Assessing the future basis of drug pricing

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Over the past few years, the use of average wholesale price (AWP) as the basis for outpatient prescription-drug pricing has been called into question. Although there have been questions for years about the validity of AWP, current litigation against First DataBank, which remains unresolved, has clearly put the spotlight on AWP. First DataBank is one of three organizations, along with Medi-Span and Thomson Red Book, that publish AWP prices for prescription and over-the-counter drugs on a regular basis.

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Payers use many different drug-pricing bases, some applying only to generic drugs, some used only by Medicare or Medicaid, and others that are only available to organizations satisfying certain requirements, such as federally qualified health centers. This article compares two pricing bases identified as potential future replacements for AWP, namely average sales price (ASP) and average manufacturer price (AMP).

Any universal drug-pricing methodology should possess certain characteristics:

- acceptable to Medicare, Medicaid, and commercial payers
- available for all products (over-the-counter, generic, repackaged, compounds, brand-name, etc.)
- straightforward, with an understandable calculation not subject to bias
- easily and periodically updated

AVERAGE SALES PRICE (ASP)

The federal government, in an effort to establish a more equitable and uniform pricing platform for Medicare Part B drugs, elected to utilize pricing based on ASP. ASP can be defined as the weighted average of nonfederal drug sales to wholesalers, including any incentives to the wholesaler or ultimately to the retailer. Thus, the pricing reflects what the wholesaler paid for drugs, not what the wholesaler charges, including any retrospective discounts it may receive at a later time, generally based on volume.

The reimbursement limit established by the Centers for Medicare & Medicaid Services (CMS) for Medicare Part B drugs is ASP+6%. CMS publishes these ASP-based drug-reimbursement rates quarterly on its Web site (http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a_2008aspfiles.asp). The broader use of ASP for all outpatient drugs would require a great deal of work in order to be used in the commercial insurance market because Medicare Part B drugs are for the most part vaccines or injectables. The following table provides a comparison of a few of the Part B drugs using ASP with the corresponding AWP pricing from Thomson Red Book.

FIGURE 1

HCPCS CODE	CORRESPONDING NDC*	DRUG PRODUCT	OCT-08 ASP	OCT-08 AWP	RATIO ASP/AWP
J1438	58406-0425-41	ENBREL 25MG	$173.87	$207.74	0.837
J8520	00004-1100-20	XELODA 150MG	$4.92	$6.42	0.765
J9170	00075-8001-20	DOCETAXEL 20MG	$334.64	$428.03	0.782
J0135	00074-3799-02	HUMIRA 20MG	$345.05	$830.96	0.415

* The NDC (National Drug Code) listed may be just one of many drugs that are assigned to the HCPCS J-Code shown in column one.

The advantages of ASP as a basis for drug pricing are that it has been adopted by Medicare, it is updated quarterly, and it is based on actual manufacturer selling price, including incentives. The disadvantages of ASP are that it is currently published for only a small set of drugs dispensed through the medical benefit and it may undermine manufacturer incentive to compete on price for single-source drugs.

Because Medicare has privatized the outpatient prescription-drug benefit through Medicare Part D, there is no incentive for CMS to establish ASP prices for outpatient drug products unless legislation is enacted to impose price controls.

AVERAGE MANUFACTURER PRICE (AMP)

The federal government adopted average manufacturer price (AMP) for the Medicaid program. AMP is defined as the manufacturer list price of drugs sold to wholesalers for drugs distributed to retailers, *excluding* prompt pay discounts. Originally AMP included prompt pay discounts but the Deficit Reduction Act of 2005 changed this provision effective Oct. 1, 2007.

AMP is used in determining if a drug qualifies as a Medicaid-covered drug by satisfying the federal rebate requirement. AMP was also intended, through the so-called *AMP Rule*, to determine generic reimbursement under Medicaid. CMS also had intended to publish AMP prices in a manner similar to ASP, but covering a much broader list of drugs, including drugs dispensed from outpatient pharmacies. However, an injunction filed by the National Association of Chain Drug Stores in the U.S. district court for the District of Columbia on Dec. 19, 2007, put a stop to the publishing and use of AMP for pricing purposes.

AMP has been proprietary and confidential and, although CMS still uses the AMP price internally in determining the rebate qualification, the injunction prevented it from allowing the public or states from seeing these prices.

The advantages of AMP as a basis for drug pricing are that it represents the bottom (manufacturer list price) of the drug-pricing totem pole, it would be applicable to almost all drugs except possibly compounds, and it would be published monthly based on CMS intentions. The disadvantage is that the price is so transparent to consumers that it may be stuck in litigation for a long time.

ASP VS. AMP

It is difficult to discern the difference between ASP and AMP, since they both seem to reflect the manufacturer selling price in some way. The difference lies in who is acquiring the drugs and whether or not future price concessions (similar to the rebate concept) are included.

Based on 2005 CMS Health and Human Resources research (HHS Report OEI 05-0500-240 OIG), AMP is, on average, about 25% lower than AWP for patent-protected brand-name medications, and about 65% lower than AWP for generics. These discounts may be slightly aggressive given the change in the definition of AMP in October 2007, as indicated above.

Additional research by CMS for a similar study period (HHS Report OEI 03-05-00200 and OEI 03-05-00430) showed that ASP prices were similar to AMP prices. As the studies were not based on the same drug products, the only conclusion that can be drawn is that the price difference is within a couple percentage points on average.

CONCLUSION

In conclusion, the basis for drug pricing remains in an AWP limbo. Because current commercial and Medicare Part D outpatient prescription-drug benefits rely heavily on AWP, it will remain the basis for drug pricing until a better solution is found. The current AWP litigation stalemate may eventually dictate a new basis for drug pricing. If either ASP or AMP is to be the successor to AWP, litigation and expansion of product-pricing issues with these methodologies will also need to be resolved.

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