

January 14, 2004

VIA COURIER

Dennis G. Smith, Acting 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—4063—IFC (Medicare Program; Medicare Prescription
Drug Discount Card)**

Dear Mr. Smith:

The Food Marketing Institute (FMI) respectfully submits the following comments in response to the interim final rule CMS—4063—IFC (“the rule”) that has been issued by the Centers for Medicare and Medicaid Services (CMS) to implement the Medicare Prescription Drug Discount Card Program as authorized by the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MPDIMA). 68 Fed. Reg. 69840 (Dec. 15, 2003).

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 CMS may

know, FMI and many of our 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. We appreciate the quick work CMS has done to begin making this legislation an operational reality.

Our comments will focus on the Prescription Drug Discount Card, but we agree with CMS that this important program will be a significant first step in the implementation of the larger drug benefit; accordingly, our comments also address the long-term significance of some of the policy decisions reflected in the interim rule for the immediate program.

I. Introduction

FMI and its member companies were strong supporters of MPDIMA and worked closely with members of Congress and their staffs to broaden the types of entities that could offer the drug card and the Medicare drug benefit and to ensure that both programs were designed to operate smoothly for pharmacies and their customers. Our comments below begin with a brief overview of some of the policies we advocated during the legislative process—focusing particularly on how these policies relate to the drug card program and the impact drug card policy choices could have in these areas as CMS moves forward to implement the larger drug benefit.

Under the Drug Discount Card Program, pharmacies will be subject to several new requirements as a direct result of MPDIMA and its implementing regulations, as well as requirements that drug card sponsors will impose on pharmacies by contract. Since pharmacies may participate in multiple drug card sponsors' networks, FMI is concerned that the implementation of contractual requirements from different card sponsors may present pharmacies with vague or conflicting guidance with respect to their responsibilities to drug card enrollees. Part III of our comments outlines some of these concerns and asks CMS to design more common standards for these card sponsor requirements. We would be happy to meet with CMS officials to explain our specific concerns in more detail and provide potential solutions. While the drug card will only be in operation for about two years, it is in the best interests of Medicare beneficiaries without drug coverage for the program to operate smoothly. Moreover, we believe that collaboration between CMS, FMI and its members will help remove some of the potential obstacles to implementation of MPDIMA's drug benefit.

Part IV of our comments addresses some of FMI's other concerns about the interim final rule, focusing mainly on areas where CMS could clarify the requirements for drug card sponsors to develop programs that will minimize confusion among their enrollees.

Finally, FMI wishes to commend CMS on its efforts. Our association was impressed with how quickly the agency was able to promulgate the interim final rule and

begin the process of MPDIMA implementation. As CMS continues the arduous process of implementing this new law, FMI stands ready to offer whatever assistance and expertise the agency may require.

II. FMI Comments on the Medicare Prescription Drug Card Program

During the Medicare reform debate, leading up to enactment of MPDIMA, FMI strongly supported private market drug coverage for senior citizens. During this time, we worked in favor of several policies to protect the interests of Medicare beneficiaries overall and drug card enrollees in particular, including pharmacy network adequacy standards, provisions to ensure that a wide variety of entities may offer new Medicare drug benefits, provisions to allow beneficiaries to receive their long term prescriptions in a retail setting and provisions to ensure that manufacturer discounts are passed on to discount card enrollees in 2004 and 2005 and Part D beneficiaries in 2006 and beyond. FMI was also concerned about potential market distortions coming from the involvement of mail-order operations that are owned or controlled by Pharmacy Benefit Managers (PBMs) administering drug discount cards and benefits.

Network Adequacy

FMI supports the efforts of the Congress and CMS in developing pharmacy network adequacy requirements. Card enrollees must have convenient access to community pharmacies and are pleased that CMS is encouraging card sponsors to offer comprehensive pharmacy networks to maximize the convenience of beneficiaries. We hope that CMS will encourage those plans that are not national in scope to be mindful of the needs of enrollees living near the borders of those plans—including offering pharmacy access outside the borders of the plan to increase convenience for those enrollees. (See also Section IV of our comments.)

Card and Benefit Sponsorship Flexibility

During the MPDIMA debate, FMI worked for eligibility requirements that would allow a variety of different types of entities to offer drug benefits and discount cards. In particular, FMI supports the ability of wholesale or retail pharmacy networks to offer Medicare-approved discount cards. We are concerned, however, that the requirement that each card sponsor include one million covered lives within a single entity limits the number and types of applicants that will qualify. We urge CMS to consider relaxing this requirement for applicants that can demonstrate the ability to cover one million covered lives even if they do not now do so. This issue will be particularly important during the design of eligibility requirements for Part D benefits; FMI believes that beneficiaries will receive higher quality drug benefit coverage options if a broader array of entities competes to provide such coverage.

Long-Term Prescriptions

With support from FMI and others, Congress included an option for beneficiaries to receive long-term prescriptions in their community pharmacy under Medicare Part D, rather than being forced to receive these prescriptions through the mail. We are disappointed that no similar option is explicitly offered under CMS's framework for the Medicare discount card.

FMI urges CMS to allow discount card enrollees the option of filling 90 day and other long-term prescriptions in the retail setting, with a lower discount than might be offered by mail-order or with the difference made up by an additional discount from the pharmacy. Discount card enrollees should have the convenience of long-term prescriptions—combined with the freedom to choose home delivery or retail delivery according to their preferences.

Conflicts of Interest: PBM-Owned Mail-Order Pharmacies

In MPDIMA, in response to concerns raised by FMI and others, Congress requested that the Federal Trade Commission study potential problems created by the ownership and control of mail-order pharmacies by PBMs. PBMs that own their own mail-order operations often have distorted incentives to switch beneficiaries to more expensive branded products for which the PBM has negotiated a special mail-order rebate—despite the fact that a generic alternative in the pharmacy may be more cost-effective for the beneficiary.

In the interim final rule, CMS includes requirements for card sponsors to audit their mail-order operations. A drug card sponsor that owns its mail-order pharmacy has a potential conflict of interest in any oversight process and should be required to submit its mail-order operations to outside auditors.

Moreover, drug card sponsors should be required to disclose their ownership of any mail-order pharmacy to their enrollees and to allow enrollees the option of purchasing long-term prescriptions at the retail level or a non-conflicted mail-order pharmacy. This recommendation is particularly important since plan sponsors will not be required to inform beneficiaries of lower priced generic alternatives until after a mail-order prescription is delivered. At that point, inconvenience and added cost might prevent beneficiaries from changing to generic alternatives.

Discount Negotiation and Disclosure

FMI applauds the requirement in the rule that card sponsors report the total percentage of manufacturer discounts being passed on to Medicare beneficiaries to CMS. While we appreciate CMS's belief that setting a minimum percentage to be passed along

might actually create a ceiling for discounts to card enrollees, we believe that some sort of minimum threshold is needed. FMI suggests that card sponsors agree to pass-through to their enrollees a percentage of manufacturer price concessions that is at least equal to the average percentage amount passed on to enrollees by all of the card sponsors in the program. Competition for beneficiaries would still leave incentives for sponsors to pass through greater percentages of manufacturer rebates and price concessions.

Also, FMI is concerned that because of the way the program is structured, card sponsors will attempt to secure most of their discounts from pharmacies. We feel that this will hurt our retail members, but would also result in lower discount levels for card enrollees. Card sponsors should be encouraged to seek the bulk of the discounts they will offer beneficiaries from pharmaceutical manufacturers and ensure that pharmacies are adequately reimbursed for their services.

III. Pharmacy Operations and the Discount Card

Much of the operation of the Medicare-approved drug discount card program will be governed, from the perspective of FMI's pharmacy members, by the contracts our members have with card sponsors. For instance, those contracts will require:

- That pharmacies offer card enrollees the lower of their usual and customary price or the negotiated discount price;
- That pharmacies notify an enrollee "at the time of purchase" about the lowest-priced generic equivalent of any product being dispensed;
- That pharmacies collect and administer coinsurance under the transitional assistance component of the drug card;
- That beneficiaries receive negotiated discounts that include manufacturer rebates at the point of sale; and
- That pharmacies offer various types of information at the point of service for beneficiaries inquiring about discount levels, transitional assistance balances and other elements of the program.

FMI appreciates CMS's position in all of these areas, but wishes to highlight some of the operational concerns with each of these requirements. First, since it will not be immediately transparent to the pharmacist at the point of sale whether or not the pharmacy's usual and customary price for a senior citizen will be lower than the negotiated rate of that senior's discount card, a pharmacy may need to adjudicate each transaction twice at the point of sale or otherwise establish separate systems to allow a price comparison. Moreover, different card sponsors may create different mechanisms for handling the "lower-of" requirement. CMS should provide appropriate guidance on the preferred means of implementing this requirement so that pharmacies will not be subject to conflicting or differing standards.

Similarly, the requirement that pharmacies notify enrollees “at the time of purchase” about their lowest priced generic equivalents for a product will also require either multiple adjudications of the sale or separate systems in place to link each covered drug with a lowest-price generic if one exists. Importantly, it is unclear from the rule or the other documents released by CMS whether all card sponsors will require pharmacies to notify beneficiaries of lower priced generics *before* purchase or after a product has been dispensed. FMI would urge CMS to clarify that sponsors should uniformly apply this requirement preferably at the time at which the prescription is given to the pharmacist and before the prescription is purchased so that the enrollee will have the opportunity to consider receiving one of several possible less expensive generic alternatives.

With respect to the administration of transitional assistance benefits, FMI applauds the requirement that pharmacies will be “held harmless” if card sponsors make errors about transitional assistance amounts. However, our members are concerned about how transitional assistance funds will be administered and, in particular, if pharmacies will encounter lengthy delays in receiving reimbursement for prescriptions dispensed to transitional assistance enrollees if card sponsors are unable to collect from CMS in an efficient manner. We appreciate the guidance CMS has given on the potential waiver of coinsurance, but we would also like the final rule to ensure that card sponsors do not require pharmacies to be “at risk” for uncollected coinsurance amounts under this program by preventing pharmacies from declining to fill prescriptions until applicable coinsurance amounts are collected.

FMI is also concerned about the requirement that manufacturer rebates be shared with beneficiaries as part of the negotiated prices offered by card sponsors (and not as rebates passed through to beneficiaries when they are received). Typically, when a pharmacy dispenses prescriptions that are covered by third party payers, the pharmacy is paid a set reimbursement amount negotiated by the PBM in question. Any rebates received from manufacturers as a result of this sale are shared between the PBM and the employer or other entity providing the coverage. Thus, the pharmacy is not a party to the rebate transaction in this situation. Conversely, under the rule, beneficiaries will be charged discounted prices that would include some portion of negotiated manufacturer rebates. Systems will have to be established for card sponsors to reimburse pharmacies for the portion of any negotiated price that is attributable to manufacturer rebates or price concessions. FMI believes that pharmacies should not be subject to delays in payment during the period before these rebates are collected and urges CMS to require card sponsors to reimburse pharmacies promptly for these rebate amounts.

FMI understands that many of these issues are complex. We offer CMS the availability of our members who are expert in pharmacy operations to discuss various ways that these issues can be resolved. Successful resolution of these questions is vital, not only to the success of the Medicare-approved discount card program, but also to

ensure that proper systems are established to ensure the smooth and efficient operation of the overall drug benefit established by MPDIMA.

IV. Protecting Discount Card Enrollees

As the discussion in Part III of these comments suggests, there are a number of areas where differing decisions about implementation may occur. Throughout the implementation process, maintaining simplicity and convenience for enrollees in the Medicare-approved discount card should be the top priority of CMS and card sponsors. FMI believes that standardization of the way the card programs will operate will be the most effective means of realizing this goal. FMI applauds CMS's many initiatives in this area that have occurred so far, and offers the following as suggestions to continue these important efforts.

For example, FMI strongly supports CMS's decision to oversee information and outreach efforts to ensure that discount card programs are accompanied by easy-to-understand materials backed by call centers with toll-free numbers and quality response times. The association suggests that a few additional requirements could further efforts in this area:

- All discount cards should follow standard electronic formats that meet the standards of the National Council for Prescription Drug Programs (http://www.ncdp.org/PDF/basic_guide_to_standards.pdf). Standardization in this area will ensure ease of administration and use at the point-of-service and a common framework for card sponsors and pharmacies operating card programs.
- Each card should include the card sponsor's toll free number and a list of the states in which the card operates. Call centers should have a mechanism for beneficiaries to quickly determine where the nearest participating pharmacy is. As noted above, card sponsors should be encouraged to extend their pharmacy networks beyond the borders of their programs so that beneficiaries that live near the borders of card programs who may choose to purchase their prescriptions in states adjoining their state of residence. Note, too, that some Medicare recipients have dual seasonal residences that are in states that are not necessarily geographically proximate, e.g., New York and Florida.
- The grievance process established under the rule should apply to all facets of the program—including any applicable mail-order programs.

FMI believes that these suggestions will help to protect enrollees in various discount cards and improve confidence in the program as whole. Efforts to improve understanding of the operations of the Medicare-approved discount card program among enrollees may also improve the confidence of these potential beneficiaries in the overall drug benefit established by MPDIMA.

Finally, FMI strongly favors CMS efforts to provide general information to beneficiaries who are eligible for the discount card. Such outreach efforts by CMS are greatly needed to help seniors understand the nuances of the discount card program in terms of enrollment policies, the use of formularies by drug card sponsors, information on lower-cost generics, and the levels of drug manufacturer discounts that will be made available to enrollees.

However, we have some concerns about the posting of price comparison information on the CMS website. FMI urges CMS to make price comparison information as “user friendly” as possible. We understand that CMS intends to give drug card sponsors the option of reporting on a plan-by-plan level or to subdivide their reports into regions or to report on a pharmacy-by-pharmacy basis. We are concerned that potential drug card enrollees may be confused if they are attempting to choose between two plans that are reporting prices at different levels. CMS might instead use a standard region—such as the state level—to report maximum pricing levels.. This would be easier to administer and could help to mitigate beneficiary confusion. In any case, the price comparison website should include a strong educational component so that enrollees can understand fully the variations in pricing that they may encounter at the pharmacy level if drug cards are not required to report on a standardized basis.

We would also urge CMS to emphasize in its price comparison information that prices will be adjusted as frequently as once a week to reflect price changes, especially price increases on the part of pharmaceutical companies and drug card sponsors. By adopting these suggestions, CMS will be able to more accurately convey drug pricing information to beneficiaries so that they will be able to understand which drug card plans offer more generous discounts to enrollees.

Moreover, in this regard, we wish to commend CMS on its recently established electronic systems to share information with regulated entities, particularly the listserv established for new information about the drug card.. Depending on the frequency with which CMS intends to post information on its website regarding pricing or other operational changes that may impact the relationship between pharmacists and beneficiaries, it would be helpful if CMS would consider establishing a similar mechanism to communicate significant changes to the public, rather than to place an affirmative burden on pharmacies or others to continually monitor the CMS website on the chance that CMS might be posting information.

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V. Conclusion

FMI appreciates the opportunity to comment on the interim final rule and hopes to establish an open and collaborative relationship with CMS as the Medicare-approved discount card program moves forward and as the agency begins to implement the longer term drug benefit. For the pharmacies that we represent, and the Medicare beneficiaries that these pharmacies serve, successful implementation of the Medicare-approved discount card program 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. We will follow-up with appropriate agency officials in the coming days.

Thank you very much for all of your work on the Medicare-approved discount card and other issues of importance to Medicare beneficiaries.

Sincerely,

A handwritten signature in cursive script, reading "John J. Motley III".

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