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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 403

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Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative

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

ACTION: Final rule.

SUMMARY: This final rule describes the Department of Health and Human Services' (HHS) Medicare-Endorsed Prescription Drug Card Assistance Initiative, and sets forth the necessary requirements to participate in the initiative.

EFFECTIVE DATE: This final rule is effective November 4, 2002.

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I. Background

A. Purpose of the Initiative

The purpose of this final rule on the Medicare-Endorsed Prescription Drug Card Assistance Initiative is to assist Medicare beneficiaries in making optimal use of their Medicare-covered services and to provide Medicare beneficiaries with information, counseling and education on private sector plans and opportunities available to them to lower their prescription drug costs. There already exist a number of private sector tools—such as formularies, use of generic drugs, and negotiation of discounts or rebates—for obtaining prescription drugs at discounted prices. Also, a number of commercial products and drug discount programs already exist that offer discounts to seniors and others. This final rule and initiative will recognize those drug discount programs that offer features we believe are most useful to beneficiaries, and will educate Medicare beneficiaries about the methods used in the private sector to lower prescription drug costs. This will assist beneficiaries in making optimal use of their Medicare covered services.

While Medicare generally does not cover the purchase of outpatient prescription drugs, Medicare Part B, in section 1832 of the Social Security Act (the Act), provides benefits for a variety of other outpatient services and procedures, including physician office visits and services for which a

prescription drug order is a critical component of the service provided. In 2000, the Medicare fee-for-service program paid for approximately 188 million physician office visits (for new and established patients) at a program cost of nearly $6.6 billion for the visits alone, not including other services such as lab tests or procedures. *See* Table 62, *Health Care Financing Review, Medicare and Medicaid Statistical Supplement, 2002,* unpublished. Our preliminary analysis of 2001 Medicare data indicates that fee-for-service beneficiaries had, on average, roughly 6 physician office visits per person.

Over the last two decades, prescription drugs have played an increasingly critical role in these outpatient medical care settings and as such, prescription drugs are an integral part of the treatment plans that physicians develop for patients during office visits. According to an unpublished analysis by the National Center for Health Statistics of data from the 2000 National Ambulatory Medical Care Survey (NAMCS), approximately 70 percent of all physician office visits for individuals 65 years of age or older include the physician prescribing new or continued medications, or supplying or administering a prescription drug to the patient. Further, published NAMCS data indicate that the number of new drug prescriptions, renewals, or drug administrations per 100 physician office visits for patients 65 years of age or older has grown from roughly 150 in 1985 to nearly 200 in 1999. *See* ''Advance Data From Vital and Health Statistics Number 322'', *National Ambulatory Medicare Care Survey: 1999 Summary,* July 2001.

Despite the increasing importance of prescription drugs in medical treatment, our data indicate that over 9 million Medicare beneficiaries are without drug coverage. Many of these individuals also are either not aware of or do not have access to the private sector methods insurance companies and drug discount card programs use to lower drug costs. Even if beneficiaries are aware of prescription drug discount cards, they frequently do not have enough information to make a meaningful choice among available prescription drug discount cards. *See* for example, Kaiser Family Foundation, *Prescription Drug Discount Cards: Current Programs and Issues,* February 2002. These beneficiaries do not benefit from lower negotiated drug prices. This means that the nation's elderly without drug coverage, along with uninsured Americans, are likely paying the highest prices for drugs in the marketplace—prices higher than those paid by working individuals, whose drugs are covered by group health insurance. The lack of drug coverage, combined with the high prices, means that some of these beneficiaries may not fill prescriptions or may have them filled less often because they cannot afford the cost. Failing to fill a prescription ordered by a doctor is not an optimal use of a physician visit paid for by the Medicare program.

Providing education to seniors on ways to access more affordable prescription drugs—especially for those beneficiaries without drug coverage—will, we believe, allow Medicare beneficiaries to make more optimal use of their Medicare-covered services, such as the service of having a physician provide an examination and issue a prescription order. We believe that when beneficiaries do not comply with the prescription drug regimens ordered by their physicians as a result of an office visit because of lack of drug coverage or lack of affordable access to prescription drugs, beneficiaries are not making the most optimal use of their Medicare-covered physician visits and other outpatient services. There is evidence that large numbers of beneficiaries, particularly those without drug coverage, do not fill some prescriptions ordered by their physicians and skip doses to make their drugs last longer due to cost concerns. A recent study of Medicare beneficiaries in eight states found that among those without drug coverage, 25 percent reported not filling a prescription due to cost, and 27 percent reported skipping doses to make drugs last longer. These rates of noncompliance with physician prescribing orders were more than double the rates reported among beneficiaries with drug coverage. *See* Dana G. Safran, et al., ''Prescription Drug Coverage And Seniors: How Well Are States Closing the Gap?'' *Health Affairs* Web Exclusive W253 (July, 2002). Additional examples of related research are discussed in section I.B of this preamble, discussing the statutory basis for the initiative.

Furthermore, analysis of 1997 and 1998 data from a nationally representative sample of Medicare beneficiaries shows that Medicare beneficiaries without drug coverage fill fewer prescriptions than those with drug coverage. *See* John A. Poisal and Lauren Murray, ''Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage,'' 20 *Health Affairs* 74, (2001). Our more recent analysis of data from the 1999 Medicare Current Beneficiary Survey (MCBS) indicates that, overall, beneficiaries without drug coverage, on average, self-report filling fewer prescriptions (17.7) than those with drug coverage (25.1). This phenomenon holds true even among groups of beneficiaries with large numbers of chronic conditions. For beneficiaries with five or more chronic conditions, those without drug coverage self-report, on average, filling approximately 38.7 prescriptions compared to beneficiaries with drug coverage, who self-report filling, on average, 44.4 prescriptions.

Not filling prescriptions, skipping doses, or cutting pills in half is referred to in the medical literature as ''medication noncompliance'' and can have adverse health effects. Medication noncompliance can lead to worsening health problems and the need for additional health care services. A study of prescription drug noncompliance among disabled adults found that about half of the individuals reporting medication noncompliance due to cost reported experiencing one or more health problems as a result, including pain, discomfort, disorientation, change in blood pressure or other vital signs, having to go a doctor or emergency room, or being hospitalized. *See* Jane Kennedy and Christopher Erb, ''Prescription Noncompliance Due to Costs Among Adults with Disabilities in the United States,'' *American Journal of Public Health,* July 2002. This study also cites other research indicating that medication noncompliance is a clinical problem, particularly related to chronic illnesses such as hypertension, and has been found to be a predictor of hospital admissions and emergency room visits in other studies. We believe that medication noncompliance can lead to additional Medicare program costs which burden the Medicare program, thus this final rule works towards furthering the interest of efficient program management.

In addition, even Medicare beneficiaries without prescription drug coverage, but who can afford to pay out-of-pocket for prescription drugs, do not have access to the most sophisticated systems used in insured products to detect and provide information between pharmacies on drug interactions, interaction prevention, and allergy monitoring. Further, a substantial number of uninsured beneficiaries, or beneficiaries with capped prescription drug coverage, have little experience or knowledge on how they might lower their prescription drug costs, for example by obtaining a prescription drug discount card or by using generic equivalents.

To fulfill the Medicare program goals and to educate Medicare beneficiaries on this important aspect of their care

and treatment plans, this final rule creates a Medicare-Endorsed Prescription Drug Card Assistance Initiative. This initiative is intended to educate beneficiaries regarding the products and tools already available to them in the private sector for reducing their prescription drug costs, including the use of generic drugs. Our initiative is intended further to inform Medicare beneficiaries about how they can receive the types of price concessions that are typical of insurance products. This final rule does not, nor does it intend to, create a new Medicare benefit. The initiative merely creates a mechanism—the Medicare endorsement for qualifying drug discount cards—to recognize those programs with features we believe are most useful to beneficiaries, and to educate and assist Medicare beneficiaries in accessing the methods used in the private sector for lowering prescription drug costs. We believe that by educating beneficiaries about opportunities to access more affordable prescription drugs, beneficiaries will be more likely to be compliant with prescription drug treatment plans and consequently will make more optimal use of their Medicare-covered services. This initiative is consistent not only with the Secretary's duty under the Medicare program to educate beneficiaries, but is also consistent with the Secretary's duties under the Act to effectuate the purposes of the Medicare program.

B. Statutory Basis for the Initiative

1. Section 4359 of the Omnibus Budget Reconciliation Act of 1990

As we explained in the preamble to the proposed rule published in the **Federal Register** on March 6, 2002 (67 FR 10262), the authority for this initiative is primarily based upon the educational and assistance authority found in section 4359(a) of the Omnibus Budget Reconciliation Act of 1990 (OBRA)(Pub. L. 101–508). Under that section, 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.'' Section 4359(c)(1)(B) of OBRA authorizes the Secretary to ''provide for information, counseling, and assistance for Medicare-eligible individuals'' with respect to benefits, whether or not 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.

As we stated in the proposed rule, we believe that this initiative meets the definition of a beneficiary assistance program because it will 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 will 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. In fact, as we state in one of the responses below, several studies have shown that access to lower-price prescription drugs can result in more effective or efficient use of medical care. One study, which we discuss in more detail below, showed that such access resulted in a lower incidence of nursing home admissions. In addition, to the extent that better pricing on drugs leads beneficiaries to comply with the drug regimens prescribed by their physicians, this initiative results in beneficiaries making better use of their Medicare-covered physician visits.

We also believe that this initiative will be a valuable educational tool for beneficiaries. It will improve their understanding of how to access better prescription drug prices, 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 prescription drugs are so intertwined with other types of Medicare-covered care, such as physician visits and medical and surgical care that beneficiaries should receive information, counseling, and assistance regarding prescription drug discount programs. Section 4359(b) of OBRA 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 several 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.''

In one of the responses to comments below, we discuss studies by the Employee Benefits Research Institute that demonstrate a lack of confidence among older Americans in the ability to afford prescription drug costs. While beneficiary confidence in Medicare is already high, we believe such confidence will be enhanced by educating beneficiaries about discount drug programs and assisting them in obtaining discounted prices, as well as other valuable pharmacy services. This initiative will 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), vacated and remanded on other grounds by 37 Fed. Appx. 542, 2002 WL 1359464 (D.C. Cir. May 17, 2002) (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.))

Comment: Several commenters stated their belief that we lack the statutory authority to implement the program. Commenters proposed that section 4359 of OBRA is merely an educational resource for providing seniors with information regarding benefits and services available under Medicare and Medicaid. Commenters also stated that a district court previously stopped the drug card program due to lack of authority, and that because this program is allegedly similar to the proposed program, we need the Congress to grant specific statutory authority.

Response: For the reasons stated in the preamble to the proposed rule, as well as in the preamble to this final rule, we believe that we possess the statutory authority to implement this initiative. We believe that section 4359 of OBRA is broad concerning the types of assistance that the Secretary may offer in order to improve beneficiary confidence in the Medicare program and to improve the relationship between beneficiaries and the program; and that therefore, the Secretary has the discretion to interpret section 4359 in a manner that will provide assistance to Medicare beneficiaries through this discount card initiative. If section 4359 were intended only for providing information, as one commenter suggests, then there would have been no need for the Congress to state that the beneficiary assistance program shall provide for ''information, counseling, *and assistance* for Medicare-eligible individuals.'' Section 4359(c) (emphasis added). The requirement that the beneficiary assistance program provide assistance, in addition to counseling and information, suggests that the Congress contemplated more than the provision of information. While the Congress's use of the term ''assistance'' would not provide authority to spend benefit dollars on prescription drugs, or to mandate discounts from manufacturers or pharmacies, this initiative does not impose requirement on any entities—it merely creates conditions that we will use to endorse card programs that we consider to be appropriate for beneficiaries. Thus, we believe that the Congress's use of the term ''assistance'' suggests that the Secretary can assist beneficiaries by informing them of, and educating them about, the private sector discount cards that we believe include features most appropriate for beneficiaries. In 4359(c), the Congress also required the ''beneficiary assistance program [to] provide such *other services* as the Secretary deems appropriate.'' *Id.* (emphasis added). If the Congress had intended to limit the beneficiary assistance programs to providing information, then there would have been no need to include the ''other services'' language in the section. Finally, if the purpose of section 4359 were merely to increase beneficiary understanding of the Medicare program, then there would have been no need for the Congress to authorize the Secretary also to increase beneficiary ''confidence in'' the Medicare program and ''to improve the relationship between beneficiaries and the program.'' *Id.*

Commenters are correct that a United States District Court judge, *in National Ass'n of Chain Drug Stores* v. *Thompson,* No. 01–1554 (D.D.C. 2001), 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 (66 FR 37563). We respectfully disagree with that preliminary finding, but we have abided by it by ceasing all activity on any applications received in response to the application published in the summer of 2001. We anticipate that, if the plaintiffs believe that the final rule is substantially similar to the program published in the July 18, 2001 **Federal Register**, they will seek further judicial review, which could result in a delay in implementation.

2. Sections 1102, 1140, and 1871 of the Social Security Act

Sections 1102, 1140, and 1871 of the Social Security Act (the Act), in conjunction with the authority provided by section 4359 of OBRA, lend further support to this 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 will 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 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 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.

Comment: One commenter stated a belief that sections 1102 and 1871 of the Act do not provide authority for this initiative, since the Secretary's general rulemaking authority is restricted by the substantive areas over which he is charged.

Response: Sections 1102 and 1871 might not, by themselves, provide sufficient authority to implement the Medicare-Endorsed Prescription Drug Card Assistance Initiative; however, in conjunction with OBRA section 4359, we believe that the general rulemaking authority provides the Secretary with authority to make rules that will further the goals of OBRA section 4359—that is, providing education and assistance to Medicare beneficiaries in their receipt of services under Medicare, Medicaid, and other health insurance programs; increasing beneficiary confidence in the Medicare program; and improving the relationship between Medicare and its beneficiaries by providing assistance on accessing lower cost drugs.

As we stated in the preamble to the proposed rule, prescription drugs are such a critical component in today's health care delivery that we believe that

improved beneficiary access to prescription drugs will improve confidence in the Medicare program and improve the relationship between Medicare beneficiaries and the program. While studies show that Medicare beneficiaries are ''very satisfied'' with the Medicare system, we believe that evidence also shows that access to affordable prescription drugs would further boost confidence in Medicare. *See* Public Opinion Strategies and Peter D. Hart Research Associates, *Medicare and Prescription Drug Focus Groups, Summary Report* (July 2001). A 2001 Health Confidence Survey conducted by the Employee Benefits Research Institute (EBRI), a private, nonprofit, nonpartisan public policy research organization, showed that 41 percent of respondents 65 and older were not confident they would be able to afford prescription drugs without financial hardship and that prescription drugs were their biggest concern. In the 2000 Health Confidence Survey, 50 percent of those surveyed responded that they were not too or not at all confident that, once eligible for Medicare, they would be able to afford prescription drugs without financial hardship. Again, prescription drugs were their largest concern (as compared to (a) the ability to get needed treatments; (b) freedom to choose a provider; and (c) ability to afford health care without financial hardship). The EBRI studies are available on the Web site, *http://www.ebri.org/hcs/.*

As shown by these surveys, Medicare beneficiaries are concerned about the prescription drug costs they are facing and their ability to pay for the drugs. We believe that providing a method for accessing discounts on prescription drugs—discounts that are available to most other insured populations—could help to partially address this concern and will demonstrate to the Medicare population that the Department of Health and Human Services is taking some action to help beneficiaries alleviate their drug costs. Of course a drug discount is no substitute for a drug benefit, but in the absence of legislation authorizing a drug benefit, we believe that we can improve beneficiary confidence in the Medicare program and improve the relationship between beneficiaries and the Medicare program through this initiative. In addition to research supporting our conclusion that this initiative will increase beneficiary confidence in and improve the beneficiary relationship with the Medicare program, there is also evidence supporting our conclusion that access to prescription drugs is an integral part of the health care services delivered by the Medicare program, and that improving access to prescription drugs directly influences the effectiveness of Medicare-covered services.

For example, one study found that patients with hypertension who lacked drug coverage were 1.4 times more likely than those with coverage not to purchase their anti-hypertension medications, thus potentially increasing their risk of more severe medical consequences (of beneficiaries with hypertension and without drug coverage, 21.8 percent failed to purchase any hypertensive tablets during the year as compared to 17.1 percent of those with coverage—thus increasing the odds of failing to purchase any hypertensive medications by forty percent (adjusted odds ratio = 1.4, p=.002)). *See* Jan Blustein, ''Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension,'' 19 *Health Affairs* 219 (2000).

Another study showed that Medicare beneficiaries without drug coverage used about 8 fewer prescriptions (or 33% fewer medications) than those with drug coverage. *See* John A. Poisal and Lauren Murray, ''Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage,'' 20 *Health Affairs* 74 (2001).

A third study found that limiting access to medications among low-income, elderly Medicaid patients increased rates of admission to nursing homes. The study analyzed Medicaid recipients aged 60 years or older who took three or more medications per month and at least one maintenance drug for chronic diseases. Limiting affordable access to prescription drugs for this population (through a reimbursement cap on medications) increased rates of admission to nursing homes. The authors concluded that for the sicker patients in the study, the limitation on medication more than ''double[d] the rate'' of admission in comparison to a group whose medications were not limited. *See* Stephen B. Soumerai *et al.*, ''Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes,'' 325 *New Engl. J. of Med.* 1072, 1074 (1991).

Finally, a study in the December 2001 issue of the *Journal of General Internal Medicine* found that certain characteristics, such as minority ethnicity, and low income (defined as income less than $10,000) significantly increase the risk that an individual will restrict medications by, for example, skipping doses or avoiding taking medication altogether. For example, the odds of medication restriction in minority subjects were 10.3 times higher in those with no drug coverage than in those with full drug coverage. Similarly, the odds of medication restriction were 14.8 percent higher in low-income subjects with no drug coverage than in those with full drug coverage. The author of the study stated: ''Policies designed to limit medication use may have serious consequences for patients' health, resulting in increased emergency department visits, nursing home admissions, use of emergency mental health services and more.'' *See* Michael A. Steinman, *et al.*, ''Self-restriction of Medications Due to Cost in Seniors without Prescription Coverage,'' 16 *Journal of General Internal Medicine* 793–799 (Dec. 2001).

Patients who skip doses or who do not take their full dose (by, for example, cutting pills in half) are not making the most effective use of their Medicare-covered services, in part, because they are not following their doctors' orders. Since a physician visit is a Medicare-covered service, patients who do not follow the drug regimen their doctor prescribes are not getting the full benefit of the Medicare-reimbursed physician visit.

While providing information and educational assistance to beneficiaries which allows them to access lower cost prescription drugs is not the same as providing drug coverage, we believe the evidence supports our conclusion that making prescription drugs available and more affordable to beneficiaries will make other Medicare-covered services, such as physician visits, more effective.

Comment: At least two commenters stated that section 1140 of the Act does not authorize the establishment of a prescription drug card program, and in fact, use of the Medicare name in connection with private prescription drug card programs will result in the kind of false impression or confusion that section 1140 is meant to prevent.

Response: Section 1140 may not by itself authorize Medicare to endorse discount drug cards meeting certain criteria; however, we believe that section 1140 indicates that the Congress recognizes that in some cases endorsements by the Medicare program may be warranted. The fact that section 1140(a) prohibits using the word Medicare ''in a manner which such person knows or should know would convey, or in a manner which reasonably could be interpreted or construed as conveying, the false impression that such item is approved, endorsed, or authorized by the . . . Health Care Financing Administration,

or the Department of Health and Human Services,'' provides evidence that the Congress understood that in some cases use of the word Medicare by private parties and organizations will be approved by the Secretary. Therefore, we cited section 1140 as further support for the initiative. Thus, while section 1140 would not necessarily independently authorize the Medicare-Endorsed Prescription Drug Card Assistance Initiative, in conjunction with OBRA section 4359 and sections 1871 and 1102 of the Act, we believe it provides further support to the initiative.

We do not believe that this initiative will lead to false impressions prohibited by section 1140, since only programs that meet the criteria of this final rule, and that enter into an agreement with us, will be endorsed and approved. Thus, there will not be confusion or false impressions regarding Medicare endorsement, since such programs will, in fact, be endorsed. In fact, in order to ensure that the Medicare name is only used in appropriate circumstances, this final rule creates specific criteria for use of the Medicare name.

Comment: Some commenters stated that Congressional bills proposing discount card programs similar to the one in the proposed rule show that we lack statutory authority to implement the discount card. In addition, Congressional proposals or enactments to establish an outpatient drug benefit for seniors show that we are not authorized to implement the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

Response: We do not think that current legislative proposals have much bearing on the Secretary's authority to implement the proposed initiative. Because bills are introduced by individual members, and not passed by the Congress as a whole, they are not viewed as reflecting the collective intent of Congress. Proposed legislation is viewed as a ''particularly dangerous ground'' upon which to base an interpretation of prior statutes. (*Pension Benefit Guar. Corp.* v. *LTV Corp.,* 496 U.S. 633, 650 (1990) (discussing interpretive value of failed legislative proposals)). Even if there were some way to divine a clear statement of congressional intent from proposed bills in Congress, later congressional interpretations of statutes passed by earlier Congresses ''[are] of little assistance'' when construing the statute's scope. (*Central Bank of Denver, N.A.* v. *First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 185 (1994)) (citation omitted).

In addition, we do not believe that previous proposals or enactments on an outpatient prescription drug benefit for Medicare beneficiaries would be relevant to this initiative. This initiative is not a drug benefit, since it does not require the expenditure of benefit dollars. The Administration continues to support modernizing the Medicare program by adding a drug benefit. However, in the interim, Medicare beneficiaries without drug coverage are paying some of the highest prices for drugs. This initiative will provide Medicare beneficiaries with the educational tools and assistance to obtain some relief on drug prices, until a Medicare drug benefit can be enacted.

C. July 2001 Program Superceded

In July 2001, the President announced the Medicare-Endorsed Prescription Drug Discount Card program. A Federal district court preliminarily enjoined implementation of that program. *National Ass'n of Chain Drug Stores* v. *Thompson,* No. 01–1554 (D.D.C. 2001). In accordance with the judge's order, we ceased all work on implementing that program and did not make any Medicare endorsements on the basis of applications received in response to that program.

On November 5, 2001, the district court in that case granted a Motion for Stay, staying the case while we submitted our new initiative for comment by publishing a proposed rule in the **Federal Register** on March 6, 2002 (67 FR 10262). This final rule describes a program that differs in important respects from the Administration's initial proposal from 2001, for example, by endorsing only those discount programs that demonstrate an ability to obtain manufacturer rebates or discounts and that can share, either directly or indirectly, a substantial portion of rebates with beneficiaries. Other changes include: additional reporting; endorsing only those cards where discounted prices remain stable for periods of 60 days; a more stringent access standard for rural and urban pharmacies; endorsing card programs with 3 years of experience; and allowing card sponsors to have two endorsed programs. If the plaintiffs in the previously mentioned district court case believe that this final rule is substantially similar to the President's initial program from 2001, they may seek further judicial review that could delay implementation of this final rule.

D. Objectives and Major Aspects of the Initiative

1. Objectives

The objectives of this initiative are to:

- Educate Medicare beneficiaries about private market methods available for securing 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 (PBMs) or insurers and pharmacies to obtain higher quality pharmaceutical care, for example, monitoring for drug interactions and allergies.
- Publicize information (including drug-specific prices, formularies, and pharmacy networks) to facilitate easy consumer comparisons that will allow Medicare beneficiaries to choose the best card for them.
- Promote 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.
- Improve beneficiaries' overall experience with Medicare by enhancing the quality and use of their Medicare-covered services through improved 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 brand name and/or generic 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.
- Assist Medicare beneficiaries in obtaining a low (in Year One, $25 maximum) or no-cost opportunity to enroll in a Medicare-endorsed prescription drug discount card program.

We solicited comments on all aspects of the proposed rule, and many commenters responded by discussing the basic issue of whether or not to implement the initiative.

Comment: Some commenters expressed support for the initiative as an interim approach prior to enactment of a Medicare prescription drug benefit. Commenters indicated that the initiative would lay the groundwork for a Medicare sponsored drug benefit by

creating the necessary infrastructure, and that it would give seniors access to coordinated pharmaceutical care and utilization review. One commenter noted that the market-based, competitive initiative would teach beneficiaries and government officials valuable lessons about pharmaceutical benefit management—a building block in virtually every drug benefit proposal before the Congress.

However, other commenters took issue with the initiative in general and other basic structural aspects of the initiative. One indicated that any long-term solution to high prescription drug prices should address the costs pharmacies pay manufacturers for drug products. Others indicated that the initiative should be run by the Federal government, and not private entities. Other commenters criticized the use of pharmaceutical benefit management organizations and their involvement in providing prescription drugs. Another commenter indicated that a better approach for an interim program would be a benefit that offers substantial coverage, not modest discounts, to those most in need.

Response: As we indicate throughout this preamble, the President strongly supports the enactment of a Medicare prescription drug benefit. We agree with the commenters that the educational initiative of the Medicare endorsement of prescription drug discount cards is especially helpful in the absence of a Medicare drug benefit. We also agree that the initiative can help lay the groundwork for a prescription drug benefit by improving beneficiary knowledge related to purchasing prescription drugs and other prescription drug services, by increasing our experience with administration of prescription drug-related programs, and by allowing the private sector to gain experience in working with the Medicare program and its beneficiaries. We also think the use of a competitive market-based approach that requires endorsed card sponsors to obtain manufacturer rebates or discounts and pass those through to beneficiaries, combined with the publishing of drug prices, will help to lower the drug prices beneficiaries face. We think that the endorsement qualification for manufacturer rebates or discounts can help to reduce the pressure on retail pharmacies to be the sole source of prescription drug discounts. We also agree that while the nature and degree varies, the major prescription drug benefit proposals being considered by the Congress place reliance on use of the private sector in administering a Medicare prescription drug benefit.

Since the subject of this regulation is not a Medicare prescription drug benefit, we are not responding to the specific comments about the nature of a Medicare prescription drug benefit.

2. Summary of Major Policies in the Final Rule in Response to Public Comments

We made a number of changes to this final rule in response to public comments, and we provide a general overview here of the major aspects of endorsement we have modified and those we have retained. Our specific responses to comments are discussed in greater detail later in the preamble.

We are modifying the rebate requirements of the endorsement to assure that the rebates negotiated with manufacturers will be for brand name and/or generic drugs. As discussed in greater detail later in this preamble, we are also planning to propose in a forthcoming proposed rule recognizing, through our outreach and education efforts, those cards with the highest rebate levels passed on to beneficiaries.

We will retain the endorsement's enrollment exclusivity provision as a criterion for endorsement, as we believe it is critical to the ability of card programs to successfully negotiate meaningful manufacturer rebates, and therefore provide meaningful assistance on drug prices to beneficiaries.

We made changes to endorsement provisions of the drug categories list based on comments and analysis of the most recent data available to us on commonly used drugs.

We will retain our proposal to endorse cards that charge a one-time enrollment fee of up to $25.

We modified the endorsement's access standard to allow for greater access in both urban and non-urban areas, in order to assure beneficiary access to retail pharmacies, particularly community-based pharmacies in rural and urban areas.

We will allow endorsed card sponsors to offer home delivery as an option, but card sponsors must meet the retail pharmacy access requirements for endorsement.

As a condition of endorsement, card sponsors will agree to report on the participation of independent pharmacies.

We will continue to require, as a condition of endorsement, that card sponsors demonstrate organizational capacity and experience, in order to ensure that we endorse only stable and reputable entities, with a capacity to enroll a large number of beneficiaries. However, we have modified our endorsement criteria to better strike a balance between this goal and our interest in promoting the inclusion of innovative programs. The experience criterion has been changed to 3 years. The covered lives requirement has been changed to 1 million lives for either a national or regional program. The covered lives criterion has been de-linked from the 3-year experience requirement, providing more flexibility for entities to combine their capabilities and qualify for endorsement if the capacity for enrollment is provided through a separate organization than the one meeting the experience criterion.

We did not modify our endorsement criteria for demonstrating financial stability because we believe they are understandable, demonstrable and appropriate, given the objectives of this initiative.

We will retain as a condition of endorsement participation by a card program sponsor in an administrative consortium, and we will require endorsed card sponsors to operate a customer complaints process. In addition, we will recommend that the consortium of endorsed cards consider establishing an advisory board to provide it with guidance.

We will retain the requirement that endorsed cards publish comparative price information. However, we have modified the price comparison methodology so that prices are expressed in dollars, and the comparison will include information about generic substitutes.

Additionally, as discussed later in this preamble, as a condition of endorsement related to formularies and the publishing of prices, card sponsors must agree that a specific drug is not dropped from the formulary, nor its price increased for periods of at least 60 days starting on the first day of the program's operation, with 30 days notice to their network pharmacies, the consortium and us before making any changes.

We will allow endorsed card sponsors to offer up to two programs with different designs, as long as each independently meet the conditions for endorsement.

Endorsed cards will be required to report periodically certain information, in order to ensure that sponsors are accountable to us.

As a condition for endorsement, card sponsors will be required to have call centers, open during usual business hours and operating in accordance with standard business practices, that are able to handle pharmacy questions.

We specify that if a card sponsor's Medicare endorsement is terminated, the card sponsor will be required to

notify network pharmacies (in addition to beneficiaries), and contracts between the sponsor and the network for the purpose of this initiative will no longer be binding after a beneficiary notification period of 90 days ends.

We will retain the opportunity for both regional and national programs to qualify for endorsement. We also clarify that national or regional programs may include Puerto Rico, Guam and the U.S. territories.

We have revised the timeline for applicants to allow a 6-month start-up from the time that endorsements are announced.

E. Conditions of Endorsement and the Endorsement Initiative

1. General

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

To be endorsed, applicants that meet the criteria for endorsement will sign an agreement with us certifying that they will comply with all requirements in the agreement, including funding and operating an administrative consortium of endorsed card sponsors to perform certain administrative functions, implementing the program as described in the application, and operating consistently within the endorsement requirements.

All applicants offering a prescription drug card program that apply for Medicare endorsement and meet or exceed these requirements for endorsement and sign the agreement will be Medicare-endorsed.

The conditions for endorsement discussed in this section reflect our interpretations of the standards included in this final regulation.

The Medicare-Endorsed Prescription Drug Card Assistance Initiative will publicize information that will 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 initiative will include the ability of each Medicare-endorsed drug card program sponsor to:

- Obtain manufacturer rebates or discounts on brand name and/or generic 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 stable access to 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.
- Provide access to other prescription drug services offered by the program for no additional fee, including drug-drug interaction monitoring and allergy alerts through detection systems linking pharmacies in the entire network.
- Ensure that beneficiaries enroll in only one Medicare-endorsed prescription drug discount card program at a time, to facilitate obtaining rebates or discounts from drug manufacturers on their behalf.
- Protect the privacy of beneficiaries and beneficiary-specific health information.
- Agree to jointly administer, and abide by the guidelines of, a private administrative consortium of endorsed card sponsors funded by the sponsors, to perform administrative functions, consisting of publishing comparable information on drug prices, operating an enrollment exclusivity system, and, by the second year of the initiative, assuming review of information and outreach materials. We will recommend that the sponsors have the consortium consider establishing an advisory board to provide it with guidance.
- Limit enrollment in its Medicare-endorsed discount card program(s) to Medicare beneficiaries only.

We believe that this initiative will offer assistance to beneficiaries in accessing low-cost prescription drugs, as it will improve upon the current drug card market. The market-based design of this initiative, and its ability to mimic many of the important design features of an insured product, will facilitate Medicare-endorsed drug discount card programs having features that current market products generally do not have. This initiative will improve upon the current market in several important respects by:

- Educating about the availability of discount card programs offered by stable and reputable firms with sufficient capacity to handle the Medicare population likely to enroll in a prescription discount card program.
- Securing manufacturer rebates or discounts on brand name and/or generic drugs, and passing them through pharmacies or directly to beneficiaries, resulting in deeper discounts.
- Providing price comparison information and 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 who participate in a card program to enroll in a low-or no-fee Medicare-endorsed prescription drug card program.
- Protecting the privacy of beneficiaries and their personal health information.
- Assuring that discount card programs' information and outreach materials meet guidelines for appropriateness, completeness and understandability.

2. Beneficiary Eligibility and Enrollment

As a condition of endorsement, card sponsors must agree to limit enrollment in their Medicare-endorsed prescription drug card programs to Medicare beneficiaries only. Card sponsors could request the beneficiary's Medicare number or use another means to assess Medicare eligibility, with data elements necessary to maintain the enrollment exclusivity system; however, we will not provide data or assistance to verify Medicare eligibility.

Drug discount card program sponsors in this initiative will also 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. Members who do not consent to group enrollment will be allowed to enroll individually in the endorsed program of their choice.

We will allow card sponsors to have M+C organizations subsidize the enrollment fee and to offer the drug

discount card program as part of their Adjusted Community Rate filing, however they will not be allowed to require enrollment in a drug discount card program as a condition of enrollment in any of their M+C plans.

Card sponsors will be required to ensure enrollment exclusivity, that is, that beneficiaries enroll in only one Medicare-endorsed card program at a time. Beneficiaries will 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.

Comment: A number of commenters expressed support for the proposed requirement that enrollment in the initiative be limited to Medicare beneficiaries only. Two commenters stated that card sponsors should not be allowed to exclude certain beneficiaries or classes of beneficiaries. If a card sponsor is endorsed by Medicare, its program should be available to any and all Medicare beneficiaries. The commenters asked that we confirm this interpretation of the provision.

Response: That is correct. Each card sponsor endorsed by Medicare to offer a discount card program must make its program available to all Medicare beneficiaries who wish to enroll.

Comment: One commenter recommended that we consider for endorsement card sponsor programs that target Medicare beneficiaries without drug coverage rather than all Medicare beneficiaries. In addition, the commenter urged us to allow endorsement of card programs that target beneficiaries with incomes below a specified level, provided the cards meet solvency and other requirements.

Response: Clearly, beneficiaries without drug coverage will realize the greatest benefit from this initiative. However, we believe that all beneficiaries should be informed of the initiative, and have the opportunity to participate, if they believe the initiative can be of benefit to them. We do not intend to exclude any Medicare beneficiary from participating in this initiative. The commenter's recommendation that we endorse card sponsor programs that target beneficiaries with incomes below a specified level is addressed elsewhere in this preamble.

Comment: The proposed rule declared that we would not provide data or assistance to verify Medicare eligibility. A number of commenters expressed concern about the ability of card sponsors to ensure that only Medicare beneficiaries are enrolled in endorsed drug discount card programs, as required, without the benefit of adequate eligibility data.

One commenter asserted that the need to verify Medicare eligibility without assistance from us would lead to unnecessary enrollment costs. Commenters strongly encouraged us to make Medicare electronic eligibility files available to endorsed card sponsors. Another commenter stated that the proposed policy may result in the enrollment of some otherwise ineligible individuals, either through fraudulent means or administrative errors.

Response: We do not intend to provide access to electronic eligibility files to card sponsors for purposes of verifying Medicare eligibility. One of the administrative consortium's primary responsibilities is to operate an enrollment exclusivity system to ensure that Medicare beneficiaries are enrolled in only one endorsed discount card program at a time. We believe that it is appropriate for the administrative consortium, on behalf of the endorsed card sponsors, to determine the best method to validate Medicare eligibility in its role in operating and maintaining this system. Card sponsors could, for example, request the beneficiary's Medicare number to confirm Medicare eligibility. Such alternative approaches should not result in added expense and, when employed uniformly and vigilantly, the risk of enrolling ineligible individuals, particularly through administrative error, should be minimal.

We do not believe we should share eligibility information because this is an endorsement initiative; it is not a benefit administered by us. The administrative consortium is not our contractor, but an external, independent entity. We have a duty to protect beneficiary-specific information housed in this eligibility file, and we do not believe it is either appropriate or essential that we provide our eligibility files to the consortium for purposes of determining Medicare eligibility as part of this initiative.

3. Card Sponsor Organization, Structure, and Experience

To be eligible for endorsement, applicants must demonstrate 3 years of private sector experience in the United States in pharmacy benefit management, the administration of drug discount cards, or low income drug assistance programs that provide prescription drugs at low or no cost. We require 3 years experience because the Medicare name is so well known and so important to beneficiaries that we do not want the name to be associated with any but the most stable and reputable organizations. The sponsors whose drug discount cards will be endorsed by Medicare should be those that have the experience and capacity to offer Medicare beneficiaries discounts and good customer service and will 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 3 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 turnover in the discount card industry, we think that requiring anything less than 3 years experience will create the risk of having the Medicare name associated with other than stable and reputable organizations.

In addition to the 3 years experience criterion, drug card program sponsors must, at the time of application for endorsement, operate a regional or national drug benefit, discount drug card, or low income drug assistance program that provides prescription drugs at low or no cost that serves at least 1 million covered lives. We interpret covered lives to mean discrete individuals who have signed enrollment agreements or paid an enrollment fee or insurance premiums, or some comparable documentation, which we will use for verification purposes. The organization with the 3 years experience does not have to be the same organization that serves the requisite covered lives. The covered lives criterion is not linked with the 3-year experience requirement, providing flexibility for entities to combine their capabilities, through a contract or other legal arrangement. An organization that has the requisite experience, but may not have the enrollment capacity, for example, may acquire this capacity under a contract for the purpose of administering its program.

In order to qualify for Medicare endorsement, national program sponsors will have to operate in 50 States and Washington, DC. In order 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, regional program sponsors must include at least 2 contiguous States, with the exception of Hawaii and Alaska, because they do not share State borders; these States could partner with 2 or more contiguous States to form a regional program. Card programs that meet the national or

regional definition may also include the Commonwealth of Puerto Rico, Guam and the U.S. territories among the areas they serve as part of their national or regional program.

As discussed in the impact analysis, we estimate that during the first year of operation, over 9 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 Medicare-Endorsed Prescription Drug Card Assistance Initiative. Endorsed card program sponsors will 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. 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 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 million lives, whether for a regional or national program, strikes a balance between ensuring a competitive marketplace with a number of different options for Medicare beneficiaries and ensuring that organizations will have the capacity to handle a large increase in covered lives. We think the 1 million lives criterion is the right threshold, but as the initiative evolves over the next year or so, we will continue to evaluate it and the 3 years experience criterion to see if they are barriers to entry for well qualified sponsors, affecting competition, and if so, we will consider revising them.

Entities will be able to combine their capabilities to meet the various requirements for Medicare endorsement. In particular, the 3-year experience requirement is not linked to the covered lives criterion or to capabilities such as operating a customer service 1–800 telephone line, providing flexibility for entities such as a chain pharmacy (with the requisite 3 years experience in operating a prescription discount card program and extensive pharmacy network that meets our access definition) to combine its capabilities, through a contract or other legal arrangement, and qualify for endorsement.

The Medicare endorsement is intended for reputable organizations only that are prepared to administer a discount card program in accordance with all of the requirements of this initiative. If multiple organizations combine to meet the following requirements: years of experience and/or covered lives; establishing a pharmacy network; negotiating manufacturer discounts or rebates; conducting enrollment; and operating the customer service call center; we require evidence of legal arrangements between or among the entities. When multiple entities combine to meet these requirements, we require either contracts or signed letters of agreement to be submitted with the application. For the pharmacy network, we require one copy of each unique contract or signed letter of agreement used across the entire network. We require evidence in these documents that manufacturer rebates or discounts shared with the pharmacies will be passed through to the beneficiaries in lower prices or enhanced pharmacy services.

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.
- Contain language obligating the subcontractor to abide by State and Federal privacy requirements that apply to the card sponsor or other subcontractors, including the privacy and security provisions specified in this regulation.
- Contain provisions in the pharmacy contracts that the contracts will no longer be binding after the program's obligation to operate under the endorsement ends.

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

An organization or entity will be allowed to have operational responsibilities in more than one drug discount card program. However, an organization or entity may be the primary sponsoring organization or entity in only two card programs at any time.

Additional requirements to assure that the Medicare endorsement will be provided to reliable and stable organizations include a demonstration of financial integrity and business ethics. We interpret this to mean that (1) the applicant; (2) any subcontractor or organization under other legal arrangement who (a) develops the pharmacy network, (b) handles the negotiation of rebates or discounts on behalf of the card sponsor, or (c) operates enrollment; and (3) the entity or entities that meet(s) the 3 years of experience and covered lives requirements meet(s) the following 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 3 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 3 years on matters relating to health care and prescription drug services and/or allegations of fraud, misconduct, or malfeasance.

Each applicant will 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 will conduct an independent investigation to include at least a review of Federal databases for issues related to any of these entities.

As a condition of endorsement, card sponsors must also agree to enrollment exclusivity, because the low-or no-fee card program to be offered under the

initiative could lead beneficiaries to enroll in more than one Medicare-endorsed prescription drug card program. Multiple enrollments will 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, each beneficiary who enrolls in an endorsed drug discount card program will 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 prescription drug card program could enroll at any time of the year. Beneficiaries will be allowed to disenroll at any time and could elect another Medicare-endorsed prescription drug card program. However, the new enrollment will not become effective until the first day of the following January or July following the date of disenrollment, whichever came first, unless the program in which the beneficiary was enrolled is no longer operating under Medicare's endorsement, in which case the beneficiary could join another card program, to become effective immediately.

a. Years of Experience and Covered Lives

We received a variety of comments concerning the years of experience and covered lives requirements for a Medicare endorsement.

Comment: Among other provisions, the proposed rule proposed as a qualification criterion, that card sponsors have 5 years experience and either serve 2 million covered lives, if seeking endorsement for a national program, or 1 million covered lives for a regional program. These linked criteria were developed because years of experience and covered lives are among the criteria used by private sector companies in selecting a third party administrator to manage their pharmacy benefits. The criteria were designed to assure that only stable organizations that also had the capacity to handle large enrollment and provide customer service would be endorsed.

While some commenters recognized the need to verify past experience, a number of commenters argued that the 5 years experience requirement is overly restrictive. Furthermore, according to the commenters, both the 5-year experience and covered lives requirements would exclude companies (including many chain pharmacy discount programs) that provide some of the best drug prices. Several commenters expressed concern that the 5 years experience criterion limits participation to large entities, and two commenters indicated that this requirement would foreclose new market entrants.

Response: We agree with the comments regarding the 5 years experience requirement, and have modified this particular criterion to permit card sponsors with 3 years experience to qualify for endorsement. We believe that this modification effectively addresses commenter concerns yet continues to provide a sufficient amount of time to enable card sponsors to adequately demonstrate a reasonable track record of good performance and stability.

Comment: A number of commenters questioned the appropriateness of the covered lives criterion. Two commenters pointed out that it would be difficult for all but the largest, most established PBMs or discount card sponsors to meet the covered lives requirement as specified in the proposed rule. One commenter recommended that we substitute ''capability for processing ''x'' transactions'' for ''covered lives'' as a more relevant and appropriate qualification criterion. The basis for this recommendation is the commenter's belief that the number of processed transactions as a benchmark measures the capabilities of a pharmacy program administrator as well as the size, reach and scope of a program. According to the commenter, the number of covered lives indicates only the number of enrollees, whereas the number of processed transactions measures how many times those enrollees use their card. The commenter argues that card sponsors must have the demonstrated capability to process a large volume of transactions efficiently and accurately.

Response: We believe the covered lives criterion is important, because it signals a card sponsor's capacity to execute large numbers of enrollments or provide customer service to a large population. As discussed elsewhere in this preamble, we have lowered the threshold for covered lives to 1 million covered lives, whether a program is regional or national. We believe this change provides a balance between the need to demonstrate capacity for large enrollment and customer service for a large population, and flexibility to enable recent and innovative programs that otherwise meet the provisions of this initiative to qualify for endorsement. We do not believe that the ability to handle a large number of transactions represents a direct measure of a card program sponsor's capacity to handle the high volume of enrollment that we expect from this initiative. However, we will continue to evaluate this as a proxy measure for enrollment capacity.

We have also de-linked the covered lives criterion from the experience requirement, which would allow an organization that has the requisite experience, but may not have the enrollment or customer service capacities, to acquire these capacities under a contract for the purpose of administering its program.

We think the 1 million lives criterion is the right threshold, but as the initiative evolves over the next year or so, we will continue to evaluate it and the 3 years experience criterion to see if they are barriers to entry for well qualified sponsors, affecting competition, and if so, we will consider revising them.

Comment: One commenter asserted that, if discounts are a function of volume, we should design the Medicare-Endorsed Prescription Drug Card Assistance Initiative on a nationwide basis, rather than a regional basis.

Response: Manufacturers will be interested in negotiating favorable terms on rebates with regional or national programs that are designed in a manner that influences market share. Volume is a consideration, but stable and exclusive enrollment are key to influencing market share. The success of card program features designed to steer usage, such as structure of the formulary, size of the pharmacy network and tools to educate and influence the behavior of beneficiaries and physicians, are dependent on beneficiaries staying in the program and being influenced by the program's incentives.

We believe that regional programs, as we have described for the purpose of this initiative, can be competitive with national programs and therefore successful at garnering manufacturer rebates, if regional programs are designed to be attractive enough to beneficiaries to drive their enrollment rates. These sponsors will potentially design programs keeping in mind the unique characteristics of the beneficiaries, physicians and pharmacies residing in that region. Regional programs have the advantage over national programs of being closer to the attitudes and behaviors of these stakeholders and can design programs that specifically address dimensions of decision making unique to the area.

Comment: A number of commenters encouraged us to include existing prescription drug card programs that are presently meeting certain criteria such as the following: (1) A nationwide network; (2) experience administering operational programs that process millions of transactions; (3) inclusion of a large number of drugs in multiple therapeutic classes covering conditions common to seniors; (4) technological infrastructure (including claims processing) that is in place and currently integrated with retail pharmacy; and (5) unlimited manufacturer and prescription drug product participation (no formulary).

Response: As part of the application process, we will seek some of the following information as evidence of a sponsor's experience: (1) Experience in pharmacy benefit management, which includes conducting activities such as enrollment, adjudicating claims at point of service, claims processing, providing discounts, and working with a contracted network of pharmacies and with drug manufacturers; (2) experience providing a prescription drug discount program, including conducting activities such as enrollment, providing discounts, and either owning or working with a contracted network of pharmacies; or (3) experience providing low-income drug assistance programs that provide drugs at low or no cost, including eligibility determination, enrollment, and arranging for access to drugs at low or no cost. In addition, as stated elsewhere in the preamble, we have de-linked the covered lives criterion from the experience requirement, which will allow an organization that has the requisite experience, but may not have the enrollment or customer service capacities, to acquire these capacities under a contract for the purpose of administering its program.

Comment: Two commenters recommended that we develop criteria that focus on value and cost savings for beneficiaries, not criteria, such as covered lives, that arbitrarily limit Medicare endorsements.

Response: Part of our qualification criteria is a rebate requirement that is defined to promote competition among the card sponsor programs and drive competitive discounts. However, in addition to assuring that card sponsors are capable of offering reasonable discounts to beneficiaries, in order to safeguard both the Medicare name and beneficiaries, we also believe it is important to consider the stability and reputation of a card sponsor in determining whether that card sponsor is deemed worthy of endorsement. As we stated in section B.1 of this preamble, one of the goals of this initiative is to increase beneficiary confidence in the Medicare program and to improve the relationship between beneficiaries and the Medicare program. If we were to endorse a card program that could not handle the volume of covered lives that we expect from this initiative, or that went out of business soon after the announcement of endorsement, this would have a negative impact on beneficiary confidence and the relationship between the Medicare program and beneficiaries. Of course, by endorsing card programs, we cannot guarantee that they will remain in business; however, we believe that by endorsing card programs with substantial experience, we can help to maximize beneficiary confidence in this initiative and in the Medicare program as a whole.

Comment: One commenter stated that the proposed rule effectively bars participation of Medicare beneficiaries who reside in Puerto Rico and the U.S. Territories. According to the commenter, Puerto Rico could not qualify for participation as either a national program, or a regional program, as defined in the proposed rule. Puerto Rico is not a State, and its geography dictates that it cannot be contiguous to any State, Guam or Territory. The geographical issue is also shared with Alaska and Hawaii.

Response: In order 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, we modified the proposed policy to clarify that regional programs must include at least two contiguous States, with the exception of Hawaii and Alaska, since they do not share State borders; these States could partner with 2 or more contiguous States to form a regional program. We further clarified that for either a national or regional program, card programs may also include the Commonwealth of Puerto Rico, Guam and the U.S. Territories as part of their programs.

b. Financial Integrity and Business Ethics

We received a number of comments related to expectations with regard to card sponsor financial integrity and business ethics.

Comment: Commenters expressed concern about the general lack of detail in the financial solvency requirements for endorsed card sponsors in the proposed rule. Commenters maintained that, while a card sponsor must demonstrate that it is ''financially solvent,'' the proposed rule does not define the term. To safeguard against endorsement of financially unstable entities, commenters expressed the importance of explicitly including stringent, but fair financial solvency criteria.

Response: We agree that stringent, but fair, financial solvency criteria must be clearly delineated in order to ensure that only the most financially stable entities are endorsed by Medicare to offer prescription drug discount card programs. We believe that the proposed rule did, in fact, clearly state the financial solvency criteria that potential card sponsors must meet in order to qualify for endorsement. For example, the proposed rule noted that the specific financial requirements would consist of the applicant effectively demonstrating that total assets exceed total unsubordinated liabilities. In addition, the applicant must demonstrate that it has sufficient cash flow to meet obligations as they come due. We retain these conditions in the final rule.

In addition to these specific financial tests, the applicant must report any financial ratings secured over the past 3 years, as well as certain specified past or pending investigations over the past 3 years. As discussed earlier in the preamble, it was originally proposed that applicants would be required to provide any financial ratings secured over the past 5 years, as well as a list of past or pending investigations over the last 5 years; however, this requirement has been modified to be consistent with the new 3 years total experience requirement for card sponsors. This initiative is intended to increase beneficiary confidence in the Medicare program and to improve the relationship between beneficiaries and the Medicare program. To further that goal, we believe it is essential that we endorse only reputable organizations. We believe these requirements are explicit and reasonable to ensure, in combination with other card sponsor requirements, that only the most stable and reliable organizations are endorsed by Medicare to offer drug discount card programs.

Comment: One commenter questioned the appropriateness of the requirement to provide the most recent audited financial statements. According to the commenter, privately held companies are not required to audit financial statements. Thus, this requirement would appear to limit participation to publicly held companies. If the intent were to obtain information regarding financial stability, the commenter would need to know what the minimum

qualification criteria are for approval of this part of the review.

Response: As part of the application process, we are requesting that applicants submit their most recent financial statements because we want to have an independent audit from a third party rather than rely solely upon the sponsor's representations. We want to attract sponsors, including privately held companies, of a sufficient scope and organization that would, in the normal course of business, have had to produce an audit (for purposes of securing a loan, or the purchase of land, buildings or equipment). It was not our intent for this requirement to limit card participation to publicly held companies. We intentionally did not specify the source of requested financial ratings or how many ratings an applicant must produce in order to provide applicants greater flexibility in this regard.

We are not in any way attempting to limit participation to publicly held companies; rather, we believe it is reasonable to presume that a wide variety organizations (for-profit entities, not-for-profit entities, PBMs, chain drug stores, insurance companies, etc.) may apply to receive Medicare endorsement. A variety of organizations submitted applications in response to the August 2, 2001 solicitation published on our web site at *http://www.cms.gov.*

Comment: One commenter questioned the need for card sponsor applicants to provide a summary of the card sponsor's history, structure and ownership, including a chart depicting the structure of ownership, subsidiaries and business affiliations. This commenter requested a clarification of the minimum requirements for this part of the review. The commenter requested that we specify who would be responsible for the review, and their qualifications to render an opinion on the information provided.

Response: This requirement is to disclose important aspects of a potential card sponsor's operating structure, (to ensure transparency of all applicable relationships that comprise the card sponsor entity and discount card program) including transparency of its ownership relationships and contracting hierarchy. This criterion, by itself, will not be the basis for making an endorsement decision, and therefore, we do not need to specify the minimum requirements for this part of the review as part of a solicitation to be issued.

Comment: Two commenters suggested that we should have a means for monitoring solvency long after a sponsor files an application for endorsement. In addition, the commenters suggest that financial solvency should at least mean that a card sponsor must have more assets than liabilities, and that we should terminate the endorsement of any company that enters into bankruptcy.

Response: For the reasons stated elsewhere in this preamble (see our responses to comments on Reporting), we do not believe that quarterly financial reporting from a sponsor is needed. The initial review of the application has two specific financial standards; that the applicant's total assets exceed total unsubordinated liabilities and that cash flow is sufficient to meet obligations as they come due. These standards are consistent with the Medicare+Choice requirements, and we believe that these standards are appropriate for this initiative.

Also, as a provision of our agreement with an endorsed card sponsor, a card sponsor must notify us in advance of any change that materially affects its ability to perform under its agreement with us. This will include, for example, bankruptcy.

In addition, we believe that a critical source of information will be complaints directed to the complaints tracking and management system to be developed and operated by us. In the event that a card sponsor has financial difficulties that affect the performance of its program, we are likely to uncover such problems based on follow-up of complaints reported to its complaint tracking system.

Comment: Some commenters stated that the proposed rule should be revised to include objective business ethics guidelines, to safeguard the program. Other commenters point out that the proposed rule stated that a card sponsor must have a ''satisfactory record of integrity and business ethics.'' However, commenters maintain that these terms are undefined and we have not proposed a method for determining what is ''satisfactory.''

The commenters suggest a number of circumstances that would be reason for us to withhold or terminate endorsement, including for example, indictments, civil liability in cases involving antitrust violations, and fraud. In addition, they believed that card sponsors should be required to report to us any lawsuits or government investigations that involve allegations of ethical violations.

Response: As part of the application process, potential card sponsors must provide a list of past or pending investigations and legal actions brought against the applicant organizations (and parent firms if applicable) by any financial institution, government agency (local, State, or Federal) or private organization over the past 3 years on matters relating to health care and prescription drug services and/or allegations of fraud, misconduct, or malfeasance. As with requirements pertaining to financial solvency, information regarding past or pending investigations and legal actions apply to the applicant organization, 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 or discounts on behalf of the card sponsor, or to operate enrollment, and including the entity (or entities) that meets the 3 years of experience and covered lives requirements. This information will be considered during the application review process by our contract specialists who routinely evaluate this type of information as part of a determination for entering into third party relationship with a contractor.

Further, ongoing monitoring and enforcement of business ethics and integrity will be specified in the agreement entered into between us and the endorsed card sponsor.

c. Enrollment Exclusivity

We received a number of diverse and conflicting comments with regard to the enrollment exclusivity policy.

Comment: Three commenters supported the exclusivity policy, including one commenter who suggested a 1-year lock-in, to coincide with the Medicare open enrollment period. Nine commenters opposed the enrollment exclusivity provision. Many of these commenters expressed concern that the exclusivity provision will reduce access to the full range of discounts, with lock-in particularly problematic in the absence of any requirements for stability in formularies or prices. Some commenters not only questioned the assumption that enrollment exclusivity was needed to facilitate card sponsor negotiation of manufacturer rebates but also questioned whether manufacturers would provide substantial rebates, even with the exclusivity feature.

One commenter noted the positive benefit that an exclusivity provision provides from a drug utilization and patient safety perspective but, on balance, expressed concern that enrollment exclusivity limited access to a wider range of lower-priced drugs.

Response: We believe that enrollment exclusivity is needed to facilitate card sponsor negotiation of manufacturer rebates. We believe that beneficiaries in

a particular drug card program will have a strong incentive to purchase drugs on the formulary, and we believe manufacturers will be persuaded to provide significant rebates or discounts to card sponsors as a result. The enrollment exclusivity feature is expected to provide card sponsors a stronger negotiating leverage, thereby increasing the level of manufacturer rebates available to beneficiaries.

Furthermore, we believe that concurrent enrollment in multiple drug card programs is potentially confusing to beneficiaries and will add an additional burden at the retail pharmacy level, because pharmacies will likely be approached by beneficiaries who will want to know which of their drug cards offers the best price on a particular drug.

Under this initiative, card sponsors will be competing for a large number of new covered lives; potentially millions of Medicare beneficiaries. We believe that competition for share of beneficiaries will result in favorable formularies and prices across the card sponsor programs. Further, given that each card sponsor must provide a discount on a drug in each of the therapeutic classes indicated elsewhere in this preamble, beneficiaries will have access to discounts on a broad range of prescription drugs.

In addition, we agree that, as part of an enrollment exclusivity provision, beneficiaries need some stability in formularies and prices. Consequently, as stated elsewhere in the preamble, we are revising our policy to specify that card sponsors must agree to publish prices on formulary drugs, and assure that a specific drug is not dropped from the formulary nor its price increased for periods of at least 60 days starting on the first day of the program's operation.

Comment: One commenter maintains that tracking whether and how often enrollees switch to different card programs would be difficult administratively. The commenter questions whether: (1) A beneficiary would risk losing any expected discounts on prescription drugs if he or she were to unknowingly or unintentionally enroll in a different card program more often than is permitted; and (2) whether the beneficiary would be required to retroactively pay back any discounts received while incorrectly enrolled in the card program.

Response: As stated elsewhere in the preamble, the responsibility for ensuring enrollment exclusivity rests with the administrative consortium. We would expect the process for ensuring enrollment exclusivity to be well defined and deliberate, with a specific focus on minimizing the potential for concurrent enrollments in multiple drug card programs. Under no circumstances would a beneficiary be required to retroactively pay back any discounts received while incorrectly enrolled in a drug card program.

4. Formulary and Discounts to Beneficiaries

Each drug discount card program will be expected 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 Table 1. This endorsement qualification is to assure that beneficiaries enrolling in Medicare-endorsed discount card programs will be offered discounts on many of the types of drugs most commonly needed. As some drugs can be classified into more than one category, a drug can be used only once to satisfy the criterion of providing a discount for a drug in a therapeutic class, group or subgroup. It is important to note that card sponsors have the flexibility to include as many drugs as they choose beyond the minimum number and types needed to satisfy this endorsement qualification criterion, and we expect that many card sponsors will choose to do so for purposes of attracting beneficiaries to their programs.

Discount card program sponsors' formularies and prices may vary geographically. As a condition of endorsement, card sponsors must agree that a specific drug is not dropped from the formulary, nor its price increased, for periods of at least 60 days, starting on the first day of the program's operation. In addition, card sponsors will notify the pharmacy network, the consortium, and us of formulary and pricing changes 30 days in advance of the change.

Also, card sponsors must guarantee that participating Medicare beneficiaries will 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. 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 will be expected to arrange with its network pharmacies that these lower prices also be made available to Medicare beneficiaries to the extent the drugs are included in the card program's formulary.

The listing of therapeutic classes, groups, and subgroups of drugs most commonly needed by Medicare beneficiaries is in Table 1. A revised Table 1 has been prepared incorporating the comments discussed below. In addition, the categories listing has been updated to reflect the top prescription drug utilization and spending data collected through the 1999 Medicare Current Beneficiary Survey (MCBS). The Table 1 listing included in the proposed rule was based in part on the 1998 MCBS data. Also, working in consultation with Federal experts in pharmacology, the lists of new drugs approved by the Food and Drug Administration during 1999, 2000, and 2001 were examined for purposes of identifying whether recently released drugs might have further implications for the drug categories to be included in the listing as those commonly needed by Medicare beneficiaries. We 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.

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. A single drug cannot be used to count in more than one category for purposes of providing a discount on a drug in each one of the listed categories (for example, propranolol cannot be used for both antiarrhythmic agents and as a beta blocker).

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	Specialty multi-vitamin low in phosphorus

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)
Hematological Agents	Other
	Hematopoietic Agents
	Antiplatelet Agents
	Anticoagulants
	Coumarin and Indandione Derivatives
	Hemorrheologic Agents
Endocrine/Metabolic Agents	Sex Hormones
	Estrogens
	Progestins
	Others
	Bisphosphonates
	Antidiabetic Agents
	Insulin
	Sulfonylureas
	Biguanides
	Thiazolidinediones
	Others
	Adrenocortical Steroids
	Thyroid Drugs
	Calcitonin-Salmon
	Agents for Gout
Cardiovascular Agents	Inotropic Agents
	Vasodilators
	Antiarrhythmic Agents
	Supraventricular, Prophylaxis
	Supraventricular, Treatment
	Ventricular, Prophylaxis
	Ventricular, Treatment
	Calcium Channel Blocking Agents
	Dihydropyridine
	Diphenylalkylamine
	Benzothiazepine
	Antiadrenergics/Sympatholytics
	Beta-Adrenegic Blocking Agents
	Cardioselective Beta-Adrenergic Blocking Agents
	Antiadrenergic Agents—Centrally Acting
	Antiadrenergic Agents—Peripherally Acting
	Other
	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
	Sympathomimetic—Long Acting
	Sympathomimetic—Short Acting
	Xanthine Deriatives
	Leukotriene Modulators
	Respiratory Inhalant Products
	Corticosteroids
	Intranasal Steroids
	Mast Cell Stabilizers
	Others
	Antihistamines—Non-Sedating
	Cough Preparations
Central Nervous System Agents	Analgesics
	Narcotic

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)
	Narcotic/sustained release
	Other
	Agents for Migraine
	Others
	Antiemetic/Antivertigo Agents
	Antianxiety Agents
	Antidepressants
	Selective Serotonin Reuptake Inhibitors
	Others
	Antipsychotic Agents
	Phenothiazines/Thioxanthenes
	Phenylbutylpiperadine Deriatives
	Indoles
	Atypical Antipsychotics
	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
	Salicylate Deriatives for Inflammatory Bowel Disease
Systemic Anti-Infectives	
	Penicillins
	Cephalosporins and Related Antibiotics
	Fluoroquinolones
	Quinolones
	Macrolides
	Sulfonamides
	Antivirals
	Antiretroviral Agents
	Tetracycline
Biological and Immunologic Agents	
	Immunologic Agents
	Immunosuppressives
	Immunomodulators
	Interferon Alpha
	Interferon Beta
	Other
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	Alkylating Agents
	Antimetabolites
	Hormones

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)
	Antiestrogens
	Aromatase inhibitors
	Antiandrogen
	Other Antineoplastics
Rheumatologicals* (***Note:** Gout agents and immunomodulators listed under other categories)	
	Nonsteroidal Anti-Inflammatory Agents
	Cox-2 Inhibitors
	Other Rheumatologicals

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; *USP 2002* United States Pharmacopeia.

We received a number of comments related to the drug classes, groups and subgroups listing included in Table 1 of the proposed rule.

Comment: One commenter indicated that the nationally recognized classification system used to develop the drug categories listing was not specified.

Response: There are several nationally recognized systems used to classify drugs. At the bottom of Table 1 in the proposed rule, the drug classification sources that were consulted to develop the Table 1 drug category listing were indicated. We chose to predominantly rely on *Drugs Facts and Comparisons* as it is a system commonly used by pharmacists. Since there are several systems for classifying drugs, for the proposed rule listing we also consulted two other sources, Goodman and Gilman's *Pharmacological Basis of Therapeutics,* and *Clinical Pharmacology,* by Melman and Morelli.

Comment: Another commenter suggested using the American Hospital Formulary system or the USP DI.

Response: As noted above we have relied primarily on *Drugs Facts and Comparisons* because of its common usage in the context of retail pharmacy. Based on this comment, though, we did also examine the *USP 2002* by United States Pharmacopeia to assist in addressing some of the comments related to specificity of categories.

Comment: Several commenters raised issues related to the specificity of the listing, indicating that the groups and subgroups were broad and nonspecific. They recommended that additional groups and subgroups should be established to more adequately reflect the full range of medicines. Some commenters suggested factors that should be considered, such as whether products are used to treat the same spectrum of disorders, patient outcomes are similar, differing mechanisms of action, significant side effects, and dosing frequencies. Another commenter thought that the approach of listing a single product for each category was not adequate from a therapeutic interchange perspective. Another commenter thought that the listing was not comprehensive enough and it did not address the needs of those who have sensitivity to certain drugs. Another commenter expressed concern that strict formularies may limit medications and not address the needs of the elderly population.

Response: It is important to keep in mind that the classes, groups, and subgroups categories were developed in the context of a drug discount program, not a drug benefit. We think that this is a very important distinction. The drug category listing for Medicare endorsement of a drug discount card serves as a minimum criterion for qualification related to the number of drugs for which discounts need to be provided. (Card sponsors could provide discounts for more than one drug per category.) This is a different concept than coverage of drugs in the context of a drug benefit. Formulary design in the context of a drug benefit would need to be done in a different manner and would need to take into account benefit coverage policy issues. Since the Medicare-Endorsed Prescription Drug Card Assistance Initiative is not a benefit, we do not think that coverage policy considerations are applicable. In addition, requiring discounts on all drugs would need to rely heavily on discounts from pharmacies rather than drug manufacturers.

In developing the listing, we focused on drugs that are commonly used by Medicare beneficiaries, based on analysis of top utilization and spending data. We examined the levels of specificity in drug classifications in order to have groupings in which generally there will be multiple products. Educating beneficiaries on how to obtain better drug prices is the focus of the Medicare-Endorsed Prescription Drug Card Assistance Initiative. We think this approach provides an adequate framework for beneficiaries to learn about use of drug formularies and choose between formulary options commonly available in the insurance market. Under this initiative, beneficiaries enrolled in Medicare-endorsed card programs will be free to purchase prescription drugs as they do today, but for at least some of their drugs that are included in the endorsed card sponsor's formulary, they would be able to obtain lower prices.

Importantly, under the Medicare-Endorsed Prescription Drug Card Assistance Initiative, beneficiaries will have ample choice and an opportunity to examine closely the differences between cards, including drug offerings and their associated prices. Some cards may offer fewer drugs, and as a consequence, garner deep discounts or rebates, while other cards may offer a broad range of drugs with a lower level of rebates or discounts. Under this initiative, beneficiaries will choose what they perceive as most valuable and gain experience to assist in making future choices. The marketplace will gain important experience designing drug products and services that meet the expectations and needs of the Medicare population.

Comment: Three commenters recommended covering all drugs. One suggested this could be done by obtaining discounts from pharmacies rather than from manufacturers. Another suggested that there should be mandatory participation by manufacturers rather than voluntary, which results in a patchwork of covered and non-covered drugs. One commenter expressed support for having card sponsors provide a discount for at least

one drug identified in the therapeutic classes, groups and subgroups.

Response: As noted previously, this initiative is distinct from a drug benefit. This initiative endorses private sector entities that meet certain minimum criteria. To require discounts on every drug might limit the rebates that will be available to card sponsors, and could result in lower discounts to beneficiaries for particular drugs. Moreover, we expect that market forces will operate to determine the number of drugs that will be offered in each therapeutic category. With regard to the comment on mandatory participation by drug manufacturers, we have no authority to mandate participation.

Comment: Several commenters identified categories of drugs for which they thought more specificity was needed, including cardiac antiarrhythmic agents, bronchodilators, and antineoplastics. One commenter noted that certain classes of drugs used by the senior population were not on the Table 1 listing, specifically benign prostatic hyperplasia, Alzheimer's drugs, and ophthalmic drugs. The commenter also noted that within the category of thyroid drugs, separate groups should be identified for hypothryroidism and hyperthyroidism. Another commenter suggested that the antidepressants category broken out into ''selective serotonin reuptake inhibitors'' and ''others'' be further specified by also identifying a category for ''serotonin and norepinephrine reuptake inhibitor (SNRI).''

Response: Because cardiac arrhythimias, respiratory conditions treated by bronchodilators, and cancer conditions are common in the Medicare population, we re-examined these three categories. We agree with the commenters that in the case of antiarrhythmic agents and bronchodilators, additional specificity will be appropriate to take into account the differing underlying conditions (for example, atrial versus ventricular arrhythmias) and treatment mechanisms for these common disorders. Furthermore, there are multiple products used to treat these conditions. Consequently, we have revised the listing to provide more specificity related to antiarrhythmic agents and bronchodilators. Four subcategories are now shown for antiarrhythmic agents in Table 1 (supraventricular/prophylaxis, supraventricular/treatment, ventricular/prophylaxis, and ventricular/treatment). For bronchodilators there are now three subcategories (sympathomimetic/long acting, sympathomimetic/short acting, and xanthine derivatives).

In the case of antineoplastics, it is important to note that Medicare currently does cover many drugs in this class because they are provided as part of physician services. However, because of the development of newer types of oral antineoplastic agents, we have expanded the listing to include alkylating agents and also provided an ''other antineoplastics'' category so the card sponsors will further need to provide a discount on an additional antineoplastic agent of their choosing.

We also agree that the sex hormone category was broad and needed additional specificity to take into account such disorders as benign prostatic hyperplasia. The sex hormone group has been further divided into estrogens, progestins, and others.

With regard to the comment on Alzheimer's drugs, the Table 1 listing includes categories for antipsychotic drugs and cholinesterase inhibitors. These drugs are used in the treatment of individuals with Alzheimer's disease.

With regard to the comment on ophthalmic agents, Table 1 in the proposed rule did include categories of ophthalmic agents, for example, drug agents to treat glaucoma, a common disorder in the Medicare population.

Table 1 includes a category for thyroid drugs, and we do not believe we need to separately identify drugs for hypothryroidism and hyperthyroidism. The purpose of the Table 1 listing is to have sponsors include discounts on drugs that are commonly needed by the Medicare population. Only one of these conditions, hypothryroidism, is common in the Medicare population. Consequently, we do not think it is necessary to further break out the thyroid drug category. Card sponsors have the flexibility to choose the thyroid drug products that they think are most appropriate for inclusion in a Medicare endorsed discount card.

As indicated previously, in developing the listing of drug classes, groups and subgroups for purposes of establishing a minimum level of drugs to be included in drug discount programs seeking Medicare endorsement, we focused on the most common prescription drug needs of the Medicare population. At the same time, we believe it is necessary to balance the drug categories listing with the design element that there generally needs to be multiple drug products in a given category. With regard to the comment for an additional breakout under the antidepressant category for serotonin and norepinephrine reuptake inhibitor (SNRI), we think this would be a very narrow grouping in terms of number of drugs within it. Consequently, we do not believe that a separate SNRI category should be included in the context of a discount card minimum listing. Card sponsors have the flexibility to include a discount for an SNRI drug under the ''other'' antidepressant subgroup if they desire. As mentioned previously, card sponsors have the flexibility to include as many drugs as they choose beyond the minimum number and types needed to satisfy the endorsement qualification criterion, and we expect that many card sponsors will choose to do so for purposes of attracting beneficiaries to their program.

Comment: We also received a number of other comments regarding other issues related to card sponsors' formularies. Several commenters suggested that Medicare-endorsed card sponsors use interdisciplinary committees consisting of physicians, pharmacists, and other health professionals familiar with medication therapy to establish formularies. They suggested that these committees, commonly known as pharmacy and therapeutics (P&T) committees, should be independent and meet on a regular basis (for example, quarterly) to ensure access to the latest medical innovations, with decisions based on scientific and economic considerations that achieve appropriate, safe and cost effective drug therapy. One commenter submitted a set of principles that have been established regarding the composition and role of P&T committees. Another commenter suggested that if formularies vary geographically that a regionally based professionally qualified body should include practicing physicians using that formulary.

One commenter raised the issue of providing for exceptions from a card sponsor's formulary when a physician determines that medical necessity dictates use of a non-formulary drug. The commenter suggested that formulary exceptions, while not necessarily provided at the same discount as formulary drugs, should be covered under the same cost-sharing requirements as formulary drugs. The commenter also suggested that enrollees, or their physicians, have access to a timely, independent, objective third party appeal of formulary disputes, with resolution as rapid as patient's condition requires.

One commenter indicated that we should provide, through the application review and acceptance process, that card sponsors adequately evaluate clinical considerations in drug selection and placement. The commenter suggested that sponsors should have to place on their formulary any product for

which they receive a discount or rebate that offers therapeutic advantage over other products in the same therapeutic class.

Response: We recognize that P&T committees play an important role in the development of formularies for use in drug benefits. They are a common industry practice and various organizations have developed guidelines working with these committees. The Medicare endorsement, however, is related to discount card programs rather than a drug benefit, where coverage policy is involved. Given this distinction and the effects on beneficiary choice, we do not think that it is necessary to specify additional provisions regarding endorsed discount card sponsors use of P&T committees. Similarly, the issues of exceptions from the formulary, cost-sharing levels, and an appeals process related to formulary disputes are all formulary-related aspects that arise in the context of the use of formularies in a drug benefit and its related coverage policy. Finally, we think that the construction of the list of drugs to be included in the context of a drug discount card is different than for a drug benefit. We think that the commenter's suggestion is more appropriate in the context of a drug benefit in terms of inclusion of drugs that offer certain advantages over other drugs in the same therapeutic class. Beyond specifying the minimum number and types of drugs that need to be included for purposes of Medicare endorsement, we think that the decisions regarding which actual drugs are to be included under card sponsors' programs need to be left to the sponsors to determine based on their negotiations with drug manufacturers and pharmacies, and what they think they can offer to beneficiaries.

Comment: A few commenters submitted comments related to generic drugs. One commenter noted the importance of physician involvement in decisions regarding generic substitution. The commenter also noted that since generic products can look different, it is important that there be proper labeling and explanation to the patient in order to avoid beneficiary confusion. Another commenter also noted the important role of medical practitioners in drug substitution. Another commenter indicated support for the language in the proposed rule supporting the use of generics, but noted that therapeutic safety and equivalency do need to be established for generic use. One commenter thought the proposed rule failed to provide specific incentives for the purchase of generic drugs when appropriate.

Response: The Medicare endorsement of prescription drug discount programs is intended to better educate beneficiaries about how to lower their prescription drug costs. The educational initiative will include information about the use of generic drugs as one way that beneficiaries may be able to lower their prescription drug costs. The potential savings to beneficiaries provides the incentive to use generic products. As part of the educational effort, we would expect to inform beneficiaries of the need to talk with their physicians about the availability of generic products for the medications they are taking.

Comment: The proposed rule provided that endorsed drug discount card programs be allowed to vary their formularies by geographic location and over the course of the endorsement period. Two commenters thought that card sponsors should not be allowed to vary formularies and prices geographically. There was concern that variation could cause confusion, with one commenter noting that this would be particularly true for beneficiaries who live in different places during the year.

Response: Allowing formularies and prices to vary geographically simply recognizes that this is how the market currently works, and that there are variations. We think it is necessary to provide for geographic variation to provide flexibility to accommodate market conditions and competition. As part of both our and card sponsors' educational efforts, the presence of geographic variation will be communicated. In addition, an endorsed card sponsor needs to make available to beneficiaries, over its customer service telephone line, upon request, information about prices and formulary at the retail pharmacy level. Beneficiaries also need to be informed that a lower price could be available due to pharmacies having special sales. Under the Medicare-Endorsed Prescription Drug Card Assistance Initiative, the beneficiary is to get the lower of the negotiated discount price or the usual and customary price available at that point in time.

Comment: Several commenters recommended that there be some stability over time in the formularies and in the prices, particularly because of the provision that beneficiaries can only be enrolled in one Medicare-endorsed card program at a time and can change among Medicare-endorsed card programs twice a year, in January and June. One commenter noted that we should prohibit sponsors from altering coverage terms for any product if the change would be to the detriment of card enrollees. The proposed rule had provided that card sponsors report to the consortium any formulary or price change within 48 hours before the change became effective. Commenters suggested different possible periods of times for maintaining stability in formularies and prices, including 60 days, 90 days, 6 months related to the enrollment period, and for the entire period of the endorsement.

Response: We agree that there is an important trade-off between having enrollment exclusivity for a period of time for purposes of market leverage and the need for some stability in formularies and prices that underlie beneficiaries' decisions regarding selection of card programs. We examined data reported by Express Scripts in its 2000 and 2001 Drug Trends Reports on changes in the average wholesale price (AWP) for the top 50 common brand drugs. The data indicate that the AWP did not change that frequently during the course of the year, typically one or two times, with the most frequent number of changes being four. Consequently, we are revising our policy to indicate that if a card sponsor seeks Medicare endorsement, it needs to agree to publish prices on formulary drugs, and that a specific drug is not dropped from the formulary, nor its price increased for periods of at least 60 days, starting on the first day of the program's operation. Within this context, card sponsors could still add drugs or lower prices at anytime, since neither of these changes has a negative impact on beneficiaries. Card sponsors will need to notify their pharmacy network, the consortium, and us of formulary and pricing changes 30 days in advance of those changes taking effect.

Comment: One commenter recommended that we develop an annual report card on the impact of formularies on beneficiaries enrolled in the Medicare-Endorsed Prescription Drug Card Assistance Initiative to better understand the impact of formularies on patient care. The commenter supports study by the industry and by us in this area.

Response: We agree with the commenter that such studies could provide a valuable source of information for policymaking and for industry sponsors as they design their programs. We will have information from each card program about their formularies. We also intend to survey beneficiaries about their knowledge of various components of the drug card program, and their perceptions of, and experiences and satisfaction with, their discount drug card. This information

will allow us to assess how well beneficiaries understand the concept of a formulary under their discount card program and how this impacts their use of the card. As this body of knowledge needs time to develop, we do not intend to develop a report card on the impact of formularies on beneficiaries under this initiative.

5. Manufacturer 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 believe that Medicare-endorsed drug discount card program sponsors will have increased visibility for their discount drug programs, which will lead to significant enrollment by Medicare beneficiaries. The attributes of this initiative, coupled with exclusive enrollment, will provide card sponsors with the ability to negotiate significant drug manufacturer rebates or discounts. Competition among card sponsors and, in turn, drug manufacturers, will attract beneficiaries through lower prices and other valuable prescription related services and assure that a substantial portion of manufacturer rebates or discounts are shared with Medicare beneficiaries either directly or indirectly through pharmacies, thereby improving the assistance this initiative can offer to beneficiaries.

In order for the endorsement initiative to ensure meaningful assistance on drug costs to Medicare beneficiaries, a condition of endorsement will be that card program sponsors meet the threshold of obtaining manufacturer rebates or manufacturer discounts on brand name and/or generic drugs. Medicare-endorsed discount card programs must pass a substantial share of those rebates or discounts through to beneficiaries either directly, or indirectly through pharmacies. Card sponsors will be required to have contractual arrangements with brand name and/or generic 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 will be required to have contractual agreements with pharmacies ensuring that the rebates or discounts be passed through to the Medicare beneficiaries in the form of lower prices or enhanced pharmacy services.

Card sponsors must share with us a detailed description of their manufacturer rebate program as part of the application for endorsement. In describing their rebate program, card sponsors will share with us information such as the aggregate level of manufacturer rebates or discounts that they will secure from brand name and/or generic manufacturers, their expected total rebate or discount, the share that will be passed through to beneficiaries, and other information necessary to assess whether or not the requirement has been met. This descriptive approach provides card sponsors with maximum flexibility within the basic requirement to design a rebate program, to negotiate rebates with a broad range of manufacturers, and to negotiate a level of rebates or discounts that is commensurate with their card program design.

We believe that competitive market forces will encourage endorsed card sponsors to secure the highest manufacturer rebates or discounts possible and pass those rebates through to enrollees, thereby maximizing the level of assistance provided to beneficiaries in lowering prices on prescription drugs. However, as a consequence of our consideration of public comments regarding this condition of endorsement, and in order to provide additional incentive for card sponsors to secure manufacturer rebates or discounts and pass them through to beneficiaries, we intend, in a future proposed rule, to propose a Gold Star policy. Under this proposed policy, we would award a Gold Star designation to those Medicare-endorsed discount card programs securing the highest levels of manufacturer rebates or discounts which are passed on to Medicare beneficiaries directly, or indirectly through pharmacies. Subject to the provisions of a future proposed and final rule, at the close of Year 1, we would anticipate awarding a Gold Star designation to no more than 10 percent of endorsed discount card programs which have secured and passed through the highest levels of manufacturer rebates or discounts. We would publicize this designation in beneficiary education materials, and card sponsors would be permitted to use the designation in information and outreach material.

A proposed Gold Star designation could serve several purposes. First, it could assist in educating beneficiaries about the various price concessions contributing to the total discount. Second, it could encourage card sponsors to secure the highest manufacturer rebates or discounts possible from both brand name and generic manufacturers. Third, it could encourage card sponsors to pass along the highest possible level of rebates or discounts to beneficiaries, directly, or indirectly through pharmacies. While retail discounts are also an important part of providing reduced prices to Medicare beneficiaries, we believe that one of the improvements of this Medicare initiative over the current market is the emphasis on securing manufacturer rebates or discounts. As discussed elsewhere in the preamble, the requirements of Medicare endorsement are designed, in part, to maximize the ability of card sponsors to secure manufacturer rebates or discounts. We believe that special recognition of card programs for obtaining and passing through to beneficiaries the best manufacturer rebates or discounts through a potential Gold Star designation would be consistent with the goals of this market-based initiative.

We believe that this overall approach to securing and passing along manufacturer rebates or discounts promotes better drug pricing for beneficiaries and may enhance pharmacy participation in a card sponsor's network.

We received numerous public comments related to manufacturer rebates or discounts.

Comment: Many commenters indicated that the final rule needs to clearly define ''substantial'', related to the level of rebate or discount card sponsors must secure from drug manufacturers (one indicated that 10% is not ''substantial'', two others indicated that each sponsor should show an ability to garner 10% average savings, and one commenter indicated that manufacturers should be required to offer a minimum discount in the range of 30%). Two commenters supportive of defining substantial recommended that we use the same rebate percentages required by Title XIX (Medicaid), two suggested the level of discounts offered by the Federal Supply Schedule, and one suggested the level secured by the Veterans Administration. One commenter suggested a minimum percentage payment from manufacturers, on a per prescription basis. Several commenters indicated that requiring a specific level of manufacturer rebate is not needed in a competitive marketplace as rebates or discounts will be reflected in fees and prices.

Response: We agree that requiring a specific level of manufacturer rebates or discounts is not necessary in a competitive market. Card sponsors will submit to us as part of the application for endorsement a detailed description of their rebate program as described above. Card sponsors seeking endorsement must meet the threshold of securing brand name and/or generic manufacturer rebates or discounts. We believe that competition among card sponsors—assisted by the price comparison web site—will encourage card sponsors to negotiate the most favorable rebates or discounts possible. The policy is designed to allow competition among card programs to drive rebates rather than government-imposed conditions.

We have deleted reference to the term ''substantial'' related to the level of manufacturer rebates or discounts card sponsors seeking endorsement must secure. We believe that the design of card sponsors' programs will determine the level of rebates they can secure, and that consumer preferences for formulary and pharmacy access will drive program design. We believe that market forces will come to bear on the level of manufacturer rebates secured by card sponsors. In addition, we believe that use of the term in this context may cause confusion as it is also used to describe the level of rebates or discounts we require be passed through to beneficiaries, either directly or through pharmacies. Given that the level of manufacturer rebates or discounts card sponsors may reasonably secure is different from the level of manufacturer rebates or discounts we require and expect will be passed through to beneficiaries, we are opting to not refer to both as substantial.

We believe that this descriptive approach also keeps card sponsors from focusing on only meeting a minimal level of rebates. For example, if we set a minimum average manufacturer rebate level that all endorsed card sponsors must secure, card sponsors may focus on attaining that level rather than striving to exceed it. Once that minimum threshold is attained, card sponsors might be less inclined to pass along any additional rebates or discounts received from manufacturers. Further, in order to encourage card sponsors to secure and pass along a maximum level of manufacturer rebates or discounts, we will propose, in a forthcoming proposed rule, a Gold Star designation policy, rather than use a defined level as suggested by some commenters.

Comment: Two commenters urged against requiring manufacturer rebates at all because they are unpredictable and unreliable. Commenters argued that if the amount of rebate on a particular drug changes, card sponsors may change their formularies. These changes might interfere with the patient/physician relationship, as changes in formularies might lead to drug switches.

Response: Securing manufacturer rebates or discounts is a tool widely used in the private insured market today. Virtually all insured products with managed pharmacy benefits are able to secure manufacturer rebates in response to shifts in market share. This initiative seeks to harness the purchasing power of Medicare beneficiaries in order to effectively negotiate rebates or discounts with manufacturers, similar to insured products. We believe that physicians are familiar with the role of formularies in insured products, and the benefits that may accrue to their patients in sometimes switching to formulary drugs. Groups representing physicians have publicly supported this initiative, while expressing, among several concerns, the need for some stability in formularies and prices. While negotiated rebate or discount levels may change from time to time, this Medicare initiative will require that a specific drug offered under the card program is not dropped from the formulary, nor its price increased for periods of at least 60 days, starting on the first day of the program's operation, and that card sponsors notify pharmacies, the consortium and us of price changes 30 days in advance of the change (see also the discussion of price stability in the previous section of this preamble).

Comment: We received several comments indicating that the proposed rule did not specify a minimum total discount that sponsors must offer to beneficiaries, and that we should require a clearly defined level of savings under this initiative. One commenter indicated that the program must be structured to give beneficiaries the greatest price reduction possible.

Response: We do not require that card sponsors offer a minimum total discount level in order to be eligible for Medicare endorsement. We believe that competition among card sponsors will encourage card sponsors to seek the highest total discount levels possible, given the broad retail pharmacy access standard they must meet in order to be considered for endorsement. In addition, we believe that card sponsors will design their programs differently, and that these differing designs may yield different discount levels. Some beneficiaries may prefer a card program with design features that may yield a lower discount level than other programs (for example, less emphasis on preferred drugs). We believe that permitting beneficiary choice among card designs, despite perhaps differing discount levels, is a positive feature we would want to preserve.

We plan to issue a proposed rule on the Gold Star designation that could help maximize the total level of discounts available to Medicare beneficiaries.

Comment: We also received numerous comments related to the level of manufacturer rebate or discounts we might expect under a Medicare discount card. Commenters indicated that this Medicare initiative will likely not garner rebates equivalent to those secured by funded products because there is little incentive to use one branded product over another; that rebates will not likely be greater than what is already available in the private market; and that rebates will likely fall below those recently announced by manufacturers for low-income beneficiaries. One commenter noted that manufacturers have given little or no rebates for discount card programs, due to lack of ability to show market share movement. One commenter indicated that the lower level of rebates expected may affect beneficiary satisfaction.

Response: The level of manufacturer rebates or discounts a card sponsor secures will depend, in part, on the design of its discount card program. For example, programs that rely heavily on the use of formularies, that are successful at educating Medicare beneficiaries regarding the benefits of using formulary or preferred drugs, and that are successful at educating physicians about formulary alternatives when available will be able to secure larger rebates. These dynamics are also at play in insured, or funded, products. We recognize that the benefit to the beneficiary of using formulary or preferred drugs is much greater in an insured product because some or most of the cost of the drug is being paid by an insurer. We assume that manufacturer rebates or discounts under this initiative may be generally below that of insured products. However, we expect that prescription drug manufacturers will respond to the ability of card sponsors to move market share as a result of the major design features of this initiative (for example, education, exclusive enrollment, 6-month enrollment period, use of formularies or preferred drugs, and rebate and discount requirements). While manufacturers may not offer the same prices on all drugs as they do under their low income assistance

programs, we believe that manufacturers will offer Medicare beneficiaries the best prices possible, particularly when the card sponsors guarantee that rebates will be passed through to beneficiaries. A full discussion of our estimates of beneficiary savings under this initiative can be found in the Impact Analysis section of the preamble.

Comment: We received a comment indicating that current discount card programs secure discounts from pharmacies only, and this program structure also finances discounts from community pharmacies.

Response: We understand that the discount card programs prevalent in the market today generally do not secure manufacturer rebates or discounts and pass those savings on to enrollees either directly, or through pharmacies. We believe that this initiative is an improvement over the current market in this respect. Card sponsors seeking Medicare endorsement must secure rebates or discounts from brand name and/or generic prescription drug manufacturers and pass a substantial share of the savings through to beneficiaries. Medicare-endorsed discount card programs may not rely solely on discounts received from community pharmacies; endorsement is contingent, in part, on securing rebates or discounts from manufacturers. We believe that the Gold Star designation, discussed in greater detail elsewhere in the preamble and in a forthcoming proposed rule, would also help encourage card sponsors to seek and secure manufacturer rebates or discounts, and to pass those concessions on to beneficiaries directly, or indirectly through pharmacies.

Comment: We requested comments on efforts to sustain the use of generic drugs in spite of manufacturers' rebates or discounts on brand name drugs. We wanted 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. Many commenters were supportive of encouraging the use of generic drugs when available. Several commenters stated that a substantial share of discounts on generic drugs secured by card sponsors should also be passed on to beneficiaries, and that this will increase the use of generics. However, there was disagreement among commenters regarding whether or not rebates, discounts, or other price concessions are commonly found in the generic drug market. One commenter indicated that rebates are greater for brand name drugs, which may dampen card sponsors' interest in encouraging the use of generics.

Response: We believe that card sponsors should be encouraged to seek rebates or discounts on generic as well as brand name drugs and pass a substantial share of those savings through to Medicare beneficiaries. However, we understand that current industry standard practice does not necessarily include traditional rebates on generic drugs flowing through discount card sponsors or insurers. We have changed our rebate requirement to state that applicants for Medicare endorsement must secure rebates or discounts from brand name and/or generic drug manufacturers.

This initiative will encourage the use of generics in other ways as well. For example, the price comparison web site will provide information about the availability of generics. In addition, we expect that the potential of generic drugs to reduce beneficiary out of pocket costs on drugs will be discussed in beneficiary education and outreach materials and activities.

Comment: We received numerous comments related to the pass through of manufacturer rebates or discounts to beneficiaries directly or indirectly through pharmacies. Many commenters noted that the proposed rule did not define what level of manufacturer rebates or discounts would be passed on to beneficiaries. Many were supportive of our establishing a required percentage of rebates or discounts that must be passed through to beneficiaries but there was disagreement regarding what the level should be. For example, one commenter supports passing through 100% of savings offered by manufacturers, two proposed requiring that 90% be passed through, two proposed using Title 19 as a model, and one proposed requiring that pharmacists determine what portion of the rebate or discount should be kept by a card sponsor. One commenter indicated that, if endorsed, they anticipate passing through all or a majority of revenues in the form of lower drug prices. Several commenters stated that we should not require specific amounts of manufacturer rebates be passed through to beneficiaries directly or through pharmacies because competition among plans (market forces) will likely lead to rebates being passed through.

Response: We require that Medicare-endorsed card sponsors pass along a substantial share of rebates or discounts received from brand name and/or generic drug manufacturers to beneficiaries, either directly or indirectly through pharmacies. Requiring that a particular percentage of rebates or discounts be passed through does not take into consideration the differing operating costs of individual card sponsors (card sponsors are permitted to use a portion of rebates or discounts to defray operating expenses). We want to encourage card sponsors to provide excellent customer service, negotiate fair dispensing fees, and provide quality assurance and drug utilization review programs that also are of benefit to beneficiaries. Placing an arbitrary limit on the percentage amount a card sponsor may retain to defray the costs of these worthwhile activities may not be in the best interest of beneficiaries. In addition, smaller or regionally operating card sponsors initially may not be able to pass through the same level of rebates or discounts on all drugs as their overhead costs as a percentage of rebates or discounts may be somewhat higher in some cases.

We believe that competition among card sponsors will encourage card sponsors to pass along the maximum amount possible to beneficiaries. Simply, beneficiaries will most likely enroll in card programs with the best prices on the drugs they take, all other things being equal (for example, card program design and customer service). We also believe that prescription drug manufacturers may put pressure on card sponsors to pass along pricing concessions to enrollees. And, we believe that our proposed Gold Star designation policy, explained elsewhere in this preamble and in a forthcoming proposed rule, would encourage card sponsors to share the maximum amount of manufacturer rebates or discounts possible. We continue to use the term ''substantial'' in describing this requirement to indicate to card sponsors that we believe that most of the savings should be passed through, and that it is our expectation that rebates and discount revenues not used to defray operating expenses be passed through to beneficiaries, directly or through pharmacies.

Comment: Several commenters are concerned that card sponsors could attribute most or all payments to overhead and avoid passing those payments on to beneficiaries directly or through pharmacies. While one comment was supportive of using manufacturer rebates to give pharmacies an incentive to participate, one commenter could not think of any case where insurers share a rebate with a retail or community pharmacy. One commenter indicated that there is no guarantee that rebates will be passed through pharmacies. One commenter offered that one way to assure that the discount is passed on to the consumer is to give card sponsors a fixed negotiating fee to improve the

probability that they will share discounts with small businesses.

Response: We believe that competitive pressure will prevent card sponsors from retaining rebates and discounts for purposes other than operating expenses that benefit the beneficiary (for example, customer service, quality assurance activities, and pharmacy counseling). Beneficiaries will select card programs that offer the best overall value, including the lowest prices on drugs they take and other valuable services offered. If card sponsors fail to pass along rebates or discounts in a form that is obvious to beneficiaries, beneficiaries will enroll in a competing discount card program that offers more clear value to them. In addition, we believe that Medicare-endorsed discount card program sponsors would have an incentive to pass along as much of the rebate as possible to beneficiaries directly or through pharmacies if we incorporate our proposed Gold Star designation policy (described elsewhere in this preamble and in a forthcoming proposed rule) into this initiative.

We agree with the commenter that currently, insurers do not pass rebates and discounts through to pharmacies. Insurers do not have an incentive to reduce the price to the enrollee directly or indirectly through the pharmacy. Generally, rebates are forfeited to the employer to reduce overall health care expenditures; there is no expectation that a substantial portion of the rebate will be passed through to the enrollee at the point of service or through pharmacies. In this initiative, we expect the consumer will take the place of the employer, and likely receive rebates and discounts from manufacturers.

Comment: In a related matter, some commenters suggested that sponsors should be required to pass through to beneficiaries a portion of all payments received from manufacturers, not just a share of manufacturer rebates or discounts.

Response: As a condition of endorsement, we will require card sponsors to pass through a substantial share of manufacturer rebates or discounts to beneficiaries directly or through pharmacies. Other payments and/or fees between the card sponsor and manufacturer that may be unrelated to moving market share in the context of this initiative are business matters between the card sponsor and manufacturer. This policy is consistent with current industry practice. Card sponsors are not precluded from using revenues from other sources to further lower prices or offer valuable pharmacy services. In addition, our proposed Gold Star designation policy, described in greater detail elsewhere in this preamble and in a forthcoming proposed rule, may provide an incentive for card sponsors to do that to the extent possible. We believe that competition among card sponsors, including publicly available price comparison information and, if ultimately incorporated into the initiative, our proposed Gold Star designation policy, will compel card sponsors to pass through a maximum amount of revenue from manufacturers.

Comment: We received several comments indicating that reporting or disclosing rebates in advance is difficult because they are often determined retroactively, and operational challenges and challenges posed by compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191) are large.

Response: We agree that offering a lower price at the point of sale is a challenge, but we believe it is in the best interests of beneficiaries to receive the benefit of lower prices at the point of sale. We believe that the significant experience of the insured population with manufacturer rebates or discounts will provide the groundwork for estimating prices at the point of sale. Card sponsors will have had experience negotiating rebates or discounts with manufacturers, either in the discount card context or, more likely, in the context of an insured product. We believe that this experience, combined with the experience of negotiating discounts with retail pharmacies, will enable card sponsors to estimate the expected total discount in advance.

Comment: One commenter said that any financial incentives on formulary drugs (such as manufacturer rebates) should not interfere with the delivery of quality care.

Response: We agree. We expect that physicians will continue to prescribe medications that are appropriate for their patients, just as they do today.

6. Access to Retail Pharmacies

To be eligible for endorsement, applicants must demonstrate that their national or regional prescription drug card program will offer Medicare beneficiaries convenient access to retail pharmacies. Convenient retail access means demonstrated contracts with retail pharmacies so that upon the start of outreach and enrollment in the discount card program at least 90 percent of Medicare beneficiaries, on average, in all Metropolitan Statistical Areas (MSAs) served by the program live within 5 miles of a contracted pharmacy (90/5) and at least 90 percent of Medicare beneficiaries, on average, in all non-MSAs live within 10 miles of a contracted pharmacy (90/10). We will require that this be demonstrated using mapping software, computed by using one hundred percent of beneficiary counts by zip code (provided by us).

Tables generated by the mapping software to be submitted to us will include both the MSA and non-MSA level in each of the States covered under the card sponsor's program, along with information on the contracted pharmacies.

In addition, as discussed later in this preamble, we will ask card sponsors to report on key aspects related to endorsement, such as aggregate level of manufacturer rebates, customer service, call center performance, complaints processes, and enrollment and disenrollment.

Drug card program sponsors will not be permitted to offer a home delivery-only (mail order) option to Medicare beneficiaries, since most 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 will be allowed to include an option to use home delivery via a mail order pharmacy, in addition to the required contracted retail pharmacy network. We will ask card sponsors to report on the aggregate level of rebates or discounts shared with beneficiaries, and participation of independent pharmacies in the card program's network.

We also will not require drug discount card program sponsors to include institution-based pharmacies in their pharmacy networks; however, neither would we preclude their participation. Institutionalized beneficiaries whose prescription drugs are covered under Medicare Part A or Medicaid will not be able to use the drug discount cards for the covered drugs. This policy comports with the conditions of participation for long-term care facilities.

Participation in a Medicare-endorsed discount card program may not always be useful or appropriate for institutionalized beneficiaries. However, there are circumstances in which beneficiaries have short stays in nursing facilities and could use the card while in the community. And, there are circumstances, specifically in assisted living facilities, where some beneficiaries purchase their drugs in the community and manage their own medication regimes. Therefore, both card sponsors and we will educate beneficiaries about the advantages and

disadvantages of enrollment in a discount card for institutionalized beneficiaries to support their making informed decisions.

a. Pharmacy Network

Comment: Two commenters asserted that the 90/10 standard allows urban areas to be underserved. For example, a single pharmacy will satisfy the standard for all of New York City. In addition, the standard allows rural areas to be underserved because access calculations are aggregated. To correct these issues, the commenters recommend that, instead of a 90/10 standard, we should impose a 90/5 standard, or less, depending on the concentration of pharmacies in a particular zip code. Another commenter expressed concern regarding the proposed access requirement, indicating that 10 miles can be a long distance for an elderly person or person with a disability who does not drive.

Response: In recognition of the commenters' concerns, we have modified the 90/10 pharmacy access requirement to include a stricter access standard for MSAs and non-MSAs. This final rule defines retail pharmacy access to mean demonstrated contracts with retail pharmacies so that, upon the start of outreach and enrollment in the discount card program, at least 90 percent of Medicare beneficiaries, on average, in all MSAs served by the program live within 5 miles of a contracted pharmacy (90/5) and at least 90 percent of Medicare beneficiaries, on average, in all non-MSAs live within 10 miles of a contracted pharmacy (90/10). We believe that a 90/5 access standard will ensure that for urban areas, beneficiaries are within a reasonable distance from a pharmacy offering Medicare discounts, and that beneficiaries have choice regarding the pharmacies from which to purchase discounted drugs. Since the pharmacies in rural areas are not as concentrated, we required a 90/10 access standard for non-MSAs. The effect of this policy is to require greater pharmacy participation in both MSAs and non-MSAs than was originally proposed. This is because the MSA and non-MSA access standard will be calculated based on MSAs only and non-MSAs only—and not the combination of non-MSAs and MSAs. We believe this standard will give beneficiaries access to pharmacies, while retaining the flexibility needed by card sponsors to have a sufficient number of pharmacies with which to contract for a network.

Comment: The proposed rule highlighted the value of certain small, urban pharmacies that provide linguistically appropriate or culturally sensitive services to Medicare beneficiaries. We solicited comments regarding the role and importance of these pharmacies to underserved populations and other populations that may have special needs. We also solicited comments on how to maintain access to these pharmacies for Medicare beneficiaries who depend on them.

One commenter noted that the health care system in the United States has come to rely on independent pharmacies and chain pharmacies, particularly in low income and rural areas. Two commenters stated that the proposed initiative would adversely impact small community pharmacies. One commenter stated that the initiative should provide more opportunities for card sponsors to partner with small retail pharmacies, particularly in low income and rural areas. Another commenter urged us to monitor card sponsors' programs to ensure that local retail pharmacies are, in fact, utilized. If utilization of mail order pharmacies, for example, becomes too high, retail pharmacies could be threatened.

Response: We recognize the valuable role that rural and other small community pharmacies serve as part of today's health care system; what we estimate as the impact on these pharmacies is discussed elsewhere in the impact analysis.

As indicated elsewhere in this preamble, we have modified our pharmacy access requirement for endorsement to provide additional opportunities for small retail pharmacies, particularly in both urban and rural areas, to be sought out and included in a drug card's network.

In addition, as described elsewhere in the preamble, as part of our monitoring efforts, we will ask card sponsors to report on a number of items related to the operational aspects of their programs, including the participation of independent pharmacies in the card program's network.

Concerning the impact of mail order on retail pharmacy utilization, as stated later in the preamble, we do not believe that this initiative will result in a significant diversion of beneficiaries to mail order. The majority of beneficiaries currently rely on retail pharmacy dispensing, and we do not believe this initiative will unduly influence beneficiary choices with regard to mail order and retail dispensing.

Comment: We received a number of comments regarding pharmacy contracting as part of this initiative.

One commenter urged us to provide specific direction on whether pharmacy network contracts for the Medicare-Endorsed Prescription Drug Card Assistance Initiative must be separate from pre-existing contractual arrangements. Similarly, the commenter asks us to clarify whether such contracts must specifically reference the Medicare program. In addition, the commenter asks that we clarify whether the network contracts must obligate participating pharmacies to remain in an approved discount card program for the duration of that program's endorsement. The commenter also recommends that we include all of the material requirements that will be imposed on organizations proposing to offer a discount card program.

Response: As a condition for endorsement, card sponsors must execute pharmacy contracts that are specific to this initiative. In addition, we expect the term of these contracts to be in effect for the entire endorsement period. This is important to ensure that there are guaranteed network pharmacies for the duration of the endorsement period. These may be separate and distinct contracts, or renegotiated contracts with existing network pharmacies. We believe that this final rule includes all substantive requirements for card sponsors. There will be some procedural and interpretive details included in the solicitation for applications.

Comment: One commenter points out that pharmacy network contracting specific to this program may not be completed at the time applications are submitted. Therefore, card sponsors should be permitted to provide in their applications information on the preliminary status of network contracting activities, including pending contracts. Approved applicants should be required, as a condition of final participation, to demonstrate after approval that their networks meet the specified standards.

Response: We understand that in Year One of this initiative pharmacy network contracting may be incomplete as the application review process commences. For this reason, we will not permit card sponsors to begin outreach and enrollment until all card sponsor contracts with retail pharmacies have been executed.

Comment: One commenter recommended that participation in this initiative be open to all pharmacy providers who are willing to accept the terms of participation, whether retail, mail order or specialty pharmacy. The commenter maintains that true patient choice will only be provided by allowing any pharmacy the option to participate, and prohibiting economic

incentives that cause patients to move from provider to provider.

Another commenter argues that small pharmacies should be permitted to choose the card sponsor program(s) with which they would like to contract, especially those that serve rural or underserved areas. Yet another commenter states that the patient-pharmacist relationship is an important link in ensuring appropriate medication use and safety. Patients who develop a relationship with a single pharmacist or pharmacy should not be penalized for wanting to maintain that relationship.

Response: We believe the stated access standards would necessitate contracting with a broad network of retail pharmacies.

Given the access ratio standards and a provision that prohibits Medicare-endorsed card sponsor programs from offering mail order services only, we believe that most retail pharmacies will be invited and encouraged to participate in card programs' networks, particularly small pharmacies in rural and underserved areas. With respect to the comment that beneficiaries should not be penalized for wanting to maintain an existing relationship with a retail pharmacy, we expect that one of many considerations in selecting a card sponsor will be whether a particular retail pharmacy is part of a card sponsor's pharmacy network. Beneficiaries will have to weigh this, among a number of considerations, in the selection of a card sponsor program.

Comment: One commenter asserts that, in order to meet the 90/10 access standard, card sponsors may have to offer lower pharmacy discounts. Some card sponsors may prefer to limit the pharmacy network to produce the deepest possible discounts. The commenter suggests that we allow card sponsors the flexibility to design their programs to meet the needs of their members.

Response: As part of its basic program, an endorsed card sponsor must meet the stated retail pharmacy access standards. However, card sponsors, if they choose, may design a program within the basic program that offers more restrictive pharmacy networks and/or formularies in order to optimize the level of discounts for beneficiaries.

Comment: One commenter declared that we should utilize our Managed Care Pre-Implementation Review Guide in assessing the quality of and access to pharmacy services as part of the drug card initiative.

Response: The Managed Care Pre-Implementation Review Guide to which the commenter refers is a document developed specifically for the 1915(b) managed care waiver program in California, and is comprised of a series of questions regarding all aspects of a Medicaid managed care organization's structure and operations. The purpose of this guide is to assess the readiness of a managed care organization to begin operations. The section of the guide to which the commenter refers includes questions regarding the adequacy of a managed care plan's pharmacy benefits program, including oversight provisions, access and quality.

We appreciate the commenter's suggestion; the Managed Care Pre-Implementation Review Guide may be a useful consideration as we define our expectations with regard to the application review process as part of the solicitation.

b. Home Delivery

Comment: One commenter indicated beneficiaries will be drawn to mail order because of financial incentives.

Response: Medicare-endorsed card sponsors are not permitted to offer a mail order only product, but may offer a mail order option. According to analysis conducted for us by Booz-Allen-Hamilton, Medicare beneficiaries with insurance for prescription drugs through Health Maintenance Organizations (HMOs) are somewhat more likely than the commercially insured to use mail order in the current market (both in terms of use and spending). Given that this analysis is based on a population in a managed care plan, we may see less reliance on mail order in the population not insured for prescription drugs. In any event, while mail order may offer lower prices on some drugs, and may offer some beneficiaries more convenience than going to a pharmacy, we know that the vast majority of beneficiaries currently purchase their prescriptions through retail pharmacies. Beneficiaries may prefer interacting with pharmacists and pharmacy staff in person. To the extent that card sponsors and pharmacies offer additional incentives to use a retail pharmacy (for example, pharmacy counseling, and discounts on future purchases), beneficiaries may be inclined to continue to prefer retail outlets.

Comment: A number of commenters indicated that, as discount card sponsors, PBMs would likely steer Medicare beneficiaries to mail order pharmacies, stating that the five largest PBMs control 90 percent of the mail order pharmacy business in the United States. According to the commenter, rather than pass through manufacturer payments directly to beneficiaries, these PBMs and other card sponsors will be tempted instead to pass these funds to their subsidiary mail pharmacies, with the justification that these payments serve to enhance network participation or provide drug utilization review or other pharmacy services to beneficiaries. The commenter asserts that the potential for misdirecting manufacturer payments could be reduced if we revised the rule to prohibit card sponsors from funneling manufacturer payments to pharmacies that the sponsors own or control. These commenters also noted that beneficiaries who are diverted to mail order pharmacies lose valuable face-to-face contact with a licensed pharmacist, resulting in a decline in quality of care for beneficiaries. One commenter stated that financial incentives to use mail order pharmacies through a discount card approach may limit a beneficiary's access to medication consultation services. According to the commenter, many beneficiaries depend on the face-to-face consultation and pharmacy counseling they receive from their community pharmacist, and studies show that these pharmacy services save the health care system millions of dollars each year. However, many beneficiaries could be enticed by the discounts offered to use mail order service. Another commenter urged us to monitor card sponsors' programs to ensure that local retail pharmacies are utilized. As an example, the commenter suggested that the existence of retail pharmacies could be threatened if utilization of mail order pharmacies increases significantly. In addition to a major loss of revenue, pharmacies will suffer from the government's intervention in this competitive marketplace and, according to the commenter, we should not endorse that outcome.

Response: Beneficiaries today are making choices with regard to how they receive their medications, whether through home delivery (mail order) or retail pharmacies. Beneficiaries make these decisions based on individual preference. Most beneficiaries purchase their prescription drugs at retail pharmacies. While some beneficiaries may be most interested in deeper discounts that may be available through mail order dispensing, others may place greater value on the personal contact via retail pharmacies. By definition, those who elect to receive their medications through mail order give up the face-to-face contact they will otherwise have through the retail pharmacy outlet.

Card sponsors will not be permitted to offer a program that only includes mail order because we recognize that

maintaining access to retail pharmacies is in the general best interests of beneficiaries, the majority of whom rely on retail pharmacies. However, to provide a choice to beneficiaries who prefer mail order, endorsed drug card programs will be allowed to include an mail order option, in addition to the required contracted retail pharmacy network. We believe that a number of card sponsor organizations will be endorsed to offer discount card programs as part of this initiative, and many of these card sponsors will offer a mail order option. We recognize that a number of large PBMs have wholly-owned mail order subsidiaries. These are recognized as legitimate businesses, and we do not intend to prohibit lawful and valid business arrangements. This initiative is market based, and we believe that card sponsors will have a strong incentive to offer beneficiaries the best discounts possible through channels that beneficiaries prefer in order to attract beneficiaries and remain competitive.

Mail order services have some real cost advantages over retail dispensing; these advantages are largely a function of the inherent operational and economic differences between mail and retail dispensing. However, mail order is not appropriate for all beneficiaries. For example, mail order is not well suited today to the dispensing of drugs for acute use, because these drugs are required immediately in most cases, and mail order involves a delay in receipt of drugs. While mail order can be particularly suited to dispensing of chronic drugs, and mail order services are, in fact, used by many beneficiaries with chronic conditions, we do not believe that this initiative will result in a significant diversion of beneficiaries to mail order. Retail pharmacies have some advantages over mail order that also translate into value from a beneficiary's perspective. Among them are face-to-face counseling and an opportunity to develop a clinically supportive role with a local pharmacist, and the capacity to immediately fill a prescription without delay in receipt, which is of particular need in the case of new and acute medications.

The majority of beneficiaries currently rely on retail pharmacy dispensing, and we do not believe this initiative will unduly influence beneficiary choices with regard to mail order and retail dispensing.

Comment: One commenter stated that card sponsors should be required to provide access to professional pharmacists who can answer questions for beneficiaries using mail order services. The commenter stated that responsible card sponsors already provide such services.

Response: We are aware that States require mail order pharmacies to provide a means, for example, a toll-free hotline, for consumers to contact mail order pharmacists with questions they may have regarding their prescriptions. As the commenter indicated, responsible card sponsors already provide access to pharmacists, and we expect endorsed card sponsors that offer mail order services to provide access to a licensed pharmacist should there be inquiries that require clinical consultation.

Comment: Two commenters point out that the geographic requirements recognize that beneficiaries need convenient access to community pharmacies and state that we should clarify that mail order pharmacies do not satisfy the access requirements.

Response: The access standards, as detailed elsewhere in the preamble, pertain to contracted retail pharmacies in a given card sponsor's network only. While we expect that many card sponsor programs will offer a mail order option, mail order is not considered in the defined access ratio standard; the ratio measures access to a card sponsor's network retail pharmacies only.

c. Institutional Pharmacies

In the proposed rule, we solicited comments on whether and how institutionalized beneficiaries who have access to institution-based pharmacies would be affected if they choose to participate in the Medicare-Endorsed Prescription Drug Card Assistance Initiative, since institution-based pharmacies are explicitly not required in this program. We were also interested in better understanding whether and how institution-based pharmacies could participate in the drug card programs.

Comment: A number of commenters urged us to consider excluding beneficiaries in long-term care facilities from this initiative. Commenters indicated that beneficiaries in long term care facilities have unique needs and receive their drugs from long term care pharmacies, which provide specialized services to this population in a closed system, and that the use of pharmacies external to this system could affect beneficiaries' health outcomes. Commenters also indicated that long-term care pharmacies obtain some of the lowest drug prices negotiated in the health care market. They also indicated that it will be inefficient and an unsafe practice to allow patients to obtain drugs outside of the carefully controlled distribution systems of long-term care facilities, which capture all the necessary data to support extensive review of patients' drug regimens by consultant pharmacists. They commented that Medicare conditions of participation provide for safe drug distribution practices, thereby making it possible for skilled nursing facilities and nursing facilities to determine how their patients can receive medications. The effect of these conditions of participation is that skilled nursing facilities and nursing facilities may restrict which pharmacies supply drugs and pharmacy services to their patients. Several of the commenters explicitly noted that they intended their comments to apply to assisted living facilities in addition to skilled nursing facilities and nursing facilities.

Response: We agree with the commenters' interpretation of the conditions of participation for skilled nursing facilities and nursing facilities. Specifically, we agree that the conditions of participation provide for safe drug distribution practices, thereby making it possible for skilled nursing facilities and nursing facilities to control how their patients can receive medications, and that the effect of these conditions of participation is that skilled nursing facilities and nursing facilities may restrict which pharmacies supply drugs and pharmacy services to their patients. We believe our policy fully comports with Medicare and Medicaid conditions of participation for long term-care facilities. Therefore, we do not believe it is necessary to change our policy to exclude beneficiaries in long term care facilities from participating in the Medicare-Endorsed Prescription Drug Card Assistance Initiative, since skilled nursing facilities and nursing facilities can and do control which pharmacies will provide drugs to beneficiaries during their stays in these facilities.

Furthermore, we do not believe it is appropriate to exclude beneficiaries in skilled nursing facilities and nursing facilities outright. While, in general, it is not expected that institution-based pharmacies will be part of discount card pharmacy networks, we will not preclude their participation should an institution-based pharmacy elect to join a discount card's network. Further, while we agree that the use of a discount card by institutionalized beneficiaries may not be useful or appropriate for many individuals, we believe all beneficiaries should have the option of enrolling in a discount card, particularly since some beneficiaries have short stays in nursing facilities.

Finally, it will be cumbersome to administer an exclusion from the drug card based on patient stay. In order to

specifically exclude institutionalized beneficiaries from participation in a Medicare endorsed discount card, we would have to ascertain whether they were residents of long term care institutions at a particular point in time and disqualify their participation upon admission if they had already obtained a card. We believe that establishing such an eligibility process will also be confusing to beneficiaries. Instead, we plan to educate institutionalized beneficiaries and their caregivers about this issue. Both we and card sponsors will have to educate beneficiaries about the advantages and disadvantages of a discount card for institutionalized beneficiaries, and emphasize that beneficiaries and their caretakers should consider each beneficiary's particular circumstances to determine whether participation in a Medicare-endorsed discount card is in the person's best interest.

The education policy for beneficiaries residing in assisted living facilities will be different. Some residents of assisted living facilities purchase their drugs outside the facility's pharmacy and manage their own drug regimens. Also, Medicare has no regulatory jurisdiction over these facilities, as they are not Medicare providers, and the State regulations that guide prescription drug distribution and pharmacy practice in these institutions vary by State. We will advise beneficiaries or their caregivers to seek guidance from an administrator of the facility regarding whether their prescription drugs can be purchased at a pharmacy participating in the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

7. Other Drug-Related Items and Services Under the Endorsement and Items and Services Outside the Scope of the Endorsement

Drug-related services, drug utilization review, and pharmacy counseling, that are not offered for an additional fee, could be offered as endorsed features of the program under this initiative. In addition, drug card sponsors could provide other services to beneficiaries who enroll in their card programs. These services could include both (a) drug-related services or items for a fee, such as disease management; and (b) non-drug-related services or items, whether for a fee or not, such as discounts on dental services and prescription eyeglasses. These services will not be covered by the Medicare endorsement and could not be described as Medicare-endorsed. Also, as described in the privacy section elsewhere in this preamble, card sponsors will need to seek beneficiary written authorization to market such services.

Comment: We received a number of public comments regarding the valuable role pharmacists currently play in drug therapy management. Two commenters cited a number of studies that demonstrate the importance of pharmacy services. One commenter expressed concern that the proposed rule does not direct card sponsors to include coverage for pharmacy services as part of the program. In particular, the proposed rule does not ensure access to pharmacist-provided medication therapy management services. The commenter states that beneficiaries must have access to pharmacist services, including: self-management education and disease management, and asserts that pharmacist services must be recognized and paid for under the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

Response: While we were not provided with specific data concerning pharmacist reimbursement for counseling services, we have carefully reviewed a number of studies and also conducted additional analysis of available research.

Under this initiative, we are recognizing that card sponsors may want to pass through a portion of rebates they garner from manufacturers to enhance the services beneficiaries receive from pharmacies. We believe that payment for such services under this initiative should be a contractual decision between a pharmacy and a card sponsor. We believe this is appropriate given the market-based approach of the Medicare-Endorsed Prescription Drug Card Assistance Initiative. If card sponsors believe specific pharmacy services are marketable to beneficiaries, then we expect them to negotiate terms that are of interest to the pharmacists to assure this is highlighted as part of the discount card program.

While we believe that beneficiaries will be most interested in their ability to obtain significant discounts and will base their card program decisions, in large part, on the level of discounts offered, we do believe that certain beneficiaries may place a higher value on card programs that offer enhanced pharmacy services. However, rather than mandate enhanced pharmacy services and associated payment for such services as part of this initiative, we believe that outreach and education efforts will be critical to make beneficiaries aware of the distinctions between card programs and, in particular, highlighting card programs that offer enhanced pharmacy services to beneficiaries.

Meanwhile, the responsibility resides with the pharmacist community to continue research using well designed studies to demonstrate the cost effectiveness of pharmacy counseling at the point of retail sale. Much of the best designed and current research is focused on pharmacy counseling in the context of disease management and consultation with physicians for a selective population. This important work will help inform future policy making at least in the circumstances to which it pertains. Whether and how the findings from such studies translates into reimbursement options at the point of retail sale will also be of interest to the government.

Comment: One commenter points to the statement in the proposed rule that beneficiaries without drug coverage often do not have access to 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. One commenter disagrees with this statement. The commenter indicates that most States have taken the requirements of the Omnibus Budget Reconciliation Act of 1990 (OBRA), which mandates pharmacy cognitive services under the Medicaid program, and (either by statute or regulation) extended these activities to all citizens by imposing a patient counseling requirement. Thus, the incentive for the pharmacist to comply is to meet a statutory or regulatory requirement. Another commenter also cites OBRA, noting that this authority mandates pharmacists to provide consultation on all medications, along with patient drug history review and special pharmacy programs such as asthma, high blood pressure and diabetes education. According to the commenter, the benefit of these programs exists only because the pharmacist provides the data to perform these services. Pharmacists identify potential allergy or drug-interaction problems and work out a solution with the prescriber and the patient. The administrative entity does not perform this service.

Response: We acknowledge that State laws and regulations prescribe various requirements for pharmacists related to such areas as prospective drug review, the provision of information on drug interactions, side effects and related information, and requiring the pharmacist to offer to counsel a patient who presents a prescription for filling. We recognize the role that pharmacists play in the provision of clinical services, including, for example, drug utilization review efforts and timely

detection of drug-drug interactions. We are also aware that pharmacies typically maintain electronic records to support these activities. However, third party administrative entities, such as pharmacy benefit managers (PBMs), are also able to warehouse data from across network pharmacies, providing a rich data source that is also available for examining patterns in utilization and monitoring drug-drug interactions. One of the benefits of this initiative could be that pharmacists are able to analyze a wider range of data, which is collected and warehoused by the card sponsors. We continue to believe that the Medicare-Endorsed Prescription Drug Card Assistance Initiative will enhance Medicare beneficiaries' access to these, and other, effective tools that are widely used in insured products and by pharmacies to obtain higher quality pharmaceutical care.

Comment: A number of commenters cited the importance of safety measures as part of discount card programs. One commenter stated that card sponsors should be required to provide automated safety programs that prevent dangerous drug interactions. According to the commenter, responsible card sponsors already provide such services. The commenter maintains that the potential for preventable harm from medication errors is too great to allow card sponsors that do not have safety programs to participate in this initiative. Several commenters emphasized the value of a discount card initiative which includes safety measures that protect consumers from possible drug interactions and promote clinically appropriate drug therapy. Optional add-on programs not only improve patient health (for example, through disease management), but can also help manage patient costs by providing education on generic drugs.

Response: We agree that safety programs that are designed to identify drug interactions and promote clinically appropriate drug therapy are generally provided by reputable card sponsors. We believe that market competition will drive card sponsors to design programs that include features that may be of interest to Medicare beneficiaries, such as those cited by the commenters. To the extent that these services will require added fees, these too will be permitted, provided the beneficiary provides written authorization for the use and disclosure of his or her personal information for this purpose.

Comment: One commenter asserted that a Pharmacists' Reimbursement Committee must be established which, much like the Physicians' Reimbursement Committee under Medicare, would address issues of pharmacist reimbursement to ensure continued viability of the community pharmacies, specifically chain and independent pharmacies.

Response: This is a beneficiary assistance initiative designed for card programs to compete on value. Establishing fees for community pharmacists is beyond the scope of this initiative.

Comment: One commenter noted that pharmacists cannot be expected to counsel on the unique aspects of each individual card's rules and drug costs, as well as drug usage and quality.

Response: We do not believe that the Medicare-Endorsed Prescription Drug Card Assistance Initiative will substantially complicate the educational responsibilities of pharmacists. Presently, discount cards have disparate outreach approaches, terminology, and discounting methodologies. Under this initiative, endorsed cards will have certain required commonalities in all of these areas, as well as the national public education offered by us to support increased public awareness of discount cards in general. Therefore, we believe that pharmacists will not be unduly burdened by this initiative.

8. Card Program Administration and Customer Service

As a condition of endorsement, card sponsors will have to agree to: (1) Charge a low or no enrollment fee to beneficiaries; (2) operate customer service call centers in accordance with standard business practices; (3) provide information and outreach to enrolled beneficiaries; (4) protect the privacy of beneficiaries' information; and (5) maintain a customer complaints system. Each of these requirements is discussed in this section.

The one-time enrollment fee for any Medicare-endorsed drug discount card will be limited (a maximum of $25 in Year One), and we encourage Medicare-endorsed card program sponsors to keep their fees as close to zero as possible. We believe this limit will allow discount card program sponsors to recoup their administrative costs through the enrollment fee, if they so choose, so more of the manufacturer rebates can be passed on to beneficiaries, but the limit is not so prohibitive as to dissuade beneficiaries from enrolling in the drug discount card programs. If a beneficiary changes drug card programs (either voluntarily or because the drug card program no longer participates in the initiative), the beneficiary could be charged a separate one-time enrollment fee by the second drug card program.

As a condition of endorsement, each endorsed card program sponsor must also maintain a toll-free customer call center to assist beneficiaries in understanding the drug card program offered. The call center must be open during usual business hours and provide customer telephone service in accordance with standard business practices. We interpret this to mean that the call center will be available at least Monday through Friday from 8:00 a.m. to 4:30 p.m. Eastern to Pacific Standard times for those zones in which the discount card program will operate. We 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 will be spent answering telephones and responding to enrollee inquiries; 80 percent of all incoming customer calls will be answered within 30 seconds; the abandonment rate for all incoming customer calls will not exceed 5 percent; and that there will be an explicit process for handling customer complaints. These standards are required or exceeded by the 1–800 Medicare call center contractors.

Card sponsors must also have in place a convenient means for accommodating pharmacy inquiries regarding the card sponsor's program. Card sponsors could, for example, accommodate pharmacist inquiries by incorporating a specific number in the Interactive Voice Response (IVR) for the pharmacist to select so that hold times will be minimized (many pharmacies use this already for ease of access for physicians).

We are aware that card sponsors, as part of their current business operations, generally have some established mechanism for responding to pharmacy inquiries. However, we do not intend to mandate a specific approach because we do not want to inadvertently force a higher cost solution. Instead, we will let individual card sponsors decide how to effectively address pharmacy inquiries.

Medicare-endorsed discount drug card sponsors will need to provide Medicare beneficiaries with information and outreach regarding the endorsed features of the discount card program. We interpret this to mean that the endorsed card program sponsors 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 includes contracted pharmacies, enrollment fees (if any), drugs included, and their prices to reflect discounts that are provided to the consumer.

Information and outreach should include information regarding the tools used for lowering prices and improving the quality of pharmacy services, as well as the importance of maintaining current drug coverage and the availability of generic substitutes under the program.

Guidance on what information to include in pre-enrollment and post-enrollment materials will be provided in the guidelines for information and outreach materials to be produced by us and appended to the solicitation for applications for the Medicare endorsement. We anticipate that the information in these materials will also be made available on the drug card sponsors' web sites and through their enrollment and customer service phone lines.

With the exception of advertising in print or broadcast media with a national audience, outreach to beneficiaries outside of a card sponsor's defined service area will be the basis for intermediate corrective actions or termination of endorsement by us. In addition, our guidelines for information and outreach materials will require that card sponsors clearly disclose the areas in which their endorsed programs are available to beneficiaries.

In addition, card sponsors that provide additional prescription drug quality services for no additional fee, such as drug interaction, allergy alerts, and pharmacy counseling will 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.

Endorsed card programs will be required to accept all Medicare beneficiaries who wish to participate in the card program. We 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.

As a condition of endorsement we also expect card sponsors, as well as the administrative consortium (described later in this preamble), to protect the privacy of beneficiaries information. Generally, card sponsors, for the purpose of administering a discount card program, are not covered entities under the regulations implementing HIPAA at 45 CFR part 164 (Privacy Rule). In some circumstances, a card sponsor, for the purpose of administering a discount card program, could be a business associate to a covered entity under the Privacy Rule, for example, to the pharmacies in the card program's network, or to a health plan that engages in group enrollment as allowed under this initiative. To the extent that a card program is a business associate to a covered entity under the Privacy Rule, or in any other way the Privacy Rule is applicable, the privacy provisions under this initiative do not modify that applicability. We are incorporating certain provisions of the Privacy Rule into this initiative, regardless of whether the rule on its face would apply to card sponsors. The provisions of the Privacy Rule incorporated into this initiative will take effect—for purposes of this initiative—beginning at the time of the endorsement agreement. These provisions do not trigger the HIPAA enforcement mechanisms; enforcement is discussed elsewhere in this rule.

Specifically, card sponsors will be required, as a term of endorsement, to agree to protect the privacy of Medicare beneficiary information consistent with the privacy provisions set forth in 45 CFR 160.103, 160.202, 164.501 through 164.514, and 164.520. These sections concern consent, authorization, notice, public policy, permissible uses and disclosures, and limiting disclosure to the ''minimum necessary''. For purposes of this initiative, a card sponsor must consider itself a ''covered entity'', as referenced in the Privacy Rule.

Prior to enrollment, or at the time of enrollment, a card sponsor must notify each beneficiary of expected uses and disclosures of the beneficiary's protected health information, as well as of the beneficiary's rights and the card sponsor's duties with respect to such information. The notice must be in plain language and must contain sufficient detail to place the beneficiary on notice of the uses and disclosures permitted or required under this rule and other applicable law. (If changes are made to the Privacy Rule, these changes will be incorporated into this initiative.) Among these expected uses and disclosures are the routine uses and disclosures to operate the program. For the purpose of this initiative, routine uses and disclosures under health care operations are defined as the routine activities to operate the card program, including the provision of information and outreach activities, as provided in the Medicare endorsement agreement.

As described elsewhere in this preamble, we will provide guidelines in the solicitation about the content, structure, and process of information and outreach for beneficiaries by card sponsors, including such things as use of the Medicare name, general information about the program, and card program features within the scope of the Medicare endorsement that card sponsors must agree to meet.

Further, card sponsors must comply with the Privacy Rule provisions for obtaining written authorization for all uses and disclosures of protected health information, including the beneficiary's rights and the card sponsor's duties with respect to such information, provided in plain language and in sufficient detail to place the beneficiary on notice as required under the Medicare-Endorsed Prescription Drug Card Assistance Initiative rule and other applicable law. Additionally, as provided in the Privacy Rule, provisions must be in the notice about how a beneficiary's authorization can be revoked.

The requirement for authorization includes, but is not limited to, marketing. For the purposes of this initiative, marketing means any use or disclosure of protected health information considered outside the scope of the Medicare endorsement. As discussed elsewhere in this final rule, non-endorsed features include (a) prescription drug related products and services for an additional fee beyond the enrollment fee of up to $25 in Year One, such as disease management for a fee; and (b) non-prescription drug related products and services, such as discounts on eye wear and travel services.

Card sponsors will be required to develop, implement and update periodically a written data security plan to assure that such information is secure from unauthorized disclosure, unauthorized modification, and destruction.

In operating the enrollment exclusivity system, or in the conduct of any other activity that could involve the use or disclosure of Medicare beneficiaries' protected health information, the consortium will be considered, for the purpose of this initiative, a business associate, as defined by the Privacy Rule. Beginning with the formation and operation of the consortium, the consortium must develop, implement, and update periodically, a data security plan to assure that this information is secure from unauthorized disclosure, unauthorized modification, and destruction.

Endorsed card sponsors must also establish and maintain a customer complaints process designed to track and address in a timely manner enrollees' complaints about any aspect of the card sponsor's operations. Card sponsors must comply with the customer complaints requirements as specified in their endorsement agreements with us.

a. Enrollment and the Enrollment Fee

Comment: The proposed rule provided that card sponsors could charge no more than an initial $25 enrollment fee. In addition, the proposed rule sought comments regarding the advisability of permitting a nominal renewal fee of up to $15 in subsequent years of the initiative. Commenters expressed conflicting points of view regarding both card sponsors' ability to impose a maximum $25 enrollment fee in Year One of the initiative, as well as the need for and appropriateness of imposing a nominal renewal fee of up to $15 in subsequent years of the initiative.

Most commenters supported both the proposed $25 initial enrollment fee as well as a renewal fee, with many expressing support for an annual renewal fee of as much as $25. These commenters argue that these fees are likely to be the principal sources of revenue for card sponsors in the absence of Federal funding to offset the administrative costs associated with the Medicare-Endorsed Prescription Drug Card Assistance Initiative. Commenters asserted that enrollment costs identified in the proposed rule are significantly underestimated. As an example, one commenter pointed out that, while, on average, it may take card sponsors 15 minutes to enroll a beneficiary (as estimated in the proposed rule), each beneficiary will likely contact several of the endorsed programs to obtain information and materials before enrollment with one program. Therefore, the costs will likely be much more than the $11.62 enrollment cost referenced in the proposed rule, and this does not include expenses associated with the development of Internet, fax, telephone, and mail channels specific to the program. In addition, based on one commenter's experience, call center costs for individual enrollment are more than three times the cost per call of a typical group enrollment client, and experience shows that the senior population calls more frequently than other age groups, talk longer and prefers to speak to call center staff rather than use automated messaging systems, all of which increase operational costs.

Other commenters believed that the $25 enrollment fee is excessive and is ''more than twice'' the actual enrollment costs that card sponsors will incur. These commenters did not believe an annual fee should be permitted.

Response: We believe that the current policy of a one-time only enrollment fee up to $25 is reasonable and appropriate, as demonstrated in Section V.G of the regulatory impact analysis. While commenters correctly point out that a proportion of beneficiaries are likely to contact multiple endorsed card sponsors to obtain information and materials before deciding to enroll in a particular discount card program, we believe an enrollment fee up to $25 adequately accommodates these added costs. We are assuming that a large number of enrollments will be completed through a mail process, thus reducing the higher level of administrative costs that may be associated with enrollment via personal contact with customer service representatives.

Furthermore, we believe an enrollment fee up to $25 will cover administrative costs. In addition, card sponsors will have the discretion to use a portion of negotiated rebates or discounts as necessary to fund operating costs. Therefore, the current policy of a one-time only enrollment fee (no annual renewal fees) will be maintained.

b. Call Center

Comment: One commenter expressed support for the tracking of call center performance levels and believes the proposed standards of performance are generally acceptable. However, the commenter suggests that, before the standards of acceptable performance are finalized and implemented, actual experience with the program needs to be analyzed. The commenter recommends that card sponsors track and report call center performance levels for the first 6 months, and then be allowed to adjust any preliminary standards to make them more workable, if necessary.

Response: We believe there should be concrete standards for card sponsor call centers. The qualification criteria that card sponsors must satisfy, including years experience, covered lives and financial criteria, have been carefully considered and serve to ensure that well established, stable organizations are endorsed by Medicare to offer discount card programs.

Requirements for card sponsor call center operations are based on standard business practices, and card sponsors expected to qualify for Medicare endorsement should already be meeting these requirements. Based on the review of applications submitted in response to our solicitation for applications for Medicare endorsement issued on August 2, 2001 on our Web site at *http://www.cms.hhs.gov,* potential card sponsors clearly expressed their ability to meet the defined customer service standards. In fact, many applicants indicated that their customer service centers currently exceed these standards.

Comment: One commenter disagrees with the specific, quantifiable customer service requirements outlined in the proposed rule, including the requirement that 70 percent of customer representatives' time will be spent answering telephones and responding to enrollee inquiries. According to the commenter, this is not an industry standard. Private industry provides specific limitations of time off from work for vacation, sick and holidays and maintains strict guidelines in terms of tracking percent of work time in queue for customer service response.

Response: The goal of this requirement is that 70 percent of a customer service representative's time while on the job is spent fielding incoming calls and inquiries.

Comment: Two commenters suggested that card sponsor call centers should be responsible for pharmacies' questions.

Response: We agree that card sponsors should have in place a convenient means for accommodating pharmacy inquiries regarding the card sponsor's program. Card sponsors could, for example, accommodate pharmacist inquiries by incorporating a specific number in the Interactive Voice Response (IVR) for the pharmacist to select so that hold times will be minimized (many pharmacies use this already for ease of access for physicians). We are aware that card sponsors, as part of their current business operations, generally have some established mechanism for responding to pharmacy inquiries. We do not intend to mandate a specific approach because we do not want to inadvertently force a higher cost solution; instead, individual card sponsors will have to provide information in their application for endorsement about how they will effectively address pharmacy inquiries.

Comment: Two commenters suggest that call centers should operate 24 hours per day. The commenters note that thousands of pharmacies across the country remain open all day and night because Medicare beneficiaries and other patients need convenient access to prescription drugs. Questions regarding prescription drugs can arise at all hours; therefore, call centers should remain open at all hours.

Response: We do not agree that endorsed card sponsors should be required to provide 24-hour call center operations. According to analysis conducted for us by Booz-Allen-Hamilton, the numbers of pharmacies that operate on a 24-hour basis are a small subset of the total number of chain drug store outlets, differentiating themselves in the industry by providing

enhanced consumer convenience and value-added services such as drive-through pharmacies or 24-hour services.

Therefore, at this time, we do not believe there is sufficient justification to mandate 24/7 customer service for all card sponsors. We do agree, however, that the customer service component is critical to this initiative, and card sponsors will need to provide convenient access to customer services throughout their program area.

We understand that a number of large PBMs currently provide 24/7 customer service access, while others offer extended hours well beyond those required for this initiative. We will, however, monitor the adequacy of the card sponsor customer service requirements, and will consider modifying the present card sponsor customer service requirements if there is a demonstrated need as we gain experience with the program. The specific customer service requirements are delineated earlier in the preamble.

c. Information and Outreach

Comment: Two commenters thought that we should prohibit card sponsors with regional programs from advertising their programs or their Medicare endorsement in print or broadcast advertisements that extend beyond their defined service areas for a Medicare-endorsed card program.

Response: We agree with the commenters that regional card programs should not advertise their programs outside their defined service areas. With the exception of advertising in print or broadcast media with a national audience, outreach to beneficiaries outside of a card sponsor's defined service area could serve as the basis for corrective actions and/or termination of endorsement by us. In addition, our guidelines for information and outreach materials will require that card sponsors clearly disclose the areas in which their endorsed programs are available to beneficiaries.

d. Privacy

Comment: We received a significant number of comments on privacy related provisions of the proposed rule. Several commenters indicated that potential drug card sponsors will prefer to operate under one set of privacy provisions in order to avoid operational inefficiencies and confusion. Of particular concern was the provision that will require obtaining written consent from beneficiaries regarding the expected uses and disclosures of their individually identifiable information. The commenters were concerned that because of this provision, the enrollment process—which otherwise could be conducted via telephone, fax, or electronically—will necessitate additional and potentially costly steps.

Other commenters expressed concern about the lack of clarity and specificity regarding privacy protections for beneficiaries in the proposed rule, including: the need for specific limitations on what will be included among the expected uses and disclosures of individually identifiable information; whether beneficiaries will be provided notice of expected uses and disclosures of personal health information; whether the information about privacy provisions will be presented to beneficiaries in a manner that will be easily recognized and understood; and, whether beneficiaries who provide authorization for the use and disclosure of their personal health information will be allowed to revoke such authorization. These commenters stressed the importance of strong privacy protections under this initiative. Some commenters were concerned that the proposed rule's privacy provisions were not tied to HIPAA and, therefore, did not offer beneficiaries the same level of protection to which they would have been entitled under HIPAA. In particular, these commenters were concerned about drug card sponsors and pharmaceutical manufacturers inappropriately using and disclosing beneficiaries' individually identifiable information to market specific drugs and other profitable services.

Response: We have significantly revised our privacy provisions for the Medicare-Endorsed Prescription Drug Card Assistance Initiative in response to public comment. These revisions reflect our understanding that companies with drug card programs will not qualify as covered entities under the Privacy Rule because of their drug card, but may be, in some circumstances, business associates of covered entities under the Privacy Rule. For example, drug card programs will be business associates of health plans where beneficiaries are group enrolled into a card program, and of pharmacies where the card sponsor performs drug utilization review or provides other health or business services as a feature of the endorsed program. Some companies sponsoring drug discount cards, however, may be covered entities due to other business activities. These revisions also reflect public comments and our understanding that without clear and specific privacy provisions that align with the Privacy Rule, there will be unintended gaps in privacy protections for beneficiaries' individually identifiable health information. Specifically, we require as a term of endorsement that card sponsors must agree to protect the privacy of Medicare beneficiary information, consistent with the privacy provisions set forth in 45 CFR 160.103, 160.202, 164.501 through 164.514, and 164.520, including relevant subsequent changes to those provisions. These sections concern consent, authorization, notice, public policy, permissible uses and disclosures, and limiting disclosure to the ''minimum necessary''. For purposes of this initiative, a card sponsor must consider itself a ''covered entity'' as referenced in the Privacy Rule. These provisions will go into effect beginning at the time of Medicare endorsement.

We recognize that there could be circumstances wherein the sponsor of a card program could be operating under two sets of privacy provisions—that is, under the card program and in other lines of business—and that this could be costly and otherwise inefficient. We also share concerns expressed that beneficiaries need to understand and agree to the uses and disclosures of their protected health information. Since we believe that the privacy provisions under this initiative should be aligned with national policy concerning privacy as established in the Privacy Rule, we have revised the initiative to incorporate certain provisions of the Privacy Rule (along with any subsequent changes to those provisions).

To protect against marketing of items or services outside of the scope of our endorsement, our definition of marketing for the purpose of this initiative includes any use or disclosure of protected health information considered outside the scope of the Medicare endorsement. Notice and written authorization will be required as stipulated in the Privacy Rule (along with any subsequent changes to those provisions), subject to our definition of marketing. The notice must contain reasonable provisions about how a beneficiary's authorization can be revoked.

Finally, we provide that card sponsors will be required to develop, implement and update periodically a written security plan to assure that beneficiaries' protected health information is secure from unauthorized disclosure, unauthorized modification, and destruction.

Comment: One commenter recommended that a card sponsor's failure to adhere to any of this final rule's privacy protections should constitute immediate grounds for withdrawal of the sponsor's Medicare endorsement.

Response: We agree that failure to adhere to the privacy protections provided under this initiative is grounds for termination of a card sponsor's endorsement. As discussed elsewhere in this rule, in the case of termination, we reserve the right to require the card program to operate for 90 days to allow time for beneficiaries to identify and enroll in an alternative card program. We also reserve the right to fully consider the merits of any claim that a card sponsor has violated the privacy protections and whether corrective action or termination is the most appropriate course of action.

Comment: One commenter noted that there are no limits in the proposed regulation text regarding what beneficiary information goes to the consortium or on how the consortium or its members use or disclose such information.

Response: We make clear that in operating the enrollment exclusivity system or in the conduct of any other activity that could involve the use or disclosure of Medicare beneficiaries' protected health information, the consortium will be considered, for the purpose of this initiative, a business associate, as defined by the Privacy Rule. Beginning with the formation and operation of the consortium, the consortium will develop, implement, and update periodically a security plan to assure that beneficiaries' protected health information is secure from unauthorized disclosure, unauthorized modification, and destruction.

e. Customer Complaints

Comment: One commenter thought that requiring that card sponsors have a formal grievance and appeals process was inappropriate. Because card sponsors will offer a discount card program and not a drug benefit, a grievance and appeals mechanism similar to that for a funded prescription drug benefit will create unrealistic expectations and confusion among beneficiaries and unnecessarily add to card sponsors' administrative costs. Instead of a formal grievance and appeals process, this commenter thought that we should simply require card sponsors to establish a process for addressing disputes. The presumed intent of a dispute resolution would be to help beneficiaries obtain their drugs expeditiously and simply.

Response: We agree with the commenter that a formal appeals process is not necessary for discount card programs. We clarify our intended definition of a customer complaints process in § 403.820 as a process ''designed to track and address in a timely manner enrollees'' complaints about any aspect of the drug card program.''

9. Administrative Consortium

As a condition of endorsement, card sponsors must agree to participate in, abide by the rules of, and fund the administrative activities of a consortium. Beginning in Year One, the consortium will operate and maintain an enrollment exclusivity system and a Web site for comparing drug prices among the Medicare-endorsed discount card programs. Beginning in Year Two, the consortium's administrative activities will include review of card sponsors' information and outreach materials under guidelines produced by us. We expect the administrative consortium to be operational no later than the first day that Year One enrollment may begin.

In structuring itself, we will also recommend that the consortium consider establishing an advisory board, comprised of beneficiary and other stakeholder representatives, such as pharmacists, physicians, and pharmacy benefit managers (PBMs), to provide guidance on the structure and operation of the consortium and publicly report on the performance of the consortium activities.

The consortium must abide by Federal and State laws, including the privacy and security provisions established by the Secretary for the purpose of this initiative.

The consortium will be financed by the Medicare-endorsed card sponsors. The administrative consortium will be free to use independent contractors to perform the review of information and outreach materials, as well as other consortium functions. As we explained in the preamble to the proposed rule, once card sponsors are endorsed, we will work with them to devise methods for funding and starting up the consortium. Card sponsors will be expected to share in start-up costs.

Review of beneficiary information and outreach materials will become the responsibility of the administrative consortium beginning in Year Two of the initiative. In the first year of the initiative, we will be responsible for developing guidelines and reviewing card sponsors' information and outreach materials. Beginning in the second year of the initiative, the consortium will assume review of these materials using guidelines drafted by us. All materials to be reviewed for approval and that could therefore be used by the card sponsor will pertain only to the drug card initiative and to the card program and its features that are recognized by us as included under the Medicare endorsement. It is essential that information and outreach materials be reviewed to ensure that the Medicare name is not misused, for example, to market services unrelated to prescription drugs.

We will also develop standards for use of a Medicare endorsement emblem and include them in the guidelines for information and outreach materials. To use the emblem on their cards, card sponsors will need to abide by the standards we develop, which will also cover the presentation of the emblem and other information on each program sponsor's discount card.

The consortium's Web site for comparing prices must express drug prices in dollars for the purpose of comparing across endorsed card programs. The price comparison will also include information about generic substitutes. This comparative information will assist beneficiaries in deciding which Medicare-endorsed discount card will offer them the greatest financial advantage. We have also revised our policy from the proposed rule, so that a specific drug on the price comparison Web site is not dropped from the formulary, nor its price increased for periods of at least 60 days, starting on the first day of the program's operation. In addition, card sponsors will notify the pharmacy network, the consortium, and us of removals from the formulary or increases in prices 30 days in advance of the change.

As discussed elsewhere in this preamble, card sponsors must also ensure that the consortium protects beneficiaries' protected health information, and therefore will be required to develop, implement and update periodically a data security plan that assures that beneficiaries' protected health information is secure from unauthorized use and disclosure, and unauthorized modification and destruction.

a. General Comments

Comment: We received numerous comments about the cost of the consortium and its activities. They include: (1) The cost will erode the value of discounts to beneficiaries as discount card programs do not produce enough margin to fund the consortium and deliver meaningful savings to beneficiaries; (2) the costs of the consortium should be borne by us if associated with criteria required for the endorsement; (3) the costs for the consortium will limit participation by card sponsors by serving as a barrier to participation of not-for-profit and

community based organizations; (4) the costs of the consortium are, in some cases, duplicative of the card program's own infrastructure, and (5) to the extent that a card program could perform for itself the administrative activities of the consortium, then the consortium costs borne by that card program should be adjusted downward accordingly.

Response: We will retain the requirement that endorsed card sponsors establish and fund an administrative consortium and the requirement that card sponsors fund it as a condition of endorsement. We believe that because the initiative is not a benefit, but instead a Medicare endorsement of private sector entities in order to educate and assist Medicare beneficiaries with their receipt of lower-priced prescription drugs, it is more appropriate for the private sector entities to operate the details of the initiative, including the consortium. We also think that card sponsors whose programs are competitively designed will have alternative sources of revenue that will more than offset the costs of the initiative through, for example, enrollment fees and negotiated manufacturer discounts and rebates on prescription drugs. Finally, many of the functions performed by the consortium, such as ensuring that information and outreach materials are accurate through the review process, providing a uniform mechanism for beneficiaries to compare prices through price comparison, and leveraging beneficiaries' negotiating power through enrollment exclusivity, will improve beneficiary confidence in the initiative and will thus improve beneficiary participation. This, in turn, should result in greater negotiating power for each of the card sponsors, and improve their ability to recoup costs of the consortium. We believe that the consortium function and its associated costs are appropriately borne by consortium and the card sponsors whose programs will benefit from the revenue stream generated under this initiative.

We do not agree that the costs of the consortium will undermine the participation of not-for-profit and community based programs. If card programs can successfully demonstrate that they meet the other requirements provided in this rule, and if their program features are perceived by beneficiaries as valuable relative to competing card programs, then not-for-profit and community based programs should have similar opportunities as for-profit programs, through the revenue streams generated under the card program, to cover their administrative costs. While it may be true that some card programs could have administrative infrastructure similar to what may be developed and maintained by the consortium for the purpose of executing its functions, we do not believe that an individual card program sponsor can successfully fulfill the functions of the consortium on its own behalf, as the value of these functions requires coordination across the card programs. Nonetheless, perhaps the infrastructure could be utilized by the consortium to promote efficiencies, provided that the necessary legal and other arrangements are made to assure the legitimate operation of the consortium. Such a determination is up to the consortium and its members.

Comment: A number of commenters expressed concern regarding the intersection between the consortium and antitrust laws. Commenters were concerned that if beneficiaries could only be in one endorsed card at a time, that might allow them to ''divide up the market for beneficiaries among themselves'' and violate antitrust laws. Commenters also expressed concern that the consortium's review of information and outreach materials in the second year of the program, or its posting of price information, could lead to potential antitrust violations.

Response: The commenters' claim that the proposed rule allows Medicare-endorsed discount card program sponsors to illegally divide up the market for program beneficiaries ignores the functional reality of what was proposed. As we stated in the proposed rule, exclusive enrollment is based on the concern that ''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'' (67 FR 10262, 10270).

Far from authorizing program sponsors to divide up the market for beneficiaries, the proposed rule is premised on program sponsors competing to attract enrollees based primarily on comparative information on the prices offered to Medicare beneficiaries for drugs covered by the discount card. Therefore, to the extent Medicare-endorsed discount card program sponsors are responsible for assuring enrollment exclusivity, they are merely implementing this requirement after competing successfully to attract enrollees over the plans' offerings. Such activity provides no support for the claim that the proposed rule allows the Medicare-endorsed discount card program sponsors to divide up the market for beneficiaries among themselves.

In addition, we do not view the review of information and outreach materials or the posting of comparative price information as inherently anticompetitive. We expect that endorsed drug discount programs will need to work—perhaps with antitrust counsel—to ensure that the endorsed entities do not violate antitrust laws when they implement the review of information and outreach material or price comparison.

Comment: One commenter stated that the final rule should more thoroughly address how the initiative is to be administered and what, if any, enforcement rights are being delegated to the consortium. The commenter also stated that there needs to be a more transparent exploration of how the consortium will work.

Response: The consortium, not CMS, will determine the final designs and build and maintain the two systems associated with price comparison and assuring enrollment exclusivity. We will assist in developing options for the consortium to facilitate the start-up of the consortium and its activities. Beginning in Year Two, the consortium begins reviewing information and outreach materials using our guidelines. In addition to controlling the content of the guidelines in future years, even when the consortium is responsible for the review, we intend to transition the role of review to the consortium by conducting our own review on a sample of materials. Further, we reserve the right to spot check materials to assure that the consortium (and the card sponsors) are following the guidelines. While the final structure and operation of the consortium is the business of the consortium and its membership, we would intend to participate in the consortium activities on an ex officio and advisory basis. The other mechanism that we have for influencing the direction of the consortium is through the endorsement agreements with each of the card sponsors that may be revised annually, which will include terms for the sponsor's obligations to the consortium. The final structure and operations of the consortium cannot be made more transparent at this time, as endorsed card sponsors will ultimately be responsible for determining much of its design.

b. Enrollment Exclusivity

Comment: A number of commmenters stated that the exclusivity system should be run by an entity other than the consortium, such as a third party which will not have access to any information about any enrollee's health or drugs purchased. One commenter

was concerned that if the consortium operates the exclusivity function, ineligible individuals may be enrolled through either fraudulent means or administrative errors if we are not going to check eligibility.

Response: As discussed elsewhere in this rule, the consortium, in addition to each individual card sponsor, will be required to assure that the operation of the exclusivity system remains inside the privacy and security boundaries established under this final rule. Further, we believe that our complaints tracking system will be an important check to assure the confidence of the public in the operation of the enrollment exclusivity system. Given the public comments that we received in support of the consortium having an advisory board, we also believe that the consortium should consider an advisory board as another way to instill confidence in the public about consortium operations. We will monitor these sources of information and may implement a random check to assure the integrity of the system if this appears necessary.

c. Review of Information and Outreach Materials

Comment: One commenter noted that there should be specific guidelines governing how we will monitor information and outreach materials to prevent unrealistic expectations among beneficiaries.

Response: We agree with the commenter. We will develop information and outreach guidelines that card sponsors will be required to follow. Review of these materials, by us in Year One and by the consortium in Year Two, will be based on these guidelines. All materials to be reviewed for approval and that could therefore be used by the card sponsor will pertain only to the drug card initiative and to the card program and its features that are recognized by us as included under the Medicare endorsement.

Comment: One commenter supported our requirements for prior review and approval of information and outreach materials based on our guidelines. One commenter opposed our requirement for prior review and approval of these materials because such review will be cumbersome and time consuming for card sponsors. Two commenters recommended that, instead, card sponsors file and use these materials based on our guidelines without prior approval, and that we audit these materials on an as-needed basis after their use.

Response: We believe that prior review and approval of information and outreach materials is important under this initiative in order to protect beneficiaries' privacy and the Medicare name, as well as to ensure that materials used by the endorsed cards meet the guidelines that will delineate, among other things, what information must be provided to beneficiaries, what will be considered appropriate context, and how the Medicare name and emblem may be used. This will facilitate card sponsors gaining experience in developing materials for beneficiaries under our guidelines without putting these important objectives at risk.

Comment: Two commenters thought that we should provide interested parties with an opportunity to review and comment on the proposed guidelines for information and outreach materials prior to finalizing the guidelines.

Response: We believe the information and outreach material guidelines are interpretive rules that govern the presentation and content of materials, once a program has been endorsed. The solicitation for applications will contain the guidelines for information and outreach materials as an appendix, and the public will have time to submit comments and questions for clarification to us. We will take these comments and questions under advisement and make any necessary changes to the guidelines once the comment period has concluded.

Comment: One commenter recommended that we require card sponsors to include a prominent statement in all their information and outreach materials that explains that the appearance of a drug on a card sponsor's formulary of discounted drugs does not mean that the drug is clinically superior to other products in that therapeutic grouping, and that clinical decisions about the proper drug for a beneficiary should be made by the treating physician in consultation with the beneficiary.

Response: We agree with the commenter that this is an appropriate and important issue about which beneficiaries should be educated. We will take this recommendation under advisement as we work to finalize the guidelines for information and outreach materials.

Comment: In support of pharmacy programs providing information about appropriate medication regimens, self monitoring, refill reminders, disease state information programs and drug therapy education, one commenter discussed the Medguide Action Plan developed by the Food and Drug Administration (FDA) in consultation with the industry as one model that could be used by the card programs to educate beneficiaries and included in expected uses and disclosure statements developed to protect the use of beneficiaries' personal information.

Response: Beneficiary education is a key component of this initiative. We believe that our guidelines, which will assure that appropriate, complete and understandable information is provided to beneficiaries in a manner that also protects their privacy, as required under the privacy provisions of this initiative, are important. As we develop our guidelines for information and outreach materials, which will be included in the solicitation for applications, we will take this comment under advisement.

d. Price Comparison

Comment: We received numerous comments on price comparison. Most commenters agreed that price comparison information could improve a beneficiary's ability to make an informed decision in choosing a discount card. One commenter claimed that comparative price information is more important to a cash-paying customer than to an insured customer. However, one commenter stated that price information reported by the individual card program should satisfy the requirement to provide information. Another commenter stated that retrospective pricing information (at the point of sale) from the card will provide the most meaningful information and will give the government the ability to audit and ensure that savings are passed to the beneficiary. Several commenters noted that comparisons of ever changing prices on the array of drugs and dosages that are available through standardized reporting procedures are among challenges that must be faced in order to develop an accurate and meaningful price comparison system. Other challenges include providing the information in a user friendly, understandable format. One commenter stated that overcoming these kinds of challenges to provide genuine comparative information is an impossible task. Commenters agreed that publishing discounts relative to the average wholesale price (AWP) will not be meaningful to beneficiaries and that price information is what is needed. One commenter said that restricting pricing disclosure to commonly used products, as was proposed in the proposed rule, would serve to protect established products to the detriment of their competitors, and that restricting the list of drugs may be construed by beneficiaries as Medicare endorsing these drugs. Several commenters said that generic or other alternative drug

therapies that may not be associated with a specific card's formulary should be provided so that beneficiaries know that an alternative is available, which may not be discounted as deeply as a brand name drug but could nonetheless be less expensive. Several commenters indicated the importance and value of working with the industry and beneficiaries to develop the comparison methodology and web site formats. One commenter stated that most people over 65 do not have access to the Internet; therefore, in addition to the web site, options need to be developed to get comparative information to beneficiaries through alternative communication channels.

Response: We agree on the importance of comparative price information for beneficiaries to make an informed decision about joining a card program. We have revised our policy, which now provides that a specific drug offered under the card program is not dropped from the formulary, nor its price increased for periods of at least 60 days, starting on the first day of the program's operation. We also provide that comparisons will be based in dollars, not AWP discounts, and that information on generics will be provided. We do not agree that providing meaningful price comparisons is impossible, but we acknowledge the challenges raised in the comments and agree that developing a comparison price methodology with input from beneficiaries and industry stakeholders is important to assuring that the price comparison methodology is feasible operationally and meaningful. We also agree that alternative channels for providing price comparison information should be developed. We will work with the consortium to assist in developing a price comparison methodology, a design for a web-based price comparison system, and alternative channels for providing information. Work will be conducted with input from beneficiaries and the industry.

Comment: In addition to prices, several commenters indicated the importance of providing other comparative information such as enrollment fees and the availability of patient management services.

Response: This information will be provided through a number of communication channels, including on our Prescription Drug Assistance Program web site and by the card sponsors themselves for beneficiaries to use in making an informed decision about what card program to join.

e. Advisory Board

Comment: We received several comments supporting an advisory board for the consortium and suggesting how it should be structured, who should be on the advisory board and whether we should be a member.

Response: We agree that the consortium could benefit from having an advisory body representing beneficiaries and a cross-section of other stakeholders in the Medicare-Endorsed Prescription Drug Card Assistance Initiative, and we will recommend that the consortium consider establishing an advisory board to provide it with guidance.

10. Our Educational Efforts

We will educate beneficiaries about this initiative, both at the time it is announced and as part of ongoing education efforts thereafter. We will create and authorize the use of a Medicare-Endorsed Prescription Drug Card emblem. This emblem will be used to communicate that Medicare has endorsed a stable and reputable drug card. We will highlight this 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 will provide general information about the initiative on the Medicare Web site (*http://www.medicare.gov*). We will post on our Web site information for each discount card program including: contact information, including toll free telephone numbers for individual programs, 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 will identify these services on our web site as well, provided they are not associated with a separate fee. We will strive to educate Medicare beneficiaries that, generally, generic drugs are less expensive than brand name drugs, even those purchased at a discount. Among the messages we will disseminate to beneficiaries are: an emphasis on the importance of drug coverage, including the messages that beneficiaries should keep their existing coverage, or access coverage, for example, through a Medicare+Choice plan in their area, or through Medicaid if the beneficiary could qualify; that many Medicare+Choice plans and other health care insurance include a discount card program as an added feature to their benefit package and that beneficiaries should check with their plan to see if this is an integrated part of their benefit package; that beneficiaries who are admitted to long-term care facilities may not be able to benefit from a discount card if the facility is operating under policies that maintain a closed drug dispensing system; and that a Medicare endorsement does not constitute an endorsement of any particular drug over another, therefore, beneficiaries should consult with their physician and pharmacist to select the best drug for their particular needs. We will develop these messages and identify and develop other necessary messages into understandable and meaningful information for beneficiaries in order to maximize the value they get from their participation in this initiative.

The information made available on our web site will 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. In addition, we will strive to disseminate information to community level organizations that represent the needs and the interests of the diverse Medicare beneficiary population.

Comment: One commenter thought that there was no quality check in place to ensure that the best drug is being dispensed to beneficiaries, and that card sponsors should inform beneficiaries about any drug that offers an advantage. Another commenter made the point that beneficiaries should be educated that the drugs contained in a card sponsor's formulary are not necessarily clinically superior.

Response: We will encourage participants in the Medicare-Endorsed Prescription Drug Card Assistance Initiative to continue to rely on their doctor and pharmacist in selecting the best drugs for their condition, emphasizing that a drug's therapeutic effectiveness and its cost do not necessarily correlate, especially when a generic alternative is available. It is not unusual for alternative, less expensive drugs to provide the same clinical benefit as more expensive drugs. One of the important features of this initiative is that discount card programs and the consortium will make available price information that can be compared so that beneficiaries can discuss with their doctor and pharmacist similarly effective, but less expensive drugs as alternative therapies.

Comment: One commenter noted that because manufacturer participation is voluntary, not mandatory, this initiative will result in a patchwork of covered and non-covered drugs, which will

create the need for a high level of consumer involvement in order to assure savings for beneficiaries' individual prescriptions. The commenter thinks that many seniors will not be familiar enough with the individual endorsed programs to enroll with a sponsor that covers their particular prescriptions and actually secure the initiative's intended savings.

Response: We are committed to educating beneficiaries and assuring that they have timely and accurate information to address their drug discount questions. As part of this initiative, we will launch a widespread educational effort to address beneficiaries' questions and concerns in a variety of formats. Card sponsors will make available drug formulary and price information, and the consortium price comparison system will assist the public in determining which sponsors' endorsed cards are offering the largest discounts on any given drug. We are confident that when provided with the appropriate information, most beneficiaries and their families will make appropriate card elections based on an examination of pertinent health care needs. In the unfortunate case when a beneficiary chooses a prescription drug card program and is dissatisfied with its discounts, he or she may enroll in a different program, to become effective the first day of the following January or July, whichever comes first. Also, as we discuss elsewhere in this preamble, endorsed cards will be required to have discounts on a drug in the therapeutic categories most common to Medicare beneficiaries, thereby giving seniors access to discounts on a broad range of prescription drugs.

Comment: One commenter thought patients' primary care physicians should be involved in educating seniors about their options.

Response: As Medicare beneficiaries rely on their physicians for medical treatment and guidance, we agree that it will be helpful to beneficiaries if their physicians were familiar with this initiative. We plan to provide information to the physician community so they may help beneficiaries obtain lower prices for the prescription drugs they take. Several major national medical organizations provided comments in support of this initiative and we plan to work with these organizations to provide educational material to physicians.

Comment: One commenter noted that due to the vast differences in educational attainment and literacy levels in the population that Medicare serves, print materials for consumers should be at the sixth grade reading level.

Response: We agree that in order to be effective in getting information about this initiative out to the public, we have to be cognizant of our beneficiaries' needs, including literacy levels. We recognize the diversity of the Medicare population and it is a priority to effectively reach out to Medicare beneficiaries at all literacy levels. To this end, we utilize many information channels beyond print materials, including the toll-free 1–800-MEDICARE help line and our annual fall television advertising campaign. When we do use print materials, we strive for a fifth grade reading level.

Comment: One commenter recommended that education materials inform beneficiaries about Medicaid and other low-income assistance programs.

Response: We are committed to educating Medicare beneficiaries about all avenues of assistance that may be available to them, including low income and drug assistance programs. On our Medicare Web site, *http://www.medicare.gov,* individuals can search the Prescription Drug Assistance Program database, which provides information on public and private programs that offer discounted or free medication, as well as Medicare health plans that include prescription coverage. The Prescription Drug Assistance Program database can be searched by geographic region to help Medicare beneficiaries find programs in their areas for which they may qualify.

Comment: Three commenters suggest that, in order to get our message to all facets of the Medicare beneficiary population, we not limit information to the Internet and telephone, but that we also utilize community organizations, public buildings, and physician's offices to disseminate our educational messages.

Response: We understand the divergent needs of the nation's 40 million Medicare beneficiaries, and that a multi-faceted education program that recognizes different cognitive levels, literacy levels, languages, racial and ethic backgrounds and socioeconomic status is necessary as part of this initiative. We will support education on the Medicare-Endorsed Prescription Drug Card Assistance Initiative via paid print media and television advertisements, disseminating information via our local information intermediaries in the State Health Insurance Programs (SHIPs) and via our national and regional partner organizations across the nation. These include a number of consumer advocates and organizations representing specific racial and ethnic backgrounds.

Comment: One commenter expressed the concern that it would be the pharmacies, not policymakers, who would be largely responsible for explaining and discussing the costs of medication under the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

Response: We recognize that pharmacists often serve as a source of information for people with Medicare, and pharmacists are likely to be approached by beneficiaries with questions about this initiative. The discount card market today is essentially unorganized, and consumers may have multiple discount cards. Therefore, consumers understandably ask questions about their discount card programs at the point of retail sale. We believe that certain features of this initiative, for example, enrollment exclusivity, and the focus on outreach and education, will minimize the need for beneficiaries to rely on their pharmacists for information about the endorsed card programs.

We believe that beneficiaries will seek information largely from their card sponsors, as well as the Medicare program, because of our role in conducting national outreach and education activities. Therefore, we do not believe that pharmacies will be unduly burdened by this initiative.

11. Oversight and Reporting

As a condition of endorsement, and in addition to the information that card sponsors will provide in their applications, card sponsors will be required to report on major features of their programs that correspond to the qualifications for endorsement, such as savings to beneficiaries and customer service, and we will ask card sponsors to certify the validity of their reported data. During the endorsement period, drug card program sponsors will 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.

We will ask card sponsors to report on the aggregate level of rebates or discounts shared with beneficiaries and the participation of independent pharmacies in the card program's network.

The information to be reported will generally consist of performance measures and indicators typically provided by third party administrators of pharmacy benefits in the current drug insurance industry.

We will provide a reporting tool in the solicitation for a Medicare endorsement of discount card sponsors to ensure consistent and comparable reporting by card sponsors. In developing this tool, we will make an effort to minimize reporting burden on card sponsors. These reports will allow us to assess card sponsors' performance relative to the endorsement qualifications. We intend, after obtaining some experience, to report on our web site the card sponsor's performance on reliable quality and satisfaction standards pertaining to key aspects of the card program related to endorsement in order to help beneficiaries make informed decisions when choosing their discount card programs.

We intend to develop and operate a complaint tracking system to monitor and manage complaints brought to our attention that are not satisfactorily resolved through the card sponsors' customer complaints process. We anticipate tracking complaints related to deceptive education, outreach, and enrollment practices, violations of the privacy provisions, persistent inconsistencies in formulary or pricing information compared to what is available at the point of sale, inadequate card sponsor customer service, persistent problems with pharmacy network services or providers, and any additional changes which put the card sponsor at risk of failing to continue to meet the endorsement requirements.

We will also refer complaints to Federal and State authorities where violations of laws under the jurisdictions of these agencies are in question.

We will reserve the right to terminate any endorsement at any time for violations of the terms of the endorsement, as well as to take appropriate intermediate corrective actions to correct persistent problems in a card sponsor's performance in cases in which immediate termination is not warranted.

Card sponsors may also terminate the endorsement, but we will require a 90-day advance notice of termination to us. Also card sponsors must notify all Medicare enrollees of termination within 10 days of either providing us with notice of termination, or within 10 days of receiving a notice of termination from us. In addition, in cases in which a card sponsor chooses to terminate its participation in the initiative or in which we terminate a card sponsor, we will require that card sponsors provide beneficiaries with notice of termination at least 90 days before discount card program operations cease, and that card sponsors suspend information and outreach activities and enrollment after sending enrollees notice of termination.

We will consider drug card program sponsor performance under an existing Medicare endorsement as one factor in determining eligibility for endorsement in future annual cycles.

a. Reporting

Comment: One commenter indicated that rebate formulas should be open to all and not be considered proprietary, while several commenters indicated that rebates (and other proprietary information) are strictly confidential and should not be shared with us.

Response: We agree that proprietary information should not be shared with the public. We do not consider all aspects of rebate reporting to be proprietary, including aggregate measures of rebates as a share of total savings to beneficiaries.

Comment: One commenter asked if we will track how often enrollees switch to different programs.

Response: We will track, in the aggregate, how many times beneficiaries switch to different programs. Data to support this analysis will be included in the expected uses and disclosures as part of normal operations of the enrollment exclusivity system. Also individual cards will be required to report enrollments and disenrollments.

In the proposed rule, we requested 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.

Comment: A number of commenters supported card sponsor reporting and monitoring of card sponsor performance on rebates or discounts to ensure that card sponsors are accountable to us for the manufacturer rebates or discounts they agree to pass on to beneficiaries. These commenters expressed various concerns and provided suggestions regarding how card sponsors should report this information to us, the types of information that should be reported to us, and how we should convey information about card program rebates or discounts to beneficiaries. Several commenters were opposed to card sponsor reporting on rebates or discounts, citing potential complications such as the proprietary nature of some of this information and the typically retrospective reporting of rebates. Two commenters discussed the need to find an appropriate balance in oversight of this initiative such that card sponsors worthy of endorsement were approved while avoiding excessive conditions of endorsement relating to program design and service delivery.

Response: We agree that periodic reporting for card sponsors is necessary in order to monitor card sponsors' performance related to the qualifications for the Medicare endorsement and use of the Medicare name. We believe the reporting requirements should be balanced relative to the risks associated with this initiative in the event of poor performance, which do not include the loss of benefits under a beneficiary entitlement or to the Medicare trust funds. We plan to rely on a variety of mechanisms to ascertain performance of individual card programs and the initiative overall, including reviewing certified card sponsor reports, operating a complaints tracking system, and surveying beneficiaries. It is our position that reporting on aggregate levels of rebates or discounts will be necessary in order to ensure that card sponsors continue to meet the endorsement qualifications and provide the program they agree to in their endorsement agreement with us. We do not believe that all the information reported to us will be immediately useful to beneficiaries in their selection and use of a card program, but that generally information will be valuable to beneficiaries once reviewed and analyzed by us and ultimately disseminated in some form to beneficiaries.

Comment: Two commenters supported measuring card sponsors' performance in terms of whether they achieve genuine cost savings for beneficiaries. They also recommended that we discontinue our endorsement of card programs that do not offer significant cost savings, that market more expensive brand name drugs instead of less expensive generic drugs, and that fail to pass manufacturer rebates on to beneficiaries. Another commenter suggested that, as part of oversight of card sponsors, we establish target generic utilization rates and evaluate sponsors' performance against those targets.

Response: This program is an endorsement of private sector drug discount programs that meet our defined criteria. While we will maintain reporting and other minimal requirements, we believe the level of government involvement should be as minimal as possible. While we believe that reporting on the level of generic drug utilization rates may be informative for both beneficiaries and us, we do not think it is appropriate to impose certain thresholds on generic

drug utilization and to require reporting related to those thresholds. By providing useful information to beneficiaries so that they can make informed comparisons, card sponsors will compete on value to beneficiaries which we believe will drive programs to offer prescription drugs, pricing, and other services favorable to beneficiaries.

Comment: One commenter recommended that we use the finalized section on ''Measuring Quality of and Access to Pharmacy Services in Managed Care Plans'' developed for *HCFA's Managed Care Pre-Implementation Review Guide.* The commenter states that the guide measures quality of and access to pharmacy services in managed care plans and delineates the government's role in oversight, access to good patient care, and quality of pharmacy services.

Response: We have reviewed this document, which appears to be a collection instrument for information regarding managed care plans' pharmacy network services. We agree that it captures important elements regarding the quality of and access to pharmacy services, and that some of these elements might be relevant to card sponsors' pharmacy networks. We will take the information in this document under advisement as we finalize the measures we will use to ensure that card sponsors continue to meet the endorsement qualifications.

Comment: Two commenters recommend that we require sponsors to demonstrate their financial solvency by filing quarterly financial reports, and that such reports should be posted on the consortium's Web site.

Response: We do not believe that quarterly financial reporting from a sponsor is needed. Applicants will be periodically reporting on certain performance-oriented data (for example, enrollment and disenrollment data, and complaints data reported to the card sponsor customer service centers). These data are likely to be more timely and useful indicators of specific service problems than evidence of financial problems reflected in historical financial reporting. Also, annual independently audited financial reports (balance sheet; revenue and expense statement; and a cash flow statement) will be required from the sponsor as part of the endorsement qualification application.

Regarding the suggestion that we post quarterly financial reports on the consortium's Web site, it is not our intention to require that card sponsors post financial reports on the consortium Web site. We believe that beneficiaries will be interested in comparing program features, including specifically prices on drugs offered for a discount. We will monitor card sponsor financial status through the endorsement application process. Additionally, once endorsements are awarded, we intend to post on our Web site card sponsor-specific performance measures related to the operation of the program that are useful to beneficiaries. Further guidance on performance measures will be included in the solicitation for card program applications.

b. Other Oversight

Comment: One commenter stated that Federal agencies should have jurisdiction and access to the necessary information to prevent abuse of the program or anticompetitive practices.

Another organization commented that it could not discern any significant role for us in this initiative beyond simply selecting and endorsing card sponsors and providing informational materials.

Response: We agree with the first commenter. We believe we have an important responsibility to beneficiaries to ensure that card sponsors continue to meet the qualifications for a Medicare endorsement after they have become Medicare endorsed. In order to protect the Medicare name and assure that the terms of the card sponsors' endorsement agreements are met, we must perform some level of oversight. This oversight will consist of: ensuring that card sponsors have a complaints process and provide periodic reports on various key aspects of the their program related to endorsement qualifications; considering a card sponsor's performance in future endorsement cycles; reviewing card sponsors' information and outreach materials in the first year of the endorsement to ensure that our guidelines are being followed; operating a complaints tracking and management process; taking any intermediate corrective actions we believe are necessary to improve deficiencies in a card sponsor's performance; and terminating the endorsement for persistent or egregious failure to comply with the qualifications for endorsement and the program that the card sponsor agrees to make available in its endorsement agreement.

Comment: Two commenters recommended that we create a process for beneficiaries and others to submit complaints or evidence of card sponsor non-compliance and stated that a compliance review process is essential to ensuring that card programs and sponsors are, in fact, qualified for Medicare endorsement. In addition, the commenters thought that we should create an administrative process such that beneficiaries and pharmacies could challenge the representations made by card sponsors and the consortium in their information and outreach materials.

Response: We agree with the commenters. As proposed in the proposed rule, we will develop and operate a system to track and manage complaints by beneficiaries and others. We expect that beneficiaries will first attempt to resolve their complaints through their card sponsor's customer complaints process. To the extent that beneficiary complaints are not satisfactorily resolved by the card sponsors and are called to our attention, our complaints tracking system will monitor and attempt to resolve those issues. Among the types of complaints we will track include those related to deceptive education, outreach, and marketing practices. We will use data from the complaints tracking system, as well as information reported to us on key aspects of card sponsors' programs, to ensure that card sponsors continue to meet the qualifications for endorsement.

Comment: Two commenters recommended that we revise the regulation text in the final rule to mandate withdrawal of endorsement if a card sponsor fails to meet or maintain the standards for endorsement or makes false or misleading statements to beneficiaries or pharmacies.

Response: We agree with the commenter that failing to meet the standards for endorsement or making false or misleading statements are potentially valid reasons for us to terminate an endorsement. However, we believe we should have the necessary flexibility to invoke intermediate corrective actions upon a card sponsor instead of automatically terminating the sponsor. We anticipate that there could be violations of the endorsement agreement that are not persistent or egregious enough to warrant immediate termination of a Medicare endorsement. To the extent that we can work with a card sponsor, for example, by taking intermediate corrective actions designed to ensure that card sponsor is able to correct its problem and bring the organization back into compliance with the terms of the endorsement agreement, we would like to maintain our flexibility to terminate an endorsement and maintain access to an otherwise useful card program for beneficiaries.

Comment: One commenter recommended that card sponsors notify enrollees at least 90 days prior to a termination to enable beneficiaries to research other options and select an alternative discount card program.

Response: We agree with the commenter that a 90-day advance notice of termination will facilitate the selection of a new card sponsor by beneficiaries. In § 403.804 of the proposed rule, we require that card sponsors notify all Medicare enrollees of termination within 10 days of either providing us with notice of termination, or within 10 days of receiving a notice of termination from us. In addition, in cases in which a card sponsor chooses to terminate its participation in the initiative or in which we terminate a card sponsor, we will require that card sponsors provide beneficiaries with notice of termination at least 90 days before discount card program operations cease, and that card sponsors suspend outreach and enrollment after sending enrollees notice of termination.

Comment: Two commenters asked that we provide more specificity regarding how we will measure a card sponsor's performance when deciding whether to re-endorse a card sponsor.

Response: We will require that card sponsors report on key aspects related to endorsement, such as aggregate level of manufacturer rebates, customer service, and discount card program operations, such as call center performance, complaints processes, and enrollment and disenrollment. As stated earlier, we will provide a reporting tool in the solicitation for Medicare endorsement of discount card sponsors to ensure consistent and comparable reporting by card sponsors. In developing this tool, we will seek to minimize reporting burden on card sponsors. We will utilize this information, as well as any data trends captured through our complaints tracking system, as one factor in determining whether to endorse a card sponsor beyond the initial endorsement.

12. Other

a. Standardized Identification Cards

Comment: Several commenters supported the use of standard benefit identification cards. Inconsistent or non-standard information can create barriers or delay in receiving necessary care, as well as inefficiencies for pharmacies, which must be able to process a variety of different cards with a variety of different formats and data fields. The commenters recommended that we adopt the identification card standards developed through the industry's national council for standards development, the National Council for Prescription Drug Programs (NCPDP). This council has broad representation from across the industry, as well as from relevant government agencies. It was noted that, since 1998, the industry has seen widespread implementation of the standardized ID card format with legislation for adopting these standards introduced or passed in 40 states. To date, 22 States have enacted legislation requiring the use of standardized cards.

Response: We agree that standardized identification card technology has the potential to promote significant efficiencies in this industry. We will ask the consortium to determine whether a standardized identification card should be used by all Medicare-endorsed card programs. Since the industry has already established guidelines for standardization through NCPDP, the consortium and its membership are best situated to determine whether standardization will create an undue burden on any particular card program or members of its pharmacy network.

b. Best Price

Comment: One commenter indicated that discount card sales should be exempt from Medicaid best price calculations; otherwise, manufacturers will keep discounts levels lower than they otherwise would.

Response: We do not have statutory authority to exclude manufacturer prices under this initiative from the Medicaid best price calculation.

c. Partnering With States

This initiative is targeted to the private sector marketplace and the conditions for endorsement are tailored to reflect the strengths of the private marketplace, as well as to protect the integrity of the initiative, beneficiaries, and the Medicare name.

Under this initiative, 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 is that the endorsed card program must continue to operate in the State (as well as in the District of Columbia, Guam, the Commonwealth of Puerto Rico, and the U.S. Territories) as it is defined in the sponsor's agreement with us. Under this initiative, the endorsed discount card program will have to be made available to all Medicare beneficiaries in a State. The Medicare-Endorsed Prescription Drug Card Assistance Initiative may not 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 information and outreach purposes, provided that such activities will not mislead or intentionally misrepresent to the public the nature of the endorsed program, and that such activities will include beneficiaries with disabilities, beneficiaries with End-Stage Renal Disease (ESRD), and beneficiaries age 65 and over.

Comment: One commenter stated that partnering between States and endorsed card programs, as well as between purchasing groups, Medicare+Choice (M+C) and Medigap plans could be of benefit to beneficiaries, making it easier potentially to identify and enroll Medicare beneficiaries. The commenter also indicated that States may be interested in offering additional discounts through these cards. Another commenter supported Medicare endorsement of State based programs under provisions that maximize State experimentation which could allow certain discount card programs that do not meet the requirements of this rule (for example, to negotiate and share with beneficiaries manufacturer rebates) to possibly be a program for endorsement by a State.

Response: We agree that there are potential synergies between States, private payers, including Medicare+Choice plans and the Medicare-Endorsed Prescription Drug Card Assistance Initiative, that could benefit beneficiaries. To inform future policy making in this area, we will monitor what States and private payers, including Medicare+Choice plans, do to partner with Medicare-endorsed card programs, and how the rapidly evolving discount card market is used and influenced by these parties.

d. Managed Care Organizations

Comment: One commenter recommended that, because managed care organizations (MCOs) currently offer drug discount cards, and because they have played a leadership role in providing beneficiaries access to prescription drugs, MCOs should have the option to participate in the Medicare-Endorsed Prescription Drug Card Assistance Initiative or to continue to offer their discount programs independently. The commenter identified a number of the initiative's provisions that will have to change, so that MCOs will likely qualify for endorsement or simply to accommodate the structures and processes in place for their health plans.

Response: We determined that MCOs should not be treated differently from other applicants for endorsement. As the commenter points out, prescription drug discount cards offered by managed care organizations are provided in the context of a system of care; the discount card is one of many integrated elements that allow managed access to a system

of care for a plan's enrollees. This is not unique to Medicare+Choice plans. Many employer and other types of health insurance use the leverage available to the plan through the volume the plan generates with enrollment and through drug utilization management schemes, in order to maintain low prices at the point of sale for an enrollee when, for example, drug coverage has been exhausted—this in effect serves the purpose of a discount card even though typically the enrollee does not have a separate card for discounts. We agree that discount cards provided in the context of a system of care are and should be a coordinated component of the health care benefit, with the health care benefit design driving the parameters of the drug discount program features. However, the target audience for this initiative is Medicare beneficiaries who do not have or want access to drug coverage or discounts in the context of a managed health care benefit; the requirements for this initiative have been established accordingly. As Medicare+Choice plans already have the imprimatur of Medicare's name, we believe that the best approach to recognizing that drug discounts may be a feature of a plan is to educate Medicare beneficiaries about that. We believe it is important to educate beneficiaries that drug coverage rather than discounts is likely to be of greatest benefit, and that many Medicare+Choice plans offer one or both.

e. Blood Glucose Monitoring Equipment and Supplies

Comment: One commenter recommended that we clarify that applicants should not include as features in their programs self-monitoring blood glucose equipment and supplies. The commenter noted that glucose strips are already covered by Medicare and do not need to be part of the initiative. Further, to the extent that an applicant includes blood glucose test strips as a non-endorsed feature of their card programs, we should require that the supplier of such strips be recognized as a Medicare supplier and that claims for these services be filed as required by Medicare Part B rules.

Response: We agree with the commenter that the Medicare endorsement of drug discount card programs is for prescription drug products. Glucose strips are already covered under Medicare and are not expected to be part of this initiative.

f. Low-Income-Only Programs

We asked for comments regarding whether the Medicare drug card program could provide easier access for eligible beneficiaries to several recently announced drug manufacturer discount programs. Since January 2002, a number of manufacturers have announced discount programs designed to help low-income individuals access prescription drugs. Lilly, Pfizer and Novartis announced programs that feature a flat ''copay'' for each monthly supply of a particular drug. Seven manufacturers (Abbott Laboratories, AstraZeneca, Aventis, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, and Novartis) have partnered together to form Together Rx, which offers discounted prices to eligible persons. Individuals enrolling in these programs are able to purchase prescription drugs offered under the programs at discounted prices at retail pharmacies. Many other prescription drug manufacturers also offer programs designed to help low-income individuals, although many of these programs do not offer the discount at the point of sale. The income requirements of these programs differ somewhat among the programs, but all are targeted at low-income individuals without coverage from other sources.

The Medicare web site and 1–800–MEDICARE already offer information about these programs. We plan to continue to highlight these programs in an attempt to raise beneficiary awareness about them. These programs may be of help to many low-income beneficiaries without drug coverage from another source.

Comment: Two commenters indicated that we should provide for endorsement of prescription drug discount cards that are targeted to low-income beneficiaries. One commenter indicated that, if we consider Medicare endorsement of low-income card programs, the same level of patient protection and value should be expected of them (including plan standards, pharmacy network, formulary requirements and drug safety programs). Another commenter indicated that we should not offer endorsement to manufacturer-based plans that direct discounts to only or principally low-income individuals because these programs do not meet the requirements on endorsement, and doing so will not be in the best interests of this initiative.

Response: Manufacturer-sponsored programs are welcome to apply for Medicare endorsement, but must meet the requirements that all card sponsors must meet to qualify for endorsement (for example, enroll all Medicare beneficiaries wishing to enroll and offer a discount on at least one drug in each of the therapeutic categories identified elsewhere in this preamble). We believe that all Medicare beneficiaries without prescription drug insurance would greatly benefit from being educated about methods of lowering their out of pocket costs for prescription drugs, and we will encourage all Medicare beneficiaries without prescription drug insurance coverage to consider enrolling in a Medicare-endorsed discount card program.

This Administration strongly supports providing assistance for low-income individuals regarding the purchase of prescription drugs. The President has proposed major programs to help low-income individuals gain access to prescription drug coverage (including Pharmacy Plus waivers under Medicaid, which has drawn much interest from states). The Administration continues to work with the Congress to enact prescription drug coverage for all Medicare beneficiaries in the context of overall Medicare reform, with additional assistance for low-income beneficiaries. However, this initiative is intended to be of assistance to all Medicare beneficiaries without drug coverage, not only low-income beneficiaries.

It is possible that manufacturer-sponsored discount programs could seek and secure Medicare endorsement of discount programs by making some changes to their programs, either alone or by partnering with other organizations. We believe that Medicare endorsement will help these programs reach as many eligible beneficiaries as possible.

Comment: Several commenters suggested that initial efforts by Medicare (either in the context of a Medicare drug benefit or this initiative) should focus on low-income beneficiaries first.

Response: As discussed above, we believe that all Medicare beneficiaries without prescription drug coverage could and should benefit from this particular initiative. This Administration has proposed and/or implemented a number of efforts to assist low-income individuals purchase prescription drugs. A Medicare drug benefit is not the subject of this final rule.

Comment: One commenter indicated that the final regulation should expressly require existing manufacturer-sponsored patient assistance programs to continue.

Response: These manufacturer-sponsors programs are voluntary efforts on the part of manufacturers. We do not have statutory authority to impose such a requirement.

Comment: One commenter indicated that we should ensure that eligible low-

income seniors receive benefits through programs such as Medicaid before enrolling in a Medicare-endorsed discount card program.

Response: We strongly support the efforts of states and others to conduct outreach to Medicaid-eligible individuals who are not currently enrolled in Medicaid. We do not require that card sponsors screen potential enrollees for Medicaid eligibility; we believe this is better done by the states. Part of the beneficiary education efforts we will undertake under this initiative will be to educate beneficiaries that if they have or are eligible for insurance coverage for prescription drugs, including Medicaid coverage, then they are better off having insurance coverage. We will be clear that this initiative is not insurance coverage, but a discount program. It is possible that our education efforts (that are the cornerstone of this initiative) will prompt some beneficiaries to consider whether or not they may be eligible for Medicaid, or state-sponsored low-income drug insurance programs.

13. Mechanics of Endorsement

A solicitation for applications for Medicare endorsement will follow this final rule. In order to qualify for Medicare endorsement, applicants will be required to submit complete applications 60 days after the OMB-approved solicitation for applications is published. Following publication of the approved solicitation, the public will have time to comment and we will entertain any questions from potential applicants seeking clarification of the final application. All applicants who qualify for Medicare endorsement will be announced by the Administrator.

The endorsement in Year One will be for a period of at least twelve months but fewer than 24 months. We anticipate card program sponsors will have six months following our announcement of endorsed programs to implement their card programs, including finalizing their pharmacy network contracts, negotiating manufacturer rebates or discounts, obtaining a signed agreement with us, operationalizing their call centers, obtaining approval for their information and education materials, and completing contracts for all aspects of the program as specified under the qualifications for endorsement. Sponsors will also use this time to organize and activate the administrative consortium.

Comment: One commenter noted that the timeline in the proposed rule is unrealistic. We should instead establish a date at least 45 days before the first day outreach is allowed to announce the endorsement of card sponsors because card sponsors will need at least this much time to finalize their materials, obtain our comments and approval of their materials, incorporate any changes, secure internal legal review of any changes, and print information and education materials and enrollment kits. The commenter recommends that, if the program is ready for enrollment on October 1, 2002, endorsement should be granted no later than August 15, 2002 to avoid the possibility that card sponsors will be unprepared to provide information and education materials and enrollment kits to interested beneficiaries by October 1, 2002. Presuming that a 60-day response time is established for interested sponsors, and we require a reasonable amount of time to turn around public comments and review the proposals, the commenter recommends that the program begin no earlier than November 1, 2002.

Response: We have revised our timeline and we anticipate card program sponsors will have six months following our announcement of endorsed programs to implement their card programs. We believe our new timeline addresses the commenter's concerns and provides potential card sponsors with ample time to implement their programs following our endorsement.

II. Provisions of the Proposed Rule

In part 403 of Title 42 of the Code of Federal Regulations we proposed to add a new subpart H—Medicare-Endorsed Prescription Drug Card Assistance Initiative, the provisions of which were as follows:

- We proposed to add a new § 403.800 to describe the basis and scope of the initiative and set forth the requirements for the initiative.
- We proposed to 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 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 define the administrative consortium as a private entity financed by the Medicare-endorsed prescription drug card program sponsors to carry out a set of specific administrative tasks required under this initiative.
- We proposed to 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 proposed to add a new § 403.806 to set forth the requirements for eligibility for obtaining Medicare endorsement under the initiative.
- We proposed to add a new § 403.807 to set forth the application process for organizations wishing to obtain Medicare endorsement under the initiative.
- We proposed to 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 proposed to add a new § 403.810 to set forth the responsibilities of the administrative consortium.
- We proposed to add a new § 403.811 to set forth the requirement that a beneficiary only be allowed to be enrolled in one drug card program at a time.
- We proposed to add a new § 403.812 to set forth the conditions under which the Medicare endorsement will be withdrawn from an endorsed drug card program sponsor.
- We proposed to add a new § 403.820 to set forth our oversight and beneficiary education responsibilities.

III. Provisions of the Final Rule

In part 403 of Title 42 of the Code of Federal Regulations, we are adding a new subpart H—Medicare-Endorsed Prescription Drug Card Assistance Initiative, the provisions of which are as follows:

- We add a new § 403.800 to describe the basis and scope of the initiative and set forth the requirements for the initiative.
- We add a new § 403.802 to define the initiative as a mechanism whereby we provide information, counseling, and assistance to beneficiaries by soliciting applications for Medicare endorsement of prescription drug card programs, reviewing them, offering agreements to program sponsors that meet all of the requirements for endorsement, and awarding Medicare endorsements to program sponsors who

sign the agreement, and educating beneficiaries about the options available to them in the private marketplace. We define a Medicare-endorsed prescription drug card program as a program developed by an organization or group 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 define the administrative consortium as a private entity established and financed by the Medicare-endorsed prescription drug card program sponsors to carry out a set of specific administrative tasks required under this initiative.

- We 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 add a new § 403.806 to set forth the requirements for eligibility for obtaining Medicare endorsement under the initiative.
- We add a new § 403.807 to set forth the application process for organizations wishing to obtain Medicare endorsement under the initiative.
- We 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 add a new § 403.810 to set forth the responsibilities of the administrative consortium.
- We add a new § 403.811 to set forth the requirement that a beneficiary only be allowed to be enrolled in one drug card program at a time.
- We add a new § 403.812 to set forth the conditions under which CMS may take intermediate actions or withdraw the Medicare endorsement.
- We add a new § 403.820 to set forth our oversight and beneficiary education responsibilities.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day 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 comment 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.

Section 403.804 General Rules for Medicare Endorsement

In this final rule, the burden associated with the application for endorsement is addressed in the discussion in § 403.806.

In this final rule, under paragraphs (g) and (h) of § 403.804, a Medicare-endorsed prescription drug card program sponsor may choose not to continue participation in the Medicare-Endorsed Prescription Drug Card Assistance Initiative and will have to notify us of its decision. It will 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.

As stated in the final rule, we do not believe that 10 or more card program sponsors will terminate their agreement on an annual basis. Therefore, this requirement is not subject to the PRA in accordance with 5 CFR 1320.3(c). However, if in the future CMS has reason to believe that this collection requirement meets the definition under 5 CFR 1320.3(c) we will submit this collection requirement to OMB for PRA approval.

Section 403.806 Requirements for Eligibility for Endorsement

In this final rule, 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.

As stated in the final rule, 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 generally believe that either the card sponsors or the contractors who administer the programs will be required under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to comply with the privacy provisions under HIPAA, either as a covered entity or as a business associate, as defined by HIPAA. Therefore, the burden associated with these collection requirements is captured under HIPAA compliance activities, and is transparent to the requirements referenced in this rule. Therefore, we assign one token hour of burden for these collection requirements. Based upon our knowledge of the industry, we have determined that fewer than 10 card sponsors would not be subject to HIPAA Privacy requirements and, therefore, not subject to the PRA as stipulated under 5 CFR 1320.3(c). In the future, if we anticipate that more than 10 card sponsors would not be subject to the HIPAA Privacy Rule, we will submit this collection requirement to OMB for approval.

In paragraph (d)(2), the applicant must develop, implement, and update periodically a written data security plan. We consider this requirement to be a reasonable and customary function of a card sponsor. Therefore, this information collection requirement is exempt from the PRA, as stipulated under 5 CFR 1320.3(b)(2).

Section 403.808 Agreement Terms and Conditions

In this final rule, 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 will 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.

It is anticipated that it will take each applicant approximately 8 hours to complete the agreement. We anticipate that 15 card sponsors will enter into an agreement with us for a burden of 120 hours.

We consider all of the information collection requirements associated with complying with this section to be usual and customary business, with the following exception. As stated elsewhere in the preamble, card sponsors may update their formularies and price lists six times per year. We consider maintenance of formulary and price data to be a reasonable and customary business practice; the only new requirement is the transmittal of such information to the administrative consortium. We believe it would take 15 minutes to transmit each formulary and

price change to the consortium. While we do not believe that a majority of card sponsors would change their formularies and prices as much as six times per year, for purposes of estimating the maximum burden associated with this requirement, we estimate that each of the 15 card sponsors would transmit data to the consortium 6 times per year, and estimate 15 minutes for each transmittal. Therefore, the maximum burden associated with this requirement is 22.5 hours.

The total burden associated with card sponsors entering into a written endorsement agreement with us is 142.5 hours. This total includes the burden associated with each of the 15 card sponsors completing their agreements and the hours associated with the requirement, to be reflected in this agreement, that card sponsors provide formulary and price updates to the administrative consortium.

Section 403.810 Administrative Consortium Responsibilities and Oversight

The administrative consortium will be responsible for a number of information collection requirements, as stipulated under this section.

Since there will only be one administrative consortium under this initiative, these requirements are not subject to the PRA in accordance with 5 CFR 1320.3(c).

Section 403.811 Beneficiary Enrollment

In this final rule, under this section, in paragraph (b), Group enrollment, card sponsors may accept group enrollment from health insurers. Card sponsors will 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 burden associated with these requirements is the time and effort required to disclose the information to beneficiaries before enrolling them in the drug card program.

We believe these disclosures will be among other communications that the health insurer would usually and customarily provide at the time of enrollment or reenrollment of a beneficiary for their health insurance. As such, the only additional burden will be the cost of producing an insert that describes the discount card program and what enrollment into the card program means for the beneficiary. We estimate the burden of developing the insert to be 8 hours per health plan. We estimate that 178 plans may offer group enrollment into a Medicare-endorsed prescription drug card program for a burden of 1,424 hours.

Section 403.820 Oversight and Beneficiary Education

In the final rule, in paragraph (a) of this section, a Medicare-endorsed prescription drug discount card program sponsor must report to us on the major features of its program(s) that correspond to the qualifications for endorsement.

As stated in the final rule, the burden associated with this requirement is the time it would take to report to us. We believe that it would take approximately 45 minutes per report. We anticipate requiring 2 reports per year, per card sponsor, for 15 sponsors, for a total annual burden of 22.5 hours. This section also requires sponsors to establish and maintain a customer service process, which is designed to track and address in a timely manner enrollees' complaints about any aspect of the drug card program. While this requirement is subject to the PRA, we believe that sponsors maintain a customer service process as a matter of normal business practice. Therefore, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

The total burden associated with the collection requirements referenced in this rule is 5,189 annual hours.

We have submitted a copy of this final 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 Strategic Operations and Regulatory Affairs, Office of Regulations Development and Issuances, 7500 Security Boulevard, Room N2–14–26, Baltimore, MD 21244–1850, Attn: John Burke, CMS–4027–F,

and,

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

V. Regulatory Impact Analysis and Regulatory Flexibility Act Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

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 the ultimate impact will depend upon the final designs of endorsed card sponsors' programs, our estimate (based on our assumptions about manufacturer discounts) is that the savings to beneficiaries under the Medicare-Endorsed Prescription Drug Card Assistance Initiative will represent a total economic impact ranging from $1.214 billion to $1.619 billion in 2004, the first full year of operation. In 2005, the total estimated savings to beneficiaries under the initiative will range from $1.364 billion to $1.819 billion. In 2008 (the fifth year of the estimate period), total estimated savings to beneficiaries will range from $1.907 billion to $2.542 billion. This represents less than 1 percent of projected total retail prescription drug spending for 2004 ($203.8 billion), 2005 ($227.8 billion), and 2008 ($309.3 billion) based on the most recent published projections released in March 2002 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 final 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 final rule.

B. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (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 final 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. While the rule will have an impact on the private sector, we do not expect that this will require direct costs or outlays approaching UMRA's $110 million threshold. In addition, this final rule does not mandate any requirements for State, local, or tribal governments.

C. 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 final rule will impose no direct costs on State and local governments, will not preempt State law, or have any Federalism implications. However, as noted earlier in 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. This is a voluntary opportunity for States, and has no Federalism implications.

D. Limitations of Our Analyses

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

Because this will be the first year of the Medicare-Endorsed Prescription Drug 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 initiative. 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 1999 Medicare Current Beneficiary Survey (MCBS). We note, however, that we have updated our analysis from the proposed rule, which used 1998 data, with 1999 data that recently became available. 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.

Another limitation of our analysis is that we develop an estimate of the number of beneficiaries with standardized Medigap drug coverage who enroll in the initiative. This estimate, however, is imprecise. As discussed in more detail later in the analysis, we believe beneficiaries who have drug coverage through standardized Medigap policies are likely to enroll in the initiative. The MCBS provides data on the number of beneficiaries with ''individually purchased'' insurance policies, which includes but is not limited to the standardized Medigap policies. Using data on beneficiaries who have drug coverage through individually purchased insurance policies, we developed a rough estimate of the number of beneficiaries with Medigap standardized drug coverage by excluding from this group individuals who appeared unlikely to have standardized Medigap drug coverage. In particular, we excluded individuals whose out-of-pocket drug spending was less than $250 and whose individually purchased insurance plan covered some drug costs, since this is inconsistent with the benefit structure of the standardized Medigap plans. However, some beneficiaries with individually purchased policies that are not the standardized Medigap drug coverage policies are still likely to be included in our estimates. In addition, some beneficiaries have multiple sources of coverage, for example, some beneficiaries are enrolled in Medicare+Choice but also report having individually purchased supplemental insurance. Therefore, we also excluded anyone who was enrolled in Medicare+Choice during at least one month of the year since we believe that the drug coverage was more likely to come from a Medicare+Choice plan than from a Medigap plan.

As we discuss later in this preamble, additional limitations to our analysis include that we have made no adjustments to take into account: current discounts obtained by some beneficiaries, possible effects of the initiative on beneficiary drug utilization, possible changes in the type of outlets through which beneficiaries purchase prescription drugs, or potential enrollment of low-income beneficiaries in the new manufacturer-sponsored cards. We did not believe that we had adequate data to inform assumptions concerning these issues.

E. Impact of the Rebate and Discount Requirements

1. Medicare Beneficiary Estimated Enrollment

Although the Medicare-endorsed prescription drug card programs will be available to all Medicare beneficiaries, we believe that those most likely to benefit from the initiative will be the approximately 9 million Medicare beneficiaries without prescription drug coverage at any point in a year (based on 1999 MCBS data). We anticipate that beneficiaries without prescription drug coverage who spend over $250 per year (the point at which a $25 maximum enrollment fee could be recouped over a 1-year period assuming at least 10 percent savings) will be more likely to enroll than those with lower spending. To the extent that card sponsors offer lower or no-cost enrollment, we expect more beneficiaries to take advantage of the savings opportunity. We also anticipate that some beneficiaries will take into account that the $25 maximum fee is a one-time only fee (for as long as they remain in the same card program) when evaluating the net savings potential offered by Medicare-endorsed discount cards.

In Table 2, we show the assumptions regarding the percentage of beneficiaries without drug coverage enrolling in a Medicare-endorsed drug card program. We assume that beneficiaries without drug coverage who have relatively higher drug spending will be more likely to enroll than those with generally very low or no spending. Based on the assumptions in Table 2 and the distribution of drug spending among beneficiaries without drug coverage, we estimate that about 75 percent of the beneficiaries without drug coverage will enroll in the Medicare-endorsed drug card programs.

Another group of beneficiaries likely to benefit from the Medicare-endorsed discount card programs will be beneficiaries with Medigap drug coverage. The standardized Medigap plans that offer prescription drug coverage (standardized plans H, I, and J) are designed with a cap on the amount of drug spending covered by the plan. The drug benefit in standardized plans has a $250 deductible, 50 percent coinsurance, and a benefit cap of $1,500 (plans H and I) or $3,000 (plan J). Because many Medigap plans do not actively negotiate discounts for enrollees, we believe that Medicare beneficiaries with standardized Medigap drug coverage will benefit from a discount card program, particularly for spending above the benefit cap.

Using the 1999 MCBS, we estimate that a little more than 2 million beneficiaries had drug coverage from a Medigap policy. We assume that 95 percent of beneficiaries with Medigap drug coverage, regardless of expenditure level, will enroll in a Medicare-endorsed card program. We believe that

beneficiaries with Medigap coverage for prescription drugs will be more risk averse than the average beneficiary and will therefore be more likely to enroll in a drug discount card program.

These estimates of Medicare beneficiary enrollment in the Medicare-endorsed card programs are one of the elements in the Office of the Actuary's estimates of the impact of the initiative.

TABLE 2.—ESTIMATED ENROLLMENT RATE OF MEDICARE BENEFICIARIES WITH NO DRUG COVERAGE 2004 TO 2008

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

During the first half of 2002, several drug manufacturers established drug card programs that offer low-income Medicare beneficiaries without drug coverage significant discounts or low copayments on drugs they manufacture. Novartis, Pfizer, and Eli Lilly have each established co-pay cards. Seven drug manufacturers (Abbott Laboratories, AstraZeneca, Aventis, Bristol Myers, GlaxoSmithKline, Johnson & Johnson, and Novartis) have established Together Rx, a discount card. The income limits of the manufacturer cards vary, ranging from $18,000 to $28,000 for individuals and from $24,000 to $38,000 for couples. With these income criteria, millions of Medicare beneficiaries without drug coverage could be eligible for one or more of the manufacturer programs.

While many beneficiaries who might benefit from the Medicare-Endorsed Prescription Drug Card Assistance Initiative may also be eligible for the manufacturer card programs, we have not factored this into our assumptions concerning beneficiary enrollment in Medicare-endorsed card programs for several reasons. First, it is unknown whether the manufacturer card programs will seek Medicare endorsement. If these programs do seek and obtain Medicare endorsement, their enrollees will be included in the enrollment count for the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

Second, even if the manufacturer programs do not seek Medicare endorsement, available data suggest that, so far, enrollment in manufacturer card programs is a small portion of the total enrollment we expect in Medicare-endorsed discount card programs. Together Rx enrolled about 140,000 individuals as of August 2002, the Pfizer co-pay card enrolled 179,000 individuals as of July 2002, the Eli Lilly co-pay card enrolled 50,000 through May 2002, and the Novartis co-pay card enrolled 15,000 as of April 2002. We expect that some individuals have enrolled in more than one manufacturer program. Since these programs are in their infancy, their ultimate enrollment levels are unknown. Enrollment in these programs is also difficult to anticipate because means-tested programs do not typically garner full uptake among eligible populations. We will be interested to see over time how enrollment grows in the manufacturer drug card programs, the types of outreach conducted, and the results of those efforts.

Finally, if manufacturer card programs do not seek Medicare endorsement, some beneficiaries may opt to enroll in both the manufacturer cards and a Medicare-endorsed drug card. Since the manufacturer cards provide savings only on specific manufacturers' drugs and the Medicare-endorsed cards have a low one-time fee, we believe that some beneficiaries, depending on the mix of prescription drugs they use, may find it beneficial to enroll in both types of programs.

We received one comment concerning our assumptions about enrollment in Medicare-endorsed cards.

Comment: One commenter stated that the assumptions about the percent of beneficiaries without drug coverage and with Medigap drug coverage that will enroll in the program were extremely optimistic.

Response: As mentioned elsewhere in the preamble, we expect that Medicare-endorsed prescription drug card programs will obtain significant beneficiary enrollment due to the recognition and acceptance of the Medicare name among beneficiaries, the outreach and educational efforts planned, and the low enrollment fee. As shown in Table 2, the enrollment assumptions for beneficiaries without drug coverage are graduated based on the level of annual drug spending, ranging from 55 percent for those with spending not exceeding $200 to 95 percent for those with spending exceeding $500. We assume 95 percent enrollment among beneficiaries with Medigap drug coverage, regardless of expenditure level, because we believe Medigap plans offering drug coverage tend to attract enrollees who either have high drug expenses or who are more risk averse than average. As stated previously, for a number of reasons, we have not incorporated the manufacturer drug card programs into our assumptions about beneficiary enrollment in Medicare-endorsed card programs. In the future, as the new manufacturer programs gain operational experience and enrollment levels in these programs become clear, as well as their decision to participate in the Medicare initiative, we will be interested in assessing their effects on and interaction with the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

While we expect there will be a phase-in of beneficiary enrollment in the Medicare-endorsed prescription drug card programs, we believe that because of the recognition and acceptance of the Medicare name and the educational efforts undertaken, beneficiaries wishing to enroll will do so over a relatively short period of time. For the purposes of this impact analysis, we assume full enrollment of 9.7 million beneficiaries by 2004. We use 2004 as the beginning point for the estimates because it will 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 will be affected by the discounts under the drug card programs. The requirements for endorsement 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 will provide discounts on more than one drug per grouping and be highly likely to provide discounts on commonly used drugs.

In the proposed rule, we estimated the percent of total drug spending accounted for by the most commonly used drugs among Medicare beneficiaries based on analysis of the top drugs in terms of both utilization and spending using the 1998 MCBS data (including a special analysis related to disabled beneficiaries). In this final rule, we update that analysis using 1999 MCBS data. As of 1999, the drugs most commonly used or having the greatest spending by Medicare beneficiaries accounted for approximately 70 percent of total drug spending for beneficiaries without drug coverage (which is up slightly from 66 percent found in the analysis of 1998 MCBS data).

The drug classification listing in Table 1, for which card sponsors must

include at least one drug, is more extensive than the specific top drug list that was used to estimate 70 percent. In addition, we assume that many card sponsors will choose to include more than one drug for the required drug grouping. Consequently, we set our lower bound estimate of the share of drug card enrollees' total drug spending that will be affected by the initiative at 75 percent, which is the same as the lower bound estimate used in the proposed rule. Since the percent of drug spending accounted for by the most commonly used drugs among Medicare beneficiaries increased only slightly from 1998 to 1999, we felt it was reasonable to maintain our 75 percent lower bound estimate from the proposed rule, particularly since we also use an upper bound estimate.

We also assume that it is possible that programs will include a discount on all drugs. To calculate this upper bound, we assume that all beneficiary drug expenditures will be affected by the Medicare-Endorsed Prescription Drug Card Assistance 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 will come from generic substitution and not just price reductions.

3. Estimated Beneficiary Savings

An April 2000 study prepared by 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 individuals 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 will 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 will 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 will 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 or discounts will be greater in response.

The savings to beneficiaries will 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 or discounts and savings from a better understanding of generic alternatives and managing prescription drug expenses will 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.

In a December 2001 report from the General Accounting Office (GAO) entitled ''Prescription Drugs: Prices Available Through Discount Cards and From Other Sources'', 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 or discounts will be greater in response.

Second, savings for the 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.

Because the Medicare-endorsed drug card programs will be modeled after insured products in terms of enrollment and the use of formularies, combined with the competitive model and the requirement of manufacturer rebates or discounts, we expect that the Medicare-endorsed drug card programs will achieve new beneficiary savings from manufacturer rebates or discounts. The share of savings will 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 will increase.

We received several comments concerning our estimates of the potential savings from the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

Comment: Several commenters asserted that the Medicare-Endorsed Drug Card Assistance Initiative will provide fewer savings or no greater savings than can be obtained through shopping around or through senior discounts at community pharmacies. Another commenter contended that a well-designed discount card will yield tangible savings for beneficiaries.

Response: We agree with the commenter who asserted that a discount card program has the potential to yield tangible savings for beneficiaries. We disagree with the commenters who claimed that the initiative will not yield greater savings than currently available through community pharmacies. We expect that the initiative will garner greater savings than typically available through community pharmacies due to the role of manufacturer rebates or discounts in the initiative. As a condition of endorsement, card sponsors must obtain manufacturer rebates or discounts on brand and/or generic drugs and pass a substantial share through to beneficiaries. As mentioned previously in the preamble, we believe card sponsors will have both the ability and the incentive to negotiate significant manufacturer rebates or discounts and pass them through to beneficiaries due to aspects of the initiative such as market leverage stemming from large enrollment, exclusivity, and market competition.

Comment: One commenter asserted that discounts of 10 to 13 percent are minimal given that drug prices are rising at 17 percent per year.

Response: According to National Health Expenditures data from our Office of the Actuary (OACT), prescription drug spending grew at 17 percent between 1999 and 2000. A combination of increased prices, increased utilization, changes in the mix of drugs, and growth in the population resulted in the overall spending increase of 17 percent. Increased drug prices were responsible for slightly more than a quarter of the increase in drug spending between 1999 and 2000. By its structure, a discount card program provides assistance with prescription drug expenditures through discounted prices. We believe that the initiative, which is expected to yield average savings of 10 to 13 percent, possibly up to 15 percent, will provide beneficiaries with needed assistance with prescription drug costs.

Comment: One commenter asserted that discounts of 15 percent are unrealistic for pharmacy and drug stores that have profit margins of 2 to 3 percent on average.

Response: As mentioned elsewhere in the preamble, the average savings estimate of 10 to 13 percent, possibly up to 15 percent, does not reflect the expected level of pharmacy discounts. Rather, it reflects estimated combined savings from manufacturer rebates or discounts and pharmacy discounts, as well as increased use of generic drugs. We believe manufacturer discounts or rebates will be an important component of the savings from the Medicare-Endorsed Prescription Drug Card Assistance Initiative as well as increased use of generics. As a condition of endorsement, card sponsors must obtain manufacturer rebates or discounts and pass a substantial share through to beneficiaries either directly or indirectly through pharmacies. We believe that competitive market forces, together with other aspects of the initiative, will encourage endorsed discount card programs to secure the highest manufacturer rebates or discounts possible and to pass those through to enrollees.

4. Projection Assumptions

Since our data on Medicare beneficiary prescription drug spending are based on 1999 MCBS data, it is necessary to make several adjustments in order to prepare 2004 estimates. In order to trend 1999 spending to 2004 dollars, we use prescription drug spending projections based on per capita drug expenditure growth from the Office of the Actuary's National Health Expenditure (NHE) Projections 1980 to 2011. These projections can be found on our Web site at: *http://cms.hhs.gov/statistics/nhe/projections-2001/t11.asp.*

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 final 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 are made based on the assumptions used for the Medicare Trustees Reports, March 26, 2002.

These assumptions are detailed in Table 3, which shows the projected increase in Medicare enrollment and per capita drug expenditures from 1999 to 2004, and annually from 2004 to 2008, using 1999 as the base year for the projections. As discussed in more detail in later sections of the impact analysis, the table also shows projections for total national aggregate retail drug expenditures, drug expenditures involved in the initiative, beneficiary savings from the initiative (both upper bound and lower bound estimates), and the impact of beneficiary savings as a percent of total national aggregate retail drug sales.

As mentioned previously, beneficiary retail prescription drug spending involved in the Medicare-Endorsed Prescription Drug Card Assistance Initiative is estimated using 1999 MCBS data, projected forward to 2004 to 2008 based on expected growth in per capita prescription drug spending and the Medicare population. For beneficiaries with Medigap coverage, estimated prescription drug spending involved in the Medicare-Endorsed Prescription Drug Card Assistance 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, as discussed subsequently, the use of National Health Accounts estimates of prescription drug spending net of manufacturer rebates provided to health insurers overstates the impact of the Medicare-endorsed drug cards on total pharmacy revenues.

To estimate the impact of the initiative on national retail prescription drug sales, we use the Office of the Actuary's National Health Expenditures projections of retail prescription drug sales, which are part of the National Health Accounts. To prepare the estimates, OACT obtains data on prescription drug sales from a variety of sources, including the National Prescription Audit conducted by IMS Health. OACT has data on retail prescription drug spending through 2000, and prepares 10-year projections.

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 the revenue 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 projections for prescription drug spending are the most appropriate to use for analysis of the impact of this initiative on 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.

TABLE 3.—ESTIMATED IMPACT

	1999	2004	2005	2006	2007	2008
Total Medicare Enrollment (millions)	39.2	41.3	41.8	42.4	43.2	44.1
Increase in Total Medicare Enrollment	.....	5.4%	1.3%	1.4%	1.8%	2.1%
Increase in per Capita Drug Expenditures	.....	88.2%	10.9%	10.1%	9.8%	9.7%
Total National Aggregate Retail Drug Expenditures ($ billions)	$103.9	$203.8	$227.8	$252.9	$279.9	$309.3
Projected Prescription Drug Spending Under the Drug Discount Card Programs ($ billions)	$6.6	$13.1	$14.7	$16.4	$18.3	$20.5
Upper Bound Impact of Estimated Beneficiary Savings ($ millions)	.....	$1,619	$1,819	$2,031	$2,269	$2,542
Upper Bound Impact as a Percent of Total National Aggregate Retail Drug Expenditures	.....	0.79%	0.80%	0.80%	0.81%	0.82%
Lower Bound Impact of Estimated Beneficiary Savings ($ millions)	.....	$1,214	$1,364	$1,524	$1,702	$1,907
Lower Bound Impact as a Percent of Total National Aggregate Retail Drug Expenditures	.....	0.60%	0.60%	0.60%	0.61%	0.62%

Note: For 2004, the increase in Medicare enrollment and per capita drug expenditures shown in the table reflect the percent change between 1999 and 2004.

5. Anticipated Effects on Medicare Beneficiaries

Among the primary purposes of the Medicare-Endorsed Prescription Drug Card Assistance Initiative are 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 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 9.7 million Medicare beneficiaries will enroll in Medicare-endorsed drug card programs by 2004. This figure is somewhat lower than was estimated in the proposed rule. The reason for the change is that we are now using the 1999 MCBS data as a basis for analysis, and a somewhat smaller number of Medicare beneficiaries did not have drug coverage in 1999. The 1999 MCBS are the most recent data available on drug coverage in the Medicare beneficiary population. It should be noted, however, that the 1999 data precede the changes that have occurred in drug coverage through the Medicare+Choice program, in which fewer beneficiaries are now enrolled.

We anticipate that Medicare beneficiaries with no drug coverage who enroll in a Medicare-endorsed prescription drug card program will save between 10 and 13 percent of their total drug costs. However, this will 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.

Beneficiaries with Medigap insurance that includes drug coverage who enroll in a Medicare-endorsed drug card program will 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 receive concerning drug prices, formularies, drug-to-drug interactions and other pharmacy counseling, generic substitution, and pharmacy networks, will provide an opportunity for beneficiaries to maximize their savings.

As shown in Table 3, for the estimated 9.7 million beneficiaries who will enroll in the Medicare-endorsed drug card programs by 2004, the base for total drug expenditures involved in the Medicare-Endorsed Prescription Drug Card Assistance Initiative is projected to be $13.1 billion in 2004, $14.7 billion in 2005, and $20.5 billion in 2008 before the savings achieved through the card initiative. Total estimated savings for these beneficiaries range from $1.214 billion to $1.619 billion in 2004, $1.364 billion to $1.819 billion in 2005, and $1.907 billion to $2.542 billion in 2008.

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 9.7 million Medicare beneficiaries estimated to enroll by 2004 pay the maximum $25 enrollment fee (a scenario we do not expect because of competition among endorsed card programs), the total beneficiary savings will be reduced by a maximum of $270 million in 2004. (We note that these beneficiaries will have likely paid the enrollment fee in 2003; however, we are counting that fee against savings in 2004 because it is the first full year of operation and the first year of our 5-year estimate period.) As mentioned earlier, to the extent that 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 2005, 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 will be reduced by a maximum of $31 million in 2005.

A beneficiary enrolled in a Medicare-endorsed card program will 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 drug coverage who choose to enroll in an endorsed discount card program can only be helped by the educational efforts and savings from the initiative.

We received one comment concerning support for this initiative from beneficiaries as well as pharmacies and drug stores.

Comment: One commenter believes the initiative is ill conceived and does not have support from beneficiaries, pharmacists, or drug stores.

Response: In response to the proposed rule, we received comments from representatives of beneficiaries, physicians, drug stores, pharmacies, and pharmacists as well as others. The majority of beneficiary and physician groups were supportive of the initiative.

We received comments from a few chain and supermarket pharmacy companies as well as a number of representatives of pharmacies, drug stores, and pharmacists. Most of these commenters opposed the initiative, with one of the chief concerns being the financial impact of the initiative on pharmacies and drug stores. As mentioned later in the impact analysis, we have taken a number of steps to mitigate the financial impact of the initiative on pharmacies.

We believe that the Medicare-Endorsed Prescription Drug Card Assistance Initiative is a highly effective way to educate beneficiaries about the tools used by private insurance programs to lower the cost of prescription drugs. We believe that through real world experience with drug card programs, Medicare beneficiaries will be better educated about private sector approaches for lowering drug costs that are a key element of all Medicare prescription drug benefit legislative proposals. This initiative will also provide beneficiaries with immediate help with the cost of prescription drugs, and also will 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 and assistance regarding prescription drug discount programs until a Medicare prescription drug benefit is enacted and implemented.

6. Anticipated Effects on the Medicare Program

We will be responsible for reviewing applications and awarding endorsements so that these card programs can begin operating to provide lower prices to cash paying beneficiaries. While not quantifiable, a positive impact of the rebate and discount requirements of the initiative will be to provide us with experience in understanding issues in the pharmaceutical industry before enactment of a Medicare drug benefit. We will increase our knowledge concerning pricing and payment issues, information technology requirements, and increasing the effectiveness of pharmacy quality improvement programs. The pharmaceutical industry will also gain more experience in working with the Medicare population before implementation of a drug benefit. We expect that this experience will make the transition to a Medicare prescription drug benefit faster and more efficient.

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

7. Anticipated 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 $203.8 billion in 2004, $227.8 billion in 2005, and $309.3 billion in 2008. *(http://www.cms.hhs.gov/statistics/nhe/projections-2001/t11.asp).*

In 2004, the first full year of the initiative, the total economic impact of the Medicare-Endorsed Prescription Drug Card Assistance Initiative is estimated to range from $1.214 billion to $1.619 billion, representing 0.60 percent to 0.79 percent of total national aggregate retail prescription drug expenditures. In 2005, the total impact is estimated to range from $1.364 billion to $1.819 billion, or 0.60 percent to 0.80 percent of total national aggregate retail expenditures for prescription drugs. In 2008, we estimate the total impact to range from $1.907 billion to $2.542 billion, or 0.62 percent to 0.82 percent of total national aggregate 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 will adjust to the impact without significant disruption, just as the industry adjusted to discounts being extended to the privately insured population during the 1990s. The 1990s saw a significant increase in reliance on pharmacy benefit management and the tools commonly used 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, the 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, the 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 conducted a similar analysis on the pharmacy acquisition costs related to generic drugs. The OIG March 2002 report ''Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products'' reported that for generic drugs there was an increase of over 55 percent in the average discount below AWP from 1994 to 1999 at which pharmacies were able to acquire generic drugs (from 42.45 percent below AWP in 1994 to 65.93 percent below AWP in 1999). Thus, during the 1990s, as more customers secured discounts on the purchase of prescription drugs, pharmacies acquired drugs at larger discounts from AWP.

The 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 brand name 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 Medicare-Endorsed Prescription Drug Card Assistance Initiative will 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 will 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 will lead to greater manufacturer discounts. We expect that access to modern competitive tools will assist in controlling prescription drug costs and improving the quality and efficiency of prescription drug services. We also expect that this initiative will 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 will be ameliorated.

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

We received a few comments concerning the impact of the initiative on pharmacy and drug store revenues.

Comment: A couple of commenters voiced concern that card sponsors that operate mail order pharmacies may steer business away from community pharmacies toward their mail order business, leading to a decline in revenues for community pharmacies.

Response: We recognize the value of both in-person pharmacy services provided by community pharmacies and mail order pharmacy services. We believe that most Medicare beneficiaries rely on their community pharmacies, and thus mail order only programs are not permitted. We have included a specific retail pharmacy access standard for Medicare endorsement purposes, and in this final rule have provided for a more stringent standard for MSA geographic areas of 90 percent of beneficiaries being within 5 miles of a network pharmacy, and for non-MSA areas 90 percent of beneficiaries being within 10 miles of a retail network pharmacy. We also believe that beneficiaries should have options of both retail and mail order available to them, and that beneficiary choice should dictate the venue through which they obtain pharmacy services. Thus, card sponsors have the option of also offering mail order services. Mail order pharmacy sales, like supermarket and mass merchant pharmacy sales, have been a growing share of total prescription drug sales in the U.S. over the last 10 years. These alternative sources for prescription drugs provide additional convenient access, and the Medicare-Endorsed Prescription Drug Card Assistance Initiative is simply recognizing the nature of the existing market.

Comment: A few commenters cited a claim by Stephen W. Schondelmeyer, Pharm.D., Ph.D., in his declaration in *National Association of Chain Drug Stores* v. *Thompson*, No. 01–1554 (D.D.C. 2001) that the initiative will cause $2 billion in revenue losses for pharmacies and result in 2,500 to 10,000 community pharmacy closures.

Response: We note that Dr. Schondelmeyer's declaration cited by the commenters relates to the discount card initiative that was proposed in July 2001, and the initiative has been revised significantly since that time. Thus, the commenters are using an analysis that predates the proposed rule that we published in the **Federal Register** on March 6, 2002 (67 FR 10262).

Dr. Schondelmeyer's estimate of a $2 billion revenue impact on community pharmacies is substantially higher than our estimate for the combined beneficiary savings from manufacturer rebates or discounts and pharmacy discounts. From the information provided in Dr. Schondelmeyer's declaration that was cited by the commenters, we believe that his estimates significantly overstate the impact of the initiative on community pharmacies in several ways.

First, his estimates are based on the assumption that the initiative will yield 15 to 25 percent savings, which will come entirely from pharmacy discounts—assumptions that are not reflective of the structure of the Medicare-Endorsed Prescription Drug Card Assistance Initiative as described in this final rule. As we note elsewhere in this preamble, it is important to distinguish between estimated savings on individual drugs and savings calculated over total drug spending. While the initiative may yield savings of 15 to 25 percent or even higher on specific drugs, overall the initiative is expected to generate average savings on beneficiaries' total drug spending of 10 to 13 percent, possibly up to 15 percent depending on the design of card sponsors programs (for example, the degree to which formularies are used).

Second, Dr. Schondelmeyer also uses in his analysis an average utilization figure of 28.5 prescriptions for discount card enrollees. This level of utilization is characteristic of a population with drug coverage, and represents a utilization level that is higher than found in a population without drug coverage. Since individuals without drug coverage are expected to be the predominant group enrolling in the initiative, we believe Dr. Schondelmeyer's use of this higher utilization level is another factor contributing to the overestimate of impact.

Dr. Schondelmeyer's assumptions concerning enrollment in the initiative may be another factor contributing to the overestimate. As discussed elsewhere in the preamble, we have projected that about 9.7 million Medicare beneficiaries will enroll in the initiative by 2004. This represents about 75 percent of beneficiaries without drug coverage and 95 percent of beneficiaries with Medigap drug coverage. While we believe there will be significant enrollment because of the Medicare endorsement, we believe that enrollment above the level we assume would be unrealistic. Dr. Schondelmeyer indicates in his declaration that it would be reasonable to assume that between 7 and 15 million Medicare beneficiaries would enroll in the card programs. While the specific enrollment assumption Dr. Schondelmeyer uses in his impact estimates is not clear from his declaration, if he uses a figure in the middle to high end of the 7 to 15 million range, we believe that would be an overestimate.

Additionally, Dr. Schondelmeyer, in his declaration, claims that discounts under the initiative will come entirely from pharmacies for several reasons including: the program announced in July 2001 did not require manufacturer rebates or discounts, discount card sponsors do not usually share manufacturer rebates or discounts with enrollees or pharmacies, and card sponsors will not have the technology to pass rebates or discounts through to enrollees. We agree that historically discount card sponsors have not passed manufacturer rebates or discounts through to enrollees or pharmacies, but we believe that the Medicare-Endorsed Prescription Drug Card Assistance Initiative represents a significant improvement on the current market, with manufacturer rebates or discounts being an important component of

beneficiary savings. We have modified the initiative from that proposed in July 2001 and added a requirement that, as a condition of Medicare endorsement, card sponsors must obtain manufacturer rebates or discounts on brand name and/or generic drugs and pass a substantial share through to beneficiaries. Furthermore, we believe Medicare-endorsed card sponsors will have both the ability and the incentive to negotiate significant manufacturer rebates or discounts and pass them through to beneficiaries due to aspects of the initiative such as market leverage stemming from large enrollment, exclusivity, and market competition. We also believe the recent development of manufacturer drug cards has demonstrated that technology does not pose a barrier to card sponsors passing through discounts to beneficiaries or pharmacies.

Looking specifically at the estimates in Dr. Schondelmeyer's statement, we note that he provides some broad information about the assumptions used to develop his impact estimates, but does not document the specific assumptions used in the calculation of the $2 billion estimate. In addition, it is unclear on which year the $2 billion estimate is based. Possibly, Dr. Schondelmeyer is using 2000 data since he cites a figure of $140.7 billion for industry sales, which is consistent with 2000 data from the National Association of Chain Drug Stores.

As mentioned previously in the preamble, we estimate that the initiative will result in beneficiary savings from a combination of manufacturers rebates or discounts and pharmacy discounts of $1.2 billion to $1.6 billion in 2004, representing 0.60 to 0.79 percent of total national retail prescription drug sales. Dr. Schondelmeyer estimates a $2 billion dollar impact on community pharmacies alone. Using the total sales figure he provides of $140.7 billion, this represents 1.4 percent of industry sales.

If, in fact, he is using 2000 data on which to base his estimate, for comparison purposes our estimate of savings in year 2000 dollars ranges from $719 to $958 million, representing 0.59 to 0.79 percent of total national aggregate retail prescription drug sales.

In sum, we believe that Dr. Schondelmeyer's estimate of a $2 billion impact on community pharmacies overestimates the impact of the initiative on community pharmacies described in this final rule. Dr. Schondelmeyer's analysis, cited by commenters, predates the initiative's provision related to manufacturer rebates or discounts and the recent developments of manufacturer discount programs. Dr. Schondelmeyer assumes higher overall savings than we expect from this initiative. He also assumes that all beneficiary savings will come as a result of pharmacy discounts. We disagree with this assumption because in the Medicare initiative, manufacturer rebates or discounts are a pre-requisite for endorsement, and thus will be an important source of beneficiary savings, along with increased use of generic drugs.

8. Regulatory Flexibility Act Analysis of Effects on Small Entities

a. *General*

The Regulatory Flexibility Act (RFA) requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. If a rule is expected to have a significant economic impact on a substantial number of small entities, the RFA requires that a regulatory flexibility analysis be performed.

The Medicare-Endorsed Prescription Drug Card Assistance 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 health maintenance organizations (HMOs) have been able to enter into arrangements similar to those in this 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. In addition, many pharmacies, including small pharmacies, offer senior discounts, and doing so in the context of this Medicare initiative may not be significantly different than current practice for some pharmacies.

The role of individual pharmacies, including small pharmacies, in this Medicare initiative is a critical one: they will be an integral part of the pharmacy networks of Medicare-endorsed card programs, serving Medicare beneficiaries at the point of retail sale. The objectives of the initiative and the related design requirements will preclude an individual pharmacy or drug store from operating the full scale of the contemplated drug card assistance initiative that will 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 final rule because of their size, type of experience and infrastructure.

Convenient access to retail pharmacies, regardless of size or ownership, by Medicare beneficiaries will be an important feature of the initiative. As discussed elsewhere in this final rule, a discount card sponsor will have to have a contracted pharmacy network of sufficient size to demonstrate that at least 90 percent of Medicare beneficiaries in metropolitan areas served by the program live within 5 miles of a contracted pharmacy (90/5) and at least 90 percent of Medicare beneficiaries in non-metropolitan areas served by the program live within 10 miles of a contracted pharmacy (90/10). This access ratio standard is consistent with the access standard of most insured products, and we believe it will require card sponsors to support an extremely broad network of retail pharmacies.

Given the access ratio requirements and the provision that Medicare-endorsed programs will not be allowed to offer a mail order only option, we believe that most pharmacies and drug stores (both chain and independent) will 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 will be included in the networks of Medicare-endorsed drug discount card programs. Further, we believe that small entities in rural areas especially will be included in order to meet the non-metropolitan 90/10 standard for endorsement. Card sponsors will be expected to report on the participation of independent pharmacies in their networks.

We received a comment concerning the role of small pharmacies in the initiative and a comment about outreach to small pharmacies during the regulatory development process.

Comment: One commenter voiced concern that small pharmacies and drug stores will have difficulty meeting the criteria for Medicare endorsement of card sponsors and asserted that we should consider alternatives such as endorsing small pharmacies as card sponsors or granting small pharmacies the right to join any card sponsor's drug card program. The commenter also recommended that we consider ways to facilitate small pharmacies pooling together for the purposes of obtaining Medicare endorsement, such as developing a database to help small pharmacies identify others that are interested in pooling together, offering small pharmacies guidance and templates related to pooling together, and minimizing administrative costs borne by small pharmacies pooling together.

Response: As stated previously, small pharmacies will play a critical role in the initiative by being an integral part of the card sponsors' pharmacy networks. However, we do not believe that individual pharmacies are in a position to be a Medicare-endorsed card sponsor. Individual pharmacies will not have the capacity nor the market position to leverage the purchasing power of a large number of beneficiaries to obtain manufacturer rebates or discounts—one of the key objectives of the initiative. The commenter's proposal that small pharmacies and drug stores be permitted to join any card sponsors' program of their choosing is addressed in more detail elsewhere in the preamble. In short, we believe card sponsors will invite and encourage most pharmacies to participate in their card programs, making this proposal unnecessary.

The commenter offered a number of suggestions for making it easier for small entities to pool together to become a Medicare-endorsed card sponsor. We have made several changes to the years of experience and covered lives criteria for endorsed card sponsors, making it easier for more organizations, including smaller entities pooling together and working with other organizations, to gain Medicare endorsement. These changes are discussed in more detail previously in this preamble.

With respect to the commenter's suggestions that we create a database of small entities interested in pooling together and offer small pharmacies guidance and templates related to pooling together, we believe that this function in this private sector-based initiative is more appropriate for trade associations. However, with regard to guidance to potential applicants as discussed earlier in the preamble, following publication of the solicitation, we will entertain questions from potential applicants to clarify the final application requirements.

Finally, with respect to the commenter's assertion that administrative costs borne by small pharmacies pooling together should be minimized, we believe that by pooling together, entities will be able to spread the administrative costs across a number of organizations, thereby reducing the burden on any one entity. In addition, card sponsors can charge beneficiaries a one-time $25 enrollment fee and use manufacturer rebates to support administrative costs. As discussed elsewhere in this preamble, to the extent that small entities pooling together form regional card programs, they will be responsible for a smaller share of the initial start-up costs than national programs. The allocation of administrative costs beyond the initial start-up costs is left to the discretion of the consortium.

Comment: One commenter stated that we had not adequately reached out to small businesses during the rulemaking process, as required by the RFA. The commenter encouraged us to conduct outreach and develop a dialogue with small businesses throughout the regulatory development process.

Response: We believe that input from small business in the regulatory development process is important. We did receive comments from representatives of small businesses in response to the proposed rule. In addition, in May 2002, our Administrator made a presentation about the proposed Medicare-Endorsed Prescription Drug Card Assistance Initiative and other of our efforts to improve Medicare beneficiary access to prescription drugs, including a question and answer period, at the National Community Pharmacists Association's Annual Conference on National Legislation and Public Affairs. We also have met with the Small Business Administration to more generally look at how we can improve our process and analyses related to the Regulatory Flexibility Act.

b. Estimated Impact on Small Entities

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. To assess whether the Medicare-Endorsed Prescription Drug Card Assistance Initiative meets these HHS criteria, we estimated the number of small entities affected and the average percentage impact on revenues. We also conducted a sensitivity analysis to estimate the impact on revenues for pharmacies with a higher than average rate of customer participation in the Medicare-Endorsed Prescription Drug Card Assistance Initiative. These analyses found that while the initiative is expected to have some impact on a substantial number of small entities, it is not expected to have a significant economic impact. Based on these analyses, we certify that the Medicare-Endorsed Prescription Drug Card Assistance Initiative does not have a significant economic impact on a substantial number of small entities.

As a result, we are not required to perform a regulatory flexibility analysis. Nevertheless, due to the concerns voiced by some commenters about the potential effects of the rule on small businesses, we have included in this section or in other sections of the preamble the various issues that are to be included in a regulatory flexibility analysis. To avoid repetition, we have not duplicated each of them here. In preceding sections of the preamble, we have included a description of the initiative and its objectives. In this and subsequent sections of the preamble, we include an estimate of the number of small entities affected and a description of the alternatives considered to minimize the economic impact on small pharmacies. We have not included a discussion of reporting, recordkeeping, and other compliance requirements for small pharmacies because we make no such requirements on small pharmacies—only for card sponsors.

We received comments concerning the HHS standard for economic impact and concerning requirements related to regulatory flexibility analyses.

Comment: Several commenters expressed concern that the HHS standard for significant economic impact does not take into account the impact on small pharmacies' and drug stores' profit margins and their financial viability.

Response: HHS uses revenues rather than profit margins to estimate the economic impact of a rule on small entities because in our experience reliable data on profit margins are very difficult to obtain, while reliable data on revenues are much more readily available and straightforward.

One example of the difficulties in obtaining reliable profit margin data and in how to interpret those data in the case of small businesses relates to how owners' salaries are treated. Profit margin estimates can vary substantially depending on how one considers the owner's salary relative to the profits of the business. For example, a 2002 study on the pharmacy industry conducted by Booz Allen Hamilton for us cites data from the National Community Pharmacist Association (NCPA), which indicate that independent pharmacies had average profit margins, in 2000, of nearly 8 percent when owners' salaries were included and about 3 percent when owners' salaries were excluded. Furthermore, when the Internal Revenue Service (IRS) determines income tax liability for sole proprietorships, it considers the businesses incomes to be profits plus the owners' salaries. In the case of pharmacies and drug stores, IRS data on sole proprietorships show fairly similar profit margin levels with NCPA—about 7 percent including owners' salaries in the late 1990s. Thus, if profit margins were used to determine the economic impact of rules on small businesses, how the owners' salaries are treated could significantly alter findings. Furthermore, data are generally not available to separate the portion of an owner's salary that compensates for labor versus the portion that reflects profit taking in the form of salary, which makes developing an accurate estimate of small businesses' profit margins very difficult.

While the HHS standard for significant economic impact focuses on revenues rather than profit margins, as stated elsewhere in the preamble, we have taken a number of steps to mitigate the financial impact on small pharmacies and drug stores.

Comment: A few commenters asserted that the proposed rule should have included an initial regulatory flexibility analysis (IRFA). One of the commenters contended that the proposed rule did not certify that the Medicare-Endorsed Prescription Drug Card Assistance Initiative would not have a significant economic impact on a substantial number of small entities, and as a result an IRFA was required.

Response: The proposed rule included an analysis of the effect of the initiative on pharmacies' and drug stores' revenues both on average and for pharmacies and drug stores with a higher than average share of their customers enrolled in the program. Based on these analyses, the proposed rule stated: ''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.'' (67 FR 10281, March 6, 2002) Section 605(b) of the RFA permits an agency to certify in the proposed rule or the final rule. The final rule includes a certification.

c. Number of Small Entities Affected

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. 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/size/naicstb2-ret.html*), provides a size standard for pharmacies and drug stores (NAICS code 446110 or SIC code 5912) of revenues of $6 million or less annually for the purpose of determining whether entities are small businesses. The revenue standard for small pharmacies and drug stores was recently increased from $5 million to $6 million in February 2002 to account for inflation.

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. We examined data from the U.S. Census Bureau's 1997 Economic Census (Table 4 on Retail Trade—Subject Series), which provides data on the number of pharmacies and drug stores by level of revenue. To identify small pharmacies and drug stores, we looked at firms with less than $5 million in revenues. Although SBA's revenue standard for small pharmacies and drug stores was increased to $6 million in 2002 to account for inflation, we use $5 million as the standard in our analysis because we are working with 1997 data so an inflation adjustment is not needed. According to the Census Bureau data, there were a total of 20,815 business firms that were pharmacies and drug stores that operated for the entire year in 1997. Those 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 2001, NACDS reports 55,581 community retail pharmacy outlets, of which 20,647 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.

From IMS' 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, those 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 2001, the data obtained by OACT indicate that 23.7 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 2001.

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 these two categories of mass merchandisers were $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 seems to indicate that prescription drugs are not their major line of trade.

We received one comment concerning analysis of the number of small business affected by the initiative.

Comment: One commenter asserted that the proposed rule did not include an assessment of the number of small entities affected by the proposed Medicare-Endorsed Prescription Drug Card Assistance Initiative, as required by the RFA.

Response: Both the proposed rule and this final rule include an analysis of the number of small entities potentially affected by the Medicare-Endorsed Prescription Drug Card Assistance Initiative. The number of small or independent pharmacies and drug stores affected is estimated using data from the Economic Census (1997) and NACDS (1997 and 2001). Both of these data sources indicate that there are about 21,000 small or independent pharmacies and drug stores in the United States.

d. Average Estimated Economic Impact on Small Pharmacies

As indicated previously, 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. To develop an estimate of the impact of the initiative on prescription drug retail sales associated with small pharmacies and drug stores, we take our national estimates in Table 3 and make assumptions about the percent of total retail prescription drug sales through small pharmacies. In addition, we make assumptions about the distribution across large and small pharmacies and drug stores of prescription drug sales to Medicare-endorsed discount card enrollees.

Assuming that 23.7 percent of total retail pharmacy sales are through small pharmacies (based on OACT's estimate of the share of total retail sales through independent pharmacies in 2001), the share of total national prescription drug sales through small pharmacies and drug stores will be $48.3 billion in 2004, $54.0 billion in 2005, and $73.3 billion in 2008. If we assume that the population most likely to enroll in the 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 Medicare-Endorsed Prescription Drug Card Assistance Initiative through small pharmacies and drug stores will be $3.1 billion for 2004, $3.5 billion in 2005, and $4.9 billion in 2008—accounting for less than 7 percent of prescription drug sales. Consequently, the portion of the estimated beneficiary savings related to retail prescription drug sales occurring through small pharmacies and drug stores ranges from: $288 to $384 million in 2004, $323 to $431 million in 2005, and from $452 million to $603 million in 2008. These amounts, as a share of the national retail prescription drug sales occurring through small pharmacies and drug stores, represent a range of 0.60 percent to 0.79 percent in 2004, from 0.60 to 0.80 percent in 2005, and from 0.62 to 0.82 percent in 2008.

This is likely to be an overestimate of the economic impact on small pharmacies and drug stores, as this economic impact will not be borne entirely by pharmacies. Card sponsors will be required to obtain substantial manufacturer rebates or discounts that will 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 reflected in our estimate, the additional beneficiary savings could come from drug manufacturers and not local pharmacies. In addition, because of the education initiative, some of the savings to beneficiaries will come as a result of increased use of generic drugs.

Other caveats to consider are the following: Our spending estimates assume no effects of the Medicare-Endorsed Prescription Drug Card Assistance Initiative on beneficiary drug use. It is possible that lower drug prices will lead to greater use, resulting in a smaller impact on pharmacy revenues. It is also possible that pharmacy services associated with the card will 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.

e. 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 Medicare-Endorsed Prescription Drug Card Assistance Initiative will comprise, on average, less than 7 percent of revenues, with the economic

impact of the initiative on total revenues related to prescription drugs estimated at less than 1 percent. For purposes of a sensitivity analysis, we estimate that in order to reach the HHS measure of significant economic impact of 3 to 5 percent of revenues, it will be necessary to have prescription drug revenues resulting from the initiative account for at least 24 percent of a business's 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 initiative. Under this highly skewed assumption, we estimated a maximum share of 17.7 percent of a business's total prescription drug revenues would be associated with the Medicare-endorsed discount card, with an economic impact of the initiative of 2.2 percent of prescription drug sales.

As noted previously, this economic impact will not be borne entirely by pharmacies, because card sponsors will be required to obtain manufacturer rebates or discounts that will defray the cost of pharmacies providing discounts on retail drug prices. In addition, part of the savings to beneficiaries also comes from increased use of generic drugs. 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 accounted for by enrollees in this initiative and the consequent impact resulting from the Medicare-Endorsed Prescription Drug Card Assistance 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 previously, we think that the beneficiaries most likely to enroll in the Medicare-endorsed discount card programs will 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 (36 percent as of 1999). Our analysis of the 1999 MCBS data also indicates that 13 percent of beneficiaries in non-metropolitan areas have individually purchased insurance policies that provide drug coverage. While individually purchased insurance policies include, but are not limited to, standardized Medigap policies, for the sake of creating an upper bound estimate of the percent of Medicare beneficiaries in a geographic area that might have Medigap standardized drug coverage, we use 13 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 of beneficiaries without drug coverage. We assumed that 36 percent of people in the hypothetical geographic area were Medicare beneficiaries and 36 percent of those beneficiaries had no drug coverage. We also assumed that the hypothetical Medicare population would have a higher portion (13 percent) of beneficiaries who obtained drug coverage through Medigap.

We estimate that nationally approximately 9.7 million Medicare beneficiaries will enroll in the Medicare-endorsed discount card programs by 2004, accounting for an estimated 3 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 (about 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 14 percent of its total population participating in the Medicare-Endorsed Prescription Drug Card Assistance Initiative. Therefore, about 86 percent of the total hypothetical area's population will not participate in the initiative, including both Medicare beneficiaries and non-Medicare beneficiaries.

To estimate the impact of the initiative on prescription drug revenues in the hypothetical locality, we estimated the per capita drug spending for participants in the initiative and non-participants in the initiative in the hypothetical area. We estimated per capita drug spending to be $1,289 for participants and $1,001 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.

For participants in the Medicare-endorsed prescription drug 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 initiative, divided by the total number of participants.

For purposes of calculating the per capita spending for non-participants in the Medicare-Endorsed Prescription Drug Card Assistance Initiative, 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 initiative. These two per capita values for non-participants in the 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 initiative (the portion of drug spending covered by Medigap plans) to yield an estimate of total drug spending outside of the 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 discount card initiative, we used the upper bound figure of all drug spending as a high-end assumption.

The results of the sensitivity analysis are shown in Table 4. 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 2.2 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 2.2 percent will be borne by the pharmacy, since discount card sponsors will be required to obtain manufacturer rebates or discounts and pass those through to beneficiaries and pharmacies in order to receive Medicare endorsement. In addition, part of the savings also comes as a result of beneficiary use of lower cost generic drugs.

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. We solicited comments, and particularly data, that could help to inform further analysis of distributional effects. We also solicited 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.

Comment: We received only one comment germane to these issues. One commenter cited testimony in *National Association of Chain Drug Stores* v. *Thompson,* No. 01–1554 (D.D.C. 2001) by a pharmacy that claimed that almost all of its patients would be eligible for the initiative. The pharmacy testified that it delivered medicines to 20 long-term care facilities and 35 residences daily.

Response: The pharmacy cited has a substantial long-term care business. We believe that the effect on the pharmacy will not be as significant as anticipated because we do not expect many long-term care facility residents to enroll in the Medicare-Endorsed Prescription Drug Card Assistance Initiative. As discussed in more detail elsewhere in the preamble, while long-term care facility residents are not prohibited from participating in this initiative, most residents of long-term care facilities will not benefit from the initiative. In addition, many long-term facility residents are Medicaid beneficiaries and have their prescription drugs paid for through that program. We plan to explicitly state in beneficiary outreach and educational materials that the initiative will not be beneficial for most long-term care facility residents.

Because we received no other data or comments to inform the distributional analysis, we believe that the sensitivity analysis constitutes a strong test of the initiative's distributional effects. 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 program design that requires manufacturer rebates or discounts, we did not generate a scenario that reaches the HHS test for significant economic impact.

TABLE 4.—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	3.34	96.66	100.00
Percent of Total Prescription Drug Sales	6.41	93.59	100.00
Estimated Beneficiary Savings as a Percent of Drug Sales	12.40	0.00	0.79
Hypothetical Example:			
Percent of Total Population	14.30	85.70	100.00
Percent of Total Prescription Drug Sales	17.68	82.32	100.00
Estimated Beneficiary Savings as a Percent of Drug Sales	12.40	0.00	2.19

We received several comments concerning the potential impact of the initiative on small pharmacies.

Comment: Several commenters expressed concern that the Medicare-Endorsed Prescription Drug Card Assistance Initiative could have an adverse financial effect on small pharmacies and drug stores and could result in business closures. A few commenters contended that the initiative will adversely affect small community pharmacies' finances, resulting in less access to medicines or pharmacists services for beneficiaries, particularly, one commenter noted, in rural areas.

Response: We believe that the Medicare-Endorsed Prescription Drug Card Assistance Initiative will not significantly harm the financial viability of small pharmacies and drug stores. The amount of revenue involved in the initiative and the amount of beneficiary savings expected represents a small share of overall national retail prescription drug sales. Total prescription drug spending for individuals expected to enroll in this initiative represents less than 7 percent of national retail prescription drug sales, and estimated beneficiary savings from the initiative represents less than 1 percent of national retail prescription drug sales. In addition, there are many forces in today's market influencing the delivery of prescription drugs, including expansion in the types of sources through which individuals can obtain prescription drugs (for example, pharmacies in supermarkets and mass merchants, mail order pharmacies, and most recently, Internet pharmacies). Furthermore, prescription drugs are one of the fastest growing components of health care. Thus, pharmacy revenues can be expected to continue to grow because of increased spending on prescription drugs. Also, the savings to beneficiaries under this initiative will not be borne fully by pharmacies, but come in part from manufacturer rebates and discounts and increased use of

generics. As mentioned elsewhere in this preamble, manufacturer rebates and discounts will be an important component of the savings generated by this initiative.

We have taken a number of steps to mitigate the effect of the initiative on small pharmacies and drug stores. This includes modifying the access ratio to 90/5 in metropolitan areas and 90/10 in non-metropolitan areas, which makes it necessary for card sponsors to have a broad, inclusive pharmacy network; prohibiting Medicare-endorsed card sponsors from providing services only by mail order; requiring that card sponsors obtain manufacturer rebates or discounts and pass a substantial share through to beneficiaries directly or through pharmacies; and requiring card sponsors to sign contracts with pharmacies for their Medicare-endorsed discount card business separate from their other lines of business. Taken together, these features of the initiative give pharmacies negotiating leverage with card sponsors who need pharmacies in order to qualify for Medicare endorsement. The alternatives considered to mitigate the effect on small pharmacies are discussed in greater detail elsewhere in this preamble.

We disagree with commenters who claimed that the initiative will result in less access to prescription drugs or pharmacist services, particularly in rural areas. We believe that the initiative promotes access to prescription drugs by offering beneficiaries reduced prices. The initiative also promotes access to pharmacy services by requiring that card sponsors pass a substantial share of manufacturer rebates or discounts on to beneficiaries directly or indirectly through pharmacies, with enhanced pharmacy services being one of the ways card sponsors can pass discounts on to beneficiaries. With respect to rural areas in particular, we expect that the discount card initiative will promote, not reduce, access in rural areas for the previously stated reasons. In addition, we expect that card sponsors will, as the current market does today, use special arrangements to encourage the participation of rural pharmacies, especially given the specific 90/10 access standard for non-metropolitan areas. We also believe that this Medicare initiative can help the market place adjust to a future Medicare drug benefit.

Comment: One commenter expressed concern that drug card sponsors might retain the manufacturer discounts or rebates, leaving small pharmacies and drug stores to absorb the full discount. The commenter recommended a fixed negotiating fee for card sponsors to prevent this from occurring.

Response: Since this is an educational initiative based on current private market methods for lowering drug costs, we believe that a fixed negotiating fee for card sponsors is inappropriate. In addition, we believe that it is unnecessary because market competition among card sponsors will spur them to pass along the maximum amount possible of rebates and discounts to beneficiaries.

f. 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 604 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 final rule will not affect small rural hospitals since the initiative will 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.

F. Alternatives Considered Relative to Pharmacies, Particularly Small Pharmacies

We considered alternatives to a number of decisions made during the development of this initiative, including several that are relevant to small pharmacies. Several policy decisions were made to mitigate the potential impact on small pharmacies and drug stores.

We considered not pursuing this initiative at all. We clearly 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 before the enactment and implementation of a Medicare prescription drug benefit. However, we concluded that the Medicare-Endorsed Prescription Drug Card Assistance Initiative is a highly effective way to educate beneficiaries about the tools used by private insurance programs to lower the cost of prescription drugs. We believe that through real world experience with drug discount card programs, Medicare beneficiaries will be better educated concerning the economic and quality decisions made by private sector purchasers and individuals with drug coverage. A Medicare prescription drug benefit will involve the private sector tools currently used by health insurers to lower prescription drug costs and provide higher quality pharmaceutical services. Experience through the Medicare-Endorsed Prescription Drug Card Assistance Initiative will better prepare Medicare beneficiaries, particularly those without drug coverage, to make informed decisions about which drug plan is best for them. Additionally, we will gain experience in educating Medicare beneficiaries about prescription drugs. Pursuing this initiative will also provide beneficiaries with immediate help with the cost of prescription drugs, and also will 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 and assistance regarding prescription drug discount programs until a Medicare prescription drug benefit is enacted and implemented.

Since we believe it is in the best interest of Medicare beneficiaries to pursue this initiative, we considered alternatives to major features of the initiative to mitigate its potential effects on pharmacies. First, we considered whether or not to require Medicare-endorsed card sponsors to secure manufacturer rebates. We decided that Medicare-endorsed card sponsors must meet the threshold of garnering manufacturer rebates or discounts from brand name and/or generic manufacturers. In deciding to require manufacturer rebates, we underscore our commitment to mitigating the effect on pharmacies and drug stores, particularly small entities. Since card sponsors will not rely solely on pharmacy discounts to compete for customers, pressure will be relieved from pharmacies. Card sponsors endorsed by Medicare will not be permitted to only negotiate discounts with retail pharmacies.

In addition to requiring manufacturer rebates, we require that a substantial portion of manufacturer rebates and discounts be shared with beneficiaries, either directly or indirectly through pharmacies. Rebates and discounts may be shared in the form of lower prices, pharmacy counseling, incentives for pharmacy participation, or other valuable pharmacy services. Permitting card sponsors to use rebates to fund pharmacy services that ultimately benefit the beneficiary has the potential

to be a positive feature for both pharmacies and beneficiaries.

Another feature that we think can be useful to securing manufacturer rebates or discounts and thus also mitigate the effects on small pharmacies is our proposal for a Gold Star designation, described elsewhere in this preamble and to be forthcoming in a notice of proposed rulemaking. Under this proposal, we would award a Gold Star to those Medicare-endorsed card sponsors securing the highest levels of manufacturer rebates or discounts and passing them through to beneficiaries. Thus, card sponsors would have additional incentives to pass through the highest possible share.

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 will be in the best interests of beneficiaries, the majority of whom rely on retail pharmacies. Requiring retail access also mitigates the impact of the initiative on 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 alternatives to ensure access to pharmacies, including small pharmacies. The proposed rule proposed 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. However, in this final regulation, we change this standard to be 90 percent of the beneficiaries in metropolitan statistical areas (MSAs) must be within 5 miles of a participating pharmacy (90/5), while 90 percent of beneficiaries in non-MSAs must be within 10 miles of a participating pharmacy (90/10). This more stringent access standard requires card sponsors to establish more inclusive pharmacy networks in order to qualify for Medicare endorsement. Beneficiary access to retail pharmacies is a critical component of this initiative, and we believe that this new standard will preserve beneficiary access to the retail pharmacies that they trust. We believe that changing the access standard to provide for separate criteria for MSA and non-MSA geographic areas will help preserve participation of both small, inner-city pharmacies, some of which are culturally sensitive and linguistically appropriate to the needs of the diverse Medicare beneficiary population, as well as garnering the participation of small rural pharmacies that serve geographically dispersed populations.

We also considered whether or not to require Medicare-endorsed card sponsors to have contractual arrangements with pharmacies, specifically incorporating elements relative to this Medicare initiative. We decided that card sponsors must have contractual arrangements with brand name and/or generic 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. In addition, card sponsors must have, specific to this Medicare initiative, contractual agreements with pharmacies ensuring that the rebates or discounts be passed through to the Medicare beneficiaries in the form of lower prices or enhanced pharmacy services. We believe that these provisions protect small pharmacies from changes being made in business relationships with card sponsors without the knowledge and permission of the pharmacy. It provides an opportunity for small pharmacies to negotiate payment for services provided to Medicare beneficiaries in the context of this initiative. The combination of the more stringent access standard discussed previously and the provision for pharmacy network contracts specific to the Medicare initiative provides pharmacies with additional negotiating leverage with card sponsors regarding participation in a card sponsor's pharmacy network. Card sponsors will be expected to report on the participation of independent pharmacies in their networks.

Finally, we also considered whether or not to require that card sponsors negotiate discounts on all drugs. We decided to require that card sponsors offer a discount on at least one drug in the therapeutic categories representing the drugs most commonly needed by beneficiaries. This requirement relieves the pressure on pharmacies since card sponsors are less likely to negotiate discounts on every drug dispensed. In addition, it is not reasonable to expect that manufacturers will provide a rebate or discount on every drug since market share will not move if this is the case.

As noted previously, we believe it is in the best interest of Medicare beneficiaries to pursue this initiative. In doing so, we believe we identified and incorporated major design features that are specifically directed at mitigating the potential impact on small pharmacies and drug stores.

G. Estimated Administrative Costs and Anticipated Benefits

The following cost and benefit analysis is prepared in 2003 dollars; it reflects the major administrative costs to discount card programs that are not a part of usual and customary practice, and the benefits we anticipate in the first and second years of this initiative. The major costs are associated with the start-up and activities of the administrative consortium, the production and distribution of information and outreach materials specific to the Medicare-endorsed discount card programs, and the operation of the customer service call centers. We did not estimate card sponsor costs associated with compliance with the privacy provisions under this rule because we believe card sponsors or organizations contracted by card sponsors to operate the drug card program will very likely be either a covered entity or business associate under the Privacy Rule and the costs for compliance will have already been incurred.

We estimate significantly higher costs in Year One than in Year Two of implementation because of the start-up of the administrative consortium and a very large initial enrollment that is assumed in the first year only. One cost reflected in Year Two that is not in the Year One estimate is the review of card sponsors' information and outreach materials, which will be our responsibility the first year of the initiative; the administrative consortium will assume this responsibility in the second year.

For purposes of this analysis, and consistent with the methodology used in the impact analysis, we assume that Year One enrollment is equal to 100 percent of the number of beneficiaries that the impact analysis assumes will be enrolled by the first full year of operation (9.7 million beneficiaries). We apply a 1.3 percent growth factor to estimate Year Two enrollment. The basis of this growth factor is Table 3 of the Medicare Trustees Reports, March 26, 2002.

Table 5 reports the per-card program sponsor costs and the per new enrollee costs for national and regional card programs for each group of administrative functions associated with a significant cost, as well as the total costs. These costs are also presented in relation to the number of new enrollees expected to enroll in each of Year One and Year Two to demonstrate these costs relative to one possible revenue stream for the card programs, a one-time enrollment fee of up to $25.

While any entity that meets all of the requirements in this regulation will be eligible to enter into an agreement with us to receive a Medicare endorsement, for purposes of estimating these costs, we assume that 15 drug card programs will be endorsed. Of those 15, we assume, for the purpose of this analysis, that 10 will be national programs (including 50 States and Washington, DC) and 5 will 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. Private Sector Administrative Consortium, Its Start-Up and Activities

Drug card sponsors are required, as a term of endorsement, to 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 card sponsors. It is expected that the consortium will be fully operational when the card programs begin outreach and enrollment in Year One.

Included in the following cost and benefit estimate are: (1) The start-up costs of the consortium and its activities, (2) staffing of the consortium, and (3) hardware costs for systems to be developed and maintained by the consortium.

A cost estimate was produced 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, $.48 million.
- Specification of requirements for the enrollment exclusivity system and software development, $.35 million.
- Options development for financial management for the administrative consortium, $.41 million.
- Development of a transition plan from consortium formation through full operation, $.12 million.
- Specification of requirements for the price comparison web site and software development, $.31 million.
- Contract support to the consortium during transition for management functions, $.22 million.
- Contract support for the consortium webmaster to implement the enrollment exclusivity system and the price comparison web site (hardware not included), $54,106.

These activities and their estimated costs equal $1.94 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 will 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 2003 dollars using a 2001 adjustment of 5.6 percent, a 2002 adjustment of 3.1 percent, and 2003 adjustment of 4.6 percent found in Table III.A1 of the 2002 Annual Report of the Board of Trustees of the Federal Hospital Insurance Trust Fund *(http://www.hcfa.gov/pubforms/tr/hi2002/tabiiial.htm).* We adjust these wages upward to include compensation (non-wage benefits) using an adjustment factor of 1.357, based on Table 6 of a U.S. Department of Labor, Bureau of Labor Statistics report entitled ''Employer Costs for Employee Compensation—March 2002,'' which reports that national wages and salaries for white collar occupations represent 73.7 percent of total wages and compensation. We assume that the administrative consortium will hire or retain the services of each type of employee on a full-time basis of 2,080 hours per year, except the lawyer and the pharmacist, whom we assume will work one-half of that time. These first year costs actually reflect a 15-month period to accommodate a 3-month consortium start-up before card programs becoming operational. Therefore, we have adjusted the first year estimates upward to reflect 3 additional months of wages, compensation, overhead, and rent for the consortium staff. The estimated first year wages and compensation will therefore be as follows:

- Public Relations Manager—$118,678
- Lawyer (1/2 time)—$88,185
- Computer Programmer—$117,754
- Pharmacist (1/2 time)—$67,073
- Executive Secretary—$62,794

The estimated total first year costs for wages and compensation is $.45 million.

We estimated overhead costs for these employees using a factor of .5 applied to the total wage and compensation rates for an additional amount of $.23 million. This amounts to a total of $.68 million for consortium staff wages and compensation and overhead. In Year Two, we expect these staff wages and compensation, as well as overhead costs to be equal to a 12-month period in Year One, $.54 million.

We estimate the cost (in 2003 dollars) of leasing space for the administrative consortium staff of five using a 2002 estimate provided by a commercial real estate broker of $20 per square foot for full service space leased 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), over a 15-month period for a total amount of $.23 million. In Year Two, costs associated with leasing space for the administrative consortium staff are based on a 12-month period, or $.18 million.

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 will 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 will require the administrative consortium to develop and maintain a secure electronic enrollment exclusivity system that will be populated by and accessible only by the administrative consortium and endorsed sponsors; as stated previously, we assume 15 card sponsors will be endorsed.

For the purpose of defining the capacity needed for this system, we also assume that the system will maintain a unique record for each beneficiary enrolled by a card sponsor. The record will 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 of which will occur in any year in a 2-month period, based on the estimated 9.7 million beneficiaries who will likely join, adjusted for disenrollment and reenrollment as well as for lost cards as described below. We do not know what

the actual rate of voluntary disenrollment will be for this initiative; it could be lower or higher than the 2000 Medicare+Choice disenrollment rate used below, depending, for example, on how much a beneficiary's card program changes its formulary and drug prices within the limits we established and whether these changes affect the drugs the beneficiary takes. Also, the voluntary disenrollment rate will 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 card programs.

We assume that of the 9.7 million beneficiaries who will enroll in the first year, 11.5 percent will disenroll and reenroll in another Medicare-endorsed drug card program. This disenrollment and reenrollment adjustment is based on the 2000 Medicare+Choice voluntary disenrollment rate of 11.5 percent. We also assume that card sponsors will 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 will be updated in real time and be of web-based technology. We assume this system will 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 will be to facilitate the publication of, or to publish, information, including comparative price information on discount drugs, that will assist beneficiaries in determining which Medicare-endorsed prescription drug card program is the most appropriate for their needs. This will 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 can 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 will update its formulary and price lists six times a year. As indicated previously, we assume that 10 of the estimated 15 sponsors endorsed by Medicare will be national programs (having a network in all 50 States and Washington, DC), and the remaining 5 programs will be regional programs (comprised of 4 States each). Because formularies could vary geographically, we assume that each card program will 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 will house as many as 1,060 unique formularies and pricing listings. We assume that only the administrative consortium will have direct interface with the system; card sponsors will 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 the enrollment exclusivity and price comparison systems, our Office of Information Services (OIS) developed a cost estimate for the first year in the amount of $.44 million for lowest common denominator technology which will 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 will be significantly less, $80,000, reflecting maintenance rather than purchase of hardware.

A third responsibility of the administrative consortium will not begin until Year Two. The consortium will be responsible for ensuring the integrity of the information distributed by the Medicare-endorsed prescription drug discount card programs. We will conduct the information and outreach material review for the first year of endorsements. The administrative consortium's reviews in future years will be based on guidelines prepared by us. Based on a cost estimate developed by our Center for Beneficiary Choices (CBC), we assume that the cost of developing the guidelines will be $.24 million. 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, will be $.29 million. We assume that the cost of transitioning the review to the administrative consortium will be $45,320. We assume reporting on the status of the information and outreach material review and findings under the review will cost $29,870. This first year cost, totaling $.61 million, will be borne by us in the context of our existing budget. In Year Two, information and outreach material review will be the consortium's responsibility, not ours, with the exception of costs associated with the development of the information and outreach guidelines and the costs associated with transitioning the information and outreach material review responsibility to the consortium. As noted, we will develop the information and outreach guidelines, not the consortium. Second year costs to be borne by the administrative consortium total $.32 million.

The total estimated Year One cost to be borne across all Medicare-endorsed card program sponsors for the administrative consortium start-up, its staffing and administrative activities will be $3.29 million (this includes $1.94 million for start-up activities plus $.68 million for consortium staff wages and compensation and overhead plus $.44 million for hardware plus $.23 million for leased space). We expect that drug card sponsors will share the costs of starting-up and maintaining the consortium and its activities. As shown in Table 5, we estimate the Year One per-card program sponsor costs for the administrative consortium, its associated start-up costs, and staffing and activities to be $.32 million for a national program, and $24,879 for a regional program. We divide those total costs for the consortium by the estimated number of new enrollees per national and regional card in the same year, since it is our policy that a one-time enrollment fee of up to $25 can be charged to a beneficiary. This allows an examination of estimated administrative costs relative to estimated enrollment fees. The estimated per new enrollee cost of the consortium start-up and Year One administrative activities, is estimated to be $0.30.

As stated previously, we estimate that the second year administrative consortium costs to be borne by all card sponsors of the consortium will be significantly lower than first year costs. Specifically, the relevant estimates for second year costs include: (1) Maintenance of the enrollment exclusivity and price comparison systems, $80,000; (2) information and outreach material review, $.29 million; (3) reporting on status of information and outreach material reviews and findings, $29,870; (4) consortium staff wages, compensation and overhead, $.54 million; and (5) leased space, $.18 million, for a total of $1.12 million. As shown in Table 5, for Year Two, we estimate the total per-card program sponsor costs for a national program will be $108,843, and for a regional

program to be $8,537, with a per new enrollee cost of $0.90.

In these estimates for the administrative consortium and its activities, we have captured the activities required in the final regulation and have attempted to reflect the significant costs associated with them.

We presume that sponsors will recover these costs in enrollment fees or by holding back a share of the pharmaceutical manufacturing rebates or discounts. The likely effect therefore is to either increase the one-time enrollment fee to as high as $25, or to lower the amount of the manufacturer rebates shared directly or indirectly with beneficiaries through pharmacies.

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

We believe that the administrative consortium's price comparison system and information and outreach material review will significantly assist beneficiaries as they seek information about selecting a drug discount card program. These activities will help beneficiaries make informed decisions and protect them from misleading information. Further, the role of the exclusivity system in ensuring that beneficiaries only belong to one drug discount card program at a time, as well as the price comparison information, will help optimize card sponsor negotiations for manufacturer rebates or discounts as sponsors compete for Medicare market share. Also, the secure exclusivity system will assist in protecting the privacy of beneficiary-specific information.

In addition, we will benefit by learning from the implementation of the requirements involving information technology, information and outreach material review, beneficiary enrollment, and education using the price comparison web site and through the card programs' enrollment.

There are several limitations to the consortium cost analysis. Since we have no experience implementing this initiative, our estimates of the number of card programs that will be endorsed is based on the number of applications we received during the 2001 solicitation process (28). While we did not complete our review of the applications before the initiative was enjoined by the court, we assume for estimating purposes that approximately half (15) would have been endorsed. If the number of actual endorsements is significantly lower or higher, then cost estimates for the consortium start-up and its administrative activities will be affected upward or downward accordingly. (This limitation also applies to the per-card cost estimates presented below for outreach and telephonic customer service.) Another limitation of the consortium cost estimate is that its actual organization and ongoing operations are not known at this time as these will be determined largely by representatives of the endorsed drug card sponsors.

Comment: We received numerous comments on the costs of the consortium, which are summarized under the first comment in section I.D.9.a of this preamble.

Response: Our response follows the summary of comments in section I.D.9.a of this preamble.

Comment: Several commenters were concerned that two-thirds of the estimated $2.75 million for start-up and administrative activities of the consortium, as delineated in the proposed rule, will be spent on the enrollment exclusivity system.

Response: Based on our estimates, we do not believe that the exclusivity system will require two-thirds of the estimated consortium costs. To qualify for Medicare endorsement, an applicant or its subcontractor must demonstrate experience with and substantial existing capacity for enrollment, as measured by the 1 million covered lives criterion. With this requirement for endorsement met, we believe that certain costs for ensuring exclusive enrollment, in particular, the costs associated with the enrollment process itself (not including outreach costs and costs associated with customer service call centers, which are addressed later in this analysis), will be part of usual and customary practice. Our costs reflect the development, maintenance, and operation of the enrollment exclusivity database only.

We believe 50 percent of the costs we have identified for developing and maintaining the enrollment exclusivity and price comparison systems will be needed for enrollment exclusivity. Our estimate for specifying the requirements for the enrollment system and software development is $.35 million. Further, of the $.44 million we identified for the cost of hardware for the two systems, we estimate that 50 percent, or $.22 million will be for the enrollment exclusivity system hardware. In addition, 50 percent, or $40,000 will be necessary in Year Two for maintenance of the enrollment exclusivity system. We assume that the consortium will hire a full time computer programmer whose salary and compensation is estimated at $118,678 in Year One (for a 15 month period), and whose office space will cost approximately $46,350 for a 15-month period; we believe that 50 percent of the programmer's time in Year One (approximately $59,339) will be spent on enrollment exclusivity. Finally, we anticipate the need for some additional technical support for the implementation of this system, in the amount of $27,500 (one-half the cost of support for both the enrollment exclusivity and price comparison systems). These costs total $.74 million.

2. Production and Distribution of Information and Information and Outreach Materials

Under this initiative, there will be a significant incremental cost associated with information and outreach materials for each Medicare beneficiary enrollee. For the purpose of this estimate, we assume that 15 drug card programs will be endorsed. We assume that a total of 9.7 million beneficiaries will enroll for the first time. Using the 2000 Medicare+Choice (M+C) disenrollment rate, we assume an additional 11.5 percent of these beneficiaries will disenroll and reenroll for a total of approximately 10.8 million enrollments in Year One.

We develop an estimate that reflects three types of information and outreach material: pre-enrollment, post-enrollment, and an annual notice of changes to the program for beneficiaries who stay enrolled into a new year. The total number of pre-enrollment mailings sent out by card sponsors will be three times the number of beneficiaries enrolling in the initiative. Pre-enrollment mailings from a card program will include such items as a cover letter, membership form, privacy notice, a summary of card program features (including prices for selected drugs commonly used by the Medicare population), a 1-page listing of network pharmacies in the beneficiary's zip code area, and return envelope with postage paid.

Further, we assume that 100 percent of beneficiaries who would actually enroll in each year will receive a post-enrollment package including items such as a cover letter, a prescription drug discount card, member handbook (including a complete directory of network pharmacies), and formulary applicable to the zip code area. Finally, we assume that currently enrolled beneficiaries will receive, beginning in Year Two, a package to include a cover letter and an annual notice of changes to the card program.

Including the costs of printing these materials, mailing them, and paying for return mail of enrollment and notice forms, we estimate a total Year One cost of $38.09 million. We estimate a per

national card program cost of $3.66 million, per regional card program cost of $.29 million, and per new enrollee cost of $3.52.

We estimate a total Year Two cost of $9.03 million. We estimate a cost per national program of $.87 million, per regional program of $68,157, and per new enrollee of $7.19.

3. Customer Service Call Center

The following estimates reflect costs for both an interactive voice-response system and access to customer service representatives by telephone. We believe that beneficiaries will have access to a variety of communication channels for receiving card program information including: Medicare outreach and education through, for example, *http://www.Medicare.gov* and the Medicare toll-free telephone number (Medicare 1–800), the consortium price comparison web site, and the card program's own outreach through its web site, which could allow beneficiaries or their caregivers to request printed material or download it, or through its print material or its own customer service 1–800 line. The cost of some of these information channels, such as Medicare 1–800, will not be borne by the card programs, and information channels such as the printed information and outreach materials produced by the card program and an interactive web site maintained by the card program will likely be less expensive than the cost of the card program's 1–800 customer service representative's time. Therefore, we assume that card programs will maximize their outreach through non-telephonic communication channels.

We also assume that the card program's 1–800 customer service line will include an interactive voice-response system where beneficiaries can receive basic information about the program and can order print material. We assume that 80 percent of beneficiaries or their caregivers will obtain print material through a communication channel that does not involve the card program's interactive voice-response system, and the remaining 20 percent will seek print material through the card program's interactive voice-response system. Additionally, we assume another 5 percent of enrolled beneficiaries will seek information through the card sponsor's interactive voice-response system that is not related to enrollment, but other types of straightforward requests, such as to receive an updated formulary listing. The following estimates reflect the marginal cost of each additional call, as we assume that each drug card program sponsor will already have the basic call center infrastructure in place. Using our experience, we estimate the cost of each additional interactive voice-response call to be $3.

For Year One, we estimate total per national card program costs for the interactive voice-response system of $.76 million, and per regional card program costs of $59,957. The estimated per new enrollee cost is $0.73.

For Year Two, we estimate total per national card program costs for the interactive voice-response system of $.21 million and per regional card program costs of $16,812. The estimated per new enrollee cost is $1.77.

In estimating the costs of access to customer service representatives by telephone, we assume that of the newly enrolled beneficiaries in a Medicare-endorsed card program in any given year, 20 percent will speak to a customer service representative either for additional enrollment information or other general program information. For this analysis, a newly enrolled beneficiary could be a first-time enrollee or a beneficiary who has disenrolled and reenrolled in a different card program. We also assume that 11.5 percent of enrolled beneficiaries will disenroll, and that each of these beneficiaries will speak to a customer service representative. We assume one-half of these disenrollees (5.75 percent) will lodge a complaint through a customer service representative. In Year One, this represents a total of approximately 3.84 million calls, across all card programs. In Year Two, we make the same assumptions as for Year One. This amounts to a total of approximately 1.95 million calls across all card programs.

To further build this estimate, we 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 Wage Estimates, Office and Administrative Support Occupations.'' (*http://www.bls.gov/oes/2000/oes_43Of.htm*). We age this wage rate to 2003 using the same factors (5.6 percent for 2001, 3.1 percent for 2002, and 4.6 percent for 2003) used to age the wages for the administrative consortium staff. We use a compensation factor of 1.357 obtained from the same report used to calculate compensation for the consortium staff, for a total 2003 wage and compensation rate of $40,979 per customer service representative. We apply a factor of .5 to this rate to provide an overhead amount of $20,489.

We estimate lease space per customer service representative using 150 square feet per office at $20 per square foot (in 2002 dollars) for full service space leased in a metropolitan area. This estimate was obtained from a commercial real estate broker. In 2003 dollars, we estimate a total per office amount of $37,080, for a 12-month period. The total cost per customer service representative for wages, compensation, overhead, and leased space will be $98,548.

Assuming that each customer service representative works 7 hours per day, 5 days per week, 50 weeks per year, each representative will work 105,000 minutes per year. This will permit each representative to respond to 10,500 beneficiaries per year (105,000 divided by 10 minutes per call).

We estimate for Year One that for all 3.84 million enrollees who will talk to a customer service representative, a total of 365 customer service representatives will be hired or retained across all Medicare-endorsed card sponsors. As Table 5 shows, the estimated Year One cost for a national card program sponsor will be $3.46 million, and for a regional card program sponsor, $.27 million, with a per new enrollee cost of $3.33.

In the second year, we estimate that approximately 1.95 million beneficiaries will talk to a customer service representative. The number of customer service representatives needed will be 185 across all card sponsors. As Table 5 shows, the estimated Year Two cost for a national card program sponsor will be $1.76 million, and for a regional card program sponsor, $.14 million, with a per new enrollee cost of $14.54.

4. Other Considerations Concerning Production and Distribution of Information and Outreach Materials and the Customer Service Call Center

We presume that sponsors will recover their costs associated with the production and distribution of information and outreach materials and with the customer service call center by charging enrollment fees or by holding back a share of the pharmaceutical manufacturing rebates or discounts. The likely effect of these costs on a card sponsor, therefore, will be a decision to either increase the one-time enrollment fee to as high as $25, or to lower the amount of the manufacturer rebate or discount shared directly or indirectly with beneficiaries through pharmacies.

We believe that beneficiaries will benefit significantly from access to print materials, an interactive voice-response system, and customer service

representatives to inform their decision about what card to join and to facilitate enrollment. We also believe that access to customer service representatives to manage complaints will improve the quality of the card program and serve to limit the number of disenrollments, as a person-to-person mechanism will be in place to handle beneficiaries' questions and concerns.

Comment: We solicited comments on different methods to efficiently enroll beneficiaries in the context of our requirements to provide information and ensure that beneficiary personal information is kept confidential. We received several comments about our proposed requirement that written consent to the expected uses and disclosures of a beneficiary-specific information be obtained from each beneficiary and its effect on enrollment by telephone or Internet. Commenters indicated that obtaining written consent could require additional steps in the enrollment process, interfering potentially with an efficient enrollment system by requiring access to the enrollment database more than once to verify enrollment status and again to execute actual enrollment after receiving written consent. One commenter stated that enrollment should be effective at the same step in the enrollment process as the card program's procedure for verifying that the beneficiary is not already enrolled in another Medicare-endorsed card program, rather than at the time that written consent is obtained. Further, the commenters noted that this requirement for written consent is not consistent with pending regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and that it is unnecessary.

Response: Our policy concerning consent for expected uses and disclosures is discussed in section I.D.8.d of this preamble.

Comment: One commenter stated that enrollment costs are higher than they would be without an enrollment exclusivity provision. Also, this commenter indicated that they would expect 5, not 15, minute phone calls by beneficiaries to the customer service 1–800 line, as estimated in the proposed rule. One commenter indicated that enrollment costs estimated in the proposed rule are significantly underestimated; that, in addition to a 15 minute call, the commenter would expect beneficiaries unfamiliar with the program to call multiple times. Also, this same commenter pointed out that fax, phone, mail, and Internet channels specific to the program need to be developed and that these costs are not reflected in the estimate. One commenter stated that individual enrollment and the frequency and length of calls for the senior population are likely to have a significant cost impact on the call center. These commenters stated that these costs suggest an annual renewal fee of up to $25 should be allowed.

Response: We agree that the enrollment costs as expressed in the exclusivity system and time and materials needed to inform beneficiaries about this requirement are higher than if enrollment exclusivity were not required; however, we believe that the benefit in negotiated rebates that will be shared with beneficiaries under this initiative far outweighs this additional cost. Concerning the estimated time for a customer service call, we believe that card sponsors will provide as much information through the most efficient communication channels to limit the potential impact on the customer service call center. We believe that a well thought out outreach strategy and the effective use of various communication channels, in addition to the information that we and the consortium's price comparison system make available, will serve to minimize the amount of time that is needed on the phone when a beneficiary does contact a customer service representative, as well as the portion of beneficiaries or their caregivers who will call to speak to a card sponsor's customer service representatives. In circumstances where the same beneficiary calls the call center, we believe each call will be for a different purpose, such as to clarify information to make an enrollment choice, to complain, or to disenroll. Our estimate accommodates what we believe is a reasonable expectation for multiple calls from a beneficiary. We did not include fax and Internet costs in this estimate because the use of these technologies by the card program sponsors is less expensive than the use of hard copy production and mail; therefore, we believe the costs of these communication channels are at least covered, if not over-represented, in our information and outreach production and distribution cost estimate. Having estimated these major administrative costs and reflecting them in terms of new enrollees, we have demonstrated that these costs can be covered with a one-time enrollment fee of up to $25, leaving potentially substantial reserve to cover other, less significant costs not expressed in this estimate. Therefore, we do not agree that an annual fee is necessary to support the administrative costs of this initiative.

5. Total Estimated Major Administrative Costs to Card Sponsors

This analysis is different from that of the proposed rule; it has been refined to more closely reflect alternative communication channels card sponsors are likely to employ to conduct outreach and enroll beneficiaries. Further, we significantly adjusted upward the size of the population in Year Two to accommodate communications attributable to disenrollments and complaints.

As shown in Table 5, we have totaled all the costs for Year One and Year Two represented in this analysis: (1) the administrative consortium, its start-up and activities; (2) information and outreach materials (production and distribution); (3) and the customer service call center. We estimate total Year One costs of $85.33 million; these costs are to be borne by the endorsed card sponsors. We estimate a per national card sponsor cost of $8.21 million, and a per regional card sponsor cost of $.64 million, with a per new enrollee cost of $7.89.

In the second year, we estimate total costs of $30.66 million across all card sponsors. We estimate a national card program sponsor cost of $2.95 million, and a regional card program sponsor of $.23 million, with a per new enrollee cost of $24.41.

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) can cover the card program's major administrative costs, including costs associated with the operation of the consortium. 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 (10.8 million enrollments, including first time and disenrolled/re-enrolled beneficiaries)
Consortium its start-up and activities:		
National	$317,212	$0.30
Regional	$24,879	$0.30
Information and outreach materials production & distribution:		
National	$3,664,892	$3.52
Regional	$287,443	$3.52
Call Center—Interactive Voice Response (IVR):		
National	$764,452	$0.73
Regional	$59,957	$0.73
Call Center—Customer service representative costs:		
National	$3,464,755	$3.33
Regional	$271,746	$3.33
Total:		
National	$8,211,311	$7.89
Regional	$644,024	$7.89
Year two	**Per sponsor cost**	**Per new enrollee cost (1.2 million enrollments, including first time and disenrolled/re-enrolled beneficiaries)**
Consortium its start-up and activities:		
National	$108,843	$.90
Regional	$8,537	$.90
Information and outreach materials production & distribution:		
National	$869,000	$7.19
Regional	$68,157	$7.19
Call Center—Interactive Voice Response (IVR):		
National	$214,352	$1.77
Regional	$16,812	$1.77
Customer Service Call Center:		
National	$1,757,709	$14.54
Regional	$137,859	$14.54
Total:		
National	$2,949,903	$24.41
Regional	$231,365	$24.41

6. Manufacturer Rebates or Discounts

We do not estimate the administrative costs of negotiating manufacturer rebates or discounts and sharing them with beneficiaries as we believe that the experience criteria for endorsement ensures that the infrastructure for this activity will already be available to the card sponsors and that this is part of usual and customary practice for the organizations likely to apply and be endorsed. We require that these rebates or discounts will have to be shared with beneficiaries either directly or indirectly through pharmacies. We anticipate that this requirement will promote better drug prices for beneficiaries or enhance pharmacy participation in a drug card program's network. Further, we anticipate that sharing indirectly with pharmacies could promote enhanced pharmacy services.

7. Medicare's Beneficiary Education and Outreach Plans

Medicare beneficiaries will benefit from the education and outreach plans we outline in this final rule. In addition to information that we anticipate will be available through the endorsed card sponsors, the information we will impart on our web site, through brochures, and in beneficiary calls to the 1–800–Medicare telephone number will assist beneficiaries in gaining knowledge about whether and how to participate in a Medicare-endorsed prescription drug card program. In addition, beneficiaries will benefit from the basic information imparted regarding how to use tools to manage drug costs. Also, we will benefit from the infrastructure built for, and the experience gained from, educating beneficiaries about using private sector tools to lower their out-of-pocket prescription drug costs and enhance the pharmacy services they will receive in preparation for a Medicare prescription drug benefit.

Comment: Two commenters made the point that development of new manufacturer discount cards, which

provide substantial savings to low-income Medicare beneficiaries, make the Medicare-Endorsed Prescription Drug Card Assistance Initiative unnecessary. The commenters indicate that the initiative will create additional administrative burden and may undermine the new manufacturer cards.

Response: We agree generally that the new manufacturer discount cards can provide substantial savings to low-income Medicare beneficiaries. We disagree that their availability makes this initiative unnecessary. We believe there is important value for Medicare beneficiaries in the education and assistance made available under this initiative that does not exist in the current discount card market. We believe that enrollment exclusivity will provide meaningful savings and limit beneficiary confusion associated with beneficiary participation in multiple card programs. Further, there are a significant number of beneficiaries who do not qualify for manufacturer card programs who will benefit under this initiative. While we agree that there is administrative burden associated with this initiative, we believe there are counter costs in time and effort to beneficiaries and administrative inefficiencies in the performance of the discount card market associated with beneficiaries participating in multiple card programs that will be minimized by this initiative. Moreover, we have demonstrated that the administrative costs of this initiative will likely be more than offset through a one-time enrollment fee. We do not believe that this initiative will undermine manufacturer card programs, as they offer obvious and significant discounts for beneficiaries who qualify. Rather, some of the impediments to participation by beneficiaries in the manufacturer cards appear to be lack of uniformity in eligibility requirements, complexity of demonstrating eligibility, and perceived stigma associated with low-income initiatives. We believe our initiative offers an important new choice for beneficiaries that is not encumbered by these impediments.

H. Conclusion to Impact Analysis

Evidence of trends in prescription drug use and spending, changes in pharmacy acquisition costs for drugs at a time of increased presence of pharmacy benefit management strategies, and strategies for varying drug prices and manufacturer rebates or discounts indicate a dynamic market that adjusts and returns to equilibrium. Pharmacy benefit management tools are a feature of the current prescription drug market and are used to lower drug costs. The implementation of the Medicare-Endorsed Prescription Drug Card Assistance Initiative in this environment will educate Medicare beneficiaries and provide them with experience with the private sector tools used to lower drug prices.

In accordance with the provisions of Executive Order 12866, this final 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 amends 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: 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.

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 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 a private entity established and financed by the Medicare-endorsed prescription drug card program sponsors to carry out a set of specific administrative tasks required under the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

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 discount 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.

Formulary means the list of specific drugs for which the Medicare-endorsed prescription drug card program offers discounts to Medicare beneficiaries enrolled in the Medicare-endorsed prescription drug card program.

Medicare-Endorsed Prescription Drug Card Assistance Initiative means an effort whereby CMS provides information, counseling, and assistance to Medicare beneficiaries by soliciting applications for Medicare endorsement of prescription drug card programs, reviewing them, offering agreements to program sponsors that meet all of the requirements for endorsement, awarding Medicare endorsements to program sponsors who sign the agreement, and educating beneficiaries about the options available to them in the private marketplace.

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 discount 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 must submit applications by the deadline announced in the solicitation 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 sponsor no more than two drug card programs. The same organization or entity may have operational responsibilities in multiple drug card programs.

(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 by the deadline announced in the solicitation that contains all information necessary for CMS to determine whether the applicant meets all of the requirements in § 403.806, and whose application 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 a period of at least 12 months but fewer than 24 months. Beginning in Year Two, the endorsement will be effective at least 12 months, but fewer than 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.

(h) *Notification to beneficiaries of termination of participation.* (1) 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.

(2) In the event of termination by the drug card program sponsor, or termination by CMS, drug card programs must remain available to beneficiaries for 90 days after beneficiaries are provided with notice of termination. In the event of termination by the drug card program sponsor, or termination by CMS, drug card program sponsors must suspend information and outreach and enrollment of beneficiaries once beneficiaries have been notified of the termination.

§ 403.806 Requirements for eligibility for endorsement.

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

(b) *Applicant structure, experience, and participation in administrative consortium.* (1) A single organization or entity that is either the applicant or a subcontractor or under other legal arrangement with the applicant must have no less than 3 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;

(2) A single organization or entity that is either the applicant or a subcontractor or under other legal arrangement with the applicant must, at the time of application for endorsement, manage at least 1 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.

(3) A single organization or entity that is either the applicant or a subcontractor or under other legal arrangement with the applicant must—

(i) Have a pharmacy network serving all 50 States and the District of Columbia to qualify as a national program; or

(ii) Have a regional pharmacy network serving at least 2 contiguous States (with the exception of Hawaii and Alaska, which can partner with 2 or more contiguous States) to qualify as a regional program.

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

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

(6) 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 card program sponsors in accordance with the requirements of this subpart.

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

(c) *Customer service.* The applicant must comply with the following customer service requirements:

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

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

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

(d) *Privacy and confidentiality of beneficiary-specific information.* (1) The applicant must comply, beginning at the time of Medicare endorsement, with 45 CFR 160.103, 160.202, 164.501 through 164.514, and 164.520, subject to the following modifications:

(i) All references to covered entities will be applicable to the drug card sponsor, and health care operations means the routine activities, including providing information and outreach, as provided under the Medicare endorsement; and

(ii) For the purpose of authorization in 45 CFR 164.508, marketing means any use or disclosure of protected health information to be outside the scope of Medicare endorsement.

(2) The applicant must develop and implement a written data security plan for protected health information.

(3) The requirements of this paragraph (d) are enforceable by CMS under the provisions of § 403.812.

(4) Nothing in this paragraph (d) modifies the applicability of 45 CFR 160.103, 160.202, 164.501 through

164.514, and 164.520 to organizations or entities independently subject to the mandates of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

(e) *Discounts, rebates, and access.* The applicant must comply with the following discount, rebate, and access requirements:

(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 pharmaceutical manufacturer drug rebates or discounts on brand name or generic drugs or both, and ensure that a substantial share is provided to beneficiaries either directly or indirectly through pharmacies.

(3) Ensure that a specific drug offered under the program is not dropped from the formulary nor its price increased for periods of at least 60 days, starting on the first day of the program's operation, and notify CMS, the consortium, and the network pharmacies of these changes 30 days before the change becomes effective.

(4) Guarantee that for the drugs for 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.

(5) 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. At least 90 percent of Medicare beneficiaries, on average, in all Metropolitan Statistical Areas (MSAs) served by the program must live within 5 miles of a contracted pharmacy; and at least 90 percent of Medicare beneficiaries, on average, in all non-MSAs served by the program must live within 10 miles of a contracted pharmacy.

(6) 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 are submitted by the deadline announced in the solicitation and 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. The agreement must include a statement that the applicant will comply with information and outreach guidelines established by CMS.

§ 403.810 Administrative consortium responsibilities and oversight.

(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;

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

(4) Developing and implementing a written data security plan for protected health information; and

(5) Abiding by applicable Federal and State laws.

(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, 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 to become effective immediately.

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

(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;

(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 Inspector General, for sanctions or prosecution under section 1140 of the Act.

§ 403.820 Oversight and beneficiary education.

(a) The Medicare-endorsed prescription drug card program sponsor must report to CMS on a periodic basis on major features of its programs that correspond to the qualifications for endorsement, including savings to beneficiaries, customer service, and discount card program operations. Card program sponsors must certify the validity of their reported data.

(b) The Medicare-endorsed prescription drug card program sponsor must establish and maintain a customer complaints process. This process must

be designed to track and address in a timely manner enrollees' complaints about any aspect of the drug card program.

(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: August 21, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 21, 2002.

Tommy G. Thompson,

Secretary.

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