FOOD MARKETING INSTITUTE

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TESTIMONY

ED HAGAN, DIRECTOR OF PHARMACY
ASSOCIATED FOOD STORES, INC.
BEFORE
HOUSE COMMITTEE ON SMALL BUSINESS
JULY 18, 2007

"MEDICAID DRUG REIMBURSEMENTS: ARE CMS CUTS BAD MEDICINE FOR SMALL BUSINESSES AND BENEFICIARIES?"

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Good Morning, Chairwoman Velázquez, Congressman Chabot, and members of the committee. I am Ed Hagan, Director of Pharmacy for Associated Food Stores, testifying on behalf of the Food Marketing Institute (FMI).

I very much appreciate the opportunity to testify before the committee about an issue of significant importance to all of its supermarket pharmacies—particularly those that are small businesses—and the Medicaid beneficiaries that we serve. FMI is extremely concerned about the implementation of Deficit Reduction Act (DRA) provisions that would base reimbursement for prescription drugs on the artificial concept of Average Manufacturer Price (AMP). We believe that this use of AMP, particularly in the way it has been implemented by the Centers for Medicare and Medicaid Services (CMS), will cause severe hardships for many pharmacies and the Medicaid recipients alike.

Associated Food Stores is a member owned cooperative that is based in Salt Lake City, Utah. In addition to the independent stores we serve, we own 21 stores and with three other wholesalers co-own the Western Family private label. 75 of our stores across 8 states and Guam have pharmacy operations. These pharmacies range in size, with some locations filling as few as 70 prescriptions per day to larger operations that fill between 400 and 500 prescriptions daily. While some of our stores are located in large metropolitan areas, Associated Foods also includes stores in small towns such as Twin Bridges, Montana, Kamas, Utah and Raymond, Washington. Many of our stores in these small towns represent the only pharmacies available. Medicaid represents about 10% of our business overall but this figure jumps to more than 15% in many rural areas.

Associated Food Stores is a member of FMI, an association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies - food retailers and wholesalers – in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion – three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets such as the ones served by Associated Foods. Its international membership includes 200 companies from 50 countries.

FMI's retail members also operate over 19,000 in-store pharmacy departments. FMI estimates that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs dispensed in the United States. Based on current industry trends toward larger store formats and the convenience of one-stop shopping, the association anticipates that the number of pharmacies located in supermarkets will continue to increase in the coming years as will the number of prescriptions that are dispensed on an outpatient basis from these community settings.

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Implications of the AMP Policy for Retail Pharmacy

Pharmacy profit margins, particularly in the case of small supermarket pharmacies, are generally only a very small percentage of total revenues, and a far lower percentage than most other pharmacy retail businesses. The gross margin for Associated Food Stores pharmacy operations is in the range of 20 percent—with net profits at about two percent. Consequently, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. The recent work by the Government Accountability Office (GAO) comparing AMP-based Federal Upper Limits (FULs) to pharmacy acquisition costs suggests that many pharmacies will lose money when AMP-based FULs are implemented. Because overall pharmacy margins are so small, many pharmacies will not be able to sustain losses under Medicaid, and will face the choice of leaving the program or going out of business.

Most of the Associated Food Stores with pharmacies are single store operations. These stores generally encounter the same per-store expenses as the stores of larger chains—the same salaries for pharmacists, the same liability and other insurance and the same operating costs—but without the ability to minimize the losses imposed by AMP policies through economies of scale and the better purchasing power of larger chains.

Depending on how states and various private payers react to the implementation of AMP as a benchmark, my rough estimate is that the policy being implemented has the potential to decrease pharmacy margins by five to seven percentage points—which would cause many of the small stores represented by Associated Foods to lose money. Even if the damage is limited solely to Medicaid, this would be a devastating cut for retail pharmacy and could result in the failure of some of our small business members.

Thus, to the extent that FULs are below pharmacy acquisition costs for generic drugs, Associated Food Stores pharmacies and other FMI members may find it increasingly difficult to serve Medicaid patients. This issue will only be compounded as states such as California seek to move to an AMP-based payment rate for prescription drugs that are not subject to the FUL and as other payers turn to AMP for their own purposes. As state dispensing fee reimbursements are even farther below the costs our members incur to dispense prescription drugs to Medicaid Patients, small supermarket pharmacies are at even greater risk if the ingredient reimbursement rate is lowered.

By dictating that CMS use AMP for both the Medicaid rebate program and the FUL for multiple source drugs, the DRA left the agency with an almost impossible balancing act. While we believe that CMS failed to exercise adequately its significant discretion to mitigate the severity of the problem, FMI believes that the competing roles of AMP as currently defined can never be successfully reconciled. We therefore urge the Congress to repeal the DRA's AMP-based in reimbursement policy and create another benchmark for pharmacy reimbursement—a benchmark

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that more closely reflects pharmacy acquisition cost. At a minimum, we believe that the Congress should enact refinements to Medicaid pharmacy reimbursement that mitigate the significant cuts that pharmacies are now facing as a result of the implementation of the DRA AMP policies.

The Policy Problem

AMP was originally created as a benchmark for the Medicaid rebate program, designed to provide savings to the states and the Federal government on prescription drug purchases for Medicaid beneficiaries. Under the balance created in the original legislation, manufacturers pay a base percentage of AMP as a rebate or pay rebates based on the difference between AMP and a manufacturer's so-called "best price." Additional rebates are imposed on products that are subject to price increases over time greater than the Consumer Price Index. In exchange, participating manufacturers are able to have their products covered by state Medicaid programs without having to negotiate discounts for formulary access.[1] Manufacturer reports are made under a set of esoteric rules that have become only marginally clearer as a result of the CMS rulemaking. What is clear, however, is that as a result of the Medicaid rebate program, manufacturers have a strong incentive to keep AMP as low as possible.

CMS acknowledged the inherent conflict in using AMP for the purposes of rebates and pharmacy reimbursement in its proposed rule implementing the prescription drug provisions of the DRA. In its final rule, the agency indicates that it believes the revised definition of AMP "accurately reflects the dual purposes of AMP." However, the fact remains that AMP, as it is defined by CMS, bears no relationship to pharmacy acquisition cost for Medicaid covered drugs.

As I have discussed above, the use of AMP as a reimbursement measure represents a significant threat to pharmacies and the Medicaid beneficiaries they serve. FMI believes that the Congress must act to address this threat.

Possible Solution: Separating Rebates from Acquisition Cost

One solution to the conflicting roles of AMP would be to eliminate the conflict by creating two separate benchmarks. The first would be akin to the pre-DRA quarterly AMP used for rebate purposes. A second benchmark, Average Manufacturer Price Available to Retailers (AMPAR) could also be manufacturer reported but would be focused more closely on the purchase prices of retail pharmacies. The use of this second benchmark would remove the need for some of the contortions CMS undertook in the proposed rule to attempt to balance the needs of pharmacies and

[1] While many states have used "preferred drug lists" to secure even deeper discounts from manufacturers, this does not change the dynamic of the current policy problem.

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drug manufacturers. It would allow for a clear and accurate reimbursement metric without interfering with the Medicaid rebate program.

This solution would be somewhat similar to others being considered based on pharmacy surveys, but would have the benefit of being based on product by product manufacturer reports. FMI is sensitive to the fact that this will add somewhat to manufacturer reporting requirements, but we believe that this benchmark would be more reliable than surveys and easier for CMS to administer—while protecting Medicaid beneficiary access to a wide range of pharmacies.

While we believe that a division of the two sets of responsibilities currently assigned to AMP is most appropriate, if Congress decides not to undertake a change of this magnitude, Congress should at least take the following steps to mitigate the negative impact of the AMP policy on retail pharmacies.

Possible Solution: Mitigating Measures

1. Define Retail Class of Trade Accurately

AMP is defined in statute based on the prices paid by "wholesalers for drugs distributed to the retail pharmacy class of trade." Defining "retail pharmacy class of trade" accurately is important because those outside of this class can command prices that are well below the prices that pharmacies – particularly small pharmacies – and others within the retail class of trade can obtain. For example, PBMs and mail order houses can harness large bulk buying power to obtain prices for drugs that are far lower than the prices Associated Food Stores can obtain for our small independent supermarket pharmacies. Including these prices in determining the average manufacturer price seriously undermines AMP and results in a reimbursement level far lower than the amount our members pay. Indeed, GAO determined that AMP was 36 percent lower than the prices paid by retail pharmacies, which will be lower again for small independent supermarket pharmacies.

While FMI is pleased that CMS removed some PBM and other third party discounts from the definition of AMP, we continue to believe that mail-order pharmacies, physician offices, outpatient clinics and a variety of other entities that CMS has included in AMP are outside the retail class of trade. Excluding discounts to these entities from AMP could help to mitigate the severe cuts that pharmacies are currently facing as a result of the CMS final rule.

2. Use Average AMP of Therapeutic Alternatives to Set FULs

The DRA modified the FUL calculation for drugs by referencing CMS regulations on the subject. The statute required CMS to substitute 250 percent of AMP in place of the previous

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benchmark for FULs, which was 150 percent of the published price. Under prior CMS regulations, FULs were set on the basis of the lowest cost therapeutic alternative. While FMI believes that CMS retained the discretion to use the weighted average AMP of therapeutic alternatives, the agency apparently does not share this view and instead set AMP on the basis of the lowest cost therapeutic alternative. This will give undue weight to outlier prices among a series of alternatives and may set FULs on the basis of products that are not available to pharmacies nationwide. Therefore, one interim step would be to require the agency to use the weighted average of therapeutic alternatives when setting FULs based on AMP.

3. Use Quarterly FUL Updates

CMS rejected comments which urged it to update FULs quarterly, to avoid the volatility that will potentially result from monthly updates. FMI believes that CMS should generally update FULs quarterly, but with discretion to allow the agency to address errors or potential product access problems more quickly.

4. Delay Publication of AMP Data

FMI also believes that Congress should place a moratorium on the publication of AMP information until the consequences of publishing the information are fully understood. FMI believes that the publication of AMP data has the potential to distort the marketplace for generic drugs, with potentially serious anti-competitive effects. Publishing AMP data could create a floor on the price discounts that generic manufacturers are willing to offer, reducing the level of competition between generic manufacturers with potentially significant negative effects on the Medicaid program.

If AMP data are published, manufacturers may find it difficult to offer discounts to some customers and not to others, as most customers will be unwilling to pay more than the average price. In this scenario, manufacturers will be more likely to sell to all buyers at the same rates, eliminating the benefits of competition that could otherwise accrue to the marketplace. In the case of Medicaid, the government will bear most of the consequences of this reduced competition—the prices paid to manufacturers on average will increase, driving AMP-based reimbursement up also.

5. Improved State Oversight

States now have the discretion to use AMP as a benchmark for estimated acquisition cost for all Medicaid drugs—not just the multiple source drugs that will be the subject of CMS FUL findings. FMI believes that states using AMP in this way must be specifically required to put in place mark-up percentages and dispensing fees that will ensure that pharmacies are adequately reimbursed for the cost of dispensing drugs under the Medicaid program. This reimbursement

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should also provide incentives for the use of generic drugs, which provide significant savings to state and federal governments, but are the main focal point for potential pharmacy losses under the framework CMS is now implementing.

Even states that do not seek to use AMP as an ingredient cost benchmark must ensure that their dispensing fees adequately cover the costs of pharmacy services. Current state dispensing fees average about $4.50 per prescription, far below estimated pharmacy costs of $10-$15 per prescription.

Conclusion

In conclusion, I appreciate the opportunity to testify on this important health care issue. And on behalf of FMI members who operate in-store pharmacies in their supermarkets, we are hopeful that the House Small Business Committee and the Congress will act to address the potentially devastating cuts that retail pharmacy is now facing as a result of the DRA's changes to Medicaid prescription drug reimbursement policies.

I am happy to answer any questions the committee may have.

Attached document: FMI formal comments to Proposed Rule to Implement Provisions of DRA Pertaining to Prescription Drugs under the Medicaid Program.

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