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October 4, 2004

VIA COURIER

Mark McClellan, M.D. Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: CMS—4068—P (Medicare Program; Medicare Prescription Drug Benefit)

Dear Dr. McClellan:

The Food Marketing Institute (FMI) respectfully submits the following comments in response to the proposed rule CMS—4068—P ("the proposed rule")[1] that has been issued by the Centers for Medicare and Medicaid Services (CMS) to implement Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's members operate close to 15,000 in-store pharmacies. We estimate that supermarket pharmacies account for nearly 22 percent of all outpatient prescription drugs dispensed in America. 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 a result of the growing importance of pharmacy in the supermarket industry and because FMI member companies dispense prescription drugs to a significant number of seniors, we are very interested in working closely with CMS to make this new and important prescription drug benefit a success for Medicare beneficiaries. As we noted in earlier comments on the prescription drug card interim final rule, FMI and many of our

[1] 69 Fed. Reg. 46632 (August 3, 2004)

supermarket members worked closely with the House and Senate Leadership in support of legislation that would provide prescription drug coverage to our nation's 40 million seniors.

As with the drug card interim final rule, FMI is once again impressed with the speed with which CMS is moving to implement the enabling legislation, and we appreciate the efforts that were necessary to publish the proposed rule in a timely fashion. We are, however, concerned about the effect that some of CMS policy decisions may have on our members and, more importantly, their customers who are Medicare beneficiaries. We hope that CMS will address these concerns in the agency's final rulemaking document.

The bulk of our comments focus on Subpart C of the Proposed Rule—"Voluntary Prescription Drug Benefit and Beneficiary Protections" and Subpart D—"Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans." However, we also offer comments on Subpart A—"General Provisions" and on other overall MMA policies.

I. Introduction

FMI and its member companies were strong supporters of MMA and worked closely with members of Congress and their staffs to ensure that the benefit was designed to operate smoothly for both pharmacies and their customers. We believe that successful implementation of this program will provide senior citizens and the disabled with a vital new addition to the Medicare program. While FMI is of the opinion that CMS has made appropriate decisions in many areas of this regulatory proceeding, we believe that a number of modifications and clarifications to the proposed rule still need to be made in order to protect the interests of Medicare beneficiaries:

- **Network Adequacy.** We believe that CMS has misunderstood the MMA's network adequacy standards and urge the agency to require that adequacy standards be applied to Prescription Drug Plan (PDP) pharmacy networks on a state-by-state basis—without allowance for smaller "preferred networks."
- **Out of Network Access.** CMS must clarify that pharmacies providing "out-of-network" service will not be able to adjudicate beneficiary claims. These pharmacies will only be able to charge beneficiaries their usual and customary prices for out-of-network access. It will be up to beneficiaries to submit their claims to PDPs in these circumstances.
- **Mail-Order Issues.** CMS must ensure that PDP self-dealing with mail-order operations is prohibited. The agency should also work to ensure that there is truly a level playing field for mail-order and community pharmacies.
- **Information on Therapeutic Equivalents.** CMS should require notice about lower cost generic alternatives to be provided *before* a prescription drug is dispensed to a Medicare beneficiary. This should include provisions for mail-

order pharmacies to call, write or electronically contact beneficiaries about the availability of lower-cost alternatives before filling and mailing a prescription.

- **Medication Therapy Management.** FMI believes that more details and standards are needed if the MMA Medication Therapy Management program is to be successful.

FMI believes that all of the above areas are open to improvement, but we should also note that we are pleased with the direction CMS has taken on a number of other matters:

- **TrOOP Issues.** We support the CMS decision to include those differentials that beneficiaries must pay (if any) in order to receive long term prescriptions in community pharmacies instead of by mail order and to receive pharmacy services out of network in "True Out of Pocket Costs" (TrOOP).
- **Price Comparison Website.** FMI agrees that an improved price comparison website could be a vital resource for beneficiaries seeking to understand their options for MMA drug coverage.
- **Other Beneficiary Interface issues.** Since our pharmacies will be the first place that beneficiaries go to seek information about MMA benefits, FMI is appreciative of any efforts CMS undertakes to simplify various enrollment processes and provide more information about MMA benefits. We particularly support the CMS decision to streamline the asset test for low-income eligibility. We hope that FMI and its members will have opportunities to provide input on the information and outreach materials that CMS develops to keep beneficiaries informed about the new MMA prescription drug coverage.

Below, we address each of these areas in more detail. FMI looks forward to continued interaction with CMS concerning various MMA implementation issues.

II. Issues Concerning "Voluntary Prescription Drug Benefit and Beneficiary Protections" (Subpart C of the Proposed Rule)

A. Preferred Pharmacy Networks

FMI is very concerned about the CMS decision to allow "preferred" networks within the overall network structure contemplated by the statute. We believe that CMS's proposal represents a misreading of the statute and of Congressional intent. Congress clearly intended Prescription Drug Plan (PDP) pharmacy networks to be subject to the TRICARE standards for network adequacy—without provision for smaller networks not subject to these standards. FMI urges CMS to correct this error in its final rule.

The pharmacy access provisions represent a carefully crafted compromise that FMI and others were involved in negotiating. We had initially urged lawmakers to allow "any willing pharmacy" networks only. We felt that this would maximize beneficiary convenience and access under the MMA. However, we understood concerns that such a

provision would prevent PDPs from realizing the savings possible through the increased leverage provided by selective contracting of their pharmacy networks. In order to allow for these savings, but also to protect beneficiary convenience, Congress determined that additional discounts could be provided for network pharmacies, but that these networks would have to meet agreed to access standards to ensure beneficiaries nationwide would have convenient access to these pharmacies—and the additional discounts provided.

Subsection (b)(1) of section 1860D-4 of the Social Security Act, as modified by MMA, provides for pharmacy network adequacy requirements. Subparagraph (A) allows for the participation of "any willing pharmacy" that meets PDP terms and conditions. Subparagraph (B) notes that despite the requirements of (A), plans may offer additional discounts for "network pharmacies." However, subparagraph (C) then requires convenient access to these network pharmacies—based on a set of requirements established by the Secretary using the TRICARE standards.

Thus, while the statute indeed permits PDPs to have networks—with additional discounts—notwithstanding the "any willing pharmacy" provision, it also clearly states that these networks must meet adequacy standards. Moreover, report language accompanying the MMA indicates, "Plan sponsors cannot create any pharmacy networks that are more restrictive than the TRICARE access standards."[2]

Clearly, Congress was not silent on this issue, and FMI is surprised that CMS has implemented these provisions to allow smaller "preferred" networks. We are particularly troubled about this issue because the NPRM would seem to allow plans to create very small preferred networks, forcing most beneficiaries to pay higher cost sharing or use mail-order pharmacies. FMI believes that this would be exactly the opposite of what Congress intended. We, therefore, urge CMS to reverse this decision in its final rule implementing Title I of MMA.

In addition to the preferred/non-preferred network issue, FMI has other concerns in the area of network adequacy.

First, FMI is concerned that CMS has not sufficiently clarified that the network adequacy standards are to be met using only retail community pharmacies. The final rule should clearly state that whether a PDP meets the TRICARE access standards should be based solely on retail pharmacies—excluding mail-order, hospital pharmacies and long-term care pharmacies.

Finally, FMI would urge CMS to require PDPs to meet the TRICARE standards on a state-by-state basis. While CMS has not yet released its proposed regional structure for the Part D benefit, we are concerned that any regions larger than individual states could, absent this requirement, create pharmacy access problems for beneficiaries in rural

[2] "Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Conference Report to Accompany H.R. 1." House Report 108-391 (November 21, 2003) at 453.

states. The larger the regions ultimately adopted by CMS, the easier it would be for plans to meet the TRICARE standards while still providing inadequate coverage for beneficiaries in certain areas.

FMI believes that proper resolution of these issues will be vital to the overall success for the program. Senior citizens and the disabled are in particular need of convenient pharmacy access—access which Congress attempted to provide while still allowing for the proper negotiations of discounts. The proposed rule, if left unchanged, upsets the Congressional balance on these issues and must be amended to reflect the true intent of Congress.

B. Out of Network Issues

In another area related to network adequacy, the MMA specifically provided for out-of-network/emergency access in §1860D-4(b)(1)(C). While the proposed rule does note (at page 46662) that paper claims may be necessary for this process, the CMS discussion of cost sharing issues is not fully clear on the fact that beneficiaries seeking out-of-network coverage will nearly always have to submit these claims manually. CMS should clarify that pharmacies will not be able to adjudicate cost sharing, deductibles and other issues for out-of-network coverage.

Out-of network pharmacies, by definition, will not have contracts with the PDPs of beneficiaries seeking their services—and therefore cannot determine beneficiary cost sharing in these instances. These pharmacies will only be able to bill their "usual and customary" price for a drug dispensed to a Medicare beneficiary—leaving the beneficiary to submit the costs to his or her PDP for reimbursement as applicable. Medicare beneficiaries must have clear information on the inconvenience they will face when seeking to have prescriptions filled in pharmacies that do not participate in their plan networks.

Given these realities, FMI again encourages CMS to require networks that are as broad as possible. While out-of-network access is necessary, it should not become a safety valve for inadequate pharmacy networks.

On the subject of usual and customary (U&C) prices by out-of-network pharmacies, CMS expresses concerns that out-of-network pharmacies may increase their U&C prices to both Medicare beneficiaries and uninsured individuals. In a highly competitive marketplace, FMI does not see retail pharmacies increasing their U&C prices simply because CMS is implementing a new outpatient drug benefit under Medicare. A U&C price is normally defined as the pharmacy's selling price to an individual consumer. The price includes the cost of the drug and the pharmacy's mark-up. The mark-up reflects allowances for business operating costs, such as rent, utilities, employee wages/benefits and dispensing fees. U&C is often a better price than what may be offered under a private third party program. This routinely happens because a U& C price is based on a cash and carry transaction with no administrative claims processing or

adjudication costs. Thus, FMI strongly believes that no action is needed by CMS on U&C prices.

C. Mail-order Issues

FMI has a number of concerns about the interaction of mail-order pharmacies with the MMA drug benefit. Particularly in cases where PDPs own or control their own mail-order operations, we are concerned about whether or not the Congressional desire for a "level playing field" between community pharmacy and mail-order will be fulfilled. Some beneficiaries may choose to receive their prescriptions by mail, while others will prefer direct contact with their community pharmacists. PDPs should not be able to create unnecessary barriers for beneficiaries who prefer direct pharmacist access when they are filling a long-term prescription.

Section 110 of the MMA requires the Federal Trade Commission to conduct a study of potential conflict of interest problems when Pharmacy Benefit Managers own the mail-order pharmacies to which they direct their patients. FMI is particularly concerned that PDPs that own mail-order operations will have incentives to use these operations in situations where it may not be in the best interest of beneficiaries or the Medicare program. CMS should address in its final rule the potential for fraud and abuse due to PDP self dealing with mail-order companies that they own or control.

Congress intended a "level playing field" (see §1860D-4(b)(1)(D)) for community pharmacies relative to mail-order, and indeed the statute specifically requires PDPs to allow beneficiaries to access long-term prescriptions in their community pharmacies. While differentials, if any, in the product cost for community pharmacies versus mail-order can be passed on to beneficiaries, PDPs should not be permitted to waive or reduce cost sharing for beneficiaries who use mail-order. These sorts of inducements run counter to Congressional intent—and are particularly troubling in light of potential PDP conflicts of interest. CMS should clarify in the final rule that the only differential that PDPs may charge beneficiaries for community access to long-term prescriptions is the difference in manufacturer discounts—if any—between the mail-order and retail classes of trade.

FMI urges CMS to encourage pharmaceutical manufacturers to make mail-order class of trade discounts available to retail pharmacies that are dispensing long-term prescriptions—thereby giving further effect to the Congressional intent that there needs to ensure a level playing field between community pharmacies and mail-order pharmacies.

D. Insurance Risk

The MMA prohibits PDPs from requiring pharmacies to accept "insurance risk" as a condition of participation in their programs (§18060D-4(b)(1)(E)). FMI agrees with

CMS that a definition of this term is necessary, and would urge the agency to provide further clarification of this term. We would particularly like the CMS definition to include specific examples of types of "risk" such as fixed fees and capitation that may not be imposed on a pharmacy by a PDP.

E. Dispensing Fees

FMI supports including overhead costs in the definition of dispensing fees as CMS has proposed in its first option (Option 1) to define dispensing fees (at 46647 of the proposed rule). However, we believe that further clarification in this area is needed. For instance, the costs for "mixing drugs" should be better defined. Moreover, FMI believes that different fee levels should be established based on what is entailed in the preparation and dispensing of a particular prescription. For example, pharmacists should receive higher fees for compounding or reconstituting drugs—areas where additional expertise is required by the pharmacist. The rule is currently silent on this issue.

FMI further recommends that the CMS rulemaking require higher dispensing fees for pharmacies that are located in rural areas. Because many of these pharmacies may not have sufficient prescription volume or adequate dispensing fees to cover their overhead costs for participation in the Medicare drug program. We believe that Congress clearly intended dispensing fees (and fees for medication therapy management, discussed below) to cover the pharmacy's overhead costs and professional services that are provided in the dispensing of a prescription to a Medicare beneficiary. Without adequate reimbursement for overhead costs, the number of rural pharmacies available may decrease—a situation that could cause particular harm to Medicare beneficiaries living in rural areas.

F. Price Disclosure for Therapeutic Equivalents

As discussed in the proposed rule, Section 1860D–4(k)(1) of the MMA requires PDPs to have systems in place through which "pharmacies inform enrollees of any differential between the price of a covered Part D drug to an enrollee and the price of the lowest priced generic version of that drug and available under the plan at that pharmacy." (Proposed rule at 46665). However, the proposed rule negates some of the savings that could be achieved through lower cost generics by requiring notice to beneficiaries that a less expensive product is available "at the time of purchase" or, in the case of mail-order, only with the delivery of a prescription.

In the mail-order environment, notice at the time a prescription is delivered will essentially eliminate the possibility that beneficiaries will be able to choose the lower cost generic. While beneficiaries given notice at the time of purchase in a community pharmacy setting could ask the pharmacist to dispense the lower cost generic instead, a beneficiary using mail order, who wants to request a lower cost generic after such notice has been given, would either have to wait until the next prescription to receive a less expensive generic or return the product to the mail-order company and request a new

delivery. This process, which would be inconvenient and potentially medically unwise, would also add new shipping costs—perhaps at the expense of the beneficiary.

To prevent this problem, the CMS regulations should allow pharmacists to provide notice that a lower cost generic alternative is available BEFORE a prescription is delivered to the patient. Mail-order pharmacies should be required to call, write or e-mail beneficiaries with this notice before filling what would be a higher cost prescription. FMI believes that this change would allow a greater number of beneficiaries to access lower cost generic drugs, which was the intent of the provision in question.

FMI would also argue that the term **"**generic" should be further defined to include multiple source branded drugs.

G. TrOOP Issues

FMI strongly supports the CMS determination that any differentials that a beneficiary must pay to access long-term prescriptions in community pharmacies (rather than by mail order) should be counted as "true out of pocket costs" (TrOOP) (Proposed rule at page 46649). We believe that this comports with the Congressional desire for a "level playing field" between community pharmacy and mail-order.

Similarly, FMI supports treatment of any differential fees that a beneficiary must pay to access prescriptions out-of-network as incurred for TrOOP purposes. We believe that while Congress did include provisions to hold PDPs harmless against out-of-network pharmacy access, it did not intend to penalize further beneficiaries who require out-of-network services by failing to include out-of-network differentials as incurred out-of-pocket expenses. This decision may be particularly important for beneficiaries who must access drugs through specialty pharmacies which are not required, under the proposed rule, to be included in PDP pharmacy networks.

III. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans (Subpart D of the Proposed Rule).

A. Medication Therapy Management Programs

§1860D-4(c)(1)(C) requires PDPs to establish Medication Therapy Management Programs (MTMPs) and to consider the resources pharmacies must use to provide MTMP services in the fees established under their plans. FMI believes that further clarification of these requirements is warranted.

FMI supports the CMS determination that MTMP fees are separate and distinct from dispensing fees. However, we do not believe that CMS lacks discretion to review the adequacy of these fees. The statute requires PDPs to take into account "the resources used and time required" to provide MTMP services. CMS should require that PDPs offer

adequate MTMP plans and then provide estimates of pharmacist resources and time along with the corresponding fees for these amounts. While the statute does not require CMS to set these fees, it clearly requires plans to account adequately for the pharmacist's time and resources used in providing MTMP services. FMI believes that a full accounting of these resources will help to ensure that community pharmacists are adequately compensated for the MTMP services they provide.

FMI is also disappointed at the lack of specificity in the proposed rule concerning how MTMP services should be delivered—and to which patient populations these services should go. While we understand the CMS desire to offer plan flexibility, FMI urges CMS—at a minimum—to require MTMP programs to be generally based on face to face contact between patients and their chosen pharmacists. Without this important, base-line standard, it is our fear that PDPs may rely solely on telephone or electronic contacts—which FMI believes would be inadequate and contrary to Congressional intent.

Finally, FMI urges CMS to develop more criteria for MTMP plans to provide a more standardized level of services. Otherwise, the situation could prove very confusing for beneficiaries and very difficult for pharmacies contracting with multiple PDPs—each with significantly different MTMP requirements—to manage.

B. Coordination of Benefits

FMI supports the efficient coordination of benefits. We are pleased that CMS has proposed to adopt the NCPDP standards for the cards PDPs will issue to their beneficiaries and we would urge CMS to adopt NCPDP standards for all coordination of benefits issues.

IV. Issues Concerning "Eligibility and Enrollment" (Subparts B and P of the Proposed Rule)

A. General Comments on Pharmacy Role in Educating Beneficiaries About MMA/Price Comparison Website

Pharmacists will be the first resort of beneficiaries looking for information on various MMA benefits, subsidies and requirements. As a result, FMI supports the CMS effort to develop comprehensive information and outreach materials for eligible Medicare beneficiaries seeking to enroll in prescription drug coverage. FMI and its members stand ready to work with CMS on its information and outreach efforts so that they maximize beneficiary education and understanding, and address some of the concerns and questions that have been—and will continue to be—presented to our pharmacists.

With regard to information and outreach efforts, FMI agrees that a properly implemented website could be an excellent resource for beneficiaries. Following implementation of the discount card, there was a period of confusion, including some

erroneous information on the discount card price comparison website. We are certain that CMS will improve upon the site used for the discount card—and would urge the agency to work closely with pharmacies and other stakeholders to ensure that the any price comparison website is understandable and free of errors before it is made public.

Price comparison information, along with other information about available drug coverage will be a vital resource for beneficiaries seeking to enroll in MMA drug coverage. Particularly in the first years of the benefit, it will be difficult for Medicare beneficiaries to evaluate the myriad choices available to them. Full, complete and correct information will be vital to this process. Given the role of our pharmacists in interpreting this information for beneficiaries with questions, we hope that CMS will enable FMI and its members to provide feedback on the materials the agency develops.

B. Streamlining Low-Income Eligibility Verification

As noted in the previous subpart of our comments, FMI is supportive of efforts to mitigate beneficiary confusion about various MMA benefits. In that regard, we are particularly pleased with the streamlined asset test that CMS has proposed to use for the purposes of determining low-income eligibility. We agree with the agency that the benefits of this simplified test will far outweigh its costs—and will ensure that more eligible beneficiaries receive the low-income subsidies they need.

V. Conclusion

FMI appreciates the opportunity to comment on the proposed rule and hopes to continue an open and collaborative relationship with CMS as the MMA implementation process continues. For the pharmacies that we represent, and the Medicare beneficiaries that these pharmacies serve, successful implementation of the drug benefit is essential. We look forward to continued communication with CMS about this important matter.

Please do not hesitate to call me at 202.220.0610 or Ty Kelley, Director of Federal Government Affairs at 202.220.0629 with any questions or to set up a time for further conversations.

Sincerely,

John J. Motley III
Senior Vice President
Government and Public Affairs