HDMA
Healthcare Distribution
Management Association

August 16, 2005

Medicaid Commission Members
Health and Human Services Medicaid Commission
C/O Nancy Barnes, Executive Secretary
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via electronic transmission

Dear Commission Members:

I am writing on behalf of the Healthcare Distribution Management Association (HDMA), to provide our perspectives on potential reforms of the Medicaid program and implications for pharmaceutical distribution and pharmacy practices. HDMA is the trade association representing the nation's pharmaceutical and healthcare product distributors. These primary healthcare distributors, representing more than 90 percent of the distribution system, are responsible for ensuring that the nation's supply of medications are safely delivered each year to tens of thousands of retail pharmacies, hospitals, nursing homes, and clinics in all 50 states.

As government-licensed entities, pharmaceutical distributors ensure product safety and provide the vital link between manufacturers and pharmacy by warehousing finished products, processing orders, providing next-day delivery, keeping records, managing inventory, processing recalls, handling returns, and extending credit. While providing these extensive services, the average net profit margin of a drug distributor is a slim 0.75 percent[1].

HDMA has three points that we would like to share with the Commission, particularly with regard to savings that may be sought through modifying the reimbursement metrics of pharmaceutical products dispensed to Medicaid recipients. They include: (1) The distribution industry provides cost savings to the healthcare system, (2) HDMA's recommended principles for pharmaceutical reimbursement, and (3) HDMA's views on potential reimbursement metrics.

[1] Healthcare Distribution Management Association (HDMA), 2005-2006 HDMA Factbook (publication anticipated October 2005).

901 North Glebe Road • Suite 1000 • Arlington, VA 22203
(703) 787-0000 • (703) 935-3200 (Fax) • www.HealthcareDistribution.org

1. The distribution industry provides cost savings to the healthcare system

A critically important point for the Commission to realize is that the services and efficiencies provided by member distributors result in an estimated **$10.5 billion** per year[2] savings to our national healthcare system.

This accomplishment -- which drives down costs for the entire healthcare system -- is the result of the service distributors provide and the extreme efficiencies they have achieved. Distributors help their pharmacy customers operate more efficiently by simplifying the ordering, receiving and stocking of pharmaceuticals. Imagine the additional labor, storage space, and capital investment needed if a pharmacy had to order thousands of drug products from hundreds of manufacturers, with varying lead times for delivery. This is why we point out that the one-stop shopping with next day delivery offered by our distribution members also improves patient care, so that products are where they need to be, when they need to be there.

Distributors also provide significant benefit to manufacturers allowing them to invest their capital in drug research and development rather than each building out distribution capabilities that could never achieve the efficiencies that distributors have managed through large scale storage, handling and billing arrangements. Through these arrangements with distributors, a manufacturer can provide its products on a next day basis to over 140,000 pharmacy settings[3] nationally, even those products that require special handling.

HDMA also wishes to make the Commission aware of the fact that distributors' returns are lower than those of manufacturers, PBMs, health plans, for-profit hospitals, and drug store chains.[4] Thus, in relative terms, there are fewer opportunities for further cost savings from the distribution system without risking the substantial cost savings achieved for the entire health care system today.

Given the substantial cost savings, the slim margins, and the potentially substantial role the distribution industry may be expected to play as the Commission seeks still more savings, HDMA urges the Commission to avoid changes that would disrupt the efficient system of distribution that has been developed in this country. HDMA believes it is critically important to bring these points to the Commission's attention because of the unique relationship between Medicaid reimbursement, the potential metrics that would be used to determine that

---

[2] Healthcare Distribution Management Association (HDMA), The Role of Distributors in the U.S. Healthcare Industry; (A study prepared by Booz Allen Hamilton) 2004.

[3] As defined in IMS Health's class of trade categories of manufacturers' sales and includes: Chain and mass merchandiser with pharmacies, Independent pharmacies, Food stores with pharmacies, Mail service, Hospitals, Clinics, Nursing homes/home health, Healthcare plans (HMO), and Miscellaneous (includes federal/state and a few others).

[4] Healthcare Distribution Management Association (HDMA), The Role of Distributors in the U.S. Healthcare Industry; (A study prepared by Booz Allen Hamilton) 2004.

reimbursement, particularly for our pharmacy customers, and the impact these determinations/metrics will have on the bona fide services that wholesale distributors provide.

Currently, wholesale distributors are not directly reimbursed by either Medicare or Medicaid, and we are not asking for them to do so. However, it is possible that some of the reimbursement metrics under consideration may unintentionally erect barriers or obstacles that will impede distributors from receiving fair compensation for services provided to manufacturers and pharmacies. For example, there is a significant risk that inclusion of prompt pay discounts and distributor service fees in some of these metrics will not only inappropriately deflate pharmacy reimbursement, but may also result in providing some manufacturers with incentives to delete these payments in order to raise reimbursement rates.

HDMA urges the Commission to recognize that Medicaid retail pharmacy reimbursement should not inadvertently erect barriers or obstacles which prevent distributors from receiving payment from manufacturers for bona fide services provided at fair market value. Preventing these obstacles from occurring should be an important aspect of the Commission's work so that distributors may continue to support our mutual goal of aiding in the overall containment of health care costs.

In section two below, we describe the basic principles that we believe any reimbursement system should adopt to achieve appropriate pharmacy reimbursement and thereby allow the distribution industry to continue to provide very critical services designed to support an efficient health care system. In section three, we further describe our views on several reimbursement metrics under consideration including specific concerns, or benefits, of each.

2. HDMA's recommended principles for pharmaceutical reimbursement

HDMA supports efforts to reform the Medicaid program so that reimbursement to retail pharmacy for prescription drugs more closely reflects product purchasing and dispensing costs and recognizes the value of medication therapy management counseling. HDMA believes that the Commission and the Centers for Medicare and Medicaid Services should follow these principles as they consider measures to identify the planned cost savings:

- Reimbursement should fairly compensate pharmacy for the final product purchase price, dispensing costs and therapy management counseling;

- Reimbursement should be market-based, that is, reflective of the continuously changing prices, availability, and operational costs, and updated frequently enough to reflect the current prices paid by pharmacy.

- The reforms should include incentives to dispense lower-cost medications if appropriate;

- Reimbursement should recognize that "class of trade" distinctions developed by manufacturers (e.g.. hospital, long-term care, mail service) generally preclude retailers from access to the rebates, discounts, and incentives offered to those groups;

- Reimbursement should appropriately recognize the costs associated with the distribution of the product as a valuable and legitimate component of the final product cost.

3. HDMA's views on potential reimbursement metrics

As the Commission seeks savings for the Medicaid program, various metrics for determining fair pharmaceutical reimbursement are being discussed and may be considered.

It has been proposed by the Administration that Medicaid reimbursement for pharmacy be based on the "average sales price" metric (ASP + 6%) recently adopted for Medicare Part B drugs. We believe applying the ASP methodology to Medicaid is an inappropriate reimbursement metric because:

- ASP prices are retrospectively calculated (based on the preceding two calendar quarters) and therefore not reflective of the current prices retail pharmacy must pay.

- ASP is based on "weighted average sales price" for all purchasers, including hospitals and physicians, taking into account their discounts and rebates. Retail pharmacy does not typically have access to the price concessions offered to hospitals, mail service, and other non-retail class of trade purchasers. Therefore, ASP-based reimbursement would not be representative of the price paid by retail pharmacy and would, in fact, be consistently and significantly lower than retail acquisition cost.

- ASP methodology would create an incentive to dispense single-source brand products over their lower priced generic counterparts; in short, 6 percent of a $100 brand product is $6.00 while 6 percent of a $20.00 generic equivalent is $1.20.

- ASP rates have not been established for most retail products, and therefore a new reporting mechanism would have to be created for most pharmaceutical products.

- The ASP calculation requires that prompt pay discounts be included in the formula, thus artificially lowering the reimbursement rate to the pharmacy.

It has also been suggested by some that the Average Manufacturer Price (AMP) might be an appropriate benchmark to use for reimbursing drugs covered under Medicaid. However, AMP as currently defined and calculated also presents a number of problems as defined below:

- AMP, particularly for generic products, may vary widely from quarter to quarter and may have negative or zero values based on the totality of discounts, rebates, and returned goods, thus rendering it inappropriate as a reimbursement metric.

- AMP, by statute, is a confidential number provided to CMS by the product's manufacturer and is used to determine manufacturers' rebates to Medicaid programs. It was never intended to be a reimbursement metric.

- AMP, like ASP, is computed from prior periods and therefore frequently lags, sometimes substantially, behind the price pharmacies must pay when they purchase the product;

- AMP lacks a final rule and little guidance has been published which has resulted in considerable variation in the formulas manufacturers apply to calculate their respective AMPs;

- AMP, similar to ASP, may unintentionally result in rewarding pharmacy for dispensing higher cost drugs and "disincentivize" appropriate substitution of lower cost or generic alternatives;

- The AMP calculation includes all rebates and discounts paid to long-term care and mail order pharmacies and, because CMS has never issued clear instructions, some manufacturers also include discounts given to PBMs and insurers. Discounts extended to such entities are generally not made available to retail pharmacy.

- AMP is tied to the 9-digit NDC, meaning all package sizes of a specific drug are "averaged" in the calculation. This becomes problematic when large package sizes not intended for retail pharmacy (e.g. bottles of 5,000) overweight the cost of the packages typically stocked by a retail pharmacy. Another negative consequence of this action is unit-of-use products such as tubes of ointments, or eye drops where the smaller sizes cost more on a per unit basis but may be the most cost-effective product to dispense to the patient.

- AMP, when applied to generics and tied to a specific NDC number, does not further the competitive forces at work in the marketplace for generic drugs today;

- The current AMP calculation, similar to ASP, includes prompt pay discounts that may be received by the wholesaler from the manufacturer. Including prompt pay discounts in a reworked AMP calculation would therefore artificially lower the actual reimbursement to the pharmacy. Moreover, since there is no specific CMS guidance on how distributor

service fees are to be treated by manufacturers in their AMP calculations now, it is probable that many manufacturers include such fees in their calculation to reduce their ultimate Medicaid rebate obligations. This would further reduce pharmacy reimbursement if AMP as it is now reported were to be used as a reimbursement metric. **Exempting payment for prompt pay discounts and bona fide service fees, therefore, is critical and must be clearly stated if a reworked AMP is to be used as a pharmacy reimbursement metric under Medicaid.**

HDMA strongly supports the National Association of Chain Drug Stores' (NACDS) Medicaid pharmacy payment model proposal. Under this approach, single-source brand drugs and single-source generic reimbursement would be based on a percentage markup of the wholesale acquisition cost (WAC) and multi-source generic reimbursement would be based on a new Federal Generic Reimbursement Level (FGRL) metric as follows:

- WAC is the current, published price that manufacturers sell and invoice to wholesalers and is a reliable price for all brand drugs;
- WAC is well established, verifiable, and readily available across the supply chain;
- WAC closely approximates actual retail pharmacy acquisition cost for brand pharmaceuticals; today, nine states (AL, FL, MD, MA, MO, OH, PA, RI, TX) use "WAC plus a percentage" as a metric for retail Medicaid pharmaceutical reimbursement;
- Wholesalers generally purchase brand Rx drugs from manufacturers at WAC and subsequently contract with pharmacies using WAC as the basis for pricing brand Rx products;
- WAC pricing is updated daily as manufacturers announce price changes; as a reimbursement base it would mitigate reimbursement shortfalls and windfalls.
- Since the largest portion of Medicaid spending, approximately 85 percent, is on Brand Rx products, WAC more closely reflects the actual acquisition cost of the majority of products used to meet the Medicaid population's health care needs;
- FGRL, a broader and better managed FUL, would be based on a percent of the weighted average of the current market prices for three or more generic drugs that are pharmaceutically and therapeutically equivalent and available nationally;
- FGRL pricing would be updated weekly, the FGRL list quarterly, resulting in more current and accurate reimbursement data;
- FGRL would incentivize the use of lower-cost generic alternatives when appropriate;

- A minimum dispensing fee should be established and paid to pharmacy to encourage generic dispensing regardless of ingredient cost.

Conclusion

HDMA appreciates the opportunity to provide our perspective on this important issue and looks forward to working with the Commission. As you consider various alternatives to achieving savings for Medicaid, we stress that the ultimate guiding principle should be ensuring that the Medicaid recipient will continue to have access to appropriate medication. If you have any questions or would like further information, please contact Anita Ducca, HDMA's Director, Regulatory Affairs at aducca@hdmanet.org or Robert Falb, HDMA's Director of Federal Government Affairs, at rfalb@hdmanet.org or 703-787-0000.

Sincerely,

Scott M. Melville
Senior Vice President, Government Affairs