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Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Room 443-G
Washington, DC 20201

Re: Medicare-Endorsed Prescription Drug Card Assistance Initiative; File Code: CMS-4027-P

Dear Sir or Madam:

The Food Marketing Institute (FMI) respectfully submits the following comments in response to a rule proposed by the Centers for Medicare and Medicaid Services (CMS) to establish the Medicare-Endorsed Prescription Drug Card Assistance Initiative. 67 Fed. Reg. 10262 (March 6, 2002).

For your information, 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 domestic member companies operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion, which represents three-quarters of all grocery store sales in the United States.

FMI's retail members also operate approximately 8,800 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. Because of the growing importance of pharmacy within our industry and in recognition of the fact that supermarket pharmacies offer a wide range of health care products and services to seniors, FMI offers the following comments to this proposed rule.

FMI commends CMS for its efforts to encourage Congress and the private sector to work together to make medications more accessible and affordable for older Americans. As CMS may know, FMI strongly supports enactment of legislation (H.R. 3626) sponsored by Reps. Jo Ann Emerson (R-MO) and Mike Ross (D-AR) that would provide a comprehensive drug benefit to seniors under the Medicare program. In addition, we are very encouraged by the recent announcements of a number of private sector programs, such as the PharmacyCareOneCard and the Together Rx Card, which will offer significant savings on prescription drugs to qualified Medicare beneficiaries. These private sector programs will provide some immediate price relief to needy seniors as Congress works toward developing consensus Medicare reform legislation that would include an outpatient drug benefit.

Nonetheless, FMI opposes the proposal CMS recently issued for a Medicare-Endorsed Prescription Drug Card Assistance Initiative because we believe that CMS lacks the statutory authority to implement such a program under Medicare. Clearly Congress does not believe that CMS has such authority given the fact that federal lawmakers are actively considering numerous legislative measures that would either establish a Medicare outpatient drug benefit or provide Medicare beneficiaries with access to more affordable medications through a discount card program. Bills of this type have been sponsored by Republicans and Democrats in both the House and Senate. Indeed, on May 1, 2002, the Speaker of the House, Dennis Hastert (R-IL) unveiled the Republican Party's Principles for Medicare Prescription Drug Coverage, which include provisions to grant the Secretary the legislative authority necessary to promulgate a drug discount card program.

Congress previously established an outpatient drug benefit for seniors with the enactment of the Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360), which was, at the time, the largest expansion of benefits provided under the Medicare program since its inception in 1965. Unfortunately, the Medicare Catastrophic Coverage Act was subsequently repealed leaving seniors without drug coverage. Thus, it is FMI's position that CMS is not presently authorized to implement any initiative relating to outpatient drug coverage under Medicare until Congress grants such authority through enactment of appropriate legislation.

The U.S. District Court for the District of Columbia apparently holds the same view. In September 2001, the Court ruled that CMS does not have the statutory authority to implement a discount drug card program under Medicare. See National Ass'n of Chain Drug Stores v. Thompson, No. 01-1554 (D.D.C. 2001). As a result, the Court enjoined CMS from moving forward with the Medicare Rx Discount Card Program, which had been described in an information collection request submitted to the Office of Management and Budget. See 66 Fed. Reg. 37563 (July 18, 2001). In response to a request from the Department of Justice, the U.S. District Court further ruled that CMS would be permitted to issue a new proposal if accompanied by an explanation of the legal authority that the Department of Health and Human Services (HHS) would use as a basis to implement a Medicare discount drug card program.

From our review of the latest CMS proposed rule for a Medicare-Endorsed Prescription Drug Card Assistance Initiative, FMI believes that the program is substantially similar to the July 2001 drug card plan that was enjoined by the court on the basis that the agency lacked sufficient statutory authority to issue such a program. As Congress has yet to enhance the scope of CMS's authority to include the development of a prescription drug benefit for seniors, we believe that the current program suffers from the same infirmity and, therefore, will also be deemed beyond the scope of CMS's statutory authority by a reviewing court.

CMS, however, claims that the statutory provisions cited in the preamble to the proposed rulemaking provide a sufficient legal basis upon which to proceed with the instant proposal. See 67 Fed. Reg. at 10263-64. For example, CMS proposes to base the regulation upon the authority contained in Section 4359(a) of the Omnibus Budget Reconciliation Act of 1990 (OBRA) (Pub. L. 101-508), which authorizes the Secretary to "establish a health insurance advisory service program…to assist Medicare-eligible individuals with the receipt of services under the Medicare and Medicaid programs and other health insurance programs." The preamble further claims that Section 4359(c)(1)(B) of OBRA authorizes the Secretary to "provide for information, counseling, and assistance for Medicare-eligible individuals" with respect to benefits, whether or not the benefits are covered by Medicare. According to the CMS proposal, the statute is broadly written, with section 4359(c) authorizing the Secretary to provide "such other services as the Secretary deems appropriate to increase beneficiary understanding of, and confidence in, the Medicare program and to improve the relationship between beneficiaries and the program."

In our view, the statutory provisions cited by CMS are quite straightforward. They allow the Secretary to function as an educational resource by providing seniors with information regarding benefits and services that are available under Medicare and Medicaid. In addition, these sections permit the Secretary to make information available pertaining to private sector health insurance programs, as well as information about those benefits that are not covered by Medicare, such as outpatient prescription drugs. However, the instant proposal is significantly more than an information provision program: its express purpose is to rely upon the proposed restrictive criteria as a basis to select and endorse certain Medicare-chosen entities to provide services to Medicare beneficiaries. The development of a complex bureaucracy to select and endorse specific pharmaceutical programs is substantially beyond the statutory authority granted to CMS to advise beneficiaries about services currently available to them.[1]

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[1] As an example of the type of activity its authorizing statute supports, CMS cites the "Guide to Choosing a Nursing Home," developed by CMS, which discusses long-term care options outside Medicare coverage. See 67 Fed. Reg. at 10263. The instant proposal is a far more substantial legal and regulatory undertaking than a guide that sets forth some characteristics that beneficiaries might consider when choosing a nursing home.

The CMS proposal further relies upon sections 1102 and 1871 of the Social Security Act, which provide the Secretary with general rulemaking authority as "may be necessary to the efficient administration of the functions with which" he is charged. From this general authority, CMS claims that "facilitating beneficiary access to lower-cost prescription drugs, and improving their access to other valuable pharmacy services, will lead to greater efficiency in the Medicare program" because beneficiaries might be more inclined to follow their drug regimens, which, in turn, might affect their need for Medicare-covered services. 67 Fed. Reg. at 10264.

Although FMI agrees that the Social Security Act grants general rulemaking authority to the Secretary, the Secretary is still only allowed to exercise such authority within the substantive bounds of the statute. That is, the Secretary's general rulemaking authority is restricted by the substantive areas over which he is charged, which do not include the development of a major beneficiary initiative for providing outpatient drug coverage to seniors under the Medicare program.

The preamble lastly cites Section 1140 of the Social Security Act, which prohibits use of the word "Medicare" in a manner that a person knows or should know would convey the false impression that an item is approved, endorsed, or authorized by the Department. 67 Fed. Reg. at 10264. The agency essentially stands this prohibition on its head to claim that, since the false use of "Medicare" endorsement is never permitted, the accurate use of "Medicare" endorsement must always be permitted. See 67 Fed. Reg. at 10264. Although private organizations are authorized to represent that they participate in the Medicare program, such participation is in programs for which there is a sufficient statutory basis. See, e.g., 42 U.S.C. § 1395ss(a). Section 1140 does not give CMS the authority to develop entirely new Medicare-endorsed programs beyond the scope of the authority given to the agency by Congress.

In terms of the Department's commitment to promoting beneficiary access to lower-cost medications, it is interesting to note that when the 106th Congress enacted the Medicine Equity and Drug Safety Act of 2000 (MEDSA), which allows the Secretary to issue rules governing the importation of less expensive prescription drugs into the United States, HHS refused to promulgate final regulations.

In closing, FMI appreciates the opportunity to comment on the Medicare-Endorsed Prescription Drug Card Assistance Initiative, but we believe that HHS and CMS lack the statutory authority to promulgate a regulation of this nature. Accordingly, FMI respectfully requests that CMS withdraw this proposal.

Sincerely,

Deborah R. White
Regulatory Counsel