DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 403

[CMS–4027–P]

RIN 0938–AL25

Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would describe the Department of Health and Human Services' (HHS) Medicare-Endorsed Prescription Drug Card Assistance Initiative, and set forth the necessary requirements to participate in the initiative. This proposed rule also cross-references an advance notice of proposed rulemaking entitled ''Medicare Program; Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative for State Sponsors'', published elsewhere in this **Federal Register** issue, outlining steps that we are considering proposing in support of State efforts to make more readily available affordable prescription drugs to Medicare beneficiaries.

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–4027–P. 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–4027–P, 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

A. History of the Initiative

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 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 the valuable services offered by some drug benefit and assistance programs, including services such as drug interaction, allergy monitoring, and advice on how medication needs might be met at a lower cost. Further, a substantial share of beneficiaries have little experience with choosing among prescription drug assistance plans as envisioned in almost all Medicare drug benefit proposals being considered by the Congress. This, along with the need for us 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 pharmaceutical management services that are commonly available in good private insurance plans.

On July 12, 2001, the President announced an initiative that would create a Medicare-Endorsed Prescription Drug Discount Card program to assist Medicare beneficiaries in accessing lower cost prescription drugs and better advice on using them, and understanding the private sector methods that are used to reduce prescription drug costs and improve the quality of pharmaceutical services. We published a notice in the **Federal Register** on July 18, 2001 (66 FR 37564) that contained the application we planned to use to select the entities eligible for the Medicare endorsement. Based on comments received on that application, we issued a revised application on August 2, 2001 on our Web site at *http://www.cms.gov.*

On September 11, 2001, the United States District Court for the District of Columbia issued a preliminary injunction against this Medicare-Endorsed Prescription Drug Discount Card program. *National Ass'n of Chain Drug Stores* v. *Thompson,* No. 01–1554 (D.D.C. 2001). In accordance with that order, we have ceased all work on implementing that program. Although we had received 28 proposals for the drug discount card endorsement in response to our August 2, 2001 solicitation before the September 11, 2001 order, we will not make any Medicare endorsements on the basis of those proposals.

On October 10, 2001, we filed a Motion for Stay with the United States District Court for the District of Columbia asking that the case giving rise to the preliminary injunction be stayed while we engage in notice and comment rulemaking on a modified prescription drug discount card program. On November 5, 2001, the court issued an order granting the Motion for Stay while we submit our proposed policy for comment by publishing this proposed rule in the **Federal Register**. By publishing this proposed rule, we are formally withdrawing the program described in the **Federal Register** on July 18, 2001. We are instead soliciting comments on all aspects of the proposed Medicare-Endorsed Prescription Drug Card Assistance Initiative described in this proposed rule.

This proposed rule describes a program that differs in important respects from the Administration's initial proposal, for example, by requiring card sponsors to obtain substantial manufacturer rebates or discounts, requiring that manufacturer rebates or discounts be shared with

beneficiaries directly or indirectly through pharmacies, and considering that the administrative consortium have an advisory body.

Furthermore, in an advance notice of proposed rulemaking entitled, ''Medicare Program; Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative for State Sponsors,'' published elsewhere in this issue of the **Federal Register**, we outline additional steps that we are considering to propose in support of State efforts to make more readily available affordable prescription drugs to Medicare beneficiaries.

The parameters of the initiative may change further based on the public comments we receive in response to this proposed rule.

If the plaintiffs in the case mentioned above believe that the initiative published in the final rule is substantially similar to the program that was described in the July 18, 2001 **Federal Register**, we expect that before implementation of that initiative, the plaintiffs would seek further judicial review, which could result in a delay in implementation.

B. Statutory Basis for Initiative

For several years we have considered ideas for obtaining significant discounts on prescription drug prices and higher quality drug services for Medicare beneficiaries. After exploring various means of enhancing the purchasing power of Medicare beneficiaries, we propose to use the authority granted to the Secretary under several statutes to achieve private purchasing power for Medicare beneficiaries by educating them about accessing certain qualified prescription drug discount programs.

First, under section 4359(a) of the Omnibus Budget Reconciliation Act of 1990 (OBRA)(Pub. L. 101–508), the Secretary is authorized 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.'' Under section 4359(c)(1)(B) of OBRA, the Secretary is authorized to ''provide for information, counseling, and assistance for Medicare-eligible individuals'' with respect to benefits, whether or not covered by Medicare. 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''. Section 4359(f) of OBRA expressly anticipates that there will be ''other health insurance informational and counseling services'' for Medicare-eligible individuals.

We believe that this proposed initiative would meet the definition of a beneficiary assistance program because it would assist Medicare beneficiaries not just with their utilization of Medicare-covered services, but also with the receipt of services common under other health insurance programs. Access to more affordable prescription drugs would assist beneficiaries in receiving services under Medicare and other health insurance programs, since access could lead them to more effectively or efficiently use Medicare services, such as physician or hospital services. We also believe that this Medicare-Endorsed Prescription Drug Card Assistance Initiative would be a valuable educational tool for beneficiaries. It would improve their understanding of how to access prescription drug discounts, as well as increase their understanding of the private sector tools currently used to lower prescription drug costs and improve the quality of pharmaceutical services.

Outpatient prescription drugs generally are not a covered benefit under Medicare. However, we believe that access to prescription drugs is so fundamental to the delivery of modern health care benefits that beneficiaries should receive information, counseling, and assistance regarding the prescription drug discount programs. Section 4359(b) of OBRA already instructs the Secretary to provide education and assistance not just about Medicare-covered benefits, but also about benefits not covered by the Medicare program. For a number of years we have offered Medicare beneficiaries education and assistance in accessing several non-covered benefits that are complimentary to Medicare, Medicaid, and other health insurance programs. Our ''Guide to Choosing a Nursing Home'' discusses long-term care options outside Medicare coverage, including assisted living, subsidized senior housing, and private long-term care insurance. We provide further education to beneficiaries regarding options for long-term care, such as adult day care and community-based services, many of which are not covered by Medicare. Finally, we provide educational assistance concerning prescription drugs. For example, the Medicare Web site (*http://www.Medicare.gov*) provides information on programs that offer discounts or free medication to individuals in need. Beneficiaries may access information on pharmaceutical companies or associations that offer assistance programs for those with low incomes, on available State assistance programs, or on community-based programs available in their area. This Web site also provides a link to an article on internet pharmacies.

Moreover, by enhancing the buying power and knowledge of beneficiaries, we believe that we will further the Congressional goal in section 4359(c) of OBRA of ''increas[ing] beneficiary understanding of, and confidence in, the Medicare program and * * * improv[ing] the relationship between beneficiaries and the program.''

Beneficiary confidence in the program would be enhanced by education about drugs that are a critical component of comprehensive health care, and by facilitation of the means by which beneficiaries can purchase drugs at a discounted price and obtain other valuable pharmacy services. This proposed initiative would allow beneficiaries to make more efficient and effective use of their Medicare services, as well as benefits that may be available to them under Medigap plans, employer-sponsored group health plans, retiree health insurance, or other health insurance programs. We believe that the broad provisions of section 4359 of OBRA permit us to pursue these important objectives. (*See Texas Gray Panthers* v. *Thompson*, 139 F. Supp. 2d 66, 76 (D.D.C. 2001)), finding that section 4359 of OBRA is ambiguous in defining what types of ''information, counseling, and assistance'' are to be provided, and therefore deferring to the Secretary's reasonable interpretation of the statute).

Finally, in the United States District Court case mentioned previously, the judge made a preliminary finding that section 4359 of OBRA did not provide the necessary legal authority for the program published in the **Federal Register** on July 18, 2001. We anticipate that, if the plaintiffs believe that the final rule is substantially similar to the program announced July 12, 2001, they will seek further judicial review. The comments submitted on this issue, and our responses to them, would assist the court in any future review of the policy. If there are commenters who wish to address whether the Secretary has sufficient authority under the statute, we also invite them to comment on how the initiative could be structured to reflect their views.

We believe that sections 1102, 1140 and 1871 of the Social Security Act (the Act) also support the creation of this proposed initiative. Sections 1102 and 1871 of the Act provide the Secretary

with general rulemaking authority. Section 1102 of the Act provides the Secretary with the authority to publish such rules and regulations as ''may be necessary to the efficient administration of the functions with which'' he is charged. 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. For example, with improved access to prescription drugs, beneficiaries would be more inclined to follow their drug regimens, which could affect their need for Medicare-covered services.

Prescription drugs are an integral part of treatment of virtually all medical problems, and Medicare beneficiaries are more likely to have multiple and complex medical problems. Therefore, easier access to drug price comparisons, greater beneficiary access to affordable prescription drugs and expertise on how to use them will lead to more effective and efficient use of items and services covered by the Medicare program. Courts have acknowledged that the authority under section 1102 of the Act is ''broad,'' (*National Welfare Rights Organization* v. *Mathews*, 533 F.2d 637 (D.C. Cir. 1976)) and have even stated that a ''more plenary great (sic) of rule-making power would be difficult to devise.'' (*Serritella* v. *Engleman*, 339 F.Supp. 738, 752 (D.N.J.), aff'd per curiam, 462 F.2d 601 (3d Cir. 1972)).

Section 1140 of the Act also supports the Secretary's creation of this initiative. That section, among other things, prohibits misuse 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 Health Care Financing Administration (the predecessor to the agency CMS) or the Department of Health and Human Services. By prohibiting the use of the term ''Medicare'' to convey the false impression that an item is approved or endorsed by us, the statute implicitly recognizes that the impression may be accurate and authorized in some circumstances. Thus, section 1140 of the Act, in combination with the educational and assistance authority of section 4359 of OBRA, as well as the general rulemaking authority of sections 1102 and 1871 of the Act, provides further support for the Secretary to endorse qualified entities as being approved by the Medicare program.

C. Objectives of Proposed Initiative

The objectives of this proposed initiative 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 discount card programs (either for profit or nonprofit), 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.

We invite comments on all aspects of this proposed rule. We specifically solicit comments on whether additional objectives or requirements should be considered. We also welcome comments on whether beneficiaries currently have adequate information and understanding of the pharmaceutical management services that can help patients use prescription drugs more effectively—such as monitoring for drug interactions and allergies, services to help patients manage chronic illnesses, and education about drug side effects and how they can be managed or avoided. We welcome comments on whether the beneficiary population would benefit from easily being able to compare the formularies, discounts, drug prices, and pharmacy networks of prescription drug discount card programs.

We also invite comments from beneficiaries and others regarding how access to lower cost prescription drugs and to better information on using prescription drugs effectively would improve beneficiary use of Medicare-covered services, and whether this access would result in more efficient use of these services. We welcome comments that include examples of how access to discounted prescription and related services may improve a medical condition.

D. Overview of the Proposed Initiative and Requirements for Endorsement

1. General

We propose to endorse prescription drug card programs that meet defined requirements, and to permit successful applicants to market and label their programs as ''Medicare-endorsed.''

The proposed Medicare-Endorsed Prescription Drug Card Assistance Initiative would publicize information that would allow Medicare beneficiaries to compare endorsed prescription drug card programs, assist Medicare beneficiaries in understanding and accessing private market methods for securing discounts and other valuable services associated with the use of prescription drugs, and raise beneficiary awareness of certain qualified prescription drug card programs available in the commercial market.

Aspects of the proposed initiative would include the ability of each Medicare-endorsed drug card program sponsor to:

- Obtain substantial manufacturer rebates or discounts on brand name drugs, and provide a substantial portion of the manufacturer rebates or discounts to beneficiaries, either directly or indirectly through pharmacies, in order to reduce the price beneficiaries pay for prescription drugs or enhance the pharmacy services they receive.
- Enroll all Medicare beneficiaries who wish to participate.
- Provide discounts on at least one brand name or generic prescription drug in each of the therapeutic drug classes, groups, and sub-groups representing prescription drugs commonly needed by Medicare beneficiaries.
- Offer a broad national or regional contracted retail pharmacy network, providing convenient retail access.
- Charge no fees to us, or any other Federal agency.
- Charge a small one-time enrollment fee (of no more than $25 per beneficiary in Year One) or no fee.
- Provide customer service to beneficiaries, including enrollment

assistance, toll-free telephone customer service help, and education about the card program services, including any other prescription drug services offered by the program for no additional fee, such as drug interaction monitoring, and allergy alerts.

• Ensure that beneficiaries enroll in only one Medicare-endorsed prescription drug discount card program at a time, so as to facilitate obtaining discounts from drug manufacturers on their behalf.

• Provide notice to beneficiaries of the expected uses of beneficiary information and obtain authorization from each enrollee for the sharing of beneficiary-specific information necessary for the operation of the drug discount card program. Also, obtain separate authorization from each enrollee for sharing information for any purpose other than the operation of the aspects of the discount card program that are part of the endorsement.

• Agree to jointly administer, and abide by the guidelines of, a private administrative consortium funded by Medicare-endorsed discount card program sponsors, to perform administrative functions, consisting of publishing information on drug prices, operating an enrollment exclusivity system, and, by the second year of the initiative, assuming review of marketing materials. The administrative consortium would be financed by the Medicare-endorsed card sponsors.

We are proposing that drug discount card program sponsors in the proposed initiative would be required to limit enrollees in their Medicare-endorsed discount card programs to Medicare beneficiaries. Card sponsors could request the beneficiary's Medicare number or use other means to assess Medicare eligibility. We would not provide data or assistance to verify Medicare eligibility.

Drug discount card program sponsors in this proposed initiative would be able to accept groups of enrollees from insurance groups, such as Medicare+Choice (M+C) plan members, Medigap enrollees, and beneficiaries with employer-sponsored retiree health insurance. If they accept group enrollments, we would require the discount card program sponsors to advise each member of the group of the enrollment exclusivity requirement and other enrollment rules, expected uses of their personal information under the discount card program, and obtain the consent of each member of the group to be enrolled in the discount card program. Members who do not consent to group enrollment would be allowed to enroll individually in the endorsed program of their choice.

We propose to allow M+C organizations to subsidize the enrollment fee and to offer the drug discount card program as part of their Adjusted Community Rate filing, however they would not be allowed to require enrollment in a drug discount card program as a condition of enrollment in any of their M+C plans.

In addition, we believe that this proposed initiative would improve upon the current drug card market. The market-based design of this proposed initiative, and its ability to mimic many of the important design features of an insured product, would give Medicare-endorsed drug discount card programs features that current market products generally do not have.

This proposed initiative would improve upon the current market in several important respects by:

• Securing manufacturer rebates or discounts, and passing them through pharmacies or directly to beneficiaries, resulting in deeper discounts.

• Educating Medicare beneficiaries about formularies, generic substitution, drug utilization review, and other ways of lowering prices and improving the quality of pharmacy services.

• Ensuring that Medicare beneficiaries receive the lower of the negotiated drug discount card price or the pharmacy's lowest price to other cash paying customers.

• Providing the opportunity for Medicare beneficiaries to enroll in a low- or no-fee Medicare-endorsed prescription drug discount card program.

In a recently released report from the General Accounting Office (GAO) entitled ''Prescription Drugs: Prices Available Through Discount Cards and From Other Sources'' (December 5, 2001), the GAO collected specific price data on 12 brand name and 5 generic commonly used prescription drugs from one regional and four large discount card programs, as well as pharmacies' prices for the same prescription drugs in four selected geographic areas. Some of the pharmacies' prices reported included pharmacy discounts, others did not. The GAO simply reported prices on the 17 drugs; they did not calculate average discount card savings. The average discounts that could be calculated from the GAO reported data are difficult to compare to our estimate of roughly 10 to 13 percent savings off total beneficiary drug spending for several reasons.

First, while the impact analysis is built on an assumption of savings of 10 to 13 percent off total drug spending, we believe that more savings may be possible, depending on the ultimate design of card sponsors' programs. If Medicare-endorsed discount card programs rely heavily on the use of formularies, we expect that manufacturer rebates and discounts would be greater in response. We solicit comments and data on how to maximize manufacturer rebates and discounts.

Second, savings for the proposed initiative are not estimated on a per-prescription basis. For certain drugs for which manufacturer rebates or discounts are secured, we expect to see, under this initiative, drug-specific discounts comparable to insured products, which are often 25 to 30 percent or sometimes more per prescription.

Finally, the price data collected by the GAO do not include all drugs or indicate the relative market share that each drug represents; that is, they are not weighted. Savings estimates calculated by simply averaging selected drug prices do not account for the differences in utilization, and thus, market share.

2. Administrative Consortium Start-Up

Medicare-endorsed drug discount card program sponsors would be expected to fund the cost of administering their own drug card program, in addition to the activities of the administrative consortium. We would not pay for enrollment, management, participation, or any other cost associated with any drug discount card program.

However, we do anticipate providing some financial support toward the start-up of the consortium and its administrative activities, which in Year One would include operating and maintaining an enrollment exclusivity system and a web site for comparing drug prices among the Medicare-endorsed discount card programs. We would expect the administrative consortium to be operational no later than the first day that Year One enrollment may begin. That date would be announced in the final rule. We anticipate providing technical support and identifying options for the administrative consortium's structure, its financial arrangements, system to ensure enrollment exclusivity, and a web site to be used to compare drug prices. Further, we would develop a short-term administrative operating plan for the administrative consortium, and assist the consortium in a short-term transition to full operation.

We would expect the drug card sponsors to share in these start-up costs, as well as to be responsible for the

assurance that the administrative consortium structure and its operation adhere to Federal and State laws, and for the execution of any legal arrangements for the consortium's formation and the implementation of the administrative tasks.

Drug card program sponsors would be required to make a lump sum payment to a privately held escrow account as a term of endorsement to cover anticipated start-up costs to be incurred by the administrative consortium. We propose that the payment amount, which would be estimated by our contractor and may not represent payment in full for these start-up activities, would be prorated by the number of States included in each endorsed card program's network area, weighted by the number of Medicare beneficiaries residing in each State (and Washington, DC). This would not necessarily be the allocation methodology for any additional start-up costs or ongoing costs of the administrative consortium. One possible method for covering costs after the card program sponsors have gained experience would be to allocate costs based on a program's number of Medicare enrollees. We welcome comments on these allocation methods and alternative methods and rationale.

We solicit information on existing systems with the capacity to assure exclusive enrollment and web-based technology that could be used to compare prices. We would like to understand what data or systems variations we could expect across card programs that would need to interface with an exclusivity system and the price comparison web site.

In addition to supporting the administrative consortium start-up, it is our plan for us to be fully responsible in Year One for developing marketing guidelines and conducting review of marketing materials under a technical support contract. We propose that the consortium would assume this responsibility, beginning in Year Two, using guidelines we would develop. The administrative consortium would be free to use independent contractors to perform the review of marketing materials, as well as other consortium functions.

3. Education, Marketing and Other Services

Medicare-endorsed drug discount card program sponsors would be expected to administer and market their discount card program and educate Medicare beneficiaries about the program. In order to secure rebates and deeper discounts for beneficiaries, Medicare-endorsed drug card program sponsors would have the discretion to use formularies, patient education, pharmacy networks, mail order, and other commonly used tools. However, beneficiaries would always have the option to purchase drugs outside of a Medicare-endorsed card program and pay the retail price or a discount price secured through existing non-endorsed cards or some other means, as they do now. Further, pharmacies sometimes offer special prices on drugs for promotional purposes to the general public. If these prices are lower than the price that could be obtained through the drug card program, the card sponsor would be expected to arrange with its network pharmacies that these lower prices must also be made available to Medicare beneficiaries to the extent the drugs are included in the card program's formulary.

We propose that we also would educate beneficiaries about the Medicare-endorsed drug card assistance initiative, both at the time it is announced and as part of ongoing education efforts thereafter. We would create and authorize the use of a Medicare-endorsed prescription drug discount card assistance emblem. We would highlight the Medicare-endorsed drug card assistance initiative in Medicare publications, such as brochures, and in the pre-enrollment package that is sent to all beneficiaries when they become eligible for Medicare. We propose to provide general information about the initiative on the Medicare web site (*http://www.medicare.gov*). We propose to include on our web site information for each discount card program of the following types: Contact information, including toll free telephone numbers for individual programs; identification of the program's web site; enrollment fee; and customer service hours.

Since other prescription drug related services, such as drug interaction notification, drug allergy notification and pharmacy counseling, could improve the overall quality of the card program, we propose to identify these services on our web site as well, provided they are not associated with a separate fee. Additionally, we would consider reporting on our web site the card program sponsor's performance on reliable quality and satisfaction standards pertaining to the card program operation, customer service, and its network's pharmacy services (including the adequacy of the network for underserved populations and populations at risk for health disparities). We request comments on, and information about, available quality measurements, including whether they are standardized and reliable, how they are or could be reported, and whether they would be meaningful to beneficiaries in their selection of a drug discount card program.

We propose that the information made available on our web site also be available to Medicare beneficiaries through the toll-free Medicare information line (1–800–MEDICARE), which is available 24 hours per day, 7 days a week.

Although not required to do so, drug card sponsors could provide other services to beneficiaries who enroll in their card programs. These services could include both drug-related services or items for a fee, such as disease management, and additional non-drug-related services or items, whether for a fee or not, such as discounts on dental services and prescription eyeglasses. These services would not be covered, however, by the Medicare endorsement. Therefore, although program sponsors would be allowed to market these other services to Medicare beneficiaries who are enrolled in their drug discount card programs, they would not be allowed to describe the services as being Medicare-endorsed, or associate them directly with the Medicare endorsement. Sponsors also would be allowed to send marketing materials for these items and services only to those beneficiaries enrolled in their drug discount card programs that elect to receive these materials.

Card program sponsors would be required to follow our marketing guidelines, including the standards we develop for use of the Medicare endorsement emblem. Guidelines would also cover the presentation of the emblem and other information on each program sponsor's discount card.

We recognize that the prescription drug and pharmacy industries are moving toward electronic transmission systems for prescription transactions, due to their inherent efficiencies, and that various systems are being tested. We also recognize that some in the industry are interested in standardization of certain identification information cards.

We would like to better understand the state of development, testing, and market readiness for electronic transmittal of prescription transactions and the standardization of identification information. We solicit comments on how these advances could be implemented to improve the efficiency and effectiveness of individual card programs, and how they could interact with the Medicare-endorsed prescription drug card assistance

initiative to better prepare us, the marketplace, and beneficiaries for a future Medicare drug benefit.

We would like to better understand the present limitations of these electronic transmittal systems, such as electronic signatures, and the efforts to standardize identification information for the card. We also solicit comments on any barriers that might be imposed by the use of these advances in the Medicare-endorsed drug card initiative. For example, we would like to understand if there are competitive advantages and disadvantages to us or the card program sponsors of requiring the pharmacy networks to use electronic transmittal systems of accepting only standardized identification information on the cards.

4. Manufacturers Rebates or Discounts

The name ''Medicare'' is extremely valuable and highly regarded by the nearly 40 million Medicare beneficiaries. Medicare focus groups have indicated that virtually all seniors recognize the name ''Medicare''. We believe its name recognition is so strong that it is unlikely to be duplicated in the commercial market.

As a result of the Medicare endorsement, Medicare name recognition, and education of Medicare beneficiaries, we anticipate that Medicare-endorsed drug discount card program sponsors would have increased visibility for their discount drug programs, which would lead to significant enrollment by Medicare beneficiaries. We expect that the attributes of this proposed initiative, coupled with exclusive enrollment, would provide card sponsors with the ability to negotiate significant drug manufacturer rebates or discounts. We expect that competition among card sponsors and, in turn, drug manufacturers to attract beneficiaries through lower prices and other valuable prescription related services would assure that manufacturer rebates or discounts are shared with Medicare beneficiaries either directly or indirectly through pharmacies.

We would require that Medicare-endorsed drug discount card program sponsors obtain substantial manufacturer rebates or discounts on brand name drugs and pass a share of those rebates or discounts through to beneficiaries either directly or indirectly through pharmacies. These requirements would be structured to promote better drug prices for beneficiaries or to enhance pharmacy participation in a card sponsor's network. In particular, card sponsors would be required to have contractual arrangements with drug manufacturers for rebates or discounts and a contractual mechanism for passing on the bulk of rebates or discounts that are not required to fund operating costs to beneficiaries or pharmacies. Card sponsors would be required to have contractual agreements with pharmacies ensuring that the rebates or discounts would be passed through to the Medicare beneficiaries in lower prices or enhanced pharmacy services. Further, we would like to structure these requirements so they do not discourage use of generic drugs.

We request comments concerning other purchasers' experiences with rebates or discounts, such as the level of rebate or discount for brand name drugs (the average amount over a specified unit or a rebate or discount percentage off a stated price), the portion of brand name drugs on a formulary for which rebates or discounts are provided, and efforts to sustain the use of generic drugs in spite of manufacturers' rebates or discounts on brand name drugs. We would also be interested in receiving reliable data on the experience under insurance products and estimates on what could be achieved under a drug discount card program given the proposed design. We would also like to better understand the effects of various levels of rebates or discounts and negotiating strategies on market competition and their impact on the use of generic drugs.

Further, we solicit comments on information and data or experiences of other purchasers regarding the level of rebates or discounts that are shared with purchasers as clients of pharmacy benefit managers, enrollees, and pharmacies. We invite comments on factors to be considered to achieve the objective of ensuring that rebates or discounts are passed through to beneficiaries. Specifically, we are interested in comments that provide information and data on how to account for factors addressed in contracts with employers such as operational expenses and profitability of card sponsors in determining what portion of the rebate or discount must be passed through. We are particularly interested in reliable data to demonstrate a reasonable level of pass through to beneficiaries, taking into account the factors noted above, or other factors that should be considered. We are also interested in the experience in the insurance market with sharing rebates or discounts with pharmacies to support discounts or as incentives for participation in networks, or the funding of other services, such as pharmacy counseling, and any reliable data to support this experience. We also are interested in information and data on the impact of rebates or discounts on the price paid for drugs.

We also solicit comments regarding existing or new operations models to provide rebates or discounts to beneficiaries (such as an estimate of additional manufacturer discount at the point of sale or a periodic rebate check or credit toward further prescription purchases) and to pharmacies (such as quarterly payments based on volume of drugs sold). This includes comments regarding whether the Medicare drug card program could provide easier access for eligible beneficiaries to several recently announced drug manufacturer discount programs. We would like to consider the strengths and limitations of any model, how it could be implemented, and whether to require a particular model.

We also request comments on, and examples of, the necessary processes, as well as time and other constraints associated with negotiating manufacturer rebates or discounts and assuring they are reliably shared with beneficiaries either directly or indirectly through pharmacies. We solicit comments on how to incorporate these considerations into our proposed requirement for substantial manufacturer rebates or discounts on brand name drugs, which would largely be given directly to beneficiaries, but could also be shared with pharmacies to enable them to offer larger discounts or other services, such as pharmacy counseling.

Finally, we solicit comments on proposed approaches for communicating information on the effect of rebates or discounts on prices that beneficiaries would pay at the retail pharmacy.

5. Partnering Opportunity for State Sponsored Drug Card Assistance Programs

The Medicare-Endorsed Prescription Drug Card Assistance Initiative is targeted to the private sector marketplace. To receive a Medicare endorsement, private drug 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. These requirements would be tailored to reflect the strengths of the private marketplace, 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 assure best practices in the private sector, we do not believe they are all well suited for States that are already sponsoring privately administered drug card programs. For example, the definition of a regional sponsor includes providing service in at least 2 contiguous States. 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 administrative roles, to review and approve sponsors' marketing materials. Also, some customer service standards and the strict beneficiary confidentiality requirements may not be appropriate for States.

Nonetheless, under this initiative, we propose that States could partner with private drug card program sponsors by selecting a Medicare-endorsed program and offering its own endorsement, and having a distinct card. One restriction would be that the endorsed card program would continue to operate in the State as it is defined in the sponsor's agreement with us. Specifically, we would allow drug formularies and prices to vary geographically, but they would not be able to vary for different populations in the same area. Also, under this initiative, the endorsed discount card program would have to be made 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 activities 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.

In the advance notice of proposed rulemaking entitled, ''Medicare Program; Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative for State Sponsors'', published elsewhere in this issue of the **Federal Register**, we outline additional steps that we are considering proposing to support 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.

E. Other Proposed Requirements

In addition to the requirements listed in section I.D of this preamble, we propose that other requirements to participate in the initiative and receive the Medicare endorsement under this proposed rule would be divided into three categories: (1) Requirements related to the applicant's experience, structure and agreement to jointly administer the administrative consortium; (2) requirements related to customer service; and (3) requirements related to discounts, rebates, and access. We would also require applicants to sign an agreement with us certifying that they would comply with all requirements in the agreement, including funding and operating an administrative consortium to perform certain administrative functions, implementing the program as described in the application, and operating consistently within the endorsement requirements.

We propose that all applicants offering a prescription drug card program that apply for Medicare endorsement and meet or exceed these requirements (in addition to any of the requirements listed in section I.D of this preamble), and sign the agreement would be Medicare-endorsed.

The requirements discussed in this section reflect our interpretations of the standards included in the proposed regulation. We would include these interpretations in an application we would append to the final rule. In addition to receiving comments as a result of this proposed rule, we expect to entertain questions from potential applicants on the application during a 14-day period after approval of the application by the Office of Management and Budget (OMB). We will provide additional details concerning this 14-day comment period in the final rule.

1. Applicant Structure, Experience, and Participation in the Administrative Consortium

The requirements relating to the organization of the drug card program sponsor would include significant private sector experience in the United States in pharmacy benefit management, or the administration of drug discount cards or low income drug assistance programs that provide prescription drugs at low or no cost. We propose to require 5 years experience because the Medicare name is so well known and so important to beneficiaries that we would not want the name to be associated with any but the most stable and reputable organizations. The sponsors whose drug discount cards would be endorsed by Medicare should be those that have the experience and capacity to offer Medicare beneficiaries discounts and good customer service and would be likely to continue in the marketplace. The drug card industry is relatively new and has seen organizations entering and leaving the market in short periods of time. The 5 years of experience provides a sufficient amount of time to adequately demonstrate a reasonable track record of good performance and stability, taking into account the history of the pharmaceutical benefit management and discount card industries. Due to the evidence of market turn over in the discount card industry, we think that requiring anything less than 5 years experience would create the risk of having the Medicare name associated with other than stable and reputable organizations.

The same organization with the five years experience would also have to currently operate a regional or national drug benefit or discount drug card, or low income drug assistance program that provides prescription drugs at low or no cost that serves a certain number of covered lives. We would interpret covered lives to mean discrete individuals who have signed enrollment agreements or paid an enrollment fee or insurance premiums, or some comparable documentation, that we could use for verification purposes. We are proposing that in order to qualify for Medicare endorsement, national program sponsors would have to operate in 50 States and Washington, DC and currently serve at least 2 million covered lives, and regional program sponsors would have to operate in at least 2 contiguous States currently serving at least 1 million covered lives. In selecting a geographic definition for regional (at least 2 contiguous States) we attempted to balance the opportunity for smaller programs to qualify with the interest in assuring beneficiary access to network pharmacies when beneficiaries are traveling across a State line.

Since the Medicare endorsement would likely create a very large pool of beneficiaries who wish to obtain the endorsed discount cards, organizational capacity to handle large numbers of people would be an important factor for qualification. Our data show that over 10 million Medicare beneficiaries are without drug coverage for an entire year. Also, beneficiaries with drug coverage through Medigap and other sources face benefit limitations, and many beneficiaries have coverage for only part of the year. Beneficiaries from all of these groups may likely be interested in

the Medicare-endorsed discount cards. Endorsed card program sponsors would need to be capable of handling a large influx of enrollees over a relatively short period of time, to negotiate rebates or discounts with pharmaceutical manufacturers and discounts with retail pharmacies, and to handle the customer service needs of the enrollees.

As discussed in the impact analysis, we estimate that during the first 6 months of operation, as many as 10 million beneficiaries may wish to enroll in a Medicare-endorsed discount card program. The capacity of a Medicare-endorsed discount card program sponsor to accept from 1 to 10 percent of this volume is critical to implementing the discount card initiative. Current levels of covered lives provide evidence of organizational capacity to handle a large enrollment and provide customer service. As a percentage increase in enrollment for organizations with as many as 1 or 2 million covered lives, a potential enrollment of 100,000 to several hundred thousand individuals represents a sizable expansion over current operations.

In examining our data on the number of covered lives served by a variety of organizations, we found that a standard of 1 and 2 million lives, for regional and national programs, respectively, would strike a balance between ensuring a competitive marketplace with a number of different options for Medicare beneficiaries and ensuring that organizations would have the capacity to handle a large increase in covered lives.

We propose that entities would be able to combine their capabilities to meet the various requirements for Medicare endorsement. If multiple organizations combine to meet these requirements, however, one of those organizations would be required to have the requisite 5 years of experience in pharmacy benefit management, or the administration of a drug discount card or low income assistance program that provides prescription drugs at low or no cost, as well as have served the requisite number of covered lives. For example, if a regional pharmacy chain partners with a pharmacy benefit administrator that has the requisite experience and covered lives (and meets all other requirements for endorsement, either individually or through contracts with other organizations), that regional pharmacy chain's program could receive the Medicare endorsement, even though the regional chain by itself does not currently serve the necessary 1 or 2 million individuals and does not have 5 years experience in pharmacy benefit management or the administration of a drug discount card or low income assistance program that provides prescription drugs at low or no cost. Or, for example, a drug manufacturer that wishes to offer discounts on its prescription drugs to Medicare beneficiaries under the Medicare-endorsed card initiative could make arrangements to have those discounts offered to beneficiaries through a pharmacy chain that has operated a drug discount card program for 5 years and is serving the requisite number of covered lives (and together, or through arrangements with other organizations, meet all other requirements for endorsement).

Further, multiple organizations would be allowed to combine under contract or other legal arrangements to assure that any other requirements would be met without regard to the entity with the 5 years experience and responsibility for covered lives.

In assuring that the Medicare endorsement would only be provided to reputable organizations that would be prepared to administer a discount card program in accordance with all of the requirements of this initiative, we propose that if multiple organizations combine to meet the requirements, including establishing a pharmacy network, negotiating manufacturer discounts and rebates, conducting enrollment, and operating the customer service call center, we would require evidence of legal arrangements between or among the entities combining for this purpose. We would require either contracts or signed letters of agreement to be submitted with the application. For the pharmacy network, we would require one copy of each unique contract or signed letter of agreement used across the entire network. We would require evidence in these documents that manufacturer rebates or discounts shared with the pharmacies would be passed through to the beneficiaries in lower prices or enhanced pharmacy services. We propose that at least the following additional requirements must be satisfied in each of the contracts or signed letters of agreement:

- Clearly identifies the parties to the contract.
- Describes the functions to be performed by the subcontractor.
- Contains language that indicates that the subcontractor has agreed to participate in the discount card program.
- Describes the payment the subcontractor will receive for performance under the contract, if applicable.
- Be for a term of at least 15 months.
- Be signed by a representative of each party with legal authority to bind the entity.
- Contains language obligating the subcontractor to abide by the same State and Federal confidentiality requirements, including those required under the Medicare endorsement, that apply to the applicant in offering its discount card program.

Where legal documentation is provided but does not constitute the actual contract for the purpose of operating the Medicare-endorsed discount card, we would allow the contract to be submitted following receipt of the Medicare endorsement, but we would not allow marketing and enrollment activities to begin until we determine that our requirements for legal agreements are satisfied.

A separate proposal for each drug card program would be required. An organization or entity would be allowed to have operational responsibilities in more than one drug discount card program. However, a sponsoring organization or entity would be allowed to be the primary sponsoring organization or entity in only one card program at any time.

Additional requirements to assure that the Medicare endorsement would be provided to reliable and stable organizations would include a demonstration of financial integrity and business ethics. We would interpret this to mean that the following requirements be met for the applicant, as well as for each of any subcontractors or organizations under other legal arrangements with the applicant to develop the pharmacy network, to handle the negotiation of rebates and discounts on behalf of the card sponsor, or to operate enrollment, and including the entity that meets the 5 years of experience and covered lives requirements:

- Provide a summary of the history, structure and ownership, including a chart showing the structure of ownership, subsidiaries and business affiliations.
- Provide the most recent audited financial statements (balance sheet, income statement, statement of cash flow along with auditor's opinions and related footnotes). Each of these entities must demonstrate that total assets are greater than total unsubordinated liabilities and that sufficient cash flow exists to meet obligations as they come due.
- Report financial ratings, if any, for the past 5 years.
- List past or pending investigations and legal actions brought against any of

these entities (and parent firms if applicable) by any financial institution, government agency (local, State, or Federal) or private organization over the past 5 years on matters relating to health care and prescription drug services and/or allegations of fraud.

Each applicant would be required to provide a brief explanation of each action, including the following:

(a) Circumstances; (b) status (pending or closed); and (c) details as to resolution and any monetary damages, if closed. Additionally, we would conduct an independent investigation to include at least a review of Federal databases for issues related to any of these entities.

Drug discount card program sponsors would also be required to jointly administer, abide by the guidelines of, and fund a private administrative consortium with all other sponsors of Medicare-endorsed discount card programs. The funded administrative tasks would include the following 3 functions: (1) Assuring enrollment exclusivity; (2) reviewing marketing materials; and (3) publishing comparative prescription drug price information for beneficiaries.

This proposed rule would require enrollment exclusivity for beneficiaries because a low-or no-fee card program could otherwise lead beneficiaries to enroll in more than one Medicare-endorsed drug card. Multiple enrollments would dilute the negotiating leverage of each organization offering an endorsed discount card, thereby lowering the discounts from drug manufacturers available to beneficiaries. In order to maximize these discounts, we propose that each beneficiary who enrolled in an endorsed drug discount card program would be required to enroll exclusively in one Medicare-endorsed card program, as is generally the case with programs that provide both discounts on, and insurance coverage of, prescription drug costs. A beneficiary enrolling for the first time in a Medicare-endorsed drug discount card program could enroll at any time of the year. Beneficiaries would be allowed to disenroll at any time and could elect another Medicare-endorsed drug discount card program; however the new enrollment would not become effective until the first day of the following January or July following the date of disenrollment, which ever came first, unless the program in which the beneficiary was enrolled was no longer operating under Medicare's endorsement; in this case the beneficiary could join another card program any time during the year.

The administrative consortium would also be responsible for reviewing marketing materials prepared by the Medicare-endorsed drug discount card program sponsors. In the first year of the initiative, we propose that we would be responsible for developing marketing guidelines and reviewing the marketing materials. Beginning in the second year of the initiative, we propose that the consortium would assume review of marketing materials using guidelines drafted by us. It is essential that marketing materials be reviewed to ensure that the Medicare name is not misused, for example, to market services unrelated to prescription drugs.

Finally, we would require Medicare-endorsed drug discount card program sponsors to publish, through the administrative consortium, comparative information on the prices offered to Medicare beneficiaries for drugs covered by the discount card. To provide time for the administrative consortium to develop a price comparison methodology for the web site that would reflect the actual price a beneficiary would encounter at the point of sale, in the first year, we propose that discounts on the web site be expressed as a percentage off the Average Wholesale Price (AWP) for a standard set of the most commonly used drugs and dosages. By the second year of the initiative, we propose that the administrative consortium would be expected to publish the actual price that Medicare beneficiaries would pay for drugs offered by each Medicare-endorsed discount card sponsor. This comparative information would assist beneficiaries in deciding which Medicare-endorsed discount card would offer them the greatest financial advantage. Since we are proposing that we would allow the discount card program sponsors' formularies and prices to vary geographically and over the period of the Medicare endorsement, we would require that the card sponsors report any price and formulary changes to the administrative consortium, for posting on the consortium's web site, at least 48 hours before the changes would become effective. We solicit comments on whether the consortium web site should also provide other information on card programs, such as prescription drug-related services for no additional fee that are considered part of the Medicare-endorsed card sponsors' programs.

We propose as a qualification requirement that the applicant provide notice to beneficiaries of the expected uses of beneficiary information within the Medicare-endorsed drug discount card program and obtain written authorization from each enrollee for the sharing of beneficiary-specific information necessary for the operation of the discount card program. Also, the applicant would be required to obtain separate authorization from each enrollee for sharing information for any other purpose. This activity would be coordinated with the enrollment process to assure that beneficiaries understand their confidentiality rights as provided under this initiative. Further, enrollment, marketing and any other activities of Medicare-endorsed card programs could not be combined with the functions for non-Medicare-endorsed card services, in order to assure the full protection of a beneficiary's personal information as required under the Medicare endorsement agreement.

2. Customer Service

We are proposing that the one-time enrollment fee for any Medicare-endorsed drug discount card be limited (a maximum of $25 in Year One), and we would encourage Medicare-endorsed card program sponsors to keep their fees as close to zero as possible. We believe this limit would allow some discount card program sponsors to recoup some of their administrative costs through the enrollment fee, so more of the manufacturer rebates could be passed on to beneficiaries, but would not be so prohibitive so as to dissuade beneficiaries from enrolling in the drug card assistance programs.

We further propose that if a beneficiary changed drug card programs, the beneficiary could be charged a separate one-time enrollment fee by the second drug card program. We recognize that the use of a one-time enrollment fee by a card program differs from the current market practice of charging annual fees; we solicit comments on the benefits and disadvantages of also permitting, for example, an annual nominal renewal fee of a maximum of $15.

We would require that the card sponsor provide to Medicare beneficiaries information and outreach regarding the discount card. We would interpret this to mean that the endorsed card programs must disclose, in customer appropriate printed material, to Medicare beneficiaries (prior to enrollment and after enrollment upon request) a detailed description of the program that included contracted pharmacies, enrollment fees (if any), drugs included, and their prices to reflect discounts that are provided to the consumer. We would anticipate that this information would also be made available on the drug card sponsors' web sites and through their enrollment and customer service phone lines. In

addition, card sponsors that provide additional prescription drug quality services for no additional fee, such as drug interaction, allergy alerts, and pharmacy counseling would be expected to educate beneficiaries about the role of and availability of these services, and provide information to us for use on our web site.

We also propose that endorsed card programs would be required to accept all Medicare beneficiaries who wish to participate in the card program. We would expect the endorsed drug discount card programs to maintain methods for enrollment similar to usual business practice—such as accepting enrollees through paper, telephone, fax or Internet. However, the beneficiary confidentiality requirements would also require that the card program sponsor collect and maintain a signed agreement to use a beneficiary's personal information as specified in the statement of expected uses of such data.

In order to be consistent with the beneficiary confidentiality requirements, the requirements also would include a restriction on drug card program sponsors that have received Medicare endorsement that would prohibit them from marketing or sending unsolicited marketing materials concerning other services they offer (including both prescription drug related services that are provided for a separate fee, such as disease management, and nonprescription drug related services whether or not for a fee, such as discounts on dental services and prescription eyeglasses) to beneficiaries who have not actively elected to receive these marketing materials.

We would require each endorsed card program sponsor to maintain a toll-free customer call center to assist beneficiaries in understanding the drug card program offered. We propose that the call center must be open during usual business hours and provide customer telephone service in accordance with standard business practices. We propose to interpret this to mean that the call center would be available at least Monday through Friday from 8 a.m. to 4:30 p.m. Eastern to Pacific Standard times for those zones in which the discount card program would operate. We would also interpret the requirement that the call center be operated in accordance with standard business practices to mean that 70 percent of customer service representatives' time would be spent answering telephones and responding to enrollee inquiries; 80 percent of all incoming customer calls would be answered within 30 seconds; the abandonment rate for all incoming customer calls would not exceed 5 percent; and that there would be an explicit process for handling customer complaints. These standards are required or exceeded by the 1–800 Medicare call center contractors.

3. Discounts, Rebates, and Access

Each drug discount card program would be required to provide a discount for at least one drug identified in the therapeutic classes, groups, and subgroups of drugs commonly needed by Medicare beneficiaries as listed in the application. This requirement would be to assure that beneficiaries enrolling in Medicare-endorsed discount card programs would be offered discounts on many of the types of drugs most commonly needed. The classes, groups and subgroups were developed from self-reported drug utilization data collected under the 1998 Medicare Current Beneficiary Survey (MCBS), and in consultation with Federal experts in pharmacology and using nationally recognized pharmacology classifications. We would anticipate modifying these classes, groups, and subgroups over time in future solicitations to remain current with beneficiary use of drugs and changes in the market, including the emergence of new drug types and drugs removed from the market. These drug groupings are listed on Table 1. Endorsed drug discount card programs would be allowed to vary their formularies by geographic location and over the course of the endorsement period.

We would also require that each drug card program sponsor obtain substantial manufacturer rebates or discounts on brand name drugs and share a substantial portion with beneficiaries, either directly or indirectly through pharmacies.

The table below shows the drug therapeutic classes and groups (and in a few cases, subgroups) that contain the drugs most commonly needed by Medicare beneficiaries.

TABLE 1.—THERAPEUTIC CLASSES AND GROUPS/SUBGROUPS OF DRUGS COMMONLY NEEDED BY MEDICARE BENEFICIARIES

Therapeutic drug classes	Drug groups/subgroups (subgroups where shown are indented)
Nutrients and Nutritional Agents	
Hematological Agents	
	Hematopoietic Agents
	Antiplatelet Agents
	Coumarin and Indandione Derivatives
	Hemorrheologic Agents
Endocrine/metabolic Agents	
	Sex Hormones
	Bisphosphonates
	Antidiabetic Agents
	Insulin
	Sulfonylureas
	Biguanides
	Thiazolidinediones
	Others
	Adrenocortical Steroids
	Thyroid Drugs
	Calcitonin-Salmon
	Agents for Gout
Cardiovascular Agents	
	Inotropic Agents
	Antiarrhythmic Agents
	Calcium Channel Blocking Agents
	Dihydropyridine

TABLE 1.—THERAPEUTIC CLASSES AND GROUPS/SUBGROUPS OF DRUGS COMMONLY NEEDED BY MEDICARE BENEFICIARIES—Continued

Therapeutic drug classes	Drug groups/subgroups (subgroups where shown are indented)
	Others
	Vasodilators 3
	Antiadrenergics/Sympatholytics
	Alpha/Beta Andrenergic Blocking Agent
	Antiadrenergic Agents-Centrally Acting
	Antiadrenergic Agents-Peripherally Acting
	Renin Angiotensin System Antagonists
	Angiotensin—Converting Enzyme Inhibitors
	Angiotensin II Receptor Antagonists
	Antihypertensive Combinations
	Antihyperlipidemic Agents
	Bile Acid Sequestrants
	HMG—CoA Reductase Inhibitors
	Others
Renal and Genitourinary Agents	
	Anticholinergics
	Diuretics
	Thiazides and Related Diuretics
	Loop Diuretics
	Others
Respiratory Agents	
	Bronchodilators
	Leukotriene Modulators
	Respiratory Inhalant Products
	Corticosteroids
	Intranasal Steroids
	Mast Cell Stabilizers
	Others
	Antihistamines
	Cough Preparations
Central Nervous System Agents	
	Analgesics
	Narcotic
	Agents for Migraine
	Others
	Antiemetic/Antivertigo Agents
	Antianxiety Agents
	Antidepressants
	Selective Serotonin Reuptake Inhibitors
	Others
	Antipsychotic Agents
	Phenothiazines/Thioxanthenes
	Butytophenones
	Indoles
	Other Antipsychotic Agents
	Cholinesterase Inhibitors
	Sedatives and Hypnotics, Nonbarbiturate
	Anticonvulsants
	Iminostilbene
	Hydantoins
	Barbiturates
	Deoxybarbiturates
	Succinimides
	Valproic Acid
	Oxazolidinedione
	Benzodiazepines
	GABA Mediating Medications
	Other Anticonvulsants
	Antiparkinson Agents
Gastrointestinal Agents	
	Histamine H2 Antagonists
	Proton Pump Inhibitors
	GI Stimulants
Systemic Anti-Infectives	
	Penicillins
	Cephalosporins and Related Antibiotics
	Fluoroquinolones
	Macrolides
	Sulfonamides
	Antivirals

TABLE 1.—THERAPEUTIC CLASSES AND GROUPS/SUBGROUPS OF DRUGS COMMONLY NEEDED BY MEDICARE BENEFICIARIES—Continued

Therapeutic drug classes	Drug groups/subgroups (subgroups where shown are indented)
	Antiretroviral Agents
Biological and Immunologic Agents	
	Immunologic Agents
Dermatological Agents	
	Anti-Inflammatory Agents
Ophthalmic/Otic Agents	
	Agents for Glaucoma
	Cholinergic
	Sympathomimetic
	Adrenergic Antagonists
	Prostaglandins
	Carbonic Anhydrase Inhibitors
	NonSteroidal Anti-Inflammatory Agents (NSAIDS)
	Anticholinergic
	Muscarinic Antagonists
	Glucocorticoids
	Anti-Infectives
	Mast-cell Stabilizers/Antihistamines
	Other Outpatient Ophthalmologics
Antineoplastic Agents	
	Antimetabolites
	Hormones
	Antiestrogens
	Aromatase inhibitors
	Antiandrogen
Rheumatologicals	
	Nonsteroidal Anti-Inflammatory Agents
	Immunomodulators
	Cox-2 Inhibitors
	Other Rheumatologicals
	Gout Agents (already listed in endocrine/metabolic class above)

Sources: *Drug Facts and Comparisons,* A Wolters Kluwer Company, 2001 edition; *Pharmacological Basis of Therapeutics,* Goodman and Gilman, 9th edition (1996); *Clinical Pharmacology,* Melman and Morelli, 4th edition, 2000

We propose as a requirement that the card sponsors guarantee that participating Medicare beneficiaries would receive, on all prescription drugs included under the card program at the point of sale, the lower of the discounted price available through the program or the price the pharmacy would charge a ''cash'' paying customer at that time.

The discount and access requirements would also require any national or regional prescription drug card program to offer Medicare beneficiaries convenient access to retail pharmacies. We propose to interpret convenient retail access to mean demonstrated contracts with retail pharmacies so that upon the start of marketing and enrollment in the discount card program, at least 90 percent of Medicare beneficiaries in the area served by the program would live within 10 miles of a contracted pharmacy (90/10). We would require that this be demonstrated using mapping software, computed by using one hundred percent of beneficiary counts by zip code (provided by us). We would require the applicant's complete list of contracted pharmacies to be available to beneficiaries for the area included under the Medicare endorsement. While we propose that the 90/10 access requirement would pertain to the largest area covered under the Medicare endorsement (either national or regional), tables generated by the mapping software would have to be submitted at both the State and either regional or national levels, depending on which designation the applicant is seeking. Also, a complete listing of the contracted pharmacies, along with an address, phone number and contact person for each, would have to be submitted.

We solicit comments not only on the overall pharmacy access requirements, but also on whether the requirements should differ by population density across different geographic areas and whether additional consideration should be given to independent pharmacies. For example, while we believe the 90/10 access requirement would generally ensure that Medicare beneficiaries would be close enough to a pharmacy for the discount card to be useful, we recognize that this access standard would allow certain rural areas with limited pharmacy access to be below the 90/10 ratio while having a higher ratio in urban areas in order to meet the overall 90/10 access requirement. We solicit comments on feasible options for raising the ratio in these areas and on current private sector criteria related to access requirements for different types of geographic areas, including adjustments based on population density or pharmacy availability. We also solicit suggestions for performance improvement steps in low-access areas to build up the ratio over time.

In addition, we are concerned about access for certain populations in urban areas. We recognize the value and role of certain small, urban pharmacies that provide linguistically appropriate or culturally sensitive services to Medicare beneficiaries. We solicit comments concerning the role and importance of these pharmacies to underserved populations and other populations that may have special needs. We also solicit comments on how to maintain access to these pharmacies under a Medicare-endorsed drug discount card initiative

for Medicare beneficiaries who depend on them.

Although we would not require the drug discount card program sponsors to include institution-based pharmacies in their pharmacy networks, neither would we preclude their inclusion. Institutionalized beneficiaries whose prescription drugs are covered under Medicare Part A or Medicaid would not be able to use the drug discount cards. Further, we intend for this proposed policy to comport with the requirements of participation for long term care facilities. We solicit comments on whether and how institutionalized beneficiaries who have access to institution-based pharmacies would be affected if they choose to participate in the drug card program initiative, since institution networks are explicitly not required in this program. We would also be interested in better understanding whether and how institution-based pharmacies could participate in the drug card programs.

Drug card program sponsors would not be permitted to offer a home delivery-only (mail order) option to Medicare beneficiaries, since Medicare beneficiaries are accustomed to purchasing prescription drugs from a local pharmacy. However, to provide a choice to beneficiaries who prefer home delivery, endorsed drug card programs would be allowed to include an option to use home delivery via a mail order pharmacy, in addition to the required contracted retail pharmacy network.

4. Time Table and Mechanics of the Endorsement

We would publish in the **Federal Register** the final rule and a solicitation for applications for Medicare endorsement at the same time. We propose that in order to qualify for Medicare endorsement, applicants would be required to submit complete applications by the effective date of the final rule, which would be 60 days after the date it is published. For a 14-day period following publication of the approved solicitation, we would entertain questions from potential applicants to clarify the final application requirements. All applicants who qualify for Medicare endorsement would be announced by the Administrator by a date set in the final rule.

We propose that the endorsement in Year One would be for a period of 15 months. Card program sponsors would be given a period of time following our announcement of the programs we have endorsed to implement their card programs, including finalizing their pharmacy network contracts and negotiating manufacturer rebates or discounts. Sponsors would also use this time to organize and activate the administrative consortium. October 1, 2002 would be the first day that programs would begin marketing and enrollment, and additionally, at their option, begin providing discounts, provided they have a signed agreement with us, approved marketing materials, an operational call center, and completed contracts for all aspects of the program as specified under the requirements. Endorsed programs, however, would be required to begin enrollment and discounts no later than January 1, 2003 in order to participate as an endorsed card program.

5. Oversight

In addition to an application and qualification process to assure that the Medicare endorsement would be provided to reputable, stable entities with the capacity to fulfill our customer service and access, and rebates and discount requirements, we propose requiring that card sponsors have a customer grievance process, and that enrollment and disenrollment reports be submitted to us once every six months in Year One, and thereafter on a schedule to be determined by us. During the endorsement period, drug card program sponsors would be required to notify us of any material modifications to their programs if the modifications could put them at risk of no longer meeting any of the terms of endorsement.

Further, we would educate beneficiaries about the Medicare-endorsed drug card programs and provide information about each endorsed program as described in this proposed rule. We would monitor in Year One, and, beginning in Year Two, the administrative consortium would monitor, to assure that marketing guidelines are being followed. We would develop and operate a complaint tracking system and also refer complaints to Federal and State authorities where violations of laws under the jurisdictions of these agencies are in question. We would reserve the right to terminate any endorsement at any time for violations of the terms of the endorsement. We would consider drug card program sponsor performance under an existing Medicare endorsement as one factor in determining eligibility for endorsement in future annual cycles.

We are considering requiring the administrative consortium to have an advisory board, composed of representatives from beneficiary advocacy groups and pharmacies, as well as from interested public organizations. We invite comments on what groups should be represented, ideas about how the advisory board could provide guidance and oversight and on what issues, and what the advisory board's reporting relationship should be with the consortium. Also, we are interested in comments on practical options concerning standards, conduct, and intermediate corrective action strategies that could be developed to promote public confidence in the administrative consortium and drug card program sponsors' performance.

II. Provisions of This Proposed Rule

In section 403 of Title 42 of the Code of Federal Regulations we would add a new subpart H–Medicare-Endorsed Prescription Drug Card Assistance Initiative, the provisions of which would be as follows:

- We would add a new § 403.800 to describe the basis and scope of the initiative and set forth the requirements for the initiative.
- We would add a new § 403.802 to define the initiative as a mechanism whereby we solicit applications for Medicare endorsement of prescription drug card programs, review them, offer agreements to program sponsors who meet all of the requirements for endorsement, and award Medicare endorsements to program sponsors who sign the agreement. We would define a Medicare-endorsed prescription drug card program as a program developed by an organization or groups of organizations endorsed by us under the Medicare-endorsed prescription drug card assistance initiative to educate Medicare beneficiaries about prescription drug programs available in the private marketplace and to provide prescription drug assistance cards to Medicare beneficiaries. We would define the administrative consortium as a private entity financed by the Medicare-endorsed prescription drug discount card program sponsors to carry out a set of specific administrative tasks required under this initiative.
- We would add a new § 403.804 to set forth the general rules for obtaining Medicare endorsement of prescription drug card programs, including meeting the requirements, submitting an application, and agreeing to the terms and conditions of the agreement with us.
- We would add a new § 403.806 to set forth the requirements for eligibility for obtaining Medicare endorsement under the initiative.
- We would add a new § 403.807 to set forth the application process for organizations wishing to obtain

Medicare endorsement under the initiative.

- We would add a new § 403.808 to set forth that each prescription drug card program sponsor eligible for Medicare endorsement must enter into an agreement with us agreeing to meet the terms and conditions in the agreement.
- We would add a new § 403.810 to set forth the responsibilities of the administrative consortium.
- We would add a new § 403.811 to set forth the requirement that a beneficiary would only be allowed to be enrolled in one drug card program at a time.
- We would add a new § 403.812 to set forth the conditions under which the Medicare endorsement would be withdrawn from an endorsed drug card program sponsor.
- We would add a new § 403.820 to set forth our oversight and beneficiary education responsibilities.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are seeking comments on these issues for the provisions summarized below:

Section 403.804 General Rules for Medicare Endorsement

The burden associated with the application for endorsement is addressed in the discussion on § 403.806.

Under paragraphs (g) and (h) of § 403.804, a Medicare-endorsed drug card program sponsor may choose not to continue participation in the Medicare-endorsed drug card assistance initiative and would have to notify us of its decision. It would also have to notify its Medicare beneficiaries that they may enroll in an alternative Medicare-endorsed drug discount card program. This notice must be provided within 10 days of the effective date of termination.

We do not believe that 10 or more card program sponsors will terminate their agreement. Because this burden would apply to less than 10 program sponsors, this requirement is not subject to the PRA in accordance with 5 CFR 1320.3(c).

Section 403.806 Requirements for Eligibility for Endorsement

Under paragraph (a) of this section, an applicant must submit an application demonstrating that it meets and will comply with the requirements described in this section.

The requirements described in this section include various disclosure, recordkeeping, and privacy policies. We anticipate that it will take each applicant approximately 120 hours to complete each application. We anticipate that we will receive approximately 30 applications, for a total burden of 3,600 hours.

We solicit comments on the information collection, recordkeeping, and third party disclosure burdens imposed by the various requirements that must be met in order to be endorsed as a drug discount card program sponsor.

Section 403.808 Agreement Terms and Conditions

Under this section, in order to receive a Medicare endorsement, an applicant that complies with all of the application procedures and meets all of the requirements described in this subpart must enter into a written agreement with us. The agreement would include a statement by the applicant that it has met the requirements of this subpart and will continue to meet all requirements for so long as the agreement is in effect.

The burden associated with this requirement is the time and effort for the applicant to review and sign the agreement and the time and effort required to comply with the information collection requirements. It is anticipated that it will take each applicant approximately 8 hours to complete the agreement. We consider all of the information collection requirements associated with complying with the requirements of this section to be usual and customary business practice, except for the requirement that card sponsors provide drug and price information from their formularies to the administrative consortium. For this information collection requirement, we estimate the burden of complying, which involves recordkeeping, information reporting, and disclosure to third parties, to be 24 hours per card sponsor.

We estimate that we would send agreements to approximately 15 applicants, for a total burden of 480 hours.

Section 403.810 Administrative Consortium Responsibilities

Under this section, the administrative consortium would be responsible for publishing, or facilitating the publication of, information, particularly comparative pricing information, that would assist beneficiaries in determining which Medicare-endorsed prescription drug discount card program is the most appropriate for their needs.

There would only be one administrative consortium under this initiative. Since that is fewer than 10, this requirement is not subject to the PRA in accordance with 5 CFR 1320.3(c).

Section 403.811 Beneficiary Enrollment

Under this section, in paragraph (b), Group enrollment, card sponsors may accept group enrollment from health insurers. Card sponsors would be required to assure disclosure to Medicare beneficiaries of the intent to enroll them as a group. They must also assure disclosure to the beneficiaries of the enrollment exclusivity restrictions and other rules of enrollment of the initiative. The card sponsors would be further required to assure that written consent of the beneficiaries to be enrolled in the drug card program as a group is obtained and maintained.

The burden associated with these requirements is the time and effort required to disclose the information to beneficiaries and obtain their consent before enrolling them in the drug card program.

We estimate that there will be 178 health insurers accepted for group enrollment and 1.218 million beneficiaries to whom information must be disclosed and whose consent must be obtained. We estimate that it will take approximately 15 minutes per beneficiary to complete the enrollment process. Within that process, the third party disclosure requirement burden would be 2 minutes per enrollee, for a total burden of 40,628 hours.

Section 403.820 Oversight and Beneficiary Education

Under this section, a Medicare-endorsed prescription drug discount card program sponsor must report to us the number of Medicare beneficiaries

enrolled in, and disenrolled from, the drug discount card program, on a form and at times specified by us.

The burden associated with this requirement is the time it would take to report to us. We believe that it would take approximately 15 minutes per report. We anticipate requiring 4 reports per year, per card sponsor, for 15 sponsors, for a total annual burden of 15 hours.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements in §§ 403.804, 403.806, 403.808, 403.810, 403.811, and 403.820. These requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and recordkeeping requirements, please mail one original and three copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Standards and Security Group, Division of CMS Enterprise Standards, 7500 Security Boulevard, Room N2–14–26, Baltimore, MD 21244–1850, Attn: John Burke, CMS–4027–P, and,

Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503 Attn: Allison Herron Eydt, CMS Desk Officer.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this document, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). While a final estimate depends on the final design of the drug card program, our preliminary estimate (based on our assumptions about manufacturer discounts) is that the savings to beneficiaries under the Medicare-Endorsed Prescription Drug Card Assistance Initiative would represent a total economic impact ranging from $927 million to $1.235 billion in 2003, the first full year of operation. In the second year of the initiative (2004), once enrollment has phased-in completely, the total savings to beneficiaries under the initiative would represent an impact estimated to range from $1.391 billion to $1.855 billion. In 2007, the total savings to beneficiaries would represent an impact estimated to range from $1.967 billion to $2.622 billion. This represents less than 1 percent of projected total retail prescription drug spending for 2003 ($175.8 billion), 2004 ($197.1 billion), and 2007 ($272.4 billion) based on published projections released in March 2001 by our Office of the Actuary. Depending on the final design features and the magnitude of additional manufacturer discounts realized, actual savings to beneficiaries could be larger.

This proposed rule is a major rule as defined in Title 5, United States Code, section 804(2). Accordingly, we have prepared an impact analysis for this proposed rule.

B. Impact on Small Entities

1. General

The RFA requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other health care providers and suppliers are small entities, either by nonprofit status, or by having revenues of $5 million to $25 million or less annually. Individuals and States are not included in the definition of a small entity. The Small Business Administration (SBA), on its web site (*http://www.sba.gov/naics/dsp_naicslist2.cfm*), provides a size standard for pharmacies and drug stores (NAICS code 446110 or SIC code 5912) of revenues of $5 million or less annually for the purpose of determining whether entities are small businesses.

Whether measured from a firm or an 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. The current market for delivery of pharmaceutical products, by its nature involves small businesses, similar to other professional health care services such as physician services. The current health insurance market demonstrates that insurance companies, pharmaceutical benefit managers, and others such as HMOs have been able to enter into arrangements similar to those envisioned in this proposed Medicare initiative involving the participation of large and small pharmacy and drug store firms. These arrangements have resulted in lower prescription drug prices being made available to consumers who have insurance coverage for prescription drugs. There is evidence that both large and small pharmacies and drug stores participate in these arrangements with pharmaceutical benefit managers, and that pharmaceutical benefit managers are able to offer (employer) clients pharmacy networks containing the majority of retail pharmacy outlets.

The role of individual pharmacies, including small pharmacies, in this proposed Medicare initiative is a critical one: they would be an integral part of the pharmacy networks of Medicare-endorsed programs, serving Medicare beneficiaries at the point of retail sale. The objectives of the proposed initiative and the related design requirements would preclude individual pharmacies or drug stores from operating the full scale of the contemplated drug card assistance initiative that would be necessary to obtain an endorsement. Individual pharmacies could participate in the initiative by voluntarily entering into a drug card program's network with other pharmacies. Individual pharmacies are not in a market position to meet the requirements for endorsement, including the ability to serve a large number of enrollees and to garner manufacturer rebates. Retail pharmacy chains could possibly be organized to meet the requirements of Medicare endorsement explained elsewhere in this proposed rule because of their size, type of experience and infrastructure.

Convenient access to retail pharmacies, regardless of size or ownership, by Medicare beneficiaries would be an important feature of the proposed initiative. As discussed elsewhere in this proposed rule, we propose to interpret this to mean that a discount card sponsor would have to have a contracted pharmacy network of sufficient size to demonstrate that at

least 90 percent of Medicare beneficiaries in the area served by the program live within 10 miles of a contracted pharmacy (90/10). This access ratio is consistent with the access standard of most insured products, and we believe it would require card sponsors to support an extremely broad network of retail pharmacies. However, we recognize that our proposed standard would be measured at the national level (or, in the case of a regional network, at the regional level), and that some rural areas may not meet this standard. We want to encourage retail pharmacy participation in the networks; elsewhere in this proposed rule we request comments on how to ensure convenient access in rural areas and for pharmacies that serve special market needs.

Given the 90/10 access ratio requirement and the provision that Medicare-endorsed programs would not be allowed to offer a mail order-only option, we believe that most pharmacies and drug stores (both chain and independent) would be invited and encouraged to participate in card programs' networks, particularly small pharmacies in rural areas. This is generally the case in the current insured market, and we do not anticipate significantly narrower networks in the Medicare-endorsed card programs. There are over 55,000 retail pharmacies in the United States. According to a report prepared for us by PricewaterhouseCoopers (PWC) (''Study of the Pharmaceutical Benefit Management Industry'', June 2001), pharmacy benefit managers (PBMs) offer, as a general practice, standard national pharmacy networks, with 42,000 pharmacies in the typical network. The PWC study also reports that one leading PBM has 50,000 pharmacies in its more restricted network. Also, according to PWC, two large national PBMs have 98 percent of all pharmacies in the United States in their standard networks.

The inclusive access standard required for Medicare endorsement, coupled with the industry norm for pharmacy networks under insured products as reported by PWC, lead us to believe that a very large number of small pharmacies and drug stores would be included in the networks of Medicare-endorsed drug discount card programs. Further, we believe that small entities in rural areas especially would be included in order to meet the standard for endorsement. We welcome comments regarding the inclusion of small pharmacies and drug stores in the networks of Medicare-endorsed card programs.

To assess the number of small entities affected by this initiative, and the amount of revenue involved for these entities, we analyzed data from several sources. The U.S. Census Bureau's 1997 Economic Census data (Table 4 on Retail Trade—Subject Series) indicate that there were a total of 20,815 business firms that were pharmacies and drug stores that operated for the entire year. The Census Bureau data also indicate that the 20,815 firms operated 41,228 establishments (some entities selling prescription drug products are not included in this count, including supermarkets and mass merchants). Of the total firms, 20,126 (or 96.7 percent) were firms that had sales of less than $5 million, and these same firms operated 21,226 establishments or 51.5 percent of the pharmacies and drug store class of trade in the Census Bureau data.

In addition to traditional pharmacies and drug stores, prescription drugs are sold through supermarkets and mass merchants. The National Association of Chain Drug Stores (NACDS) offers data that include these outlets, so we examined this data source as well. The NACDS analyzes industry data from a variety of sources, including IMS Health, the National Council of Prescription Drug Programs, and American Business Information, and reports industry statistics on their web site (*http://www.nacds.org*). For 1997, NACDS reports a total of 51,170 community retail pharmacy outlets, of which 20,844 were independent and 19,119 were chain drug stores (for a total of 39,963)—a number very similar to the Census Bureau's 1997 count of 41,228 pharmacy and drug store establishments. We assume that there is a great deal of overlap between the 21,226 establishments that the Census Bureau identifies as those with sales of less than $5 million and the NACDS report of 20,844 independent pharmacies in 1997. For 2000, NACDS reports 55,011 community retail pharmacy outlets, of which 20,896 are identified as independent drug stores.

In addition to the number of outlets, we examined revenues. The Census Bureau data indicate that, in 1997, total pharmacy and drug store sales for firms operating the entire year were $97.47 billion, of which firms with $5 million or less in sales accounted for 25.5 percent ($24.82 billion). However, these sales include more than just prescription drugs, as most pharmacies and drug stores sell other products. Since firms may differ in the proportion of revenues obtained from prescription drugs, we think that the analysis should focus, to the extent possible, on revenues from prescription drugs, rather than the broader set of sales occurring through pharmacies and drug stores, so we also examined information prepared by our Office of the Actuary (OACT). It is important to note that focusing only on prescription drug sales, rather than all sales through this class of trade, yields an estimated impact that is larger than the actual impact on total sales.

The Office of the Actuary is responsible for preparing the official Federal estimates of national health spending, that are used for research and policy analysis. As part of preparing the estimates, OACT obtains data on prescription drug sales from a variety of sources, including the data on prescription drug sales from the National Prescription Audit conducted by IMS Health. OACT has data on retail prescription drug spending through 2000, and prepares 10-year projections. For 1997, OACT, in its published projections (released in March 2001), estimated that total retail prescription drug spending was $75.1 billion. OACT adjusts the data from the National Prescription Audit to take into account a number of factors. The major factors involved in these adjustments include: benchmarking to the Economic Census, subtracting prescription drug sales to nursing homes (which are accounted for in nursing home spending), and adjusting the data to subtract an estimate of manufacturer rebates provided to health insurers related to insurance coverage for prescription drugs. Thus, in some respects, the National Health Accounts' estimate of prescription drug spending reflects a sales level that is somewhat lower than what is actually received by pharmacies, drug stores, and other retail business outlets selling prescription drugs. Consequently, when National Health Accounts figures are used as the denominator in calculating the percentage impact on revenues (as we do later in this impact analysis), the result is somewhat larger than is actually the case. Nevertheless, we believe that OACT's estimates for prescription drug spending are the most appropriate to use for analysis of prescription drug revenues. OACT's estimates are specific to the prescription drug market, and the National Health Accounts are recognized as a public source of data on health care spending.

From the National Prescription Audit data obtained by OACT, it is possible to estimate the portion of sales occurring through independent and chain pharmacies. The data obtained by OACT do not permit analysis by firm size. However, these data are specific to prescription drug sales for a more recent time period. Furthermore, we believe

that there is a great deal of overlap between the firms identified as independent pharmacies and the small pharmacy and drug store firms identified in the Census data. Consequently, we think that the data from the Prescription Drug Audit are an appropriate source for analysis.

For 1997, that data indicate that 29.2 percent of sales were through independent drug stores—a figure slightly higher than the share (25.5 percent) indicated by the Census data. For 2000, the data obtained by OACT indicate that 25.3 percent of sales were through independent pharmacies. For purposes of calculating the share of revenues from prescription drug sales through small firms, we think it is reasonable to use the more recent estimate of prescription drug sales through independent pharmacies obtained from our analysis of the Prescription Drug Audit for 2000. The numerical value from the 2000 National Prescription Drug Audit is essentially the same as what would be used if we selected the 1997 Census data proportion.

The Census Bureau data contain information on supermarkets (NAICS code 445110) and mass merchants (discount or mass merchandising department stores—NAICS code 4521102, and warehouse clubs and superstores—NAICS code 45291). We assume that for both supermarkets and the mass merchants, prescription drug sales comprise a small share of sales, and consequently have not included them in this small business analysis. This assumption is supported by data from the Census Bureau, Prescription Drug Audit, and NACDS web site. The 1997 Census data indicate that total supermarket product sales were $351.4 billion. OACT's analysis of 1997 data from the Prescription Drug Audit indicates that $8.8 billion in prescription drug sales occurred through food stores, or 2.5 percent of total product sales. Similarly, the 1997 Census data indicate that total product sales for the two categories of mass merchandisers identified above was $208 billion. Since data from the Prescription Drug Audit obtained by OACT include mass merchants with other chain stores, we used prescription drug sales data from the NACDS web site. The NACDS web site indicates that prescription drug sales through the mass merchant category were $8.9 billion in 1997, or 4.3 percent of total product sales. Furthermore, the fact that businesses are identified as supermarkets and mass merchandisers would seem to indicate that prescription drugs is not their major line of trade.

The Department of Health and Human Services (HHS) uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent. For purposes of the analysis related to small business, it is necessary to develop an estimate of the share of national drug sales associated with small pharmacies and drug stores. OACT projects that total national retail prescription drug spending for 2003 will be $175.8 billion, $197.1 billion by 2004, and will reach $272.4 billion by 2007. Given that 25.3 percent of sales were through independent pharmacies in 2000, we calculated that the share of total national prescription drug sales through pharmacies and drug stores with $5 million or less in revenues would be $44.5 billion in 2003, $49.9 billion in 2004, and $68.9 billion in 2007.

For purposes of both the impact analysis and to examine the impact on small pharmacies and drug stores, it is also necessary to understand the share of prescription drug spending for the population that is expected to enroll in the Medicare-endorsed discount card programs as a portion of total national prescription drug spending. Total drug expenditures involved in the Medicare-endorsed discount card programs are projected to be $13.3 billion in 2003 (not adjusted for enrollment phase-in), $14.9 billion in 2004, and $21.1 billion by 2007, before the savings achieved through the card initiative. The data used to develop these estimates come from the Medicare Current Beneficiary Survey (MCBS). This data base and the methodology for preparing these estimates are described later in the impact analysis. Thus, total prescription drug spending involved in the Medicare-endorsed cards is estimated to account for approximately 7.6 percent of total national prescription drug sales in 2003 (not adjusted for enrollment phase-in), 7.6 percent in 2004, and 7.7 percent by 2007. In terms of the total market of retail prescription drug revenues, spending for the Medicare population to be assisted by the Medicare-endorsed discount card initiative is estimated to account for less than 8 percent of revenues on prescription drugs.

If we assume that the population most likely to enroll in the proposed Medicare-endorsed drug discount card programs splits its purchases between large and small pharmacies in the same proportion as the total population, then the estimated sales involved in the discount card initiative through small pharmacies and drug stores would be $3.4 billion out of the $44.5 billion in sales for 2003 (not adjusted for enrollment phase-in), $3.8 billion out of the $49.9 billion in sales in 2004, and $5.3 billion out of the sales of $68.9 billion in 2007 (again accounting for less than 8 percent of prescription drug sales).

The total estimated savings to beneficiaries under this proposed initiative would represent a total economic impact ranging from $927 million to $1.235 billion in 2003, from $1.391 billion to $1.855 billion in 2004, and $1.967 billion to $2.622 billion in 2007. Thus, again assuming 25.3 percent of sales were through independent pharmacies, the portion of the estimated beneficiary savings (described later in this analysis as the upper and lower bound) related to retail prescription drug sales occurring through small pharmacies and drug stores ranges from: $234 to $313 million in 2003, $352 to $469 million in 2004, and from $498 million to $663 million in 2007. These amounts, as a share of the national retail prescription drug sales occurring through small pharmacies and drug stores, would represent a range of from 0.53 percent to 0.70 percent in 2003, from 0.71 to 0.94 percent in 2004, and from 0.72 to 0.96 in 2007.

This is likely to be an overestimate of the economic impact on small pharmacies and drug stores, as this economic impact would not be borne entirely by pharmacies. Card sponsors would be required to obtain substantial manufacturer rebates or discounts that would defray the cost to pharmacies of providing discounts on retail drug prices. In addition, to the extent that the discount card programs achieve larger savings from drug manufacturers than are included in our estimate, the additional beneficiary savings would come from drug manufacturers and not local pharmacies.

Other plausible caveats to consider are the following: Our spending estimates assume no effects of the drug card program on beneficiary drug use. It is possible that lower drug prices would lead to greater use, resulting in a smaller impact on pharmacy revenues. It is also possible that pharmacy services associated with the card would lead to some drug substitution, simplification of drug regimens, or avoidance of complications that require further drug therapy, leading to a somewhat greater impact on pharmacy revenues.

We welcome any comments and information on whether there is evidence that Medicare beneficiaries without drug coverage use small pharmacies and drug stores more or less than the share of revenues that these firms represent in terms of the overall market. We have assumed the share to

be the same, but it would be helpful to have data on where Medicare beneficiaries, particularly those without drug coverage (who make up the largest group expected to use the Medicare-endorsed discount cards), purchase their prescription drugs. Knowing where these beneficiaries purchase their drugs would help us better understand whether there are any distributional issues. However, we currently do not have this type of data available.

We are particularly concerned about ensuring beneficiary access to pharmacies in rural areas. We do have some evidence to believe there could be a disproportionate number of beneficiaries in rural areas who would use the Medicare-endorsed discount cards. Data from the 1998 MCBS indicate that 37 percent of Medicare beneficiaries in rural areas do not have drug coverage compared to the national average of 27 percent. We also assume that pharmacies and drug stores in rural areas are more likely to be small businesses.

We recognize that the 90/10 access ratio may be difficult to obtain in rural areas, and we solicit suggestions on feasible options for raising the ratio in these areas.

According to the PWC study mentioned above, because there is less competition among pharmacies in rural areas, pharmacy benefit managers have had to make special arrangements in order to obtain the participation of rural pharmacies in the networks. We expect the current market practice of making special arrangements (for example, special pricing for ingredient costs and additional dispensing fees) with rural pharmacies would carry over in the Medicare-endorsed discount card programs.

2. Sensitivity Analysis

In order to assess the potential for differing distributional impacts among pharmacies, we conducted a sensitivity analysis. We estimate that the total prescription drug spending involved in the proposed Medicare-endorsed drug discount card initiative would comprise, on average, less than 8 percent of revenues, with the economic impact of the proposed discount card initiative on total revenues related to prescription drugs estimated at less than one percent. For purposes of a sensitivity analysis, we estimate that in order to reach the Department of Health and Human Services (HHS) measure of significant economic impact of 3 to 5 percent of revenues, it would be necessary to have prescription drug revenues involved in the proposed Medicare-endorsed discount card initiative account for at least 24 percent of a business' revenues. In the sensitivity analysis, we developed a hypothetical geographic locality skewed to contain a very large share of Medicare beneficiaries who enroll in the proposed Medicare-endorsed discount card initiative. Under this highly skewed assumption, we estimated a maximum share of 19.6 percent of a business' total prescription drug revenues would be associated with the Medicare-endorsed discount card, with an economic impact of the Medicare-endorsed discount card initiative of 2.4 percent of prescription drug sales.

As noted previously, this economic impact would not be borne entirely by pharmacies, because card sponsors would be required to obtain substantial manufacturer rebates or discounts that would defray the cost of pharmacies providing discounts on retail drug prices. Thus, the sensitivity analysis still yielded an impact level below the 3 to 5 percent of revenues used by HHS to measure significant economic impact. The following discussion describes the assumptions and supporting data used in the sensitivity analysis.

In order to prepare the sensitivity analysis, we identified key variables that could change the market share of revenues and consequent impact resulting from the proposed Medicare-endorsed discount card initiative. One key variable is the Medicare population as a portion of a pharmacy's geographic locality customer base. We assume that a pharmacy's customer base is derived in large part from the population in close geographic proximity to its business location. Therefore, we examined the variation in the geographic distribution of the Medicare population. On average nationally, Medicare beneficiaries were 13.6 percent of the total population as of July 2000. Using several States with the highest Medicare population rates, we examined, at the county level, the percent of the population over age 65 based on Census Bureau data. For counties with high elderly population compositions, we obtained the actual counts of Medicare enrollment (aged and disabled) and calculated Medicare enrollment as a percentage of the counties' populations. Based on this analysis at the county level, we estimate in a high-end scenario that Medicare beneficiaries could potentially comprise up to approximately 36 percent of a geographic area's population.

A second key variable that we assume could alter the revenues being impacted is the percent of the Medicare population in an area that may enroll in the Medicare-endorsed discount card programs. As discussed later in this impact analysis, we think that the beneficiaries most likely to enroll in the Medicare-endorsed discount card programs would be those without insurance coverage for prescription drugs (including those with supplemental insurance coverage that does not include prescription drugs) and those with Medigap drug coverage. In terms of demographic variables, the highest rates of Medicare beneficiaries without drug coverage occur among Medicare beneficiaries in non-metropolitan areas (37 percent). Our analysis of the MCBS data also indicates that 15 percent of beneficiaries in non-metropolitan areas have drug coverage through Medigap insurance, compared to the national average of 10 percent.

For purposes of a sensitivity analysis, we developed a hypothetical geographic location with a large share of Medicare beneficiaries that also had a high portion without drug coverage. We used the 36 percent figure from our analysis discussed above on geographic areas with larger Medicare population composition, and the 37 percent as the high rate for no drug coverage, to adjust the national averages underlying the overall impact analysis. We also assumed that the hypothetical Medicare population would have a slightly higher portion (15 percent) of beneficiaries who obtained drug coverage through Medigap.

We estimate that nationally approximately 10 million Medicare beneficiaries would enroll in the proposed Medicare-endorsed discount card programs by the end of 2003, accounting for an estimated 3.5 percent of the total U.S. population. Adjusting the data, using the population and drug coverage weighting factors for the sensitivity analysis and using the overall uptake assumptions described later in this impact analysis (75 percent overall uptake in the Medicare population without drug coverage and 95 percent in the Medigap population with drug coverage), results in the hypothetical area having approximately 15 percent of its total population participating in the Medicare-endorsed drug discount card initiative. Therefore, about 85 percent of the total hypothetical area's population would not participate in the Medicare-endorsed discount card initiative, including both Medicare beneficiaries and non-Medicare beneficiaries.

To estimate the impact of the drug discount card initiative on prescription drug revenues in the hypothetical locality, we estimated the per capita drug spending for participants in the proposed initiative and non-participants

in the initiative in the hypothetical area. We estimated per capita drug spending to be $1,351 for participants and $990 for non-participants in the hypothetical locality in 2004. These figures differ from per capita estimates for participants and non-participants at the national level due to the skewed demographic composition of the hypothetical area (which would have a large Medicare population and have beneficiaries with Medigap drug coverage comprising a slightly greater share of drug discount card program participants than at the national level). The per capita spending estimates for both participants and non-participants include individuals without drug expenditures. The per capita spending estimates were done for 2004 since that would be the year we assume full phase-in of enrollment in the drug discount card program initiative.

The per capita drug spending data for the Medicare population participating in the discount card initiative come from the MCBS, and the methodology for calculating drug spending from that data is described later in the impact analysis. For participants in the Medicare-endorsed discount card programs, the per capita value consists of the estimated total spending for enrolled beneficiaries without drug coverage plus the share of spending for the Medigap enrollees that is purchased through the discount program, divided by the total number of participants.

For purposes of calculating the per capita spending for non-participants in the Medicare-endorsed discount card programs, we used prescription drug spending data from the National Health Accounts and estimates from the MCBS to develop per capita drug spending estimates for the non-Medicare population and for the Medicare population not participating in the discount card program. These two per capita values for non-participants in the drug card initiative were then weighted relative to the population distribution they represented in the hypothetical area's non-participant population to create a per capita drug spending for non-card participants.

We then adjusted per capita drug spending for non-participants to include participants' drug spending that was not purchased through the discount card program (the portion of drug spending covered by Medigap plans) to yield an estimate of total drug spending outside of the proposed drug discount card initiative. Consequently, this inclusion of the Medigap covered drug spending means that the per capita drug spending figure for non-participants is this adjusted per capita (including the Medigap related spending) for the hypothetical area rather than the actual per capita for the non-participant population in the hypothetical area. For purposes of the sensitivity analysis calculation of the impact of the proposed discount card programs, we used the upper bound figure of all drug spending as a high-end assumption. This corresponds to the upper bound estimates discussed in subsequent sections of this impact analysis.

The results of the sensitivity analysis are shown in Table 2. For the hypothetical area that is skewed to have a very high Medicare beneficiary population composition and a high enrollment in the discount card initiative, the negative impact on revenues from prescription drugs reached 2.4 percent, still below the HHS measure for significant economic impact of 3 to 5 percent of revenues. Furthermore, as noted above, not all of the 2.4 percent would be borne by the pharmacy, since discount card sponsors would be required to obtain manufacturer rebates or discounts and pass those through to beneficiaries and pharmacies in order to receive Medicare endorsement.

We recognize that reliance on nationally calculated per capita averages weighted for different demographic compositions has limitations, and pharmacies may have customer populations with per capita drug spending levels that differ from the population specific averages calculated at a national level. Nevertheless, we think that the sensitivity analysis is comprised of differentiating factors that can influence market shares and we skewed these to be at the highest values identified in the available data. Consequently, we think that the sensitivity analysis reflects a reasonable test of potential distributional effects. We welcome comments, and particularly data, that could help to inform further analysis of distributional effects.

TABLE 2.—NATIONAL AVERAGE VERSUS SENSITIVITY ANALYSIS—HYPOTHETICAL EXAMPLE

[In percent]

2004	Discount card participants	Discount card non-participants	Total population
National average for comparison purposes:			
Percent of total population	3.52	96.48	100.00
Percent of total prescription drug sales	7.60	92.40	100.00
Estimated beneficiary savings as a percent of drug sales	12.40	0.00	0.94
Hypothetical Example:			
Percent of total population	15.12	84.88	100.00
Percent of total prescription drug sales	19.60	80.4	100.00
Estimated beneficiary savings as a percent of drug sales	12.40	0.00	2.40

3. Policy Considerations

Several policy decisions were made to mitigate the impact on pharmacies, including small pharmacies and drug stores. We would require manufacturer rebates or discounts that could be passed through to pharmacies to defray the costs of pharmacies providing discounts on retail prices. In addition, the funding from manufacturer rebates could be used to provide other incentives for pharmacies, such as rural pharmacies, to participate in the proposed Medicare-endorsed card sponsors' networks.

Also to mitigate the impact on pharmacies, we would require very broad retail pharmacy networks and would not endorse mail order-only discount card programs. We believe that strong access to retail pharmacies is important for the Medicare population.

One group of pharmacies about which we would like more information is small, independent, urban pharmacies. These pharmacies frequently serve an important role for underserved populations and populations at risk for health disparities. We solicit comments on data sources and information concerning these pharmacies, including

whether or not they are usually included in the networks of insured products and the extent to which Medicare beneficiaries rely on them.

We realize that there is some risk to revenues of a pharmacy not participating in the networks of proposed Medicare-endorsed programs, particularly for small or rural pharmacies. At the same time, we believe that the proposed access standard of 90 percent of the beneficiaries being within 10 miles of a retail pharmacy would create the need for card sponsors to develop inclusive networks. Consequently we believe that, as the market does today for insured products, card sponsors would use special arrangements to encourage the participation of rural pharmacies and other pharmacies that serve segments of the Medicare population with special needs.

Also, participation of Medicare beneficiaries in this proposed initiative is voluntary, and beneficiaries with drug cards always would remain free to make prescription drug purchases at the pharmacy of their choice (although they may pay more at a non-network pharmacy) or to use existing voluntary discount cards; and they could purchase a drug not on a formulary (at the price offered by the pharmacy).

Based on the data we have available, the impact of the proposed Medicare endorsement initiative, on average, is estimated to be well below the 3 to 5 percent of revenues that HHS uses as the measure of significant economic impact. Furthermore, our sensitivity analysis indicates that even taking into account significantly different market characteristics, and even if all of the impact were assumed to be coming from pharmacies rather than our proposed program design that requires manufacturer rebates or discounts, we did not generate a scenario that reaches the HHS test for significant economic impact. We welcome comments, and particularly data, that could help to inform further analysis of distributional effects.

4. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This proposed rule would not affect small rural hospitals since the initiative would be directed at outpatient prescription drugs, not drugs provided during a hospital stay. Prescription drugs provided during hospital stays are covered under Medicare as part of Medicare payments to hospitals. Therefore, we are not providing an analysis.

C. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1998 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We have determined that this proposed rule is not an unfunded mandate as defined by the UMRA. In particular, section 101 of the UMRA only requires estimation of direct costs to comply with the definition of a private sector unfunded mandate. In addition, this proposed rule does not mandate any requirements for State, local, or tribal governments.

D. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule would impose no direct costs on State and local governments, would not preempt State law, or have any Federalism implications. However, as noted in section I.A of this preamble, States may choose, on a voluntary basis, to partner with private drug card sponsors by selecting a Medicare-endorsed drug card program and offering State endorsement of it as well. In addition, as noted in the advance notice of proposed rulemaking entitled, ''Medicare Program; Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative for State Sponsors'', published elsewhere in this issue of the **Federal Register**, we outline steps we are considering proposing in support of State efforts to make prescription drugs more readily available to Medicare beneficiaries. These are voluntary opportunities for States, and have no Federalism implications.

E. Limitations of Our Analyses

The following analyses present projected effects of this proposed rule on Medicare beneficiaries, the Medicare program, total national retail prescription drug spending, and drug card sponsors.

Because this would be the first year of the Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative, we do not have the benefit of the experience of prior years. Therefore, we present a range rather than a single estimate for the impact of the prescription drug rebate and discount requirements of the proposal. Another limitation of this particular analysis is that our most recent available data on beneficiary use of prescription drugs come from self-reported survey data from the 1998 Medicare Current Beneficiary Survey (MCBS). (The MCBS is a continuous multipurpose survey of a representative sample of the Medicare population.) We have adjusted the data for trends in drug spending and for under reporting.

In the cost and benefit analysis, we do not estimate the costs and benefits of sharing manufacturer rebates and discounts with beneficiaries indirectly through pharmacies. We require that these rebates and discounts would have to be shared with beneficiaries either directly or indirectly through pharmacies. We anticipate that this requirement would promote better drug prices for beneficiaries or enhance pharmacy participation in a card program's network. Further, we anticipate that sharing indirectly with pharmacies could promote enhanced pharmacy services. We request public comment on the costs and benefits to pharmacies, beneficiaries and card program sponsors of various possible arrangements to achieve enhanced pharmacy participation in a card program's network, as well as to promote the enhancement of pharmacy services for beneficiaries.

The cost analysis of the effects of the proposed requirement that applicants jointly administer, abide by the guidelines of, and fund a private administrative consortium is limited by the following condition. While subject to the oversight described in section I.E.5 of this preamble, the consortium would be a private operation independent of the government. Its actual organization and ongoing operation, including specifications of the final details of its three major administrative tasks, would be determined largely by the representatives of the drug card sponsors; and, if included in the final design, its advisory board; and in the case of reviewing marketing materials, subject to guidelines provided by us. Further, both the number of drug card sponsors that receive Medicare endorsement and how the card sponsors choose to operate the consortium may

effect the costs borne by any one card program sponsor.

F. Impact of the Rebate and Discount Requirements

1. Medicare Beneficiary Estimated Enrollment

Although the Medicare-endorsed prescription drug card programs would be available to all Medicare beneficiaries, we believe that those most likely to benefit from the initiative and those most likely to enroll in a drug card program would be the approximately 10 million Medicare beneficiaries without prescription drug coverage at any point in a year (1998 MCBS).

Another group of beneficiaries likely to benefit from and enroll in Medicare-endorsed discount card programs would be beneficiaries with Medigap insurance. The Medigap plans that offer prescription drug coverage (including standardized plans H, I, and J) generally are designed with a cap on the amount of drug spending covered by the plan. Plans H and I have a drug benefit cap of $1250 and Plan J has a drug benefit cap of $3000. In addition, these plans each have a $250 deductible and 50 percent copayments. Many Medigap plans do not actively negotiate discounts for enrollees. Thus, we believe that Medicare beneficiaries with standardized and non-standardized Medigap drug coverage would benefit from a discount card program, particularly for spending above the benefit cap. According to the 1998 National Association of Insurance Commissioner's (NAIC) Medigap experience files, covered lives in standardized and non-standardized Medigap plans totaled 10.7 million. Using the 1998 MCBS, we estimate that approximately 2 million of these covered lives had drug coverage from a Medigap policy, recognizing that a large share of this estimated population was enrolled in non-standardized plans. According to the NAIC, of the beneficiaries enrolled in the standardized Medigap plans offering drug coverage in 1998, 56 percent were enrolled in plans H and I and 44 percent of the beneficiaries were enrolled in plan J.

We anticipate that beneficiaries without prescription drug coverage and with relatively higher spending would be more likely to enroll than those with generally very low or no spending. We assumed that beneficiaries without prescription drug coverage who spend over $250 per year, the point at which a $25 maximum enrollment fee could be recouped (assuming 10 percent savings on $250 in drug spending) would be the most likely to enroll. To the extent that card sponsors would offer lower or no-cost enrollment, we would expect more beneficiaries to take advantage of the savings opportunity. We expect some beneficiaries would realize that the $25 maximum fee is a one time only fee, and to the extent they stay in the same card program over time, the more value the card represents in terms of annual savings.

In Table 3 we show the assumptions regarding the percentage of beneficiaries without drug coverage enrolling in a Medicare-endorsed drug card program. Based on these assumptions and the distribution of drug spending in the Medicare population without drug coverage, we estimate that 75 percent of these beneficiaries would enroll in the Medicare-endorsed drug card programs.

TABLE 3.—ESTIMATED ENROLLMENT RATE OF MEDICARE BENEFICIARIES WITH NO DRUG COVERAGE 2003–2007

Annual drug spending	Percent enrolling
$0–200.00	55
$200.01–300.00	80
$300.01–400.00	85
$400.01–500.00	90
$500.01+	95

In addition, we believe that 95 percent of beneficiaries with Medigap coverage for prescription drug costs, regardless of expenditure level, would also enroll in a Medicare-endorsed card program. We believe that beneficiaries with Medigap coverage for prescription drugs would be more risk averse than the average beneficiary and would therefore be more likely to enroll in a drug discount card program.

While we expect there would be a phase-in of beneficiary enrollment, we believe that because of the recognition and acceptance of the Medicare name and the educational efforts to be undertaken, beneficiaries wishing to enroll would do so within the first 6 months of the initiative. Thus, we assume that the percentage of beneficiaries enrolling in 2003 would be about equal to the percentage enrolling in 2004 and beyond. In 2003, we expect approximately 10 million beneficiaries would enroll. We use 2003 as the beginning point for the estimates because it would be the first full year of operation.

2. Estimated Portion of Drug Spending Included

For purposes of estimating the impact of the Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative, it is necessary to make some assumptions concerning the portion of spending that would be affected by the discounts under the drug card programs. The requirements for endorsement would include provision of a discount on one brand name or generic drug in each therapeutic grouping commonly used by Medicare beneficiaries. However, we expect that the card programs probably would provide discounts on more than one drug per grouping and would be highly likely to provide discounts on commonly used drugs. In addition, we anticipate that many card sponsors would choose to provide a discount on all drugs, with large manufacturer rebates and deeper discounts on a subset of drugs on a formulary. Analysis of 1998 MCBS spending for the drugs most commonly used by Medicare beneficiaries, identified in Attachment B of the August 2, 2001 application for the Medicare-endorsed drug discount card program, found that those drugs accounted for approximately 66 percent of total drug spending for beneficiaries without drug coverage. However, the drug classification listing included in Attachment C of the August 2, 2001 application, for which card sponsors were required to include a drug, is more extensive than the top specific drug list shown in Attachment B, which was used to estimate 66 percent.

We assume that many card sponsors would choose to include more than one drug for the required drug grouping. Consequently, we increased our estimate to 75 percent of total drug spending for beneficiaries enrolled that would be affected by the drug card initiative. We assume that this is the lower bound of drug spending that would be affected by the drug card initiative.

We also assume that it is possible that programs would include a discount on all drugs. To calculate this upper bound, we assume that all beneficiary drug expenditures would be affected by the drug card initiative. We note, however, that we have made no adjustment to take into account that some beneficiaries currently receive discounts and that a large portion of the savings to beneficiaries would come from generic substitution, and not as a result of price reductions on brand name drugs.

3. Estimated Beneficiary Savings

An April 2000 study prepared by the Department of Health and Human Services (HHS) entitled, ''A Report to the President: Prescription Drug Coverage, Spending, Utilization and

Prices'', indicated a significant price differential between individuals paying cash for prescriptions at a retail pharmacy versus those with insurance. This was true for both the Medicare and non-Medicare populations. According to the study, in 1999 the price paid by cash customers was nearly 15 percent more than the total price paid under prescription drug insurance, including the enrollee cost sharing. For 25 percent of the most commonly prescribed drugs, this price difference was higher—over 20 percent. Thus, in today's market, individual Medicare beneficiaries without drug coverage and the related market purchasing leverage, not only face having to pay the full cost for medications from their own pockets, but ironically are also charged the highest prices. Furthermore, the HHS study did not include the effect of rebates on total prices paid. It did, however, note industry experts as indicating that insurers and employers typically receive 70 to 90 percent of the rebates negotiated for their enrollees. While currently, rebates in insured products may not necessarily reduce prices paid at the retail point of sale, the rebates do lower the per-prescription cost for plan sponsors, and thus tend to lower premiums or program costs for insured beneficiaries.

We anticipate that the estimated savings for Medicare beneficiaries in a Medicare-endorsed drug card program would be a first step toward the savings that could be achieved under an insurance product. Based on information on savings from insurance products and information on the current discount card market, we assumed that beneficiaries enrolling in the Medicare-endorsed prescription drug discount card programs would save, on average, between 10 and 13 percent of their total drug costs compared to their spending in the absence of this initiative. The percentage savings on particular prescription drugs would vary and may be substantially higher for certain products, particularly generics, due to their lower prices. While the impact analysis uses an assumption of savings of 10 to 13 percent off total drug spending, we believe that savings of 15 percent may be possible, depending on the ultimate design of card sponsors' programs. If Medicare-endorsed discount card programs rely heavily on the use of formularies, we expect that manufacturer rebates and discounts would be greater in response. Earlier in this proposed rule we solicited comments and data on how to maximize manufacturer rebates and discounts.

The savings to beneficiaries would be attributable to the combination of lower prices paid at the point of sale as a result of manufacturer and pharmacy discounts, as well as the effects of beneficiary education leading to greater use of generic drugs and more effective management of prescription drug expenses by beneficiaries. Because pharmacy discounts are increasingly available to beneficiaries through existing voluntary card programs, we expect that manufacturer rebates and discounts and savings from a better understanding of generic alternatives and managing prescription drug expenses would be important sources of savings in this initiative. For purposes of calculating the estimates of beneficiary savings, we assumed an average overall drug spending savings to beneficiaries of 12.4 percent. These estimates do not take into account possible increased use of prescription drugs by Medicare beneficiaries resulting from paying reduced out-of-pocket amounts for drugs.

Because the Medicare-endorsed drug card programs would be modeled after insured products in terms of enrollment and the use of formularies, combined with its competitive model and the requirement of manufacturer rebates or discounts, we expect that the Medicare-endorsed drug card programs would achieve new beneficiary savings from manufacturer rebates or discounts. The share of savings would vary depending on the drug, but savings from manufacturers are expected to be substantially greater than those available through existing voluntary cards. According to the HHS study, industry experts report that private insurance plans garner rebates on individual brand name drugs ranging from 2 to 35 percent. We assume that the portion of beneficiary savings attributable to manufacturers may increase over time as competition forces card sponsors to secure manufacturer rebates or discounts in order to remain competitive. To the extent that card program sponsors design formularies to mimic those of insured products, the ability to garner manufacturer rebates or discounts would increase.

4. Projection Assumptions

Since our data on Medicare beneficiary prescription drug spending are based on 1998 MCBS data, it is necessary to make several adjustments in order to prepare 2003 estimates. In order to trend 1998 spending to 2003 dollars, we use prescription drug spending projections based on per capita drug expenditure growth from the National Health Expenditure (NHE) Projections 1980 to 2010. These projections can be found on our Web site at: *http://www.hcfa.gov/stats/NHE-Proj/proj2000/tables/t11.htm.*

MCBS data on prescription drug utilization are self-reported by beneficiaries, and consequently are subject to under reporting. We are studying this under reporting in order to develop adjustment factors to be used for estimating purposes. For purposes of the estimates in this proposed rule, the spending data from the MCBS are adjusted to account for the estimated 16.4 percent in under reporting that has been identified through our research thus far.

It is also necessary to adjust for growth in the Medicare beneficiary population. The adjustments were made based on the assumptions used for the Medicare Trustees Reports, March 19, 2001.

These assumptions are detailed in Table 4, which shows the estimated impact, using 1998 as the base year for projections. The estimated increase in total Medicare enrollment for 2003 and the estimated increase in per capita drug expenditures (97.4 percent) are shown as increases from 1998 to 2003. These estimates are based on the 1980 to 2010 NHE projections.

For the estimated 10 million beneficiaries who would enroll in the proposed Medicare-endorsed drug card programs, the base for total drug expenditures involved in the discount card initiative is projected to be $13.3 billion in 2003 (not adjusted for enrollment phase-in), $14.9 billion in 2004, and $21.1 billion in 2007 before the savings achieved through the card initiative.

As indicated above, these projections are estimated using 1998 MCBS data, projected forward to 2003 to 2007 based on expected growth in per capita health care spending and the Medicare population. For beneficiaries with Medigap coverage, estimated prescription drug spending involved in the discount card initiative may be understated because our projection method implicitly assumes that the Medigap drug benefit structure (deductible and coverage limits) grows as per capita spending grows. However, we believe that this does not significantly alter the overall findings in the impact analysis because it is likely counterbalanced by other assumptions that tend to overstate the discount card programs' impact on retail prescription drug sales through pharmacies. For example, in the impact analysis, we use NHE estimates of prescription drug spending net of manufacturer rebates provided to health insurers. Because removing the rebates understates total prescription drug sales realized by

pharmacies, the impact of the Medicare-endorsed drug cards as a percent of total pharmacy revenues is overstated.

TABLE 4.—ESTIMATED IMPACT

	1998	2003	2004	2005	2006	2007
Total Medicare Enrollment ($ millions)	38.9	40.9	41.4	42.0	42.6	43.4
Increase in Total Medicare Enrollment	.....	5.2%	1.3%	1.3%	1.5%	1.8%
Increase in per Capita Drug Expenditures	.....	97.4%	11.2%	10.7%	10.7%	10.2%
Total National Aggregate Drug Expenditures ($ billions)	$85.2	$175.8	$197.1	$219.9	$245.3	$272.4
Projected Prescription Drug Spending Under the Drug Discount Card Programs ($ billions)	$6.4	$13.3	$14.9	$16.8	$18.8	$21.1
Projected Beneficiary Savings ($ millions)	$793	$1,647	$1,855	$2,081	$2,338	$2,622
Implementation Phase-in	.....	0.75	1.00	1.00	1.00	1.00
Upper Bound Impact of Estimated Beneficiary Savings ($ millions)	.....	$1,235	$1,855	$2,081	$2,338	$2,622
Upper Bound Impact as a Percent of Total National Retail Prescription Drug Expenditures	.....	0.70%	0.94%	0.95%	0.95%	0.96%
Lower Bound Impact of Estimated Beneficiary Savings ($ millions)	.....	$927	$1,391	$1,561	$1,753	$1,967
Lower Bound Impact as a Percent of Total National Retail Prescription Drug Expenditures	.....	0.53%	0.71%	0.71%	0.71%	0.72%

5. Anticipated Effects

a. Effects on Medicare Beneficiaries

Among the primary purposes of the proposed Medicare-Endorsed Prescription Drug Card Assistance Initiative would be to:

- Educate beneficiaries about the private market methods for securing discounts on the purchase of prescription drugs.
- Encourage beneficiary experience with the competitive discount approaches that are a key element of all Medicare prescription drug benefit legislative proposals.
- Assist beneficiaries in accessing lower cost prescription drugs through new competitive manufacturer rebates or discounts and better understanding of how to manage their prescription drug needs.

We estimate that at least 10 million Medicare beneficiaries would enroll in Medicare-endorsed drug card programs. We anticipate that Medicare beneficiaries with no drug insurance who enroll in a Medicare-endorsed prescription drug card program would save between 10 and 13 percent of their total drug costs. However, this would vary by the mix of drugs beneficiaries use, and as noted previously, may be even higher depending on the ultimate program design used by card sponsors.

Also, beneficiaries may be required to pay a one-time enrollment fee of up to $25 to join a Medicare-endorsed drug card program. If all 10 million Medicare beneficiaries estimated to enroll by the end of Year One would pay the maximum $25 enrollment fee (a scenario we do not expect because of competition among endorsed card programs), the total beneficiary savings would be reduced by a maximum of $250 million in 2003. However, as noted earlier, to the extent a beneficiary stays in the same drug card program, beyond the first year, the more value the card represents in savings to the beneficiary. In Year Two, based on our estimates of growth in the Medicare population and the disenrollment rate (discussed later in this analysis), we estimate that if beneficiaries paid the maximum $25 enrollment fee, total beneficiary savings would be reduced by a maximum of $32 million in 2004.

Beneficiaries with Medigap insurance that includes drug coverage who enroll in a Medicare-endorsed drug discount card program would also experience savings, particularly before the Medigap drug deductible is reached, and after the spending cap is exceeded. We also believe that the education beneficiaries would receive concerning drug prices, formularies, drug-to-drug interactions and other pharmacy counseling, generic substitution, and pharmacy networks, would provide an opportunity for beneficiaries to maximize their savings.

A beneficiary enrolled in a Medicare-endorsed card program would be free to purchase prescription drugs outside the drug discount card program, either at a non-network pharmacy or a non-formulary drug. Thus, beneficiaries without prescription drug coverage would not be any worse off than they would be in the absence of the proposed Medicare-endorsed initiative.

b. Effects on the Medicare Program

We would be responsible for reviewing applications and awarding endorsements so that these proposed card programs could begin operating to provide lower prices to cash paying beneficiaries. The cost associated with this process, as well as all other activities we would undertake associated with implementing this proposed initiative, would be subsumed in the agency's existing administrative budget. No new agency resources are budgeted for implementation of this initiative.

While not quantifiable, a positive impact of the rebate and discount requirements of the proposed initiative would be to provide us with experience in understanding issues in the pharmaceutical industry prior to enactment of a Medicare drug benefit. We would increase our knowledge concerning pricing and payment issues, information technology requirements, and increasing the effectiveness of pharmacy quality improvement programs. The pharmaceutical industry (including pharmacy benefit managers) would also gain more experience in working with the Medicare population prior to implementation of a drug benefit. We expect that this experience would make the transition to a Medicare prescription drug benefit faster and more efficient.

Because this proposed initiative is not a Medicare benefit, we do not anticipate any significant change in the Medicare baseline as a result of its implementation.

c. Effects on National Retail Prescription Drug Spending

Total national retail spending (spending for total population, not just Medicare beneficiaries) on prescription drugs is projected to be $175.8 billion in 2003, $197.1 billion in 2004, and $272.4

billion in 2007 (*http://www.hcfa.gov/stats/NHE-Proj/Proj2000/tables/t11.htm*).

The total estimated economic impact of the Medicare-Endorsed Prescription Drug Card Assistance Initiative of $927 million to $1.235 billion in 2003 would range from 0.53 percent (the lower bound) to 0.70 percent (the upper bound) as a share of total national retail prescription drug expenditures in 2003. In the second year of the initiative (2004), once enrollment has phased-in completely, the total impact is estimated to range from $1.391 billion to $1.855 billion, or 0.71 percent to 0.94 percent of total national retail expenditures for prescription drugs. In 2007, we estimate the total impact to range from $1.967 billion to $2.622 billion, or 0.72 percent to 0.96 percent of total national retail drug expenditures. Thus, the economic impact is estimated to be less than 1 percent of total retail prescription drug spending.

We expect that the various sectors involved in the prescription drug industry would adjust to the impact without significant disruption, just as the industry adjusted to discounts being extended to the Medicaid population and the privately insured population during the 1990s. The 1990s saw a significant increase in reliance on pharmacy benefit managers and the tools they use to manage pharmaceutical benefit costs.

For example, evidence of market adjustment can be seen in the changes in pharmacies' acquisition costs during the 1990s. In the August 2001 HHS Office of Inspector General (OIG) Report entitled ''Medicaid Pharmacy-Actual Acquisition Cost of Brand Name Prescription Drug Products'', the OIG reports on changes in pharmacy acquisition costs for both single source and multi-source brand name drugs. The OIG uses the common industry pricing metric of average wholesale price (AWP). The findings from the OIG study indicate that the acquisition prices pharmacies face for a broad spectrum of brand name drugs have been declining as the percentage of AWP during the period 1994 to 1999. Based on 1994 pricing data, OIG estimates that pharmacies acquired brand name drugs (both single source and multi-source) at a discount of 18.30 percent below AWP. For 1999 pricing data, OIG estimates a discount of 21.84 below AWP. The OIG reports that this represents an increase of 19.3 percent in the average discount below AWP for which pharmacies were able to purchase a mixture of single source and multi-source brand name drugs. The OIG is preparing a similar analysis on the pharmacy acquisition costs related to generic drugs. Thus, during the 1990s, as more customers secured discounts on the purchase of prescription drugs, pharmacies' acquired drugs at larger discounts from AWP.

The pharmacy acquisition costs reported by the OIG are similar to those reported in the PricewaterhouseCoopers (PWC) study conducted for us entitled ''A Study of Pharmaceutical Benefit Management'', June 2001. That study reported that pharmacies generally now acquire drugs at AWP minus 20 to 25 percent. According to the PWC report, absent a discount arrangement (such as a pharmacy-sponsored senior discount), pharmacies, on average, sell to the uninsured population at full retail price, roughly AWP plus a dispensing fee (generally $2 to $3).

We also believe that the proposed Medicare-endorsed prescription drug card programs would accelerate the use of generic drugs. The HHS study reports that, generally, pharmacies earn higher margins on generic drugs. In addition, PWC found that generic manufacturers sometimes provide pricing incentives to pharmacies based on generic volume or market share. These are other examples of adjustments that take place related to the market place in pharmaceuticals.

Our expectation is that the discounts offered by retail pharmacies and drug manufacturers would be no greater than the discounts already offered to insured individuals, including insured Medicare beneficiaries, unless there is a legitimate business reason for the pharmacies and the drug manufacturers to offer a greater discount. It is possible that the requirements of final price publication and the establishment of a large number of competing discount cards would lead to greater manufacturer discounts. We expect that access to modern competitive tools would assist in controlling prescription drug costs and improving the quality and efficiency of prescription drug services. We also expect that this initiative would somewhat level the playing field between the insured and uninsured, and the current differential in pricing between populations with drug coverage and Medicare beneficiaries without drug coverage would be ameliorated.

Further, since this proposed initiative is not a Medicare benefit, we do not expect that this effort would have any impact on the number of Medicare beneficiaries with drug coverage through employer-sponsored health insurance. We do not anticipate that employers would alter their drug coverage in response to this initiative.

G. Estimated Costs and Anticipated Benefits of Other Proposed Requirements and Medicare's Beneficiary Education and Outreach Plans

The following cost and benefit analysis is prepared in 2002 dollars and reflects costs and benefits we anticipate in the first and second year of this proposed initiative. We estimate significantly different costs in Year One and Year Two of implementation because the start up of the administrative consortium and a very large enrollment is assumed in the first year only. Also, in the second year, the administrative consortium would be responsible for review of card sponsors' marketing materials; we propose that marketing review would be our responsibility in the first year.

Table 5 reports the per card program sponsor costs and the per new enrollee costs for national and regional card programs for each administrative function associated with a significant cost. While any entity that meets all of the requirements in the regulations would be eligible to enter into an agreement with us to receive a Medicare endorsement, for purposes of estimating these costs, we assumed that 15 drug card programs would be endorsed. Of those 15, we assume that 10 would be national programs (including 50 States and Washington, DC) and 5 would be regional programs (including 4 States). We do not make adjustments for differences in Medicare population per State, which would cause the actual impact on regional programs to vary.

1. Organizational Size, Experience, and Structure Requirements

We believe that the organizational size and experience requirements would be necessary to assure beneficiary confidence in the initiative so they would enroll and stay enrolled, protect the Medicare name, and assure the necessary administrative capacity to handle a large volume of new enrollment. Large enrollment volume, along with the exclusivity provisions of this proposed rule, would be necessary for a drug card sponsor to garner significant market share and negotiate manufacturer rebates and discounts to successfully compete with other card programs on price and customer and pharmacy service.

We do not think it would be practical and therefore possible for independent pharmacies to obtain an endorsement. We nonetheless expect most pharmacies would be able to participate in an endorsed card program sponsor's pharmacy network. To improve the

opportunity for a variety of organizations, such as chain pharmacies, nonprofit groups, and other private entities to qualify for Medicare endorsement of their card program, the proposed initiative provides flexibility in the way that entities may organize to meet these size, experience and structure requirements.

We seek comments concerning the anticipated costs and limitations that would be faced by entities interested in organizing with other entities to meet any of the requirements necessary to obtain Medicare endorsement that one entity could not meet by itself.

2. Private Sector Administrative Consortium and Its Tasks

We propose that drug card sponsors would agree to, and demonstrate the ability to, jointly administer, abide by the guidelines of, and fund a private administrative consortium with other Medicare-endorsed prescription drug program sponsors.

Following are the systems specifications we used to estimate the costs of hardware to run an enrollment exclusivity system and a price comparison web site. One administrative responsibility of the consortium would be to ensure that beneficiaries are not enrolled in more than one Medicare-endorsed prescription drug card program at the same time. We assume that this would require the administrative consortium to develop and maintain a secure electronic enrollment exclusivity system that would be populated by and accessible only by the administrative consortium and endorsed sponsors; as stated previously, we assume 15 card sponsors would be endorsed.

For the purpose of defining the capacity needed for this system, we also assume that the system would maintain a unique record for each beneficiary enrolled by a card sponsor. The record would contain such information as name, address, telephone number, a unique number identifier, date of enrollment, date of disenrollment, card program identifier, provision for enrollment changes, and whether the beneficiary was group enrolled through the sponsor. We estimate the number of system transactions, most occurring in any year in a two month period, based on the estimated 10 million beneficiaries who would likely join, adjusted using the 2000 Medicare+Choice voluntary disenrollment rate of 11.5 percent.

We do not know what the actual rate of voluntary disenrollment would be for this proposed initiative; it could be lower or higher depending on how much a beneficiary's card program changes its formulary and drug prices and whether these changes affect the drugs the beneficiary takes. Also, the voluntary disenrollment rate would depend on the diligence of beneficiaries in tracking any changes to the formularies and drug prices of the card programs they join and the perceived value of these changes relative to comparable information available to them on other cards.

We assume that of the 10 million beneficiaries who would enroll in the first year, 11.5 percent would disenroll and reenroll in another Medicare-endorsed drug card program. We also assume that sponsors would access the system to check enrollment records for an additional 10 percent of beneficiaries for reasons such as a lost discount card. We assume the system would be updated in real time and be of web based technology. We assume this system would be maintained by a webmaster hired by the administrative consortium. We also assume reports, such as enrollment rates in a particular time frame by a particular card and percent of beneficiaries enrolled as a group, could be generated off this system by the consortium's webmaster.

Another administrative responsibility of the consortium would be to facilitate the publication of, or to publish, information, including comparative price information on discount drugs, that would assist beneficiaries in determining which Medicare-endorsed prescription drug card program is the most appropriate for their needs. This would require the administrative consortium to develop and maintain a web-based, searchable database accessible to the public so that interested Medicare beneficiaries or their advocates could access comparable price data on the drugs they take for the drug discount card programs available in their zip code area. We assume that each of 15 card sponsors would update its formulary and price lists four times a year. Because we propose that formularies could vary geographically, we assume that 10 of the estimated 15 sponsors endorsed by Medicare would be national programs (having a network in all 50 States and Washington, DC), and the remaining 5 programs would be regional programs, comprised of 4 States each. We assume that each card program would have a unique formulary and price list for each State, differentiated by urban and rural areas. Based on these numbers, we estimate that the price comparison web site would house as many as 1060 unique formularies and pricing listings. We assume that only the administrative consortium would have direct interface with the system; card sponsors would submit files in a uniform format to the consortium's webmaster to be uploaded. We assume reports, such as price comparisons for a list of drugs within a geographic area, could be generated off this system by the consortium's webmaster.

To fulfill these specifications for both of the enrollment exclusivity and price comparison systems, our Office of Information Services (OIS) developed a cost estimate for the first year in 2002 dollars in the amount of $400,000 for lowest common denominator technology which would permit the system to be hosted virtually anywhere by a professional internet technology organization. The estimate includes the costs of a database server, redundant database server, application server, redundant application server and the cost for an internet service provider. Second year costs would be significantly less, $80,000, reflecting maintenance rather than purchase of hardware.

A third responsibility of the administrative consortium would not begin until the second year. We propose that the consortium would be responsible for ensuring the integrity of the information distributed by the Medicare-endorsed prescription drug discount card programs. We propose that we would conduct the marketing material review for the first year of endorsements. We propose that the administrative consortium's reviews in future years would be based on guidelines prepared by us. Based on a cost estimate, prepared in 2002 dollars, developed by our Center for Beneficiary Choices (CBC), we assume that the cost of developing the guidelines would be $237,500. We assume the cost of conducting the review from the estimated 15 endorsed sponsors and tracking the status of the review and approval process, including the cost of a database for this activity would be $282,000. We assume that the cost of transitioning the review to the administrative consortium would be $44,000. We assume reporting on the status of the marketing review and findings under the review would cost $29,000. This first year cost, totaling $592,500, would be borne by us in the context of our existing budget. We use the same estimates to reflect the second year costs to be borne by the administrative consortium, however the consortium would not develop guidelines, for a total of $355,000 ($592,500 minus $237,500). This estimate does not include guideline development because this activity would be conducted by us.

A cost estimate in 2002 dollars was produced by CBC for key activities associated with the start-up of the administrative consortium, and the development of the specifications and software to run the enrollment exclusivity system as well as the price comparison web site. These activities and their estimated costs include:

- Analysis and development of recommendations for an appropriate organizational structure and governance, including review of legal considerations, $405,000.
- Specification of requirements for the enrollment exclusivity system and software development, $301,500.
- Options development for financial management for the administrative consortium, $345,600.
- Development of a transition plan from consortium formation through full operation, $104,850.
- Specification of requirements for the price comparison web site and software development, $261,000.
- Contract support to the consortium during transition for management functions, $184,500.
- Contract support for the consortium webmaster to implement the enrollment exclusivity system and the price comparison web site, $45,900.

These activities and their estimated costs equal $1.65 million for the start-up of the administrative consortium.

As an additional cost in the first year of operation, we assume that the administrative consortium would hire or retain the services of several professionals. We use national mean hourly wage data produced by the U.S. Department of Labor, Bureau of Labor Statistics, and reported in ''Occupational Employment Statistics, 2000 National Occupational Employment and Wage Estimates''. Administrative consortium staff and their estimated 2000 national mean hourly wage rates are as follows:

- Public Relations Manager—$29.54.
- Lawyer—$43.90.
- Computer Programmer—$29.31.
- Pharmacist—$33.39.
- Executive Secretary or Administrative Assistant—$15.63.

We age these wages to 2002 dollars using a 2001 adjustment of 3.8 percent, and a 2002 adjustment of 4.0 percent, found in Table II.F1 of the 2001 Annual Report of the Board of Trustees of the Federal Hospital Insurance Trust Fund (*http://www.hcfa.gov/pubforms/tr/hi2001/tabiifl.htm*). We adjust these wages upward to include compensation using an adjustment factor of 1.355 based on Table 6 of a U.S. Department of Labor, Bureau of Labor Statistics report entitled ''Employer Costs for Employee Compensation—March 2001'', which reports that national wages and salaries for white collar occupations represent 73.8 percent of total wages and compensation. We assume that the administrative consortium would hire or retain the services of each type of employee on a full-time basis of 2080 hours per year, except the lawyer and the pharmacist, whom we assume would work one-half of that time. The estimated 2002 annual wages and compensation would be as follows:

- Public Relations Manager—$89,876.
- Lawyer—$66,783.
- Computer Programmer—$89,177.
- Pharmacist—$50,795.
- Executive Secretary—$47,555.

The total of these yearly costs would be $344,188. We estimated overhead costs for these employees using a factor of 1 applied to the total wage and compensation rates for an additional amount of $344,188.

We estimate the cost of leasing space for the administrative consortium staff of 5 using an estimate provided by a commercial real estate broker of $25 per square foot for full service leasing in a metropolitan area. We apply this rate to an estimated 150 square foot office per worker, an estimate provided by the staff of the Government Services Administration (GSA), for a total amount of $18,750.

We anticipate providing some financial support for the start-up of the administrative consortium. As this support would be provided in the context of our existing budget and other program priorities, a determination of the actual amount is pending the outcome of this public notice and rule making process. We recommend at this time that interested parties assume no support aside from the costs of developing marketing guidelines and conducting the marketing review in the first year of the proposed initiative.

The total estimated cost to be borne across all Medicare-endorsed card program sponsors for the administrative consortium start-up and administrative activities in the first year would be $2.75 million ($1.64 million for start-up activities plus $400,000 for hardware plus $344,188 for staff wages and compensation plus $344,188 in overhead plus $18,750 for leased space).

We expect that drug card program sponsors would share the start-up costs. We propose that a lump sum payment be made into a privately held escrow account by each endorsed card program. The payment would be prorated by the number of States included in each endorsed card program's network area, weighted by the number of Medicare beneficiaries residing in each State (and Washington, DC). As reported in Table 5, we estimate the per card program sponsor costs for a national program would be $265,149, and for a regional program to be $20,796, with a per new enrollee cost of $0.25.

We estimate that second year administrative consortium costs to be borne by all sponsors of the consortium would be significantly lower than first year costs. Specifically, the relevant estimates for second year costs include: maintenance of the enrollment exclusivity and price comparison systems, $80,000; marketing review, $355,000; consortium staff, $344,188; overhead costs, $344,188; and leased space, $18,750; for a total of $1.14 million. As reported in Table 5, we estimate the per card program sponsor costs for a national program would be $109,902, and for a regional program to be $8,619, with a per new enrollee cost of $0.88.

In these estimates for the administrative consortium and its activities, we have captured the activities required in the proposed regulation and have attempted to reflect the significant costs associated with them. We seek public comment on the adequacy of this estimate.

We presume that sponsors would recover these costs in enrollment fees and from the portion of pharmaceutical manufacturing rebates that are not shared either directly or indirectly with beneficiaries through pharmacies. These costs would have the effect of lowering the amount of negotiated rebate that could be passed through to beneficiaries, or of increasing the enrollment fee.

We believe that card program sponsors would benefit in preparation for a future Medicare drug benefit by developing the infrastructure implied by the activities detailed above.

We believe that the administrative consortium's enrollment exclusivity responsibility, as well as its marketing review responsibility, would significantly benefit beneficiaries as they seek information about selecting a drug discount card program. These activities would help beneficiaries make informed decisions and protect them from misleading information. Further, the role of the exclusivity system in assuring that beneficiaries only belong to one drug discount card program at a time, as well as the price comparison information, would help optimize card sponsor negotiations for manufacturer rebates and discounts as sponsors compete for Medicare market share. Also, the secure exclusivity system

would assist in protecting beneficiary confidential information.

We would benefit by learning from the implementation of the requirements involving information technology, marketing material review, beneficiary enrollment, and education using the price comparison web site and through the card programs' enrollment.

3. Customer Service Requirements

Given the types of potential sponsors who would likely meet the size and experience requirements that we propose for a card program to be Medicare-endorsed, we believe that the proposed customer service requirements would represent usual and customary practice for the programs we endorse and would be associated with minimal new costs except as described below.

There would be an incremental cost associated with each additional enrollment of a Medicare beneficiary. For the purpose of this estimate, we assume that 15 drug card programs would be endorsed. We assume that a total of 10 million beneficiaries would enroll. Using the 2000 Medicare+Choice (M+C) disenrollment rate, we assume an additional 11.5 percent of beneficiaries would disenroll and reenroll for a total of 11.15 million enrollments. As reported in the Collection of Information Requirements section elsewhere in this proposed rule, we believe that each additional enrollment would take 15 minutes. This time estimate reflects the time necessary to provide beneficiaries with all the information required in the proposed regulations including: Educating the beneficiary by phone on how the discount card program works, answering questions about specific drugs in the formulary and their prices, explaining the confidentiality requirements, obtaining and storing a hard copy of the beneficiary's enrollment signature, and processing the transaction electronically.

This estimate reflects the marginal cost of each additional enrollment in the first year; we assume that each drug card program sponsor would have the basic infrastructure. We assume that the card program sponsor would hire or retain the services of customer service representatives to conduct the enrollment function.

We again use wage and compensation data produced by the U.S. Department of Labor, Bureau of Labor Statistics. The national mean hourly wage rate of $12.75 for a customer service representative was taken from a report entitled, ''2000 National Occupational Employment and Age Estimates, Office and Administrative Support Occupations'' (*http://www.bls.gov/oes/2000/oes_43Of.htm*). We age this wage rate to 2002 using the same aging factors (3.8 percent for 2001 and 4.0 percent for 2002) used to age the wages for the administrative consortium staff. We use a compensation factor of 1.355 obtained from the same report used to calculate compensation for the consortium staff, for a total 2002 wage and compensation rate of $38,792 per customer service representative. We apply a factor of 1 to this rate to provide an overhead amount of $38,792.

We estimate lease space per customer service representative using 150 square feet per office at $25 per square foot for full service, leasing in a metropolitan area, obtained from a commercial real estate broker for a per office amount of $3,750. The total cost per representative for wages, compensation, overhead and leased space would be $81,334.

Assuming that each customer service representative works seven hours per day, 5 days per week, 50 weeks per year, each representative would work 105,000 minutes per year. This would permit each representative to enroll 7000 beneficiaries per year (105,000 divided by 15 minutes per enrollment).

We estimate that for all 11.15 million new enrollees to be processed by telephone, a total of 1,593 customer service representatives would be hired or retained. As Table 5 shows, the estimated cost for a national card program sponsor would be $12.46 million, and for a regional card program sponsor, $977,774, with a per enrollee cost of $11.62.

In the second year, we estimate that 1.29 million beneficiaries would be enrolled. This number reflects a growth factor in Medicare enrollment of 1.3 percent, from Table 4 of this regulatory impact analysis, applied to the 10 million beneficiaries enrolled in the first year, and also accounts for only the 11.5 percent who we assume would disenroll and reenroll. The number of customer service representatives needed would be 185. As Table 5 shows, the estimated cost for a national card program sponsor would be $1.44 million, and for a regional card program sponsor, $113,557, with a per enrollee cost of $11.62.

The enrollment process described above would assure that beneficiaries understand how to fully benefit from the drug discount card program in which they enroll, and would assure the confidentiality of their personal information, as required in this proposed regulation. We welcome comments on different methods to efficiently enroll beneficiaries in the context of our requirements to provide information and assure that beneficiary personal information is kept confidential. We would also be interested in comments concerning the reliability, security, and ability to audit electronic rather than hard copy signatures, and on differential costs for an electronic enrollment process.

Another customer service requirement that would be significantly affected by the large number of anticipated additional enrollments per drug discount card program is the additional capacity and maintenance of the customer service call center for non-enrollment related calls. We estimate that for the first year the customer service lines, across all card program sponsors, would be used for disenrollment, or 11.5 percent of all card programs' enrollees, or 1.28 million disenrollee related calls. We assume an additional 50 percent of this number for other non-enrollment related calls, for a total of 1.92 million calls. Using our CBC estimated additional cost per call, reported in 2002 dollars in the amount of $5 for the Medicare 1–800 line, we estimate, as reported in Table 5, that the cost of the additional call volume generated by this proposed initiative for a national card program sponsor in the first year would be $925,397, and for a regional card program sponsor, $72,580, with a per new enrollee cost of $0.86.

For the second year estimate, the call volume is adjusted to reflect 1.3 percent growth in Medicare enrollment, for a total cost per national card program sponsor of $937,427, and $73,523 per regional card program sponsor, with a per new enrollee cost of $7.52.

We believe that beneficiaries would benefit significantly from telephone access to the card programs to register their concerns and complaints, or to obtain information for evaluating which card program would best meet their needs.

We presume that sponsors would recover these customer service costs in enrollment fees and that portion of the pharmaceutical manufacturing rebates that are not shared either directly or indirectly with beneficiaries through pharmacies. These costs would have the effect of lowering the amount of negotiated rebate that could be passed through, or of increasing the enrollment fee.

4. Total Costs of Requirements for Card Sponsors

As shown in Table 5, the costs of the administrative consortium operations and the customer service requirements, in the first year would total, per national card program sponsor, $13.65 million, and per regional card program sponsor,

$1.07 million, with a per new enrollee cost of $12.73.

In the second year, total costs for a national card program sponsor would be $2.49 million, and for a regional card program sponsor, $195,701, with a per new enrollee cost of $20.02.

For national and regional programs, this cost analysis for both the first and second year of operation demonstrates that a one-time enrollment fee of $25 (a new fee could be charged if the beneficiary switches programs) could cover the major administrative costs associated with this proposed initiative. Alternatively, a drug card program sponsor could choose to charge a lower or no enrollment fee and support operating expenses through a portion of the manufacturer rebates.

The numbers in Table 5 do not add exactly due to rounding.

TABLE 5.—SUMMARY OF COST ESTIMATES FOR MAJOR ADMINISTRATIVE ACTIVITIES

Year One	Per sponsor cost	Per new enrollee cost (11.15 million enrollments: 10 million first time)
Consortium & Its Administrative Cost:		
National	$265,149	$0.25
Regional	20,796	0.25
Enrollment Cost:		
National	12,466,618	11.62
Regional	977,774	11.62
Non-enrollment Call Center Costs:		
National	925,397	0.86
Regional	72,580	0.86
Total:		
National	13,657,165	12.73
Regional	1,071,150	12.73
Year Two	**Per sponsor cost**	**Per new enrollee cost (1.29 million total enrollments)**
Consortium & Its Administrative Cost:		
National	$109,902	$0.88
Regional	8,619	0.88
Enrollment Cost:		
National	1,447,860	11.62
Regional	113,557	11.62
Non-enrollment Call Center Costs:		
National	937,427	7.52
Regional	73,523	7.52
Total:		
National	2,495,191	20.02
Regional	195,701	20.02

5. Medicare's Beneficiary Education and Outreach Plans

Medicare beneficiaries would benefit from the education and outreach plans we outline in this proposed rule. The information we would impart on our web site, through brochures, and in beneficiary calls to the 1–800–Medicare telephone number would assist beneficiaries in gaining knowledge about whether and how to participate in a Medicare-endorsed prescription drug card program, and impart basic information on how to use tools to manage drug costs.

Also, we would benefit from the infrastructure built for, and the experience gained in educating beneficiaries about, using private sector tools to lower their out-of-pocket prescription drug costs and enhance the pharmacy services they would receive in preparation for a Medicare prescription drug benefit. The costs associated with these efforts would be subsumed in our existing budget.

H. Conclusion

Evidence of trends in prescription drug use and spending, changes in pharmacy acquisition costs for drugs at a time of the increased presence of pharmacy benefit management strategies, and strategies for varying drug prices and manufacturer rebates or discounts seems to indicate a dynamic market that adjusts and returns to equilibrium. Pharmacy benefit management has been a feature of all the major Medicare prescription drug benefit legislative proposals. The implementation of a Medicare-endorsed prescription drug discount card assistance initiative in this environment would educate Medicare beneficiaries and provide them with experience with the private sector tools used to provide pharmacy benefits to practically all Americans who have a drug benefit. The Medicare-endorsed prescription drug card programs would need to garner significant Medicare market share to successfully negotiate manufacturer rebates and discounts to cover administrative costs, keep enrollment fees low and pass through an amount to beneficiaries to keep their drug prices and pharmacy services competitive. This initiative may help ease the transition of the market to a full Medicare prescription drug benefit.

I. Alternatives Considered

We are committed to working with the Congress on a prescription drug benefit in the context of Medicare reform. We considered not pursuing any other immediate effort to assist and

educate Medicare beneficiaries about how to lower their out-of-pocket costs prior to the enactment and implementation of a Medicare prescription drug benefit. However, we concluded that the drug card initiative would provide beneficiaries with immediate help with the cost of prescription drugs, and also could improve access to better quality prescription drug related services. We believe that access to prescription drugs is so fundamental in today's health care environment that beneficiaries should receive information, counseling, and assistance regarding prescription drug discount programs until a Medicare prescription drug benefit is enacted and implemented. Furthermore, we believe that through real world experience with drug assistance card programs, Medicare beneficiaries would be better educated concerning the economic and quality decisions made by private sector purchasers and individuals with drug coverage. A Medicare prescription drug benefit would probably involve the private sector tools currently used by health insurers to lower prescription drug costs and provide higher quality pharmaceutical services. Experience through the proposed drug discount card initiative would better prepare Medicare beneficiaries, particularly those without drug coverage, to make informed decisions about a drug plan that is best for them. Additionally, we would gain experience in educating Medicare beneficiaries about prescription drugs.

We considered alternatives to major proposed features of the initiative, including requiring manufacturer rebates and not permitting mail order only programs to be Medicare endorsed. In deciding to propose requiring manufacturer rebates, we underscore our commitment to mitigating the effect on pharmacies and drugs stores, particularly small entities. Manufacturer rebates would have to be shared with beneficiaries, either directly or indirectly through pharmacies (lower prices, pharmacy counseling or other services that ultimately benefit the Medicare beneficiary). Since card sponsors would not rely solely on pharmacy discounts to compete for customers, pressure would be relieved from pharmacies. To the extent that rebates would be shared through pharmacies, both pharmacies and beneficiaries would benefit. Requiring rebates also would bring the design of the proposed initiative closer to that of insured products, which rely on manufacturer rebates, as well as any discount offered by the pharmacies, to lower costs.

We also considered permitting a mail order only option. Mail order programs have some popularity, and may be a convenient option for some beneficiaries. However, we decided not to propose a mail order-only option because we believe that requiring strong access to retail pharmacies would be in the best interests of beneficiaries, the majority of whom rely on retail pharmacies. Requiring retail access also would mitigate the impact of the proposed initiative on retail pharmacies, particularly small pharmacies that rely on Medicare beneficiaries to make purchases on non-prescription drug items when they enter the pharmacy to fill prescriptions.

We also considered alternative sets of requirements for Medicare endorsement. For example, we could have proposed only requirements pertaining to rebates, discounts, and access to retail pharmacies, while eliminating the size, structure and experience, and customer service requirements. However, we concluded that beneficiary confidence in discount card programs would also depend on the stable availability of reputable card programs and high quality customer service, which we believe only the full set of proposed requirements could assure. We think that beneficiary confidence would be an essential element to beneficiaries' participation, and consequently the role of competition in driving better pricing and quality.

More specifically, among the key requirements we are proposing are requirements related to the following three areas: (1) Requirements related to the applicant's experience, structure, and agreement to jointly administer the administrative consortium; (2) requirements related to customer service; and (3) requirements related to rebates, discounts, and access.

In the area of experience, structure, and agreement to jointly administer the administrative consortium, for example, we would require that national drug discount card program sponsors have 5 years of experience in pharmacy benefit management, or the administration of drug discount cards or low income drug assistance programs that provide prescription drugs at low or no cost and currently serve 2 million covered lives. We believe that these requirements would be necessary in order to help ensure that Medicare would endorse stable organizations that would be likely to exist for some time, and would be capable of serving large populations.

In the area of customer service, we would require that card sponsors charge Medicare beneficiaries no more than a $25 initial enrollment fee. Card program sponsors would be allowed to choose to offer a lower, or no, initial enrollment fee. Unlike the current industry practice of assessing annual fees, we would require card sponsors that choose to charge an enrollment fee to do so only upon initial enrollment, not on an annual basis. We believe that this approach to enrollment fees would be a reasonable way for card program sponsors to defray operating expenses, while providing Medicare beneficiaries with a feature that is generally not found in the current market. We believe that the added market leverage achieved by the Medicare endorsement would more than offset the need to charge an annual enrollment fee. We also believe that the customer service call center would be essential to beneficiary education, assuring that beneficiaries would understand the best use of the card program's features, as well as providing a vehicle for problem solving to promote beneficiary confidence in the card program.

In the area of rebates, discounts, and access, we would require, for example, that for the area to be served by the card program sponsor (either national or regional), 90 percent of the beneficiaries would have to live within 10 miles of a contracted pharmacy. Beneficiary access to retail pharmacies would be an important component of this proposed initiative, and we believe that this standard would preserve beneficiary access to the retail pharmacies that they trust.

Another alternative we considered was to select one or more card program sponsors through a competitive approach. We considered this because we believed it could have allowed for deeper discounts, as potential card sponsors compete for the Medicare business. However, we decided to endorse all qualified applicants meeting the requirements in order to give beneficiaries an array of choices, and to let the market determine which card programs offer the best value to Medicare beneficiaries. We believe that our approach would more easily accommodate additional programs seeking Medicare endorsement, and that beneficiaries would select a Medicare-endorsed card program that is right for them.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental

relations, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV, part 403 as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

1. The authority citation for part 403 is revised to read as follows:

Authority: Sec. 4359 of the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C. 1359b–3) and secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Add a new subpart H, consisting of §§ 403.800 through 403.820, to part 403 to read as follows:

Subpart H—Medicare-Endorsed Prescription Drug Card Assistance Initiative

Sec.

403.800 Basis and scope.
403.802 Definitions.
403.804 General rules for Medicare endorsement.
403.806 Requirements for eligibility for endorsement.
403.807 Application process.
403.808 Agreement terms and conditions.
403.810 Administrative consortium responsibilities.
403.811 Beneficiary enrollment.
403.812 Withdrawal of endorsement.
403.820 Oversight and beneficiary education.

Subpart H—Medicare-Endorsed Prescription Drug Card Assistance Initiative

§ 403.800 Basis and scope.

(a) *Provisions of the legislation.* This subpart implements, in part, the provisions of section 4359 of the Omnibus Budget Reconciliation Act of 1990 (OBRA). Section 4359 of OBRA requires the Secretary to establish a health insurance advisory service program (the beneficiary assistance program) to assist Medicare beneficiaries with the receipt of services (including both covered and uncovered benefits) under the Medicare and Medicaid programs and other health insurance programs. The subpart is also based on sections 1102 and 1871 of the Social Security Act.

(b) *Scope of subpart.* This subpart sets forth the standards and procedures CMS uses to implement the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

§ 403.802 Definitions.

For purposes of this subpart, the following definitions apply:

Administrative Consortium means the group of Medicare-endorsed prescription drug card program sponsors formed to jointly carry out specific administrative tasks associated with operating the Medicare-endorsed prescription drug card programs in accordance with the Medicare endorsement agreement.

Applicant means the organization or entity (along with any subcontractors or others with whom it has legal arrangements for the purpose of meeting the requirements for endorsement) that is applying for Medicare endorsement of its prescription drug card program.

Application means the document submitted to CMS by an applicant that demonstrates compliance with the requirements specified in this subpart in order to obtain Medicare endorsement of the applicant's drug card program.

Medicare-endorsed prescription drug card assistance initiative means an effort whereby CMS solicits applications for Medicare endorsement of prescription drug card programs, reviews them, offers agreements to program sponsors who meet all of the requirements for endorsement, and awards Medicare endorsements to program sponsors who sign the agreement.

Medicare-endorsed prescription drug card program means a program developed by an organization or group of organizations, endorsed by CMS under the Medicare-endorsed prescription drug card assistance initiative to educate Medicare beneficiaries about tools to lower their prescription drug costs and to offer prescription drug cards to Medicare beneficiaries.

Medicare-endorsed prescription drug card program sponsor means any applicant that has received endorsement from Medicare for its prescription drug card program.

Solicitation means a notice published in the **Federal Register** announcing a request for applications from applicants seeking Medicare endorsement for their prescription drug card programs.

§ 403.804 General rules for Medicare endorsement.

(a) *Applications.* Applicants may submit applications to participate in the Medicare-endorsed prescription drug card assistance initiative and become a Medicare-endorsed prescription drug card program sponsor.

(b) *Number of programs sponsored.* An organization or entity may have operational responsibilities in more than one drug card program. A separate application must be submitted for each program. A sponsoring organization or entity may be the primary organization or entity in only one application per solicitation, and may sponsor only one Medicare-endorsed prescription drug card program at any time.

(c) *Requirements.* In order to be eligible for endorsement, applicants must submit applications and meet all of the requirements specified in § 403.806.

(d) *Eligibility to receive endorsement.* Any applicant that submits an application containing all information necessary to determine whether the applicant meets all of the requirements in § 403.806; and that meets all of the requirements in § 403.806; will be eligible to enter into an agreement with CMS to receive a Medicare endorsement.

(e) *Period of endorsement.* In Year One of the initiative, the Medicare endorsement will be effective for 15 months. CMS will consider card program sponsor performance under an existing Medicare endorsement as a factor in determining eligibility for endorsement in future annual cycles.

(f) *Termination of endorsement by CMS.* CMS may terminate the endorsement at any time.

(g) *Termination of participation by Medicare-endorsed drug card sponsor.* A Medicare-endorsed prescription drug card program sponsor may choose not to continue participation in the Medicare-endorsed prescription drug card assistance initiative. In Year One, termination would be effective 30 days after providing written notice to CMS.

(h) *Notification of beneficiaries of termination of participation.* In the event of termination of participation in the initiative by the drug card program sponsor, or termination by CMS, the Medicare-endorsed prescription drug card program sponsor must notify all of its Medicare beneficiary enrollees in writing that they may enroll in an alternative Medicare-endorsed prescription drug card program. This notice must be provided by United States mail within 10 days of providing CMS with notice of termination or within 10 days of receiving notice of termination from CMS.

§ 403.806 Requirements for eligibility for endorsement.

(a) *General.* To be eligible for Medicare endorsement, an applicant must submit an application demonstrating that it meets and will comply with the requirements described in this section.

(b) *Applicant structure, experience, and participation in administrative consortium*—(1) The applicant must

apply as either a national or a regional program.

(i) To qualify as a national program, a single organization or entity that is either the applicant or a subcontractor or under other legal arrangement with the applicant must—

(A) Have no less than 5 years experience in pharmacy benefit management, in administering a prescription drug discount program, or in administering a low income drug assistance program that provides prescription drugs at low or no cost;

(B) Currently manage at least 2 million covered lives in an insured pharmacy benefit, prescription drug discount program, or a low income drug assistance program that provides prescription drugs at low or no cost; and

(C) Have a pharmacy network serving all 50 States and the District of Columbia.

(ii) To qualify as a regional program, a single organization or entity that is either the applicant or a subcontractor or under other legal arrangement with the applicant must—

(A) Have no less than 5 years experience in pharmacy benefit management, in administering a prescription drug discount program, or in administering a low income drug assistance program that provides prescription drugs at low or no cost;

(B) Currently manage at least 1 million covered lives in an insured pharmacy benefit, a prescription drug discount program, or a low income drug assistance program that provides prescription drugs at low or no cost; and

(C) Have a regional pharmacy network serving at least two contiguous States.

(2) The applicant must demonstrate that it is financially solvent.

(3) The applicant must have a satisfactory record of integrity and business ethics.

(4) The applicant must agree to, and demonstrate the ability to, jointly administer, abide by the guidelines of, and fund a private administrative consortium with other Medicare-endorsed prescription drug program sponsors in accordance with the requirements of this subpart.

(5) The applicant must comply with all applicable Federal and State laws.

(c) *Customer service.* The applicant must do the following:

(1) Limit its one time enrollment fee in Year One to no more than $25. In future years, CMS may adjust the fee based on a determination of what is a reasonable amount to defray costs of the applicant's administrative activities.

(2) Provide information and outreach materials regarding its Medicare-endorsed prescription drug card program to all enrolled Medicare beneficiaries.

(3) Enroll all Medicare beneficiaries who wish to participate in its Medicare-endorsed prescription drug card program.

(4) Maintain a toll free customer call center that is open during usual business hours and that provides customer telephone service in accordance with standard business practices.

(5) Protect the privacy and confidentiality of beneficiaries and beneficiary-specific information.

(6) Not send or otherwise direct market to beneficiaries materials unrelated to the Medicare-endorsed prescription drug card program, unless the beneficiary provides prior written consent to receive these materials.

(7) Maintain written privacy policies describing how privacy and confidentiality will be protected. Such privacy policies must explain how the applicant will notify beneficiaries of the expected uses of their personal information.

(d) *Discounts, rebates, and access.* The applicant must—

(1) Offer a discount on at least one brand name or generic prescription drug in each of the therapeutic drug classes, groups, or subgroups representing the prescription drugs commonly needed by Medicare beneficiaries;

(2) Obtain substantial pharmaceutical manufacturer drug rebates or discounts on brand name drugs, and ensure that a substantial share is provided to beneficiaries either directly or indirectly through pharmacies;

(3) Guarantee that for the drugs on which the applicant will offer discounts, Medicare beneficiaries enrolled in its Medicare-endorsed prescription drug discount card program will receive the lower of the discounted price available through the program, or the price the pharmacy would charge a cash paying customer;

(4) Have a national or regional contracted pharmacy network sufficient to ensure that pharmacies are locally accessible to beneficiaries where the drug discount card will be offered; and

(5) Provide to the administrative consortium information on drugs and their pricing included in the applicant's formularies.

§ 403.807 Application process.

(a) CMS will solicit applications through an application process.

(b) CMS will review applications and determine whether the applicant has met and is able to comply with all of the requirements set forth in § 403.806 to become Medicare-endorsed.

(c) All applications that demonstrate that the applicant has met and is able to comply with all of the requirements to become Medicare-endorsed will be eligible to enter into an agreement to receive Medicare endorsement from CMS.

§ 403.808 Agreement terms and conditions.

In order to receive a Medicare endorsement, an applicant that complies with all of the application procedures and meets all of the requirements described in this subpart must enter into a written agreement with CMS. The agreement must include a statement by the applicant that it has met the requirements of this subpart and will continue to meet all requirements as long as the agreement is in effect.

§ 403.810 Administrative consortium responsibilities.

(a) The administrative consortium will be responsible for—

(1) Ensuring that beneficiaries are not enrolled in more than one Medicare-endorsed prescription drug card program at the same time;

(2) Facilitating the publication of, or publishing, information, including comparative price information on discounted drugs, that assists beneficiaries in determining which Medicare-endorsed prescription drug card program is the most appropriate for their needs; and

(3) Ensuring the integrity of the information distributed by the Medicare-endorsed prescription drug card programs.

(b) In order to facilitate the formation of the administrative consortium and ensure that all functions are performed in a timely manner, CMS may assist in the start-up of the administrative consortium and perform any of the functions in this section for a transitional period of time.

§ 403.811 Beneficiary enrollment

(a) *Individual enrollment.* (1) Medicare beneficiaries who are enrolling in a Medicare-endorsed prescription drug card program for the first time may enroll at any time.

(2) Once enrolled, a Medicare beneficiary may belong to only one Medicare-endorsed prescription drug card program at a time.

(3) Once enrolled, and except as provided in paragraph (a)(4) of this section, enrollees may change enrollment to a different Medicare-endorsed prescription drug card program every 6 months, to be effective the first day of the following January or July following the request for change, whichever comes first.

(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.

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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