FOOD MARKETING INSTITUTE

April 14, 2008

Via Courier

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Medicaid Program; Multiple Source Drug Definition (CMS–2238–IFC, March 14, 2008)

Dear Mr. Weems:

The Food Marketing Institute (FMI) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) interim final rule with comment period that changes the definition of "multiple source drug" under the Medicaid program. FMI remains quite concerned about the impact of the Average Manufacturer Price provisions of the Deficit Reduction Act (DRA)—and particularly the revised Federal Upper Limits (FULs) for multiple source drugs. We are pleased that CMS has recognized the need to make changes to the regulatory framework that will affect pharmacy reimbursement for multiple source drugs under the Medicaid program going forward, but we believe that additional changes will be necessary to ensure that Medicaid beneficiaries continue to have convenient access to prescription medications at their local pharmacies. Moreover, we agree with the comments submitted by the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacy Association (NCPA) that the specific change CMS has made does not accomplish the agency's stated goal of conforming its definition of "multiple source drug" more closely with the Social Security Act. We are particularly concerned that CMS has chosen to place the burden on determining whether a drug is generally available in a state on that state and its pharmacies—contrary to the statutory direction that availability in each state should be determined before an FUL is imposed.

2345 Crystal Drive, Suite 800 • Arlington, VA 22202-4801 • T 202.452.8444 • F 202.429.4519 • fmi@fmi.org • www.fmi.org

FMI 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. Its international membership includes 200 companies from 50 countries.

FMI's retail members also operate more than 14,000 in-store pharmacy departments. We estimate 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, we anticipate 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.

As we have stated in previous correspondence to CMS,[1] FMI believes that CMS has inappropriately included mail-order prices and other discounts outside of the retail class of trade in AMP to the detriment of Medicaid beneficiaries. Further, we continue to believe that FULs should be set on the basis of the weighted average AMP of therapeutic alternatives and that CMS must act to ensure that dispensing fees at the state level are adequate to cover pharmacy dispensing costs. We believe that these issues must be addressed before AMP based FULs are implemented—and the current change to the definition of multiple source drugs will not address these issues.

Since our central concern is that the CMS policy announced in the DRA Final Rule[2] will set FULs on the basis of discounts that are not available to retail pharmacies, FMI believes that removing those drugs that are not generally available to the public through retail pharmacies in a state from the FULs that are applicable in that state is wholly appropriate. We urge the agency to apply this same principle to the mail-order and other discounts that are not available to the retail pharmacies on which Medicaid beneficiaries depend. Unavailable discounts should not influence the FUL any more than unavailable drugs. FMI is hopeful that the present interim final rule with comment period signals that CMS recognizes the need for a shift in its AMP and FUL policies to ensure that these benchmarks are more closely aligned with the economic reality of retail pharmacies.

However, as indicated above, we do not agree that the interim final rule with comment period is successful in resolving the differences between CMS's definition of "multiple source drug" and the definition envisioned by the statute. Along with other associations representing retail pharmacies, we believe that CMS must affirmatively establish that each drug product used in establishing a FUL is generally available to the public through retail pharmacies in a state before the FUL can be applied in that state.

---

1 FMI Letter to Leslie Norwalk February 20, 2007. FMI Letter to Kerry Weems January 2, 2008.

2 72 Fed. Reg. 39142 (July 17, 2007).

FMI appreciates the opportunity to offer these comments on the impact that CMS' proposed regulation will have on supermarket pharmacies. We respectfully request that you consider our comments fully on the record.

We look forward to working with CMS on these issues in the future. Please feel free to call me or Cathy Polley, FMI's Vice President for Pharmacy Services at (202) 220-0631, with any questions you might have.

Sincerely,

Tim Hammonds
President and CEO