FOOD MARKETING INSTITUTE

February 20, 2007

Via Courier

Leslie Norwalk, Esq.
Acting Administrator
The Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Proposed Rule To Implement Provisions of DRA Pertaining to Prescription Drugs under the Medicaid Program; (Docket No. CMS--2238--P)

Dear Administrator Norwalk:

The Food Marketing Institute (FMI) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid program. 71 Fed. Reg. 77174 (Dec. 22, 2006). FMI is highly concerned about the impact of the proposed rule on its supermarket pharmacy members. As CMS notes in the proposed rule, the use of Average Manufacturer Price (AMP) as a benchmark for pharmacy reimbursement represents a departure from the previous role of AMP in the Medicaid rebate calculation. Understanding the difficulties that the agency faces in reconciling these conflicting roles for AMP, we believe that several of the decisions CMS has proposed would unduly reduce AMP. Our comments and recommendations are discussed more fully below and in the attached Appendix A, which translates our comments into regulatory language for your consideration.

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.

Headquarters:
2345 Crystal Drive, Suite 800
Arlington, VA 22202-4801

T 202-452-8444
F 202-429-4519

www.fmi.org
fmi@fmi.org

FMI's retail members also operate more than 10,000 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.

A. Executive Summary

FMI urges CMS to take the steps necessary to ensure that pharmacies are adequately reimbursed for serving Medicaid patients. Recent studies suggest that Federal Upper Limits (FULs) based on AMP may result in ingredient cost reimbursement that is below pharmacy acquisition cost.[1] While FMI is not certain that this situation can be fully addressed in regulations, we believe that CMS should take the following steps to mitigate this problem:

- Restrict the scope of discounts included in the "retail class of trade" to reflect only those prices that are provided to wholesalers for drugs distributed to retail pharmacies;
- Define "wholesaler" in a manner that better reflects current law and practice;
- Remove from the proposed rule's definition of AMP sales to PBMs, outpatient hospitals, clinics and mail-order pharmacies that fall clearly outside of the statutory definition of AMP;
- Remove from AMP those prices that Congress excluded from "best price" to allow for deep discounts that could otherwise artificially deflate AMP;
- Set FULs based on the average AMP of various therapeutic alternatives, rather than the lowest cost alternative;
- Exercise discretion to delay publication of AMP information to ensure that the consequences of publishing this information are fully understood;
- Reduce the potential for volatility in the AMP-based reimbursement system by removing a larger number of outliers when establishing FULs;
- Base FULs on the AMPs of those products that are nationally available and in sufficient supply to meet the needs of pharmacies over time;
- Revise the regulatory definition of "dispensing fee" to ensure that all pharmacy costs are identified; and
- Require states to update their Medicaid dispensing fees to be sure that these fees are adequate in light of newly implemented DRA policies, particularly to ensure appropriate utilization of generic drugs.

The remainder of this letter provides more details on each of these issues as well as proposed regulatory language in Appendix A.

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[1] Government Accountability Office "Medicaid Outpatient Prescription Drugs: Estimated 2007 Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs", Letter to Rep. Joe Barton (R-TX) (December 22, 2006).

B. Policy Context

Supermarket pharmacy profit margins are generally only a very small percent of total revenue, far lower than most other businesses. In this context, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. FMI and its members are particularly concerned about the impact of the DRA's FUL policies on retail pharmacies. According to the GAO's comparison of AMP-based FULs to pharmacy acquisition costs, AMP-based FULs were 36% lower than average pharmacy acquisition costs when calculated using information from the first quarter of 2006. To the extent that FULs are below pharmacy acquisition costs for generic drugs, our members may find it increasingly difficult to serve Medicaid patients. This situation is exacerbated by dispensing fee amounts at the state level that are far below the costs our members incur to dispense prescription drugs to Medicaid patients.

FMI is aware that the use of AMP in setting FULs is dictated by the DRA, and of the difficulty facing the agency in balancing between the use of AMP for reimbursement and its use in the calculation of manufacturer rebates to the Medicaid program. Along with others in the pharmacy community, FMI is involved in efforts to address this problem legislatively. However, as we discuss in the balance of this letter, we believe that CMS has significant discretion to mitigate the severity of the problem, discretion that the agency has not fully exercised. We urge CMS to emphasize the role of AMP as a reimbursement benchmark in the final rule to ensure that our member pharmacies can continue to serve Medicaid patients.

C. Analysis of Issues

1. Revise Proposed AMP Definition To Exclude Sales to Mail Order and PBMs That Are Outside the Statutory Definition of AMP.

While FMI recognizes the difficulties that the DRA has imposed on CMS by requiring AMP to be used for a very distinct new purpose, we believe that CMS errs in the proposed rule by defining AMP as encompassing a variety of sales that are outside of the statutory definition of AMP. The statute is clear: AMP is the *average* price paid to the manufacturer for the drug in the United States *by wholesalers* for drugs *distributed to the retail pharmacy class of trade*.[2] In contrast, CMS proposes to include price structures that are beyond the statutory definition either because they do not reflect prices paid by true wholesalers or because they do not reflect discounts and concessions that are ultimately realized by the retail class of trade. Accordingly, and as explained more fully below, CMS has proposed a regulatory definition for AMP that is neither adequately supported by the statute nor an effective benchmark for pharmacy reimbursement.[3]

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[2] §1927(k)(1) of the Social Security Act (42 U.S.C. 1396r-8(k)(1).

[3] As noted, FMI does not believe that AMP – even as defined by the statute – can be an effective benchmark for pharmacy reimbursement under the Medicaid program. Nonetheless, given the enactment of the DRA, we recognize that Congress has made a determination in this regard, and CMS is obligated to implement that legislative decision.

a. Exclude Discounts Given to PBMs and Mail Order Pharmacies Because These Businesses are Outside the Retail Class of Trade.

FMI's primary concerns with the proposed definition of AMP are the overly broad view of retail class of trade and the definition of wholesaler. Section 1927(k)(1) of the Social Security Act defines AMP in relevant part as "the average price paid to the manufacturer for the drug in the United States by *wholesalers* for drugs distributed to *the retail pharmacy class of trade*." We believe that this definition in fact counsels that AMP "should only reflect prices of sales to those pharmacies which dispense drugs to the general public", an option that CMS chose to reject as inconsistent with "past policy."[4] We would note, however, that the "past policy" to which CMS refers was implemented at a time when AMP was not being used for pharmacy reimbursement purposes, but only for the purpose of calculating rebates owed by manufacturers to CMS and the states. Accordingly, CMS is not bound by its past policy, nor should the agency feel constrained to operate within it. Rather, given the new task imposed on CMS by the DRA, CMS should establish a new policy reflective of the multiple purposes that AMP must now serve.

Indeed, reading the statutory definition of AMP in light of its new use as a reimbursement benchmark counsels for excluding sales to PBMs, mail-order pharmacies and other entities that are outside the retail class of trade. The inclusion of PBM discounts and mail order prices that are clearly not accessible to retail pharmacies artificially deflates AMP, potentially impeding the convenient access of Medicaid beneficiaries to supermarket pharmacies if these retail outlets cannot receive adequate reimbursement for their pharmaceutical acquisition costs for generic drugs.

In addition, it is our understanding that some manufacturers consider both mail order pharmacies and PBMs to be separate and distinct from the retail class of trade. Indeed, it is difficult to describe PBMs as falling within the retail class of trade, as their pharmacy benefit management functions are not directly involved in the supply chain for pharmaceuticals. Only in their role as mail order pharmacies do PBMs typically participate directly in the purchase and delivery of prescription drugs, an activity which is also outside the retail class of trade. Mail order pharmacies take title and deliver products to patients but are a separate and distinct option for consumers in contrast to the supermarket and community pharmacies that are typically considered "retail". Indeed, in its rule implementing the Medicare Modernization Act, CMS explicitly excludes mail order pharmacies from its definition of "retail pharmacy."[5]

b. Discounts Given to PBMs and Mail Order Pharmacies – Entities Typically Outside of the Wholesaler Distribution System – Cannot Be Included in AMP

Not only does the statute limit the data to be used to calculate AMP to prices paid for drugs distributed within the retail class of trade, the statute expressly defines AMP as the

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4 71 Fed. Reg. at 77178.

5 70 Fed. Reg. 4493, 4535 (January 28, 2005).

price *paid by wholesalers*. Therefore, although discounts to PBMs and mail order pharmacies may affect the "net price realized by manufacturers," as asserted by CMS, the statute requires the use of wholesaler pricing in the determination of AMP. Indeed, many of the sales to PBMs and mail order do not flow through wholesalers at all, so the discounts received by PBMs and mail order generally do not affect the price paid by "wholesalers," as this term is typically defined.

Specifically, CMS proposes to define "wholesaler," as follows:

> Any entity (including a pharmacy, chain of pharmacies or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drugs.

Proposed 42 CFR 477.504(f). The proposed regulatory definition, which includes retail outlets, overreaches common and statutory wholesaler definitions resulting in a situation that is contrary to state licensing practices and conflicts with related federal statutes.

First, treating pharmacies as wholesalers is inappropriate and could unduly burden FMI's members with new licensing requirements at the state level. Supermarket pharmacies are licensed as pharmacies – not wholesalers, to which different licensing and regulatory requirements apply. Accordingly, supermarket pharmacies are not properly considered wholesalers.

Moreover, the distribution functions typically performed by wholesalers are far different from the administrative functions performed by PBMs. Section 510(g) of the Federal Food, Drug, and Cosmetic Act defines "wholesale distributor" as an entity "who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user."[6] As discussed, PBMs generally do not take title to prescription drugs except in limited instances, and then generally because they are operating as mail order pharmacies and not in their traditional functions as PBMs. Therefore, CMS should not include PBMs within the regulatory "wholesaler" definition either.

c. AMP Should Not Include Discounts that Fall Outside the Medicaid Program

Many of the discounts that CMS seeks to include within the definition of AMP are given by manufacturers to entities that are able to increase the market share of particular products through therapeutic switching and other mechanisms. Under the Medicaid program, which prohibits formularies and a variety of other cost containment tools, pharmacies cannot engage in these practices and are, therefore, ineligible for many of the discounts predicated on these practices. Consequently, it is inappropriate to apply these discounts to AMP when it will be used as a Medicaid pharmaceutical reimbursement benchmark.

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[6] 21 U.S.C. 360.

For these reasons, FMI believes that CMS has erred in its proposed definition of AMP. We urge CMS to promulgate a final regulatory definition of AMP consistent with the recommendations in Appendix A of our comments that omits pricing given to PBMs and mail order pharmacies from the definition and, therefore, will better reflect the retail class of trade and wholesaler elements of the statutory definition.

2. Revise Proposed AMP Definition To Exclude Sales Excluded from Medicaid's "Best Price"

CMS proposes to include within the definition of AMP certain sales, notably sales to Part D plans and State Pharmacy Assistance Program (S-PAPs), that are excluded from Medicaid's "best price". These sales are excluded from "best price" to provide deeper discounts to S-PAPs and Part D plans. Indeed, the Congressional Budget Office specifically scored the exemption from "best price" for sales to Part D plans as producing savings because it "gives those plans more leeway to negotiate steeper price discounts from manufacturers since those manufacturers will not have to pass on the same discount to Medicaid."[7]

The "best price" exclusion reflects the policy judgment of Congress that deeper discounts should be available for particular classes of sales than are typically available to the retail marketplace. The exclusion has been available for many years for various government sales and was extended to prescription drug plans under Medicare Part D in the Medicare Modernization Act.

In contrast to S-PAPs and Part D plans, sales to retail pharmacists are not exempt from best price, and pharmacists are unlikely to receive the level of discounts available to those entities. Thus, including sales that are exempt from "best price" in AMP will artificially lower AMP as a reimbursement benchmark by including discounts in AMP to which pharmacists do not have access. FMI therefore urges CMS to exclude from the definition of AMP those sales that are exempt from "best price" under §1927(c)(1)(C)(i) of the Social Security Act.

3. Statute Requires CMS To Use Weighted Average of AMPs to Set FULs, Not Lowest Cost Therapeutic Alternative

CMS proposes to set AMP-based FULs at 250% of the AMP of the lowest cost therapeutic alternative. While the DRA requires FULs to be set at 250% of AMP, the statute itself does not reference the lowest therapeutic alternative – that benchmark was defined in previous CMS regulations.

Thus, CMS retains the discretion to improve pharmacy reimbursement by using a weighted average of all therapeutic alternatives of a particular prescription drug and should, in

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[7] "A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit." (July 2004). http://www.cbo.gov/ftpdocs/56xx/doc5668/07-21-Medicare.pdf

fact, do so to reflect the standard set by the statute properly. Particularly in light of the GAO's findings that AMP-based FULs are below pharmacy acquisition costs, FMI believes that the use of a weighted average could mitigate the number of instances where pharmacies are to be reimbursed below their acquisition costs and urges CMS to change to a weighted average FUL calculation in the final rule.

4. CMS Should Exercise Its Discretion To Delay Publication of AMP Data

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 prices paid to manufacturers on average will increase, driving AMP-based reimbursement up also.

FMI and others are exploring legislation to ensure that AMP data remain confidential. In the interim, we believe that CMS has the discretion to delay publication of this information and we urge the agency to exercise this discretion.

5. CMS Should Reduce Volatility by Excluding Outlier Prices Less than 10 Percent of Next Highest AMP, Implementing Smoothing Mechanisms Similar to ASP

FMI is concerned about the potential for volatility in the drug reimbursement system, particularly in light of the CMS decision to rely on monthly AMP reports in setting FUL rates. We believe that relying on monthly AMP reports to set FULs and seeking to update FULs on a monthly basis could create significant volatility in the system, along with an undue burden on states seeking to administer FUL rates. We understand that Average Sales Price (ASP) based rates for certain products reimbursed under Medicare Part B have been highly volatile – even though ASP rates are calculated quarterly – and we believe that smoothing mechanisms will also be needed for AMP-based rates.

a. Possible Range Between AMP of Lowest Therapeutic Alternative and Next Highest AMP Should be Reduced

To avoid setting FULs based on "very low" AMPs, CMS proposes to set each FUL based on the lowest AMP "that is not less than 30 percent of the next highest AMP for that

drug."[8] However, as the competition between generic therapeutic alternatives tends to reduce differences between competing products to very small levels, the proposed 70 percent range would still capture and incorporate a wide range of outliers in AMP-based FULs.

Thus, to reduce volatility and ensure a nationally available AMP, we encourage CMS to exclude "outlier" percentages that are more than 10 percent below the next highest AMP. A wider gap between therapeutic alternatives would likely be indicative of problems in AMP data or temporary spikes that would not actually reflect prices nationally available in the marketplace. Using a small percentage range will also improve the ability of pharmacists to purchase prescription drugs at prices below the FUL and better serve the agency's stated purpose of ensuring that drugs are "nationally available at the FUL price."[9]

b. AMP Should Employ "Smoothing" Mechanisms Similar to Those Used in the ASP Reporting System Under Medicare Part B.

In Medicare Part B, CMS created various mechanisms for "smoothing" ASP reporting to limit volatility. For example, manufacturers must calculate "lagged discounts" using a percentage methodology that reduces the potential for these discounts to be over-stated or understated in a particular quarter. The proposed rule for AMP does not employ such a smoothing methodology, which could contribute to volatility in Medicaid reimbursement for generic drugs. FMI urges CMS to require manufacturers to "smooth" those discounts that are included in AMP.

c. CMS Must Ensure That FULs Are Based on Nationally Available Prices.

Finally, CMS should ensure that no FUL is based on an AMP for a generic pharmaceutical produced by a manufacturer that does not make the product nationally available. It is common for generic manufacturers to work directly with select pharmacy chains and wholesalers to meet market share goals in a manner that may not provide national access to their products. Consistent with others in the industry, FMI believes that AMP should only be calculated based on generic products that are AB-rated in the FDA *Orange Book* and are consistently available from the three major national wholesalers in supplies adequate to afford national distribution. Products that are erratically available or that are available only in limited supplies should be excluded from the weighted average AMP calculation. We are particularly concerned that a FUL could be set by a manufacturer undercutting the market, but without enough supply to meet market demands for an extended period of time. Particularly if CMS does not move to a FUL based on weighted average AMP, we would urge the agency to take steps to ensure that each AMP used to represent a FUL reflects a product that continues to be available to all retail pharmacies.

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[8] 71 Fed. Reg. at 77188.

[9] *Id.*

6. CMS Should Take All Necessary Measures To Ensure Adequacy of State Dispensing Fees

In order to protect convenient access to prescription drugs for Medicaid beneficiaries, CMS must ensure that the final regulatory definition of "dispensing fee" captures all of the applicable pharmacy operating costs. Specifically, the definition of dispensing fee in the proposed rule should be amended to include medication therapy management services and a reasonable return for pharmacies. As Medicaid may no longer adequately reimburse pharmacies for the ingredient costs of generic drugs, setting dispensing fees adequate to cover pharmacy costs in delivering pharmaceuticals to Medicaid beneficiaries is absolutely essential. (Suggested regulatory language for CMS's consideration in this regard is included in Appendix A.)

According to various sources, the current average dispensing fee at the state level is approximately $4.50. Recent studies of the actual costs to pharmacists to dispense prescription drugs have placed those dispensing costs at between $9 and $14 per prescription, depending on the state, with a national average of more than $10.[10] Thus, dispensing fees at the state level are clearly inadequate to cover pharmacy costs.

Accordingly, CMS should take an active role in informing the states about the need to adjust dispensing fees, especially in light of the DRA FUL policy. CMS should require each state to make a specific finding that the existing dispensing fee structure is not only adequate to cover pharmacy costs (including a reasonable return), but also that these fees provide adequate incentives for generic usage in light of the revised FUL policy. CMS should direct states to increase dispensing fees that will not allow for adequate generic usage.

These suggestions reflect Congressional intent in enacting the DRA. Specifically, during the DRA debate, Senator Grassley stated that "states will need to review and increase the fees that they pay pharmacies for dispensing Medicaid prescriptions" in response to the revised FUL policy.[11] Without significant changes in state dispensing fees, pharmacy incentives to encourage generic utilization will be significantly reduced, with the corresponding potential to reduce greatly the savings that the DRA's imposition of AMP-based FULs was intended to provide. Given that brand name prescriptions cost an average $120 while generic drugs average $12 per prescription, the impact of reduced generic utilization could be significant indeed. State dispensing fees should be set in a manner that provides adequate incentives for the use of generic drugs and protects the convenient access of Medicaid beneficiaries to retail supermarket pharmacies.

D. Conclusion

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

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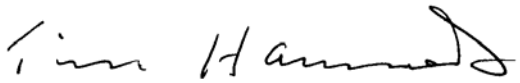
[10] "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies", Grant Thorton LLP (January 2007). Also, C. Mullins and A. Davidoff, et al, "Analysis of Cost of Prescription Drug Dispensing in Maryland" (December 2006).

[11] See Congressional Record, Senate, November 3, 2005, p. S12326 (Colloquy between Senators Grassley and Reed).

consider our comments fully on the record and that you utilize the regulatory changes proposed in Appendix A of our comments.

We look forward to working with CMS on these issues in the future. Please feel free to call me or Deborah White, FMI's Associate General Counsel and Vice President of Regulatory Affairs at 202-220-0614, with any questions you might have.

Sincerely,



Tim Hammonds
President and CEO

APPENDIX A:

Specific Regulatory Proposals

§447.502 Definitions

Amend paragraph 2 of the definition of "dispensing fee" as follows:

Dispensing fee means the fee which – …

"(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling (including medication therapy management services), physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy (including a reasonable profit); and".

S447.504 Determination of AMP

(e) *Retail pharmacy class of* trade means any independent pharmacy, chain pharmacy, ~~mail order pharmacy, pharmacy benefit manager (PBM),~~ or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

(f) *Wholesaler* means any entity ~~(including a pharmacy, chain of pharmacies or PBM)~~ to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug that is licensed in a state as a wholesale distributor of pharamaceuticals.

Amend subsection (g) by striking paragraphs 3, 6, 7, 8, 9 and 12 and re-designating paragraph numbers accordingly.

Amend subsection (h) by inserting a new paragraph after paragraph 3 (and re-designating paragraph numbers accordingly) that reads as follows: "Sales exempt from best price (as defined by §447.505)."

Amend subsection (i)(1) by striking "PBM price concessions,".

§447.514 Upper Limits for multiple source drugs

(b) *Specific upper limits*. The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the weighted average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for ~~the least costly therapeutic equivalent~~ all therapeutic equivalents for sale nationally (as described in subsection (c).

Amend subsection (c) by:

(1) striking "30" in paragraph 2 and replacing it with "90"; and
(2) inserting a new paragraph as follows:

"(4) Any product that is not consistently available from the three largest wholesalers in amounts reasonably adequate to supply the retail pharmacy sector will be excluded from the FUL group."

§447.518 State plan requirements, findings and assurances

Amend subsection (b)(1) by:

(1) in clause (i) by striking at the end "and";
(2) in clause (ii) striking the period at the end and inserting in lieu thereof "; and"; and
(3) inserting the following new clause:

"(iii) In the aggregate, the dispensing fees paid to pharmacies cover the costs described in §447.502 and are designed to encourage the utilization of multiple source drugs where appropriate."