May 3, 2002

The Honorable Thomas Scully
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 309-G, Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Medicare-Endorsed
Prescription Drug Card Initiative (CMS-4027-P)

Dear Administrator Scully:

The Office of Advocacy respectfully submits the following comments on the Medicare-endorsed Prescription Drug Card Initiative. The Office of Advocacy of the U.S. Small Business Administration was created in 1976 to represent the views and interests of small businesses in Federal policy making activities.[1] The Chief Counsel for Advocacy participates in rulemakings and other agency actions when he deems it necessary to ensure proper representation of small business interests. In addition to these responsibilities, the Chief Counsel monitors agencies' compliance with the Regulatory Flexibility Act (RFA), and works with Federal agencies to ensure that their rulemakings demonstrate an analysis of the impacts that their decisions will have on small businesses.[2]

Introduction

On March 6, 2002, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the *Federal Register* concerning the Medicare-Endorsed Prescription Drug Card Initiative (hereinafter the Prescription Drug Rule).[3] Advocacy appreciates CMS's effort to provide prescriptions at reduced prices to uninsured low income and senior citizens. Advocacy welcomes the opportunity to help CMS assess potential impacts of the rule on small business and is confident that CMS will take steps prior to finalizing the rule to minimize adverse affects on small businesses.

[1] Pub. L. No. 94-305 (1976). (codified as amended at 15 U.S.C. §§ 634a-g, 637)
[2] Pub. L. No. 96-354, 94 Stat. 1164 (1981). (codified as amended at 5 U.S.C. §§ 601-612)
[3] 67 Fed. Reg. 10262 (March 6, 2002).

The health care system in the United States has come to rely on independent and chain pharmacies, especially in low income and rural areas. For example, pharmacists are allowed to administer inoculations in an effort to assure that all citizens are protected against communicable diseases. The importance of small pharmacies is highlighted in the rule by CMS. CMS notes that the U.S. Small Business Administration defines a small pharmacy as being one that has revenues of $5 million or less annually (NAICS code 446110 or SIC code 5912). Based on this definition and Census Bureau data, there are 20,126 pharmacy firms that qualify as small businesses, amounting to 96.7% of the total number of pharmacies (20,815). Further, data provided in the rule indicates that small pharmacies represent 25.3% of all pharmacy sales in the U.S.

In Advocacy's opinion, the proposed Prescription Drug Rule will adversely impact small pharmacies and other small entities. CMS concedes as much in the rule by noting, "Whether measured from a firm or establishment perspective (as reflected in Census Bureau data), the proposed Medicare-endorsed drug discount card initiative may involve some impact on a substantial number of small businesses."

I. CMS's Economic Projections as Outlined in the Regulatory Impact Analysis Need Improvement

While Advocacy applauds CMS for providing a Regulatory Impact Analysis (RIA), the analysis is incomplete. The RFA requires administrative agencies to consider the effect of their actions on small entities, including small businesses, small non-profit enterprises, and small local governments.[4] When an agency issues a rulemaking proposal, the RFA requires the agency to "prepare and make available for public comment an initial regulatory flexibility analysis [IRFA]" which will "describe the impact of the proposed rule on small entities." [5]

The law states that an IRFA shall address the reasons that an agency is considering the action; the objectives and legal basis of the rule; the type and number of small entities to which the rule will apply; the projected reporting, record keeping, and other compliance requirements of the proposed rule; and all Federal rules that may duplicate, overlap or conflict with the proposed rule. The agency must also provide a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.[6]

In its RIA, CMS estimated the cost as a percent of revenue for the typical small pharmacy under two scenarios: one where the small pharmacy is located in a community with the national average rate of program participation and another where participation is expected to be extremely high.

[4] 5 U.S.C. §§ 601, et. seq.; Northwest Mining Association v. Babbitt, 5 F. Supp. 2d 9, (D.D.C. 1998).
[5] 5 U.S.C. § 603(a).
[6] 5 U.S.C. § 603(c).

The CMS analysis shows that under a typical participation rate, small pharmacies would incur a cost representing approximately 1% of revenue. Under the high participation rate, the cost would be 2.4% of revenue. CMS stated that it considers any impact that exceeds 3-5% of revenue to be significant and when compared with this, the cost (as a percent of sales) doesn't appear unreasonable.

Advocacy is concerned about CMS's assumption that small pharmacies will only suffer an economic impact of 1% of revenue. Groups testifying before the U.S. House of Representatives Small Business Committee in October 2001 stated that many pharmacies operate with 2% profit margins; that is, profit represents 2% of revenue. If small pharmacies' costs represent 1-2% of revenue, it follows that those costs represent 50-100% of profit. Further, at the hearing, one witness testified that in West Virginia, where a drug-discount card similar to the one CMS is advocating was launched, seniors saved about 10% on the cost of their prescriptions. At the same time, the local pharmacy's gross profit on those prescriptions fell 37%. In the Prescription Drug Plan, CMS assumes seniors will be able to save 12% on their prescriptions – at what cost to small participating pharmacies?

Advocacy appreciates CMS's preparation of the RIA that was published within the proposed rule. We urge CMS to take the next step and consider alternatives that would be less burdensome on small businesses while still meeting the underlying goal of the proposed rule.

II. The Draft Rule May Result in Banning Small Pharmacies From Participation in the Plan

Under the proposal, small pharmacies will be required to meet certain requirements for participation in the drug sponsorship program. A sponsor will be required to, among other things, (1) obtain substantial manufacturer rebates or discounts on brand name drugs, and provide the discounts to Medicare beneficiaries; (2) have the capability to enroll all Medicare beneficiaries who wish to participate (estimated to be at least 1 to 10 percent of the 10 million participants); (3) have at least a 5-year record as a national (operate in all 50 States and the District of Columbia and currently serve at least 2 million covered lives) or regional (providing service in at least two contiguous states) retail pharmacy network; (4) have the capability of serving at least 90% of Medicare beneficiaries that live within 10 miles of a contracted pharmacy.

The average small pharmacy will not be able to meet the criteria necessary for participation in the program based on very basic economies of scale principles. CMS acknowledges this stark reality by stating, "We believe that the organizational size and experience requirements would be necessary to assure beneficiary confidence in the initiative. We do not think it would be practical and therefore possible for independent pharmacies to obtain an endorsement." Because small pharmacies will have difficulty obtaining endorsement, CMS should examine alternatives as is required by the RFA.[7]

[7] Id.

Advocacy offers the following to guide CMS in their consideration of alternatives that can be taken to minimize the proposal's impact on small pharmacies.

III. Allow Small Pharmacies to Participate in the Plan

While Advocacy appreciates CMS's mention of flexibility allowing small entities to pool together to meet the plan's requirements, we believe that falls short of what is needed to encourage small pharmacy participation in the plan. Advocacy suggests that CMS consider waiving the barriers to entry for small pharmacies. CMS should recognize the value small pharmacies play in the service to those Medicare beneficiaries who need prescriptions by simply endorsing small pharmacies' plan participation.

Another approach that deserves consideration would be for CMS to grant any small pharmacy the right to choose whatever sponsorship program it wishes to join, especially in rural or under-served areas.

IV. A Fixed Negotiation Fee for Pharmacy Benefit Management Organizations (PBMs) May Help Level the Playing Field for Small Pharmacies

The rule assumes that it will be to the Medicare-endorsed sponsor's benefit to assimilate small pharmacies into their program voluntarily, especially in rural areas. An unfortunate likelihood will be that sponsors shut out small pharmacies for fear that inclusion will endanger their profit margin. This leaves small entities in a difficult position – either don't participate in the plan, pool together in large enough numbers to be able to negotiate reduced rates with pharmaceutical manufacturers, or align with one of the large sponsors to ensure Medicare-endorsement.

If small pharmacies can pool together, their transaction costs should be minimized. Advocacy is concerned that the proposed rule's administrative costs will prohibit small pharmacies from pooling together.

The potential exists that the PBM will negotiate the reduced pharmaceutical rates with the manufacturers and keep any rebates offered by the manufacturers leaving the retail pharmacies to pick up the cost of the discount. This also serves to limit the discount drug benefit that is expected to be passed along to Medicare beneficiaries. This scenario could prove fatal to small pharmacies that are already facing reduced revenue by participating in the plan.

Advocacy believes that one way that CMS could assure that any discount is passed on to the consumer would be to offer the PBM a fixed negotiating fee. This would minimize the chance that the PBMs would pass on the cost of the reduced rates to small businesses.

V. CMS's Creation of a "Consortium of Sponsors" May Not Adequately Protect Small Businesses' Right of Participation in the Program

The rule indicates that after the first year, administration of the plan will be undertaken by a "consortium of sponsors." Advocacy believes that the final rule should more thoroughly address how the program is to be administered and what, if any, enforcement rights are being delegated to the consortium. What happens if a Medicare-endorsed sponsor perpetrates fraud or harms millions of Medicare beneficiaries in some other manner? Who is ultimately responsible – the Federal government, the sponsor consortium, or the Medicare-endorsed sponsor? Is there a guarantee that the consortium will address any anti-competitive practices that may arise between small pharmacies and the large sponsors?

Advocacy submits that the appropriate Federal agencies should have jurisdiction and access to the necessary information to prevent abuse of the program or anti-competitive practices. We recommend that the questions be answered in the final rule by a more transparent exploration of how the consortium of sponsors will work.

VI. Consider a Database to Help Independent Pharmacies Participation in the Plan

Along with the less burdensome alternatives discussed above, CMS could offer to develop and maintain a database of names and contact information of independent pharmacies interested in participating with others in a drug plan.[8] Such a database would serve to reduce small pharmacies' search costs. CMS could also offer to provide guidance and a template of an acceptable plan which small businesses considering banding together could adopt and tailor to their needs when attempting to form a pool.

VII. Conclusion

In conclusion, the proposed rule presents a number of significant issues for small business concerns. As written, CMS's proposal could exclude small pharmacies from meaningful participation in the program, effectively barring them from market entry. Advocacy is confident that CMS will take this into account in the drafting of the final rule.

In summary, CMS should consider the following recommendations made by Advocacy:

- Advocacy believes that one way that CMS could assure that any discount is passed on to the consumer would be to offer the PBM a fixed negotiating fee. This would minimize the chance that the PBMs would pass on the cost of the reduced rates to small businesses.

[8] A similar database was established by the Office of Advocacy with the cooperation of the Securities and Exchange Commission to provide a mechanism whereby small business entrepreneurs could reach accredited investors to fund their businesses.

- Advocacy believes that the rule should provide more mechanisms for sponsors to partner with small retail pharmacies in an effort to maximize the rule's benefits to Medicare beneficiaries especially in low income and rural areas.

Considerations of these alternatives, a more thorough description of how the consortium will operate, and a more complete regulatory impact analysis will undoubtedly result in a better final product. Thank you for consideration of our views and please do not hesitate to contact Advocacy to pursue any of these options.

Sincerely,

\s\

Thomas M. Sullivan
Chief Counsel for Advocacy

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Linwood L. Rayford, III
Assistant Chief Counsel for Advocacy