THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

April 2, 2012

Ms. Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-2345-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicaid Program; Covered Outpatient Drugs; Proposed Rule to Revise Requirements Pertaining to Medicaid Reimbursement for Covered Outpatient Drugs to Implement the Affordable Care Act; 77 Fed. Reg. 5318 (February 2, 2012)

File Code: CMS-2345-P

RIN 0938-AQ1

Dear Administrator Tavenner:

On February 2, 2012, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule in the Federal Register which would revise requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of the Patient Protection and Affordable Care Act of 2010 as amended by the Health Care and Education Reconciliation Act of 2010 (the "Proposed Rule"). The Proposed Rule would also revise other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program.

The Food Marketing Institute (FMI) conducts programs in public affairs, food safety, research, education and industry relations on behalf of its nearly 1,250 food retail and wholesale member companies in the United States and around the world. FMI's U.S. members operate more than 25,000 retail food stores and almost 22,000 pharmacies with a combined annual sales volume of nearly $650 billion. FMI's retail membership is composed of large multi-store chains, regional firms and independent operators. Its international membership includes 126 companies from more than 65 countries. FMI's nearly 330 associate members include the supplier partners of its retail and wholesale members.

FMI submits the following comments on the Proposed Rule:

Section 447.502 Definitions

Actual Acquisition Cost: FMI is concerned that the move to require states to use actual acquisition cost (AAC) for brand name drugs without a requirement that dispensing fees be increased will negatively impact patient access to community pharmacy services. We believe that the definition should be amended to require that the word 'currently" be included in the definition between "prices" and "paid. States have an obligation to pay pharmacies based on current prices paid, not outdated prices.

Multiple Source Drug: A drug can be considered a multiple source drug if it is sold or marketed in any state in the United States during the rebate period. For the purposes of determining Federal upper limit (FULs), it should be the most immediate monthly rebate period. However, a drug should only be considered a multiple source drug for the purposes of determining whether there are three sources of supply when such drugs are nationally available. A simple listing of the drug in the FDA Orange Book does not mean it is nationally available to all pharmacies. A drug should be considered nationally available when it is generally and widely available for purchase by all pharmacies in the United States, such as when it is available in purchase for sufficient quantities by supermarket pharmacies from the national wholesalers.

Professional Dispensing Fee

The Proposed Rule makes no changes to the definition of dispensing fee (447.502) but proposes to rename the term "professional dispensing fee." We support this change.

We applaud the agency's statement in the preamble to the Proposed Rule that "One component of the reimbursement formula should not be revised without appropriately evaluating the other part." While state and federal policymakers have focused efforts on reimbursing pharmacies at the cost of drug product, there has been comparatively little discussion on the importance of reimbursing pharmacies accurately for the cost to dispense. As discussed above, numerous studies have shown that state Medicaid dispensing fees have been below the cost of dispensing. That is one of the reasons we remain deeply concerned with current attempts by states to further decrease pharmacy dispensing fees.

Rather than asking states to "reconsider" dispensing fees, we urge CMS to require states to reevaluate dispensing fees to assure that they adequately cover costs and to include specific factors on assessing dispensing fees in this rulemaking. Elements that make up the cost to dispense prescription medications include, but are not limited to:

- Prescription Department Payroll /Personnel Expenses
- Prescription Department (Direct Costs):

  - Prescription supplies
  - Professional liability insurance for pharmacists
  - Prescription department licenses, permits and fees
  - Dues, subscriptions and continuing education for the prescription department
  - Delivery expenses (only prescription-related)
  - Postage and mailing
  - Inventory services
  - Lost inventory
  - Warehouse expense
  - Bad debts for prescriptions (including uncollected co-pays)
  - Computer systems (related only to the prescription department) including software and maintenance
  - Prescription claim transmission expenses, Switching Fees, FSA Tracking, E-prescribing charges (transaction fees, enrollment, etc.)
  - Compounding equipment expenses
  - Third party-prescription audit adjustments (write-offs)
  - Other prescription-department-specific costs

- Pharmacy-Wide Expense Items (indirect cost shared with other departments):
  - Building depreciation
  - Taxes (personal property, real estate, payroll, sales etc.)
  - Rent (building, computer equipment and other equipment rent)
  - Building and equipment maintenance and repairs
  - Custodial services
  - Insurance (general liability not including professional liability, property/casualty, workers compensation and employee medical insurance, life insurance)
  - Other employee benefits (pension fund, profit sharing and similar benefits paid by the pharmacy)
  - Legal and professional service fees (attorneys, accountants, etc.)
  - Bad Debts other than third-party prescription audit expenses
  - Security services
  - Charitable contributions
  - Telephone/internet
  - Utilities
  - Other operating and office supplies
  - Advertising (promotional and non-promotional)
  - Credit card transaction fees
  - Central administration expenses

Section 447.504(a) Definition of Retail Community Pharmacy: The statute clearly defines retail community pharmacy as an independent pharmacy, a chain pharmacy, a

supermarket pharmacy and a mass merchandiser that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Mail order, long-term care facility pharmacies, hospital pharmacies, clinics, government pharmacies and pharmacy benefit managers are not and should not be included in the definition.

Section 447.504 Determination of Average Manufacturer Price (AMP): In general, we support the definition of AMP as outlined in the proposed regulation. However, we strongly object to CMS permitting manufacturers to include within the AMP determination, sales to entities other than retail community pharmacies. There is no statutory basis for CMS to permit the inclusion of manufacturer sales to specialty pharmacies, home infusion pharmacies and home health providers, or other entities that act or conduct business as wholesalers or community pharmacies. This is a back end way to allow potential mail order sales in the calculation of AMP which is prohibited by statute. This will lower AMPs and underpay pharmacies.

Section 447.507 Inhalation, Infusion, Instilled, Implanted and Injectable Drugs: With regard to inhalation, infusion, instilled, implanted and injectable drugs, we agree that a drug is not generally sold through a retail pharmacy if 90% or more are sold to non-retail pharmacy outlets. We also believe that CMS must provide for a higher multiplier than 175% of the weighted average AMP to set the FUL for these drugs. That is because inclusion on non-retail pharmacy sales will lower AMPs, and a multiplier of only 175% will not cover retail community pharmacies acquisition costs for these drugs.

Section 447.510 Requirements of Manufacturers: We support the use of a 12-month rolling percentage to estimate the value of lagged price concessions. This will smooth out fluctuations in AMP from month to month that can negatively impact pharmacy reimbursement.

Section 447.512 Drugs: Aggregate Upper Limits of Payments: We believe that CMS should allow States to use estimated acquisition cost (EAC), as well as AAC as a benchmark for brand name drugs. Moreover, CMS must require that states can only use AAC if they increase their dispensing fees to more accurately reflect pharmacies' cost to dispense.

Section 447.514 Upper Limits for Multiple Source Drugs: Though the Affordable Care Act provides CMS with the authority to calculate FULs at 'no less than' 175% of AMP, we believe that CMS must provide itself the opportunity to use the flexibility given to it by the law to set the FUL at greater than 175% of the weighted average AMP in certain justifiable cases in order to maintain patient access to prescription medications. We further believe that CMS should establish a process to suspend an FUL when a product is no longer nationally available. If a terminated product reduces the number of A-rated products to two, then CMS should immediately suspend the FUL and not wait for several months for the product's AMP to be omitted from the FUL calculation.

Section 447.518 State Plan Requirements: Findings and Assurances: We agree that states must "provide adequate data" when proposing changes to the ingredient cost reimbursement or professional dispensing fee for reimbursement. We encourage CMS to require that states demonstrate, through surveys that reflect state-based data, that their ingredient costs reimbursement and dispensing fees are reflective of pharmacy costs of dispensing. The requirements for approval of State plan amendments regarding reimbursement changes should also extend to different classes of pharmacies, as different pharmacies have different costs of purchasing as well as different costs of dispensing.

CMS should also require states to demonstrate that both their brand name drug reimbursement as well as MAC lists for generics are justified based on state-based data, and not permit states to make reductions in these State maximum allowable cost lists without justification to CMS. Moreover, States should be required to demonstrate that their MAC methodology is based on community pharmacies costs of purchasing prescription drugs, and also include a process by which such values are changed in a timely manner so that they are more transparent to the pharmacy.

Finally, we believe that CMS has no statutory authority to make public individual AMPs for brand name or multiple source drugs. Thus, there should be no ability for states to use AMPs to set Medicaid reimbursement.

We appreciate your consideration of these comments.

Sincerely,

Erik R. Lieberman
Regulatory Counsel