicaid has not taken full advantage of other opportunities because of system limitations. The capability to do edits between the medical and pharmacy programs, limited in the past by the age of the respective systems, needs attention especially now that the pharmacy system has been upgraded and the Medicaid Management Information system is currently undergoing replacement. Better case management, disease management, medication therapy management, and enhanced program analysis, research and design become a distinct reality when both systems are fully replaced.

Legislative mandates prohibit limitations (e.g., PDL) on drugs comprising one-third of reimbursements. Careful and thoughtful application of scientific principles to the PDL process and the DUR program yield savings when appropriately utilized.

Summary

Continued expansion of the PDL and the SMAC program still represent significant means for controlling costs, yet in summary, an AAC system is the most obvious path to restricting cost increases for Utah Medicaid. Thoughtfully undertaken and with legislative mandates concerning the provider surveys, it would represent a 100 percent SMAC program. This allows other tools to be fully utilized.

Finally, allowing the Medicaid program to properly apply, in equal fashion, measures used with other drug categories characterize a significant opportunity for savings in the Medicaid program.