(4) If the Medicare endorsement of a prescription drug card program is terminated, either by CMS or by the sponsor, enrolled Medicare beneficiaries may enroll in a different Medicare-endorsed prescription drug card program at any time.

(b) *Group enrollment.* (1) The prescription drug card program sponsor may accept group enrollment from health insurers and must assure —

(i) Disclosure to Medicare beneficiaries of the intent to enroll them as a group;

(ii) Disclosure to beneficiaries of the enrollment exclusivity restrictions and other enrollment rules of the initiative;

(iii) Disclosure to beneficiaries of all expected uses of their personal information under the endorsed drug discount program; and

(iv) Written consent is obtained and maintained from each beneficiary in the group to be enrolled in the drug card program.

(2) Medicare+Choice (M+C) organizations may subsidize the enrollment fee and offer the drug card program as part of their Adjusted Community Rate filing, but may not require enrollment in a drug card program as a condition of enrollment in any of their M+C plans.

§ 403.812 Withdrawal of endorsement.

If CMS obtains evidence that a Medicare-endorsed prescription drug card program or its sponsor has failed to meet any of the requirements for endorsement or has not complied with the agreement necessary to receive endorsement under this subpart, CMS may withdraw the endorsement. CMS may also take appropriate intermediate actions, and may also refer the card program sponsor to appropriate Federal or State authorities, including the Office of the Inspector General, for sanctions or prosecution under section 1140 of the Social Security Act.

§ 403.820 Oversight and beneficiary education.

(a) The Medicare-endorsed prescription drug card program sponsor must report to CMS the number of Medicare beneficiaries enrolled in, and disenrolled from, the Medicare-endorsed prescription drug card program on a form and at times specified by CMS.

(b) The Medicare-endorsed prescription drug card program sponsor must maintain a customer grievance process acceptable to CMS.

(c) CMS will conduct beneficiary education about, and oversight of, the Medicare-endorsed prescription drug card programs, as determined by CMS.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 18, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 18, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 02–5129 Filed 2–28–02; 4:00 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 403

[CMS–4032–ANPRM]

RIN 0938–AL30

Medicare Program; Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative for State Sponsors

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This advance notice of proposed rulemaking cross-references the proposed rule entitled ''Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative'', published elsewhere in this **Federal Register** issue. This advance notice of proposed rulemaking describes how States could partner with private discount card sponsors under that proposed rule, and outlines additional steps that the Department of Health and Human Services (HHS) is considering to propose in support of current State efforts to make more readily available affordable prescription drugs to Medicare beneficiaries, including efforts to help low income Medicare beneficiaries access lower prices for prescription drugs.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 6, 2002.

ADDRESSES: In commenting, please refer to file code CMS–4032–ANPRM. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4032–ANPRM, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Room 443–G, Washington DC 20201, or Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Room C5–16–03, Baltimore, MD 21244–1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Debbie Van Hoven, (410) 786–8070.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, telephone (410) 768–7197.

I. Background

In a related proposed rule entitled, ''Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative'', published elsewhere in this **Federal Register** issue, we propose providing assistance and education to all Medicare beneficiaries, and especially those without prescription drug coverage, to lower their out-of-pocket prescription drug costs. We would provide a Medicare endorsement to reputable and high quality private sector prescription drug discount card programs, based on requirements designed to make the best use of the strengths of the private sector. We would also educate beneficiaries about the private sector tools these programs would use, so that beneficiaries who could benefit from a prescription drug discount card would be able to compare and understand which Medicare-endorsed card would best meet their needs. While it would be possible for States to cooperate and partner with

these private sector programs under that proposed rule, a State would not be allowed to apply directly to us to have its own privately administered prescription discount card program endorsed by Medicare. This advance notice of proposed rulemaking outlines additional steps that the Department of Health and Human Services (HHS) is considering to propose in support of current State efforts to make more readily available affordable prescription drugs to Medicare beneficiaries, including efforts to help low income Medicare beneficiaries access lower prices for prescription drugs.

With limited exceptions, the Medicare benefit package currently does not include an outpatient prescription drug benefit. While approximately 73 percent of Medicare beneficiaries have drug coverage at any given time (under, for example, employer-sponsored retiree health plans or Medicaid), an estimated 10 million have no drug coverage. Without access to the discounts and rebates that come with most kinds of prescription drug coverage, many beneficiaries either pay list prices for drugs or have access only to drug discount programs that include modest discounts at the pharmacy. These beneficiaries often do not have access to many of the valuable services offered by some drug benefit and drug assistance programs, including services such as drug interaction and allergy monitoring. Further, a substantial share of beneficiaries have little experience with choosing among prescription drug plans, as envisioned in almost all Medicare drug benefit proposals being considered by the Congress. This, along with our need to operationalize such a complex benefit, implies a substantial ''lead time'' for successful implementation of a prescription drug benefit. In his fiscal year 2002 and 2003 budgets, the President proposed adding a prescription drug benefit for all Medicare beneficiaries. In the interim, before the Medicare drug benefit can be enacted and fully implemented, the President believes that beneficiaries should have access to rebates or discounts from pharmaceutical manufacturers on prescription drugs, as well as to the pharmaceutical management services that are commonly available in good private insurance plans.

The objectives of the private sector oriented Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative described in the proposed rule published elsewhere in this **Federal Register** issue would be to:

- Educate Medicare beneficiaries about private market methods available for securing substantial discounts from manufacturers and other competitive sources on the purchase of prescription drugs.
- Provide a mechanism for Medicare beneficiaries to gain access to the effective tools widely used by pharmacy benefit managers and pharmacies to get higher quality pharmaceutical care, for example, monitoring for drug interactions and allergies.
- Publicize information (including drug-specific prices, formularies, and networks) to facilitate easy consumer comparisons that would allow Medicare beneficiaries to choose the best card for them.
- Enhance and stabilize participation of Medicare beneficiaries in effective prescription drug assistance programs, increasing the leverage and ability of these programs to negotiate manufacturer rebates or discounts for Medicare beneficiaries and to provide other valuable pharmacy services.
- Enhance the quality and use of Medicare-covered services by improving access to prescription drugs.
- Endorse qualified private sector prescription drug card programs (either for profit or non-profit), based on structure and experience; customer service; pharmacy network adequacy; ability to offer manufacturer rebates or discounts (passing through a substantial portion to beneficiaries, either directly or indirectly through pharmacies), and available pharmacy discounts; and permit endorsed entities to market their programs as Medicare-endorsed.
- Provide Medicare beneficiaries a low (in Year One, $25 maximum) or no-cost opportunity to enroll in a Medicare-endorsed prescription drug discount card program.

To receive a Medicare endorsement, private prescription drug discount card program sponsors would be required to apply for endorsement, demonstrate that they meet all of the requirements concerning: (1) applicant structure, experience and participation in the administrative consortium; (2) customer service; and (3) rebates, discounts and access; and enter into a formal agreement with us.

The proposed requirements for Medicare endorsement are tailored to reflect the strengths of the private market place to provide Medicare beneficiaries with high quality services, as well as to protect the integrity of the initiative, beneficiaries, and the Medicare name from firms with questionable business practices.

While we believe that all of these requirements are important to assuring best practice in the private sector, we do not believe they are all well suited for States that are already sponsoring privately administered discount card programs. For example, the definition of a regional sponsor includes providing service in at least two contiguous states. Clearly a single State would not meet this criterion.

Private sector drug discount program sponsors also would have to agree to abide by the guidelines of, jointly administer, and fund a privately run administrative consortium, intended, among other roles, to review and approve sponsors' marketing materials. It is not clear that a State would be able to participate in and fund such an administrative consortium as a full member, as contemplated in the proposed rule.

Additionally, some customer service standards and the specific beneficiary confidentiality requirements for private sector sponsors may not be appropriate for States, as their infrastructure to support the public is designed to serve a myriad of needs, and these requirements are intended to protect Medicare beneficiaries, a goal already shared and being acted upon by States.

Also, some State programs may currently enroll other populations, as well as Medicare beneficiaries. A State may need flexibility to design its program to be more inclusive in order to be consistent with its public mission. In particular, some State programs may be targeted to people with low incomes, including Medicare beneficiaries. Similarly, States may also want flexibility concerning the requirements to accept all Medicare beneficiaries and to limit enrollment to only Medicare beneficiaries. For example, some States may have prescription drug discount programs for some segments of the Medicare population, such as only those 65 years old and older, or for larger segments of the senior population beyond those eligible for Medicare, such as those age 60 and older.

Under the private sector initiative described in the proposed rule published elsewhere in this **Federal Register** issue, States would be able to partner with private discount card program sponsors by selecting a Medicare-endorsed program and offering its own endorsement, and having a distinct card that reflects the State endorsement. States would not be given a Medicare endorsement for a discount card program. Rather, States could provide their own endorsement of a private sector discount card program that was also endorsed by Medicare, with the following restrictions.

One restriction would be that the private sector program would be required to continue to operate for the

State as it is defined in the private drug discount card program sponsor's agreement with us. Specifically, we would allow drug formularies and prices to vary geographically, but they could not vary among different populations in the same area. Also, the endorsed discount card program would only enroll Medicare beneficiaries. Further, the card program would have to be available to all Medicare beneficiaries in a State, and we would not allow it to be restricted to only certain Medicare beneficiaries, such as those age 65 and over, or those with certain levels of income. However, different populations could be segmented for marketing purposes provided the marketing materials would not mislead or intentionally misrepresent to the public the nature of the endorsed program, and marketing activities would include marketing to beneficiaries with disabilities, beneficiaries with End-Stage Renal Disease (ESRD), and beneficiaries age 65 and over.

II. Purpose of Advance Notice of Proposed Rulemaking

We are aware that a number of States are implementing privately administered programs that would lower the out-of-pocket prescription drug costs of low income Medicare beneficiaries. Some of these State programs parallel the proposed Medicare private sector initiative published elsewhere in this **Federal Register** issue in three important aspects—using voluntary market participation, obtaining manufacturer rebates or discounts, and administering the programs through private enterprise. State programs contain different design elements to secure discounts on prescription drugs for Medicare beneficiaries.

We are particularly interested in exploring cooperative approaches we could pursue with the States to support the types of State initiatives that, like the proposed Medicare private sector initiative, rely on market forces and on the private sector for administration. These are structures that underlay Medicare drug benefit proposals being seriously considered by the Congress. Concerning market forces, we are specifically considering support for State programs in which the rebates and discounts are driven by competition for market share rather than by mandated levels. The experience gained under these State initiatives would inform policy makers as Medicare drug benefit proposals are being debated, and would assist beneficiaries, government, and the market place in preparing for a Medicare drug benefit.

We invite comments on a possible Medicare endorsement of States efforts to lower beneficiaries' out-of-pocket costs for prescription drugs, using market-based strategies. For example, one consideration regarding State programs is whether the requirement under the private initiative to obtain rebates or discounts from drug manufacturers and share them with beneficiaries should apply to State efforts as well. We are aware that some State drug discount programs, at least initially, have not included manufacturer rebates or discounts that are passed on to consumers.

Concerning State partnerships under the proposed private sector initiative published elsewhere in this **Federal Register** issue, we invite comments to better understand State-specific circumstances under which we would consider a private sponsor's agreement with us to vary from the required terms and conditions. Specifically, we would like to understand whether we should allow enrollment beyond Medicare beneficiaries, for example to include people with low incomes, or allow targeting of deeper discounts to low income Medicare beneficiaries, in order to help align the terms of our endorsement with the State's objectives to assist consumers in lowering their out-of-pocket spending on prescription drugs and accessing high quality prescription drug services.

III. Objectives of the Advance Notice of Proposed Rulemaking

We are considering issuing a proposed rule that would provide Medicare endorsement for State efforts built on market principles and private sector administration to make more readily available affordable prescription drugs to Medicare beneficiaries, including efforts to help low income Medicare beneficiaries access lower prices for prescription drugs, where these efforts also parallel the objectives of the proposed Medicare Endorsed Prescription Drug Card Assistance Initiative.

We believe that the statutory authorities cited in the related proposed rule entitled, ''Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative'', published elsewhere in this **Federal Register** issue, would also support an initiative to endorse State sponsored efforts that provide access to lower cost prescription drugs for Medicare beneficiaries. Access to more affordable prescription drugs would assist beneficiaries in receiving services under Medicare and other health insurance programs, because this access could lead them to more effectively or efficiently use Medicare services, such as physician or hospital services. Endorsement of State sponsored drug discount programs would also improve beneficiary understanding of the various tools and programs available for receiving rebates and discounts on prescription drugs and for improving the pharmacy services they receive.

Accordingly, we are considering a proposal to provide Medicare assistance in the form of an endorsement for, and beneficiary education about, State programs for those States that volunteer to apply for the Medicare endorsement and meet the following objectives:

- Educate Medicare beneficiaries about market-based methods available for securing substantial discounts from manufacturers and other competitive sources on the purchase of prescription drugs.
- Provide a mechanism for Medicare beneficiaries to gain access to the effective tools widely used by pharmacy benefit managers and pharmacies to get higher quality pharmaceutical care, for example, monitoring for drug interactions and allergies.
- Publicize information (including drug-specific prices, formularies, and networks) to facilitate easy consumer comparisons that would allow Medicare beneficiaries to choose the best card for them.
- Enhance and stabilize participation of Medicare beneficiaries in effective drug assistance programs, increasing the leverage and ability of these programs to negotiate manufacturer rebates or discounts for Medicare beneficiaries and to provide other valuable pharmacy services.
- Enhance the quality and use of Medicare-covered services by improving access to prescription drugs.
- Endorse qualified State sponsored prescription drug card programs that are privately administered and for which lower prescription drug prices are driven by competition, using criteria concerning: structure and experience; customer service; pharmacy network adequacy; ability to offer manufacturer rebates or discounts (passing through a substantial portion to beneficiaries, either directly or indirectly through pharmacies), and available pharmacy discounts; and permit States to market their programs as Medicare-endorsed.
- Provide Medicare beneficiaries a low (in Year One, $25 maximum) or no-cost opportunity to enroll in a Medicare-endorsed prescription drug discount card program.

We invite comments on the appropriateness and adequacy of these objectives for States assisting consumers, particularly Medicare beneficiaries, in lowering their out-of-pocket costs for prescription drugs and improving the accessibility and quality of prescription drug services using market based approaches.

We request comments on the appropriateness of the qualifications requirements for selecting States for endorsement concerning: (1) Applicant structure, experience, and relationship with the administrative consortium; (2) customer service; and (3) rebates, discounts, and access, as found in Section I.E of the proposed rule cross-referenced in this advance notice of proposed rulemaking, and published elsewhere in this **Federal Register** issue. We also request comments on other terms of the proposed initiative described in that proposed rule, as they would apply to State sponsored drug discount card programs.

IV. Response to Comments

Because of the large number of comments we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, we will consider all comments we receive by the date and time specified in the **DATES** section of this advance notice of proposed rulemaking, and will address these comments in any proposed regulation that results from this advance notice.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 18, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 18, 2001.

Tommy G. Thompson,

Secretary.

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