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Federal Register

Monday,
December 15, 2003

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403 and 408

Medicare Program; Medicare Prescription Drug Discount Card; Interim Rule and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403 and 408

[CMS–4063–IFC]

RIN 0938–AM71

Medicare Program; Medicare Prescription Drug Discount Card

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

ACTION: Interim final rule with comment period.

SUMMARY: Section 101, subpart 4 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, codified in section 1860D–31 of the Social Security Act, provides for a voluntary prescription drug discount card program for Medicare beneficiaries entitled to benefits, or enrolled, under Part A or enrolled under Part B, excluding beneficiaries entitled to medical assistance for outpatient prescription drugs under Medicaid, including section 1115 waiver demonstrations. Eligible beneficiaries may access negotiated prices on prescription drugs by enrolling in drug discount card programs offered by Medicare-endorsed sponsors.

Eligible beneficiaries may enroll in the Medicare drug discount card program beginning no later than 6 months after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and ending December 31, 2005. After December 31, 2005, beneficiaries enrolled in the program may continue to use their drug discount card during a short transition period beginning January 1, 2006 and ending upon the effective date of a beneficiary's outpatient drug coverage under Medicare Part D, but no later than the last day of the initial open enrollment period under Part D.

Beneficiaries with incomes no more than 135 percent of the poverty line applicable to their family size who do not have outpatient prescription drug coverage under certain programs—Medicaid, certain health insurance coverage or group health insurance (such as retiree coverage), TRICARE, and Federal Employees Health Benefits Program (FEHBP)—also are eligible for transitional assistance, or payment of $600 in 2004 and up to $600 in 2005 of the cost of covered discount card drugs obtained under the program. In most cases, any transitional assistance remaining available to a beneficiary on December 31, 2004 may be rolled over to 2005 and applied toward the cost of covered discount card drugs obtained under the program during 2005. Similarly, in most cases, any transitional assistance remaining available to a beneficiary on December 31, 2005 may be applied toward the cost of covered discount card drugs obtained under the program during the transition period.

The Centers for Medicare & Medicaid Services will solicit applications from entities seeking to offer beneficiaries negotiated prices on covered discount card drugs. Those meeting the requirements described in the authorizing statute and this rule, including administration of transitional assistance, will be permitted to offer a Medicare-endorsed drug discount card program to eligible beneficiaries. Endorsed sponsors may charge beneficiaries enrolling in their endorsed programs an annual enrollment fee for 2004 and 2005 of no more than $30; CMS will pay this fee on behalf of enrollees entitled to transitional assistance.

To ensure that eligible Medicare beneficiaries take full advantage of the Medicare drug discount card program and make informed choices, CMS will educate beneficiaries about the existence and features of the program and the availability of transitional assistance for certain low-income beneficiaries; and publicize information that will allow Medicare beneficiaries to compare the various Medicare-endorsed drug discount card programs.

DATES: *Effective Date:* The provisions of this interim final rule with comment period are effective December 15, 2003.

Comment date: Comments will be considered if we receive them no later than 5 p.m. on January 14, 2004, at the appropriate address, as provided below.

ADDRESSES: In commenting, please refer to file code CMS–4063–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Mail written comments (1 original and 3 copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4063–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

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

If you prefer, you may deliver (by hand or courier) your written comments (1 original and 3 copies) to one of the following addresses: Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

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

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

FOR FURTHER INFORMATION CONTACT: Teresa DeCaro, (410) 786–6604.

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Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please call: (410) 786–7197.

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I. Background

A. Statutory Basis for the Program

The purpose of this interim final rule is to establish requirements for the Medicare Prescription Drug Discount Card and Transitional Assistance Program (hereafter referred to as the ''Medicare drug discount card program''). This program was established by section 101, subpart 4, of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and is codified in section 1860D–31 of the Social Security Act (the ''Act'').

Section 1860D–31(a)(2)(A) of the Act requires us to ensure that eligible Medicare beneficiaries have access to negotiated prices for prescription drugs and transitional assistance under the Medicare discount card program within 6 months of the date of enactment of the program's authorizing statute. To enable us to meet this implementation deadline, the statute authorizes us to issue this interim final rule, which is effective immediately on an interim basis, as of the date of publication. Although the rule will be effective prior to receipt of public comments, we will accept comments on this interim final rule during a 30-day comment period and may, at a future date, revise this regulation based on the comments we receive. In addition, we will continue to monitor the implementation of this program during its operation. If we become aware of operational difficulties in the program, or of activities resulting in fraud, waste, or abuse we may revise the policies announced in this rule using appropriate procedures.

Section 105(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides for expedited implementation by—

- Exempting the Medicare drug discount card program from the requirements of the Paperwork Reduction Act, including the public comment and Federal clearance processes associated with it;
- Exempting the drug discount card program from the requirement in the Congressional Review Act for a 60-day delayed effective date for major rules (5 U.S.C. 801(a)(3)(A)), and from the requirement under the Administrative Procedure Act (5 U.S.C. 553(d)) that regulations not become effective until 30 days after their publication.
- Allowing the Secretary of the Department of Health and Human Services (hereinafter the ''Secretary'') to enter into contracts without regard to provisions of law or regulation governing the performance, amendment, or modification of contracts that may be inconsistent with furthering the Medicare drug discount card program.
- As provided under sections 105(c)(4)(A) and (B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, prohibiting judicial review of a CMS determination not to endorse a sponsor applicant and providing that, in the event any provision of section 1860D–31 of the Act is enjoined, the order will not affect the remaining provisions of section 1860D–31.

To meet the six-month implementation deadline, we will pursue a compressed timeframe for soliciting and reviewing endorsed sponsor applications.

B. Purpose of the Program

Congress intended for the Medicare drug discount card program to serve as a transitional program providing Medicare beneficiaries with immediate assistance with prescription drug costs during calendar year (CY) 2004 and CY 2005 while preparations are made for implementation of the Medicare drug benefit under Medicare part D in 2006. Medicare currently does not cover the

cost of outpatient drugs, with a few exceptions. In directing us to establish the Medicare drug discount card program, Congress sought to provide Medicare beneficiaries—particularly those lacking outpatient drug coverage—with access to negotiated prices on prescription drugs through enrollment in Medicare-endorsed drug discount card programs operated by endorsed sponsors. In addition, to help low-income beneficiaries meet their drug costs, Congress authorized up to $600 of annual transitional assistance that eligible beneficiaries may apply toward the cost of covered discount card drugs purchased under the program.

The Medicare drug discount card program is designed to increase beneficiaries' access to low-cost prescription drugs by building upon best practices in the private drug benefit market today.

C. Relationship to Medicare-Endorsed Prescription Drug Card Assistance Initiative

On September 4, 2002, we published a final rule (67 FR 56618) establishing the Medicare-Endorsed Prescription Drug Card Assistance Initiative based primarily on the educational and assistance authority in section 4359 of the Omnibus Budget Reconciliation Act of 1990 (OBRA) (Pub. L. 101–508). Similar to the Medicare drug discount card program, this initiative called for us to endorse private sector prescription drug card programs that met certain criteria, including offering Medicare beneficiaries discounted drug prices through retail pharmacy networks that met our access standards. On January 8, 2003, we posted a solicitation of application.

On January 23, 2003, the Federal Court for the District of Columbia enjoined us from proceeding with the initiative. In accordance with the court order, we withdrew the solicitation, ceased all work on the initiative, and neither received any applications nor made any endorsements on the basis of the September 4, 2002 rule.

The Medicare drug discount card program described in this rule is based on entirely different statutory authority—the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—than the 2002 initiative and has significantly different features than the earlier initiative, most notably the provision of transitional assistance to eligible beneficiaries. Therefore, parties interested in the implementation and operation of the Medicare drug discount card program should not refer to the September 4, 2002 final rule or the January 8, 2003 solicitation for guidance on the program that we will implement under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Also, by publishing this interim final rule with comment under the authority of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, we hereby withdraw the regulation and solicitation published September 4, 2002 and January 8, 2003, respectively.

II. Provisions of the Interim Final Rule With Comment Period

A. Eligibility and Enrollment

Sections 1860D–31(b)(1) and (2) of the Act establish the eligibility criteria for the Medicare drug discount card program and for transitional assistance, which we have incorporated into § 403.810(a) and § 403.810(b) of our regulations. Section 1860D–31(f)(1)(A) of the Act directs the Secretary to specify the procedures for determining a beneficiary's eligibility for the Medicare drug discount card program or transitional assistance and section 1860D–31(c)(1) directs the Secretary to establish a process for eligible beneficiaries enrolling in, and disenrolling from, an endorsed program. Sections 403.810 and 403.811 of our regulations set forth these procedures. The obligations of endorsed sponsors related to eligibility determinations and enrollment are discussed in section II.C.6 of this document.

1. Eligibility for the Medicare Prescription Drug Discount Card and Transitional Assistance Program

In accordance with section 1860D–31(b)(1) of the Act, a Medicare beneficiary is eligible for the Medicare drug discount card if the beneficiary is entitled to benefits, or enrolled, under Medicare Part A or enrolled under Medicare Part B, and does not already receive drug coverage through a State medical assistance plan under either a Title XIX program or under a demonstration program that is approved by us under sections 1115(a)(1) and (2) of the Act, hereinafter referred to as a ''section 1115 waiver demonstration.''

The benefit package available to beneficiaries enrolled in section 1115 waiver demonstrations varies, with some demonstrations offering comprehensive outpatient prescription drug coverage and others offering more limited or no outpatient drug coverage. Section 1860D–31(b)(1)(B) of the Act provides that beneficiaries entitled to ''any'' medical assistance for outpatient prescribed drugs under a section 1115 waiver demonstration are ineligible for the Medicare drug discount card program. We interpret this section as rendering ineligible for the program all beneficiaries enrolled in a section 1115 waiver demonstration program with some outpatient drug coverage, even if limited coverage. Beneficiaries enrolled in a section 1115 waiver demonstration that does not provide outpatient drug coverage are eligible for the program provided they meet all other eligibility criteria. Similarly, beneficiaries enrolled in Medicaid under title XIX of the Act who do not receive outpatient drug coverage may be eligible for the program.

We have the authority to establish procedures for eligibility determinations under section 1860D–31(f)(1)(A) of the Act. Under this authority and in the interest of promoting efficient administration of the program, we specify in § 403.810(d) of our regulations that beneficiaries determined eligible for the program will remain eligible for the entire period of their enrollment. We therefore provide in section 403.810(a) of the regulations that a beneficiary is eligible for the Medicare drug discount card program if he or she satisfies the above requirements at the time of applying to enroll in the program. Consequently, once a beneficiary has been determined eligible for the Medicare drug discount card program, he or she will remain eligible for the duration of the program unless he or she disenrolls from an endorsed program and is ineligible for a special election period that would allow the individual to enroll in another program in accordance with § 403.811(b)(2) of the regulations, as discussed below in section II.A.6, or if involuntarily disenrolled as provided in § 403.811(b)(6). If, after such a disenrollment from the Medicare drug discount card program in 2004, a beneficiary wishes to later re-enroll in the program, he or she must re-apply and re-qualify for the program for 2005.

Section 1860D–31(b)(4) directs the Secretary to issue appropriate rules addressing the eligibility of medically needy beneficiaries, as described in section 1902(a)(10)(C) of the Act, for the Medicare drug discount card program. Medically needy beneficiaries will be treated the same as all other beneficiaries applying for the program and therefore will be eligible for the program if at the time of applying for the program they meet the eligibility criteria set forth in § 403.810(a) of the regulations.

Medicare beneficiaries residing in the U.S. territories, which include American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Puerto

Rico, and Virgin Islands, are eligible to enroll in an endorsed program. Whereas Medicare beneficiaries residing in the 50 States and the District of Columbia are ineligible for the Medicare drug discount card program if they have outpatient prescription drug coverage under Medicaid or a section 1115 waiver demonstration, as provided in § 403.817(d) of our regulations and as discussed in section II.J. of this document, Medicare beneficiaries residing in the territories who also receive outpatient prescription drug coverage under Medicaid or a Medicaid section 1115 waiver are eligible for the Medicare drug discount card program.

2. Eligibility for Transitional Assistance

Under section 1860D–31(b)(2) of the Act, and as provided in § 403.810(b) of our regulations, a beneficiary is eligible to receive transitional assistance if the beneficiary is eligible for the Medicare drug discount card program and meets the following requirements:

(1) The beneficiary resides in one of the 50 States or the District of Columbia;

(2) The beneficiary's income is not more than 135 percent of the poverty line applicable to the beneficiary's family size; and

(3) The beneficiary does not have coverage for covered discount card drugs under one or more of the following sources: (a) TRICARE coverage under chapter 55 of title 10, (b) a Federal Employee's Health benefit plan under chapter 89 of title 5, or (c) a group health plan or health insurance coverage, as those terms are defined under section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), other than a plan under Medicare Part C or a group health plan or health insurance coverage consisting solely of excepted benefits, as that term is defined under section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91(c)).

The poverty line is defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), and is revised annually by the Secretary. Excepted benefits include, but are not limited to, medical supplemental insurance (Medigap insurance), limited scope dental or vision benefits, liability insurance (for example, automobile insurance), coverage for a specific disease or illness, and workers' compensation insurance.

Under section 1860D–31(f)(2)(B) of the Act, beneficiaries who have been verified as eligible for transitional assistance will be considered so eligible for the entire period of their enrollment in any endorsed program. We therefore provide in § 403.810(b) of the regulations that a beneficiary is eligible for transitional assistance if he or she satisfies the above requirements at the time of applying for transitional assistance. Thus, we specify in 403.810(d) that once a beneficiary has been determined eligible for transitional assistance, he or she will remain eligible for transitional assistance for the duration of the beneficiary's enrollment in the Medicare drug discount card program. A beneficiary will no longer be eligible for transitional assistance if he or she disenrolls from the program; specifically, if he or she disenrolls from an endorsed program and is ineligible for a special election period that would allow the individual to enroll in another endorsed program in accordance with § 403.811(b)(2) of the regulations, as discussed below in section II.A.6.

Although beneficiaries with outpatient drug coverage under a group health plan or health insurance coverage generally are ineligible for transitional assistance, as noted above, the statutory definition of transitional assistance eligible beneficiaries carves out from this exclusion outpatient drug coverage under a Part C plan described in section 1851(a)(2) of the Act or a policy consisting solely of excepted benefits. Consequently, provided that they meet all other eligibility criteria, beneficiaries with outpatient drug coverage under a Part C plan or a policy consisting solely of excepted benefits, such as Medigap, are still eligible for transitional assistance even if their employer pays all or a portion of the premium for such plans or policies.

Section 1860D–31(f)(1)(B) of the Act gives the Secretary the authority to define ''income'' and ''family size'' as it pertains to determinations of a beneficiary's eligibility for transitional assistance. Income refers to the amount, type, and ownership of income that will be counted in determining whether an applicant's income is no more than 135 percent of the poverty line for the beneficiary's family size. For purposes of the Medicare drug discount card program, we have defined ''income'' as including the components of adjusted gross income, as defined under 26 U.S.C. 62, and, to the extent not included in the components of AGI retirement and disability benefits, or, if the beneficiary is married, the sum of such income for both the beneficiary and his or her spouse.

Family size means the number of beneficiaries by which 135 percent of the poverty line must be adjusted to determine the income threshold the beneficiary's income may not exceed in order to be eligible for transitional assistance. For purposes of this program, we have defined ''family size'' as one for unmarried individuals and two for individuals who are married. This definition is based on the rules of the Supplemental Security Income (SSI) program established under title XVI of the Act. While the SSI program does not actually define ''family'' or ''family size,'' it makes eligibility determinations based in part on whether a beneficiary is single or married. The income definition above is not based on the SSI definition because the systems-based process we intend to use to determine eligibility for transitional assistance is different from the interview determination process used to determine eligibility for SSI, and from the process we will use under Part D. For this short-term program, the statute directs us to determine eligibility based on self-certification, with CMS to perform eligibility verifications via computer matching of Federal databases, as discussed below. We will not use an individual determination process as SSI uses; hence we have chosen a simpler definition than the elaborate definition SSI uses.

In section 1860D–31(f) of the Act, the statute directs us to determine eligibility based on self-certification, with CMS to verify self-certified eligibility through data matching. We have developed an information system for verifying beneficiaries' eligibility for the Medicare drug discount card program. Among other functions, this system will verify, to the extent possible, that the income of beneficiaries applying for transitional assistance does not exceed 135 percent of the poverty line for their family size. As provided in section 1860D–31(f)(3) of the Act, this system relies on income and retirement benefit information provided by the Internal Revenue Service (IRS) and the Social Security Administration, and may include additional data sources as they become available.

As part of the standard enrollment form, a beneficiary must certify, under penalty of perjury that, to the best of the beneficiary's knowledge, the information about his or her current income status and outpatient prescription drug coverage, as provided on the form, is accurate. If we are unable to conclusively verify whether an individual's income is no more than 135 percent of the poverty line for his or her family size, we may request that the beneficiary provide us with additional financial information. In § 403.810(f)(2) of our regulations, we reserve the right to make the provision of this additional information a condition of receiving transitional assistance.

Section 1860D–31(f)(3)(C)(i) of the Act gives the Secretary the authority to find

that Medicare beneficiaries eligible under title XIX as Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs), or as Qualifying Individuals (QIs) satisfy the income threshold requirement for eligibility for transitional assistance. Therefore, § 403.810(c) of our regulations specifies that these individuals by definition will be deemed to have met the income threshold requirement for transitional assistance. However, these individuals must meet the other eligibility criteria set forth in § 403.810(b) of our regulations to be determined eligible for transitional assistance.

Section 1860D–31(b)(4) directs the Secretary to issue appropriate rules addressing the eligibility of medically needy beneficiaries, as described in section 1902(a)(10)(C) of the Act, for transitional assistance. Medically needy beneficiaries will be treated the same as all other beneficiaries applying for transitional assistance and therefore will be eligible for transitional assistance if at the time of applying for transitional assistance they meet the eligibility criteria set forth in § 403.810(b) of the regulations. An individual who is already enrolled in an endorsed discount card program and subsequently qualifies for outpatient drug coverage under Medicaid as a medically needy beneficiary, will not be disenrolled or denied transitional assistance solely because he or she is now receiving outpatient drug coverage under Medicaid.

Under § 403.810(b)(2) of our regulations, residents of the territories are not eligible for transitional assistance under the Medicare drug discount card program. However, under section 1860D–31(j)(2) of the Act, and as provided in § 403.817(e) of our regulations, a territory may establish its own transitional assistance plan. As discussed in section II.J. of this document, a territory choosing to establish its own transitional assistance plan may offer transitional assistance to any individual entitled to benefits, or enrolled, under Medicare Part A or enrolled under Medicare Part B, whose income is no more than 135 percent of the poverty line for the individual's family size, regardless of whether that individual receives outpatient drug coverage under Medicaid or a section 1115 waiver demonstration.

As specified in section 1860D–31(g)(6) of the Act and provided in § 403.810(e) of our regulations, any benefits received under the Medicare drug discount card program will not be taken into account in determining a beneficiary's eligibility for, or the amount of benefits under, any other Federal program.

3. Enrollment in an Endorsed Program

Section 1860D–31(c)(1) of the Act requires the Secretary to establish a process through which beneficiaries enroll in endorsed programs. Section 403.811(a) of our regulations specifies the programmatic requirements of this process.

We anticipate that endorsed sponsors will begin enrolling eligible beneficiaries in their endorsed programs no later than six months after enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Throughout this document, when we refer to a beneficiary, enrollee, or individual in the context of taking action regarding the Medicare drug discount card program, such as applying for the discount card, transitional assistance, or reconsideration, we also mean the individual's authorized representative. This representative can complete an enrollment form on a individual's behalf, certify the accuracy of its content, authorize CMS to verify the individual's eligibility information, conduct other enrollment and disenrollment transactions, and otherwise represent the individual with regard to this program. Our regulations at § 403.806(l) specify the way endorsed sponsors must treat authorized representatives.

Under the authority in section 1860D–31(c)(1)(A) of the Act, we provide in § 403.811(a)(5) of our regulations, that an individual who is not currently enrolled in an endorsed card program can enroll in any endorsed program serving residents of their State at any time during the enrollment period. As provided in section 1860D–31(c)(1) of the Act and § 403.811(a)(6) of our regulations, an individual may only enroll in one endorsed program at a time. Relying on the authority in section 1860D–31(c)(1) of the Act, we provide in § 403.811(a)(7) of our regulations that an individual can enroll in one endorsed program per year during the enrollment period. Finally, § 403.811(a)(9) of our regulations specifies that no new enrollment or changing of endorsed card election can occur during the transition period.

Under section 1860D–31(c)(1)(A) of the Act, and as provided in § 403.811(a)(10) of our regulations, a discount card eligible individual not already enrolled in an endorsed program may enroll in any endorsed program serving residents of the State in which the beneficiary resides, with the exception of beneficiaries enrolled in certain Part C or reasonable cost reimbursement plans offering ''exclusive card programs.'' (A Part C organization as described in section 1851(a)(2)(A) of the Act that offers enrollment in a coordinated care plan or an organization that offers enrollment under a reasonable cost reimbursement plan described in section 1876(h) of the Act are hereinafter referred to as ''Medicare managed care organizations'' and the plans they offer, ''Medicare managed care plans,'' respectively.) An ''exclusive card sponsor'' is a Medicare managed care organization that offers an endorsed program with enrollment limited to members of one or more of its Medicare managed care plan(s). Under section 1860D–31(c)(1)(E) of the Act, members of Medicare managed care plans offered by exclusive card sponsors that include access to an exclusive card program as part of the plan's benefit package, may only enroll in such exclusive card programs. Medicare managed care organizations as card sponsors, including exclusive card sponsors, are discussed in section II.G. of this document.

As part of our verification system, we will verify whether each beneficiary seeking enrollment receives outpatient drug coverage under Medicaid or a section 1115 waiver demonstration, is enrolled in another endorsed program, or is a member of a Medicare managed care plan offering an exclusive card program. This system will include files provided to us by the State Medicaid programs and a database for tracking beneficiaries' enrollment and disenrollment from endorsed programs.

If a beneficiary wishes to apply for transitional assistance when he or she applies to enroll in an endorsed program, the endorsed sponsor may not enroll the beneficiary in its endorsed program until the beneficiary is determined eligible for transitional assistance. If the beneficiary is determined ineligible for transitional assistance and still wishes to enroll in the endorsed sponsor's endorsed program, the sponsor must provide the beneficiary with an opportunity to actively choose to enroll in the drug card only through enrollment processes as specified by the Secretary and permitted by the endorsed sponsor. This requirement is specified in § 403.811(a)(3) of our regulations. We create this requirement because we believe a beneficiary's eligibility or ineligibility for transitional assistance may influence his or her decision to enroll in the Medicare drug discount card program and which endorsed program he or she selects.

Section 1860D–31(c)(2) of the Act provides that endorsed sponsors may charge an annual enrollment fee up to, but no more than, $30 per year. Discount card enrollees, other than transitional assistance enrollees, must pay this fee to their endorsed sponsors. We discuss enrollment fees in greater detail in section II.C.6. of the document.

A discount card enrollee will remain enrolled in the same endorsed program for CYs 2004 and 2005 and the transition period unless the beneficiary changes endorsed programs following the annual coordinated election period, the beneficiary disenrolls, or the endorsed card program terminates, as provided in § 403.811(a)(8) of our regulations. This means that a beneficiary remaining enrolled in an endorsed program with an annual enrollment fee from CYs 2004 to 2005 is responsible for paying any new annual enrollment fee for 2005.

Section 1860D–31(c)(4) of the Act gives the Secretary the discretion to establish the date upon which access to an endorsed program's negotiated prices will take effect. We specify in § 403.811(a)(11) of our regulations that the date upon which the beneficiary can access negotiated prices is the date when a beneficiary's enrollment in an endorsed program becomes effective.

Under the Secretary's authority to develop an enrollment process under section 1860D–31(c)(1) of the Act, and as stated in § 403.814(b)(5) of the regulations, if a Medicare managed care organization limits enrollment in an exclusive card program to members of one or more of its Medicare managed care plans, we will permit the Medicare managed care organization to automatically enroll, or group enroll, into its exclusive card program eligible individuals enrolled in the Medicare managed care plan(s), unless such beneficiaries affirmatively notify the Medicare managed care organization of their desire not to enroll in its exclusive card program. Prior to group enrolling such beneficiaries in its exclusive card program, the Medicare managed care organization must notify its eligible members of its intent to do so and inform them of their right not to enroll. As provided in § 403.814(b)(6) of our regulations, a member affirmatively electing not to enroll in the exclusive card program offered as part of the benefit package available through his or her Medicare managed care plan is ineligible to enroll in any other endorsed program.

We believe our permitting group enrollment will not limit the voluntary nature of this program because section 1860D–31(c)(1)(E) of the Act restricts members of a Medicare managed care plan offering an exclusive card program to enrollment in the exclusive card program. In addition, group enrollment will not impose on these beneficiaries any unwanted cost without consent since they will have the opportunity to decline enrollment in the exclusive card program.

4. Applying for Transitional Assistance

As provided in § 403.811(a)(12) of our regulations, beneficiaries may apply for transitional assistance at the same time that they apply for enrollment in the Medicare drug discount card program, or after they have already enrolled in the program. We permit beneficiaries to apply for transitional assistance at any time because discount card enrollees may, following their enrollment in the program, have a change in their economic circumstances or outpatient drug coverage that would qualify them for transitional assistance.

Beneficiaries wishing to receive transitional assistance must complete the standard enrollment form for transitional assistance, which is described in greater detail in section II.C.6. of this document. The standard enrollment form will require the beneficiary to indicate all elements necessary to determine eligibility, including, but not limited to, the amount of the beneficiary's income (or, for married individuals, the beneficiary and spouse's combined income), the beneficiary's family size, and whether the beneficiary has outpatient prescription drug coverage under certain sources.

As required by section 1860D–31(f)(2)(A) of the Act, a beneficiary applying for transitional assistance must certify, on the standard enrollment form, under penalty of perjury or similar sanction for false statements, that to the best of the beneficiary's knowledge the information he or she provides is accurate. We therefore require in § 403.810(b)(5) of our regulations that beneficiaries wishing to receive transitional assistance sign the enrollment form. This signature represents the beneficiary's certification that the information provided on the form is accurate to the best of the beneficiary's knowledge, as well as his or her consent to our verifying the accuracy of the information provided, including verification of the beneficiary's income using Federal sources of income data. Consequently, beneficiaries wishing to apply for transitional assistance must submit to the endorsed sponsor a dated and signed enrollment form by mail or, at the endorsed sponsor's discretion, by facsimile.

a. Coinsurance

Under section 1860D–31(g)(1)(B) of the Act and as provided in § 403.808(e) of our regulations, a transitional assistance enrollee is entitled to have payment made of 90 or 95 percent, depending on the beneficiary's income, of the charges incurred for covered discount card drugs obtained through the Medicare drug discount card program, up to the total amount of transitional assistance available to that beneficiary. Transitional assistance enrollees with incomes greater than 100 percent but no more than 135 percent of the poverty line applicable to their family size are responsible for paying 10 percent of the charge for covered discount card drugs obtained under the program. Transitional assistance enrollees with income not greater than 100 percent of the poverty line applicable to their family size are responsible for paying 5 percent of the charge for a covered discount card drug.

b. Proration

Section 1860D–31(g)(2)(A) of the Act provides that transitional assistance beneficiaries may receive up to $600 each year in transitional assistance. However, section 1860D–31(g)(2)(B) of the Act permits us to prorate the amount of transitional assistance available to beneficiaries applying for transitional assistance. We do not intend to prorate transitional assistance amounts in 2004 in recognition that it may take time for our education campaign to reach all beneficiaries and that beneficiaries need sufficient opportunity to learn about the Medicare drug discount card program without penalty. As provided in § 403.808(b) of our regulations, we will prorate the transitional assistance available to eligible enrollees applying for transitional assistance in 2005 based on the beneficiary application date according to the schedule set forth in Table 1. The beneficiary application date is the date upon which the endorsed sponsor receives from the beneficiary the complete enrollment form for transitional assistance. Beneficiaries disenrolling from an endorsed program for reasons that warrant a special election period, however, are not considered to have left the transitional assistance program and are not subject to proration should they elect another endorsed program during CY 2005.

We elect to prorate transitional assistance in 2005 because we believe that, by 2005, beneficiaries will have had ample time to learn about the

Medicare drug discount card program. In addition, prorating transitional assistance encourages transitional assistance eligible beneficiaries to enroll in the Medicare drug discount card program as early as possible in order to maximize their transitional assistance amount, which in turn will increase the volume of covered discount card drugs obtained under an endorsed program and enhance an endorsed sponsor's ability to negotiate deeper discounts for discount card enrollees. We will calculate the amount of transitional assistance a transitional assistance enrollee may receive and notify endorsed sponsors of this amount.

TABLE 1.—2005 PRORATION SCHEDULE

Beneficiary application date	Amount payable
January 1–March 31, 2005	$600
April 1–June 30, 2005	450
July 1–September 30, 2005	300
October 1–December 31, 2005	150

In accordance with section 1860D–31(g)(2)(A)(ii)(II) of the Act, and as provided in § 403.808(f) of our regulations, any transitional assistance remaining available to a transitional assistance enrollee on December 31, 2004 may be rolled over to 2005 and applied toward the cost of covered discount card drugs obtained under the Medicare drug discount card program during 2005. As provided in § 403.811(b)(5) of our regulations, transitional assistance enrollees who disenroll from the Medicare drug discount card program in 2004 and who are not eligible for a special election period as provided in § 403.811(b)(2) of our regulations, however, may not rollover any unused transitional assistance if they re-enroll in the program in 2005. Any transitional assistance remaining available to a transitional assistance enrollee on December 31, 2005 may be applied toward the cost of covered discount card drugs obtained under the program during the transition period provided the transitional assistance enrollee remains enrolled in the program through the end of 2005 and during the transition period.

As required by section 1860D–31(c)(2)(E) of the Act and as provided for in § 403.808(c) of our regulations, CMS will pay to an endorsed sponsor the annual enrollment fee, if any, for its transitional assistance enrollees.

Section 1860D–31(c)(4) of the Act gives the Secretary the discretion to establish the date upon which access to transitional assistance through an endorsed program will take effect. As specified in § 403.811(a)(11) of our regulations, transitional assistance will be made available to beneficiaries determined eligible for transitional assistance beginning on the effective date of their enrollment in the transitional assistance program specified in their transitional assistance eligibility determination notice.

5. Reconsideration of Eligibility

As discussed above, section 1860D–31(f) of the Act also provides for an eligibility determination process consisting of self-certification and, at the discretion of the Secretary, verification through data matching. For beneficiaries applying for the Medicare drug discount card program, we will verify their eligibility for the program by reviewing State data, for example, on beneficiaries with outpatient drug coverage under Medicaid or a section 1115 waiver demonstration. For beneficiaries applying for transitional assistance, we will verify their income by reviewing our data on their income and other retirement and disability benefits.

Section 1860D–31(f)(4) of the Act requires the Secretary to establish a reconsideration process for beneficiaries initially determined ineligible for transitional assistance. Under our authority to establish procedures for determining beneficiaries' eligibility for the Medicare drug discount card program, as provided for in section 1860D–31(f)(1)(A) of the Act, we also will establish a reconsideration process for beneficiaries initially determined ineligible for the program. Accordingly, as provided in § 403.810(g)(1) of our regulations, every beneficiary determined ineligible for the program and/or transitional assistance can request that we reconsider this determination.

A beneficiary will be given specific instructions on how to request reconsideration when he or she is notified of our negative eligibility determination. We will provide standardized language for this notice in the information and outreach materials that will accompany the solicitation, as discussed in section II.C.7. of this document. As provided in § 403.810(g)(2) of our regulations, reconsideration requests must be filed within 60 days from date of notice of a negative eligibility determination, unless the individual can demonstrate good cause for why the 60-day time frame should be extended.

Section 1860D–31(f)(4)(B) of the Act authorizes the Secretary, and § 403.810(g)(4) of our regulations provides that the Secretary will enter into a contract for the performance of reconsiderations. We will contract with an independent entity to conduct reconsiderations on our behalf. Finally, § 403.810(g)(3) of our regulations provides that beneficiaries requesting reconsideration may provide, in writing, to our reconsideration contractor additional documentary evidence or an explanation about his or her eligibility. The reconsideration contractor will provide the beneficiary a written final eligibility determination.

6. Disenrollment and Enrollment in Another Endorsed Program

In accordance with section 1860D–31(c)(1)(D)(i) of the Act, § 403.811(b)(1) of our regulations provide that a discount card enrollee may voluntarily disenroll from an endorsed program at any time; however, such a beneficiary may only enroll in another endorsed program without having to re-apply and re-qualify under two conditions—during the annual coordinated election period or during a special election period, as described below.

Section 1860D–31(c)(1)(C)(ii) of the Act and § 403.811(a)(7) of our regulations provide that beneficiaries enrolled in an endorsed program in 2004 may elect to change endorsed programs during the annual coordinated election period from November 15 through December 31, 2004. The effective date of an enrollment election made during the annual coordinated election period will be January 1, 2005.

Under section 1860D–31(c)(1)(C)(i) of the Act, and as provided in § 403.811(a)(7) of the regulations, discount card eligible individuals generally may enroll in only one endorsed program during a calendar year. Beneficiaries voluntarily disenrolling from an endorsed program during the enrollment period, and not changing programs during the annual coordinated election period, may immediately enroll in another endorsed program during the enrollment period only under limited circumstances. Section 1860D–31(c)(1)(C)(iii) of the Act authorizes the Secretary to establish exceptions to the limitation of enrolling in only one endorsed card program per year. As specifically permitted by section 1860D–31(c)(1)(C)(iii) of the Act and as set forth in § 403.811(b)(2) of our regulations, a beneficiary disenrolling from an endorsed program for any of the following reasons is awarded a special election period and may enroll in another endorsed program at any time in the enrollment period.

(1) The beneficiary moved outside his or her endorsed program's service area;

(2) The beneficiary changed his or her residence to or from a long-term care facility;

(3) The beneficiary enrolled in or disenrolled from a Part C plan or a Medicare cost plan; or

(4) Other exceptional circumstances as determined by the Secretary.

In addition, we will permit beneficiaries to enroll in new endorsed programs if their prior endorsed program terminates or they enroll in or disenroll from a reasonable cost reimbursement plan.

We consider a discount card enrollee who disenrolls for reasons other than those provided above to have left the Medicare Drug Discount Card program entirely, as provided in § 403.810(d) of our regulations. As permitted under sections 1860D–31(c)(1)(D)(i) and (f)(2)(B) of the Act and as provided in our regulations at § 403.811(b)(4), beneficiaries voluntarily disenrolling from an endorsed program in 2004 other than for one of the above reasons, or who are involuntarily disenrolled, must re-apply as if they were new to the program for the Medicare Drug Discount Card Program for 2005 if they wish to enroll in another endorsed program. The earliest an individual may re-apply for the Medicare Prescription Drug Discount Card is during the annual coordinated election period. Because an individual may only enroll in one endorsed card program in each calendar year, as provided in § 403.811(a)(7) of our regulations, beneficiaries voluntarily disenrolling from an endorsed program in 2005, other than for one of the above reasons, or who are involuntarily disenrolled, cannot reenroll in an endorsed card program. Individuals disenrolling for any reason during the transition period cannot re-enroll.

With respect to beneficiaries enrolling in or disenrolling from a Part C plan or reasonable cost reimbursement plan, section 1860D–31(c)(1)(C)(iii) of the Act permits but does not mandate that we allow these beneficiaries to disenroll from their current endorsed program and enroll in another endorsed program during a special election period. Beneficiaries enrolling in or disenrolling from a Medicare managed care plan offering an exclusive card program will be automatically disenrolled from their endorsed programs, as they will no longer be eligible for such endorsed programs under § 403.814(b)(6)(i) of our regulations. We believe that Medicare beneficiaries entering and leaving a Part C plan or a Medicare cost plan without an exclusive card program will wish to choose an endorsed program based on the benefit package under their current health coverage, including other Part C plans and Medicare cost plans, and that this benefit package may change when beneficiaries enroll in or disenroll from a Part C plan or Medicare cost plan. To promote beneficiaries' coordination of their health benefits, we will allow beneficiaries enrolling in or disenrolling from any Part C plan or a Medicare cost plan to disenroll from their current endorsed program and enroll in another endorsed program during a special election period.

We will automatically disenroll beneficiaries from an endorsed program if their endorsed program terminates, the beneficiary enrolls in or disenrolls from a Medicare managed care plan offering an exclusive card program, or the beneficiary elects another endorsed program during the Annual coordinated election period. All other beneficiaries wishing to disenroll from their endorsed program must notify their endorsed sponsor of their intent, and, if they wish to enroll in another endorsed program during a special election period, provide the endorsed sponsor their reason for disenrollment.

As required in section 1860D–31(c)(1)(D)(ii) of the Act, and as specified in § 403.811(b)(6) of our regulations, an endorsed sponsor may involuntarily disenroll any discount card enrollee, other than a transitional assistance enrollee, if the discount card enrollee fails to pay any annual enrollment fee charged by the endorsed sponsor.

As provided in § 403.811(b)(7) of our regulations and as discussed under section II.C.6 of this document, a discount card enrollee who changes endorsed programs during a special election period may be charged a separate annual enrollment fee by the endorsed sponsor operating the newly selected endorsed program.

Under section 1860D–31(g)(2)(E) of the Act and § 403.811(b)(5) of our regulations, transitional assistance enrollees who disenroll from their endorsed programs generally will forfeit any transitional assistance remaining available to them at the time of their disenrollment. Transitional assistance enrollees who disenroll during the first year of the program and are ineligible for a special election period must re-apply and re-qualify for transitional assistance for the second year of the program should they wish to receive additional transitional assistance. The earliest an individual may re-apply for the Transitional Assistance Program for 2005 is through their re-enrollment in an endorsed card program during the annual coordinated election period. Any transitional assistance provided to these individuals during the second year of the program may be prorated depending on when they re-apply for transitional assistance in accordance with § 403.808(b) of our regulations.

Section 1860D–31(g)(2)(E) of the Act gives the Secretary the discretion to identify exceptions to this policy. As specified in § 403.808(f) of our regulations, we will permit transitional assistance enrollees who change their endorsed program during the annual coordinated election period or who enroll in another endorsed program during a special election period to carryover to their newly selected endorsed program any transitional assistance remaining available to them at the time of their disenrollment from their former endorsed program.

B. General Rules About Solicitation, Application, and Medicare Endorsement Period

We will solicit applications from entities seeking to offer beneficiaries negotiated prices on covered discount card drugs. We will endorse applicants' drug discount card programs that meet the requirements discussed below, and will permit successful applicants to market and label their programs as ''Medicare-approved.''

Although under section 1860D–31(h)(2)(D)(ii) of the Act we have the discretion to limit the number of endorsed sponsors in a State to two, we will endorse all applicants that, together with their subcontractors and other entities with which they have entered into a legal arrangement to operate an endorsed program (hereinafter collectively referred to as ''subcontractors''), meet or exceed the requirements for endorsement and sign our endorsed sponsor contract. We will also select a limited number of applicants for special endorsement. Endorsed sponsors receiving special endorsement are, for the purpose of fulfilling their responsibilities as special endorsed sponsors, exempt from meeting certain conditions of endorsement provided they agree to:

- Apply transitional assistance toward the cost of covered discount card drugs obtained from pharmacies serving residents of skilled nursing facilities and nursing facilities (hereafter referred to as ''long-term care pharmacies'') and/or pharmacies serving American Indians or Alaska Natives (AI/ANs) operated by the Indian Health Service, Indian tribe and tribal organizations, or urban Indian organizations (hereinafter referred to as ''I/T/U pharmacies''); and/or

• Offer an endorsed program in all the U.S. territories.

We will select applicants for special endorsement based on a competitive process, with consideration given to which applicants can best serve these populations. Applicants seeking special endorsement also must apply and, except in specified circumstances, meet the requirements for basic endorsement; however sponsors seeking special endorsement may request waivers of requirements, allowing, for example, an applicant to apply for special endorsement solely for the purpose of long-term care pharmacy business to the exclusion of all other types of pharmacies. The requirements and procedures related to special endorsements are discussed in further detail in sections II.I. and II.J. of this document.

Except as provided in section 403.804 (c)(2) of our regulations and discussed below in section II. O.2.C. of the preamble, we anticipate that endorsed sponsors may begin information and outreach activities, as well as enrollment activities as early as Spring 2004, and expect that these activities will begin no later than 6 months from the date of enactment of the Act; we reserve the right to terminate an endorsed sponsor's endorsement if the endorsed sponsor is not ready to fully operate its endorsed program and begin information and outreach activities by the 6 month deadline. The date upon which we will permit an endorsed sponsor to begin these activities will depend on its satisfaction of certain conditions, including—

• Finalizing pharmacy network contracts;

• Negotiating manufacturer rebates or discounts;

• Entering into an endorsed sponsor contract with us;

• Operationalizing call centers;

• Entering into all subcontracts necessary to ensure full compliance with the conditions of endorsement;

• Obtaining our approval of all information and outreach materials; and

• Establishing and obtaining CMS approval of a system for conducting electronic transactions with us (or our subcontractor), including successful testing of such system.

As stated above, we expect these requirements to be met within 6 months of enactment, and may terminate an endorsed sponsor's endorsement if the requirements are not met by this time. These requirements are discussed in greater detail below.

A solicitation for applications for Medicare endorsement under the Medicare drug discount card program will follow publication of this interim final rule. We expect to publish the solicitation on or near the date of publication of this rule. Following publication of the solicitation, potential applicants seeking clarification on the application process and requirements for endorsement may submit questions to us. In addition, we will hold a pre-application conference for potential applicants approximately 2 weeks after publication of the solicitation.

In order to ensure that we successfully implement the Medicare drug discount card program no later than 6 months after enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, we anticipate that applicants will first need to submit completed applications to CMS within 45 days after the publication date of the solicitation. Applicants must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

We will require applicants to provide with their applications certain information and test files, as specified in the solicitation. Such information and files will be used by us to expedite our implementation of the data systems necessary to support enrollment in the Medicare drug discount card program, determinations of beneficiaries' eligibility for transitional assistance, and comparison of endorsed programs negotiated prices.

Medicare endorsement of a sponsor's drug discount card will be valid for the duration of the Medicare drug discount card program, which in accordance with section 1860D–31(a)(2)(C)(i)(I) of the Act will terminate on December 31, 2005. Section 1860D–31(a)(2)(C)(ii) of the Act authorizes the Secretary to issue rules governing the transition period, including rules ensuring that the balance of any transitional assistance remaining available to a transitional assistance enrollee on January 1, 2006 remain available during the transition period. Under this authority we require endorsed sponsors to continue operating their endorsed program during the transition period, including ensuring that their card enrollees have access to negotiated prices and that transitional assistance enrollees can apply any transitional assistance remaining available to them toward the cost of covered discount card drugs obtained under the program during the transition period.

See section II.F. of this document for a discussion of termination of an endorsed sponsor's endorsement.

Section 403.804(d) of our regulations specifies that as a condition of endorsement, an endorsed sponsor must sign a contract. The contract signature will certify that the endorsed sponsor will comply with all requirements set forth in the contract, will implement its endorsed program in accordance with the program description contained in its application, and will operate its endorsed program consistent with the requirements set forth in the Act, this rule, and all other applicable Federal and State laws, including administering transitional assistance for eligible enrollees and conducting information and outreach activities consistent with our guidelines.

C. Sponsor Requirements for Eligibility for Endorsement Under the Medicare Drug Discount Card and Transitional Assistance Program

Section 1860D–31(a)(1)(A) of the Act requires the Secretary to endorse qualified applicants seeking to offer endorsed discount card programs to Medicare beneficiaries. Section 1860D–31 of the Act sets forth specific requirements that applicants must satisfy to be eligible for endorsement and that endorsed sponsors must meet to retain their endorsement. In addition, section 1860D–31(h)(8) of the Act authorizes the Secretary to prescribe additional requirements of endorsement that the Secretary concludes protect and promote the interests of beneficiaries. Accordingly, we require applicants seeking endorsement under the Medicare drug discount card program to demonstrate that they meet a series of requirements related to—

• Organizational structure and experience;

• Service area;

• Pharmacy network access;

• Administering transitional assistance;

• Prescription drug offering;

• Eligibility and enrollment processes;

• Customer service, including information and outreach;

• Grievance processes;

• HIPAA administrative simplification provisions and other marketing and security provisions;

• Document retention; and

• Data reporting to CMS.

In this section of the document we describe these conditions for endorsement.

Special rules govern Medicare managed care organizations wishing to limit enrollment in their endorsed programs to members of one or more of their Medicare managed care plans.

Rules governing these exclusive card programs are discussed in section II.G. of this document.

Applicants seeking special endorsement—that is, applicants wishing to offer an endorsed program in the U.S. territories and/or applicants willing to include within their pharmacy networks' long-term care and/or I/T/U pharmacies—also are subject to special rules, as set forth in § 403.816 and § 403.817 of our regulations and discussed in sections II.I and II.J of this document.

1. Applicant Structure and Experience

Under section 1860D–31(h)(1)(A) of the Act, the Secretary is authorized to designate the type of non-governmental entities that are appropriate to act as endorsed sponsors, which may include pharmacy benefit management companies, wholesale or retail pharmacy delivery systems, insurers (including insurers offering Medicare supplemental policies), and Part C plans. Although we have the authority to limit the types of entities that may act as endorsed sponsors, the only specific structural requirement for a sponsor is that it be a non-governmental, single legal entity doing business in the United States. We choose not to impose other structural requirements at this time because our conditions for endorsement ensure that applicants, either individually or through subcontracts, will have the necessary experience and integrity to act as endorsed sponsors. Thus, as long as an applicant can meet our conditions for endorsement through subcontracting, except as stated above, we do not mandate the legal form of the endorsed sponsor.

Although only one legal entity may act as the applicant, our regulations at § 403.804(c)(1) permit applicants to combine their capabilities with other entities in order to meet the requirements for endorsement. As further discussed below, applicants must include documentation related to their legal arrangements with subcontractors.

As specified in section 1860D–31(h)(1)(B) of the Act, an applicant is eligible for endorsement under the Medicare drug discount card program if the applicant, together with its subcontractors, has demonstrated experience and expertise in operating a drug discount card or similar program and meets certain requirements related to business stability and integrity. We interpret this provision to mean that applicants, together with their subcontractors, must: (1) Demonstrate 3 years of private sector experience in pharmacy benefit management; (2) currently serve at least 1 million covered lives; and (3) demonstrate fiscal stability and business integrity, as provided in § 403.806(a) and § 403.806(b) of our regulations. Medicare managed care organizations offering exclusive card programs, while required to comply with most of the conditions related to applicant structure, are subject to alternative requirements, as discussed in greater detail in section II.G. of this document.

a. 3 Years of Private Sector Experience

Section 403.806(a)(2) of the regulations provides that each applicant, together with its subcontractors, must have 3 years of private sector experience within the United States in the following:

- Adjudication and processing of claims at the point of sale;
- Negotiating with prescription drug manufacturers and others for rebates and discounts on prescription drugs; and
- Administration and tracking of an individual subsidy or benefit in real time.

We require that this experience must have occurred in the United States to ensure that the applicant, together with its subcontractors, is familiar with applicable Federal laws, including those enforced by the Food and Drug Administration. We believe requiring 3 years prior experience will ensure that endorsed sponsors are able to quickly establish their endorsed programs, thereby promoting implementation of the Medicare drug discount card program within 6 months of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. In addition, the 3 years prior experience requirement ensures that endorsed sponsors have the necessary experience and capacity to offer card enrollees quality discounts and customer service. Moreover, given the relative newness of the drug card industry and high market turnover, we believe requiring less than 3 years experience would create an untenable risk of having the Medicare name associated with less than stable and reputable organizations.

b. 1 Million Covered Lives

In addition to requiring 3 years of relevant experience, our regulations at § 403.806(a)(3) require that a single entity which is either the applicant or a subcontractor operate a pharmacy benefit program, a drug discount card, a low-income drug assistance program, or a similar program that serves at least 1 million covered lives.

We interpret covered lives to mean discrete individuals who have signed enrollment agreements with or paid (or have paid on their behalf) an enrollment fee or insurance premium to the applicant (or its subcontractors), or some comparable documentation. An applicant must include in its application documentation demonstrating that the applicant meets this requirement. If an applicant contracts with other entities for purposes of administering an endorsed program, the entity satisfying the 1 million covered lives requirement need not be the same entities satisfying the 3 years experience requirement. We choose not to link the 1 million covered lives requirement with the 3-year experience requirement in order to provide entities the flexibility to combine their capabilities. For example, an entity with the requisite experience may not have the enrollment capacity, but may acquire this capacity by contracting with another entity for purposes of administering the endorsed program. (A single entity, however, must meet the 1-million covered lives requirement. Therefore, an entity with 600,000 covered lives could not combine with an entity with 400,000 covered lives and meet the conditions for endorsement.)

As discussed in the impact analysis, we estimate that during the first year of the Medicare drug discount card program, over 7 million beneficiaries may wish to enroll in the program, and anticipate that endorsed sponsors should have the capacity to accept between 1 to 10 percent of this volume. This influx of Medicare beneficiaries—100,000 to several hundred thousand beneficiaries—enrolling in an endorsed program would represent a sizable expansion over most card programs' current operations. Our 6-month implementation timeline requires that endorsed sponsors be able to quickly accommodate this potentially large influx of enrollees over a relatively short period of time. Current levels of covered lives provides evidence of an applicant's immediate capacity to do so.

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 strikes a balance between ensuring a competitive marketplace with a number of different endorsed programs available to Medicare beneficiaries and ensuring that endorsed sponsors have the capacity to handle a large influx of card enrollees.

c. Demonstration of Financial Stability and Business Integrity

As required by section 1860D–31(h)(1)(B) of the Act, and as provided for in § 403.806(b)(1) of our regulations, an applicant must demonstrate the financial stability and business integrity of itself, and any of its subcontractors on which the applicant relies to—

(1) Develop the pharmacy network;

(2) Handle the negotiation of drug rebates or discounts;

(3) Administer enrollment, including transitional assistance eligibility determinations;

(4) Administer transitional assistance; or

(5) Meet the 3-years of experience and/or covered lives requirements.

The application should include the following documents or information for the applicant and each of these subcontractors:

- A summary of the entity's history, structure, and ownership, including a chart showing the structure of ownership, subsidiaries, and business affiliations;
- The most recent audited financial statements (balance sheet, income statement, statement of cash flow along with auditor's opinions, and related footnotes), which must demonstrate that the entity's total assets are greater than total unsubordinated liabilities and that the entity has sufficient cash flow to meet its obligations as they come due;
- Financial ratings, if any, for the past 3 years; and
- Listing of past or pending investigations (if known to the entity) and legal actions brought against the entity (and its parent entities, 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. The application should include a brief explanation of each action, including the following: (1) Circumstances giving rise to the action; (2) the action's status (pending or closed); and (3) if closed, details as to resolution of the action and any monetary damages.

Additionally, we plan to conduct an independent investigation of each entity, with respect to the above factors, which will include a review of Federal databases available to us that may contain information pertaining to legal issues involving the entity.

In deciding whether to endorse an applicant with a record of legal actions brought against it, we will evaluate that record based on factors that include: (1) Whether the action is a pending investigation or has resulted in a settlement or judgment against the applicant, (2) whether the settlement or judgment has been issued recently (for example, within the past 3 years), (3) whether the conduct on which the judgment or settlement was based involved allegations of fraud or abuse, (4) whether the conduct was related to reimbursement for health care services or products, and (5) whether the applicant is currently operating under a corporate integrity agreement with the DHHS Office of the Inspector General.

We require the applicant to demonstrate the business stability and integrity of the applicant and these subcontractors to ensure that we endorse only those endorsed sponsors that will be reliable, stable, and operate with integrity. We believe the specific requirements are an appropriate method for determining the business integrity and financial stability of an applicant and its subcontractors. For example, by requiring that assets exceed liabilities, we increase the likelihood that an endorsed sponsor will remain in the Medicare drug discount card program for the life of the program. Similarly, reviewing financial ratings and past or pending investigations allows us to represent to our beneficiaries that we have endorsed applicants that are financially sound and committed to a high level of business integrity.

As discussed elsewhere in this document, an applicant that is a Medicare managed care organization offering an exclusive card program will be deemed to have met these business stability and integrity requirements through its compliance with § 422.400, if a Part C plan, or §§ 417.120 and 417.122, if a Medicare cost plan.

Following its receipt of endorsement, as provided in § 403.806(b)(2) of our regulations, an endorsed sponsor (including both the applicant and its subcontractors) must continue to operate with fiscal stability and business integrity, in accordance with the same standards applicable to the applicant. Also, we require at § 403.806(c) that endorsed sponsors comply with all applicable Federal and State laws, including the Federal anti-kickback statute, section 1128B(b) of the Act (42 U.S.C. 1320a–7b(b)). As provided in § 403.806(b)(3) of our regulations, Medicare endorsement of a discount card program shall not be construed to express or imply any opinion that an endorsed sponsor or any subcontractor is in compliance with or not liable under the False Claims Act, Federal anti-kickback statute, or other laws, regulations, or policies regarding improper billing, claims submission, or related conduct.

d. Contracts With Subcontractors and Pharmacies

Although only one legal entity may act as the applicant, our regulations at § 403.804(c)(1) permit applicants to combine their capabilities with other entities in order to meet the requirements for Medicare endorsement. As will be further described in the solicitation, applicants must include documentation, including contracts or signed letters of agreement, related to their legal arrangements with these subcontractors if the applicant has combined with such entities to meet the following requirements—

- Years of experience and/or covered lives;
- Establishing a pharmacy network or home delivery through mail order;
- Negotiating manufacturer discounts or rebates;
- Conducting enrollment and transitional assistance eligibility;
- Administering transitional assistance;
- Operating the customer service call center;
- Administering a grievance process; and
- Developing information and outreach materials.

The contracts or signed letters of agreement must—

- Clearly identify the parties to the contract;
- Describe the functions to be performed by the subcontractor;
- Contain language indicating that the subcontractor has agreed to participate in the Medicare drug discount card program (except for a network pharmacy if the existing contract would allow participation in this program);
- Describe any payment the subcontractor will receive under the contract;
- Extend for the lifetime of the Medicare drug discount card program;
- Be signed and executed by representatives of each party with legal authority to bind the party;
- Require the subcontractor to comply with State and Federal privacy and security requirements applicable to the endorsed sponsor or the subcontractor, and our marketing and document retention requirements, including the requirements provided in § 403.812 and § 403.813 of our regulations and discussed in section II.C.9. of this document.

In addition, as will be further explained in the solicitation, an endorsed sponsor also must include in

its contracts with pharmacies participating in its network such terms and conditions as necessary to ensure that the endorsed sponsor meets all requirements for endorsement. This includes the requirement that subcontractors comply with all applicable Federal and State laws (including the anti-kickback law). Each application for endorsement must include one sample copy of every customized contract or letter of agreement used across the entire network. That is, we are asking to see every version of the contracts/letters of agreement across the network.

If the applicant is unable to provide with its application final versions or templates of letters of agreement or contracts that represent the exact terms and conditions under the program with each of its subcontractors and pharmacies satisfactory to CMS, the applicant may submit revised documentation following receipt of the Medicare endorsement. We expect the applicant, however, to provide such documentation no later than 6 months after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and we reserve the right to revoke endorsement if the materials are submitted later. In addition, an applicant may not commence outreach and enrollment activities prior to our receipt of such documentation and our determination that such documentation meets our requirements. The 6-month deadline and prohibition on outreach and enrollment activities may be waived for endorsed sponsors receiving special endorsement for the purpose of fulfilling obligations related to special endorsement provided such sponsors make a good faith effort to meet these documentation requirements as soon as possible, as provided in § 403.816 and § 403.817.

2. Service Area

As provided in section 1860D–31(h)(3) of the Act, if an endorsed program enrolls beneficiaries residing in any part of a State, the program must permit any discount card eligible beneficiary residing in any portion of the State to also enroll in its endorsed program. We interpret this to mean, and provide in § 403.806(f)(1) of our regulations, that a State is the smallest service area permitted under the Medicare drug discount card program. Accordingly, an endorsed program may not limit enrollment to only a portion of a State, with the exception of exclusive card programs, which, as discussed in section II.G. of this document, may limit their service area to the service area of the Medicare managed care plan(s) whose members may enroll in the exclusive card program (which may include part of a State). Further, an endorsed program's service area could be regional, meaning it operates in more than one State (contiguous or not). In addition, we define ''national'' endorsed programs as endorsed programs operating in each of the 50 States and the District of Columbia; an endorsed program that does not operate in each of the 50 States and the District of Columbia may not describe itself as a ''national'' endorsed program. Finally, an endorsed program may not operate outside of the 50 States and the District of Columbia, with the exception of sponsors receiving special endorsement permitting them to operate in the territories, as discussed in section II.J of this document.

3. Pharmacy Network Access

As provided in section 1860D–31(e)(1)(B) of the Act, an endorsed discount card sponsor must ensure that its card enrollees have convenient access to covered discount card drugs at negotiated prices by securing the participation in its network of a sufficient number of pharmacies that dispense drugs (other than solely by mail order) directly to card enrollees. Specifically, consistent with the statement of work of solicitation #MDA906–03–R–0002 of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003, we are requiring in § 403.806(f)(3) of our regulations that, at all times during the program, beginning upon the date an endorsed sponsor initiates its outreach and enrollment activities—

- In urban areas served by the endorsed program, at least 90 percent of Medicare beneficiaries, on average, live within 2 miles of a pharmacy participating in the endorsed program's network;
- In suburban areas served by the endorsed program, at least 90 percent of Medicare beneficiaries, on average, live within 5 miles of a pharmacy participating in the endorsed program's network; and
- In rural areas served by the endorsed program, at least 70 percent of Medicare beneficiaries live, on average, within 15 miles of a pharmacy participating in the endorsed program's network.

For the purposes of meeting these access standards, as also defined in the statement of work of solicitation #MDA906–03-R–0002 of the Department of Defense—

- Urban is defined as a five-digit ZIP Code in which the population density is greater than 3,000 persons per square mile;
- Suburban is defined as a five-digit ZIP Code in which the population density is between 1,000 and 3,000 persons per square mile; and
- Rural is defined as a five-digit ZIP Code in which the population density is less than 1,000 persons per square mile.

The endorsed sponsor must meet or exceed these access standards at the endorsed program level, that is, across the entire geographic region serviced by the endorsed program. Only pharmacies that are under contract and are not mail order can be included in the count.

As we will explain further in the solicitation, applicants must demonstrate their capacity to satisfy the pharmacy network access standard using mapping software, provided by us, which will compute beneficiaries' access to the pharmacies participating in the applicant's network using one hundred percent of beneficiary counts (that is, the entire beneficiary population) by zip code. These data and the population density information will be provided by CMS on request. Tables generated by the mapping software must be included with the application and must include the urban, suburban, and rural areas in each of the States covered under the applicant's drug discount card program.

As discussed in greater detail in II.J. of this document, endorsed programs receiving special endorsement to operate in the territories may exclude the territories from the calculation as to whether the endorsed sponsor meets the above pharmacy access standard.

Exclusive card programs are not required to meet these same pharmacy access standards; rather, as discussed in greater detail in section II.G. of this document, exclusive card programs will be subject to an alternative access standard.

In accordance with section 1860D–31(e)(1)(B) of the Act, § 403.806(f)(4) of the regulations provides that endorsed sponsors will not be permitted to offer a mail order only option to their card enrollees. However, because some card enrollees may prefer to obtain their drugs from mail order pharmacies, endorsed programs will be allowed to offer a home delivery option via a mail order pharmacy, in addition to including their retail pharmacy in their networks. As discussed in greater detail in II.J. of this document, we may waive this requirement to allow mail order only in the territories for endorsed programs receiving special endorsement to operate in the territories.

4. Prescription Drug Offering

a. Covered Discount Card Drugs

Endorsed sponsors must offer their card enrollees discounts on covered discount card drugs. Section 1860D–31(a)(4)(A) of the Act states that the term ''covered discount card drug'' has the same meaning given the term ''covered Part D drug'' in section 1860D–2(e) of the Act. Section 1860D–2(e), in turn, is based on sections 1927(k)(2)(A)(i), (A)(ii), and (A)(iii) of the Act. This definition is incorporated into § 403.802 of our regulations under the definition of ''covered discount card drug.'' The definition applies only to the following types of prescription drugs:

(1) FDA-approved drugs;

(2) Drugs used or sold prior to the enactment of the Drug Amendments of 1962 (Pub. L. 87–781); and

(3) Drugs described in section 107(c)(3) of the Drug Amendments of 1962 and any drug for which the Secretary has determined there is a compelling justification for its medical need.

If the Secretary has determined, in the context of the Medicaid program, that there is a compelling justification for the medical need of a drug, such drug will be incorporated into our definition of ''covered discount card drug'' for purposes of this program.

Section 1860D–2(e) of the Act also includes in the definition of ''covered discount card drug'' a biological product which (1) may only be dispensed upon prescription, (2) is licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) and (3) is produced at an establishment licensed under each section to produce that product. Vaccines licensed under section 351 of the Public Health Service Act also are ''covered discount card drugs.'' Finally, section 1860D–2(e) of the Act includes insulin in the definition of covered discount card drug.

Necessary medical supplies associated with the injection of insulin are also included in this definition. We interpret necessary medical supplies for this purpose to include syringes, needles, alcohol swabs, and gauze. We do not consider test strips or lancets to be supplies associated with injection since these supplies are more directly related to testing.

The definition of covered discount card drug includes drugs when they are used for a medically accepted indication. The term ''medically accepted indication'' is defined in section 1927(k)(6) of the Act and generally means any use of a covered drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the following compendia: American Hospital Formulary Service Drug Information; United States Pharmacopoeia-Drug Information; the DRUGDEX Information System; and American Medical Association Drug Evaluations. While we do not expect endorsed sponsors to collect diagnosis information to confirm diagnoses associated with every dispensed drug, endorsed sponsors should make an effort to responsibly comply with this provision.

Section 1860D–2(e)(2)(A) of the Act categorically excludes from the definition of ''covered discount card drug'' the following drugs or classes of drugs, or their medical uses, and we have no authority to alter this Congressional exclusion:

- Agents when used for anorexia, weight loss, or weight gain.
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.
- Outpatient drugs for which the manufacturer seeks to require associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale.
- Barbiturates.
- Benzodiazepines.

Additionally, as provided in section 1860D–2(e)(2)(B) of the Act, a drug prescribed for a card enrollee that would otherwise be a covered discount card drug will not be considered a covered discount card drug if payment for that drug, as prescribed and dispensed or administered to the card enrollee, is available under Part A or Part B of Medicare (or would be available except for application of a deductible). That is, for prescribed drugs that may be payable under Medicare Part A or Part B, Medicare participating pharmacies should bill Medicare for the drug, and not the card enrollee or, in the case of transitional assistance enrollees, the endorsed sponsor, and non-Medicare participating pharmacies should refer the beneficiary to a Medicare participating pharmacy. When a pharmacy submits a claim under Medicare Part B, the rules applicable to pharmacies' claims adjudication under Part B will apply. Only after denial of a claim submitted under Part B may a pharmacy adjudicate a claim under the Medicare drug discount card program.

Furthermore, endorsed discount card sponsors should not reconcile any claims under the Medicare drug discount card program previously rejected under Medicare Part A or Part B when the covered discount card drug was purchased by a non-pharmacy provider to provide to the card enrollee. For example, if a physician provides a drug to a card enrollee incident to an office visit that is not covered by Medicare Part B, then endorsed sponsors may not apply transitional assistance toward the cost of such drug.

b. Formulary and Minimum Prescription Drug Offerings

Studies performed for the Department of Health and Human Services (BoozAllenHamilton, *Pharmaceutical Industry Scan,* August 6, 2002) have shown that one of the primary methods pharmacy benefit management companies and insurers negotiate drug discounts is through the establishment of a formulary. Through formularies that are properly structured, pharmacy benefit management companies, in consultation with a panel of physicians, pharmacists, and other health care professionals, establish clinically appropriate, safe, and cost-effective lists of covered prescription drugs. While clinical appropriateness must be foremost in the development of a formulary, a properly designed formulary can also promote lower costs for beneficiaries as pharmaceutical manufacturers compete, using, among other things, rebates, volume discounts, and generic drugs to supply the drugs that meet the formulary requirements at the lowest price. Therefore, in § 403.806(d)(1) of our regulations, we allow endorsed sponsors to establish formularies, whereby endorsed sponsors limit the set of drugs for which a discount is offered. However, even if an endorsed sponsor uses a formulary, it must permit transitional assistance enrollees to apply transitional assistance toward the cost of any covered discount card drug, including those not on the endorsed sponsor's formulary, offered by a pharmacy contracted by the sponsor for the endorsed discount card program's network. Our past research demonstrates that allowing sponsors to use a formulary will result in deeper discounts for card enrollees, and enhanced use of generic drugs, and we therefore have the authority to permit such formularies under section 1860D–31(h)(8) of the Act, as larger discounts and reduced prescription drug costs promote the interests of card enrollees.

While we recognize the useful role of formularies in providing discounts to beneficiaries, we also want to insure that sponsors, in constructing their formularies, include, at a minimum, the types of drugs commonly needed by beneficiaries. In establishing a minimum requirement, it is not our intention to build the operating framework of a sponsor's formulary, but rather to present a floor, as we believe a minimum requirement is better than none at all. As provided in § 403.806(d)(2) of our regulations and consistent with promoting and protecting beneficiaries as specified in section 1860D–31(h)(8) of the Act, each endorsed discount card program will be required to provide a negotiated price for at least one drug in each of the lowest level categories under each of the therapeutic groupings (hereafter, collectively referred to as ''categories'') representing the drugs commonly needed by Medicare beneficiaries as listed in Table 2. This minimum requirement in no way precludes sponsors from adding additional categories or differentiating the categories we provide as they construct their formularies. In fact, we anticipate that sponsors would do that through their usual process involving a pharmacy and therapeutics committee. The categories in Table 2 were structured to ensure that beneficiaries enrolling in Medicare-endorsed discount card programs will be offered discounts on many of the types of drugs most commonly needed by the Medicare population. There are a total of 209 categories (represented in italics within the table) for which card sponsors are required to offer a drug at a negotiated price. 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 negotiated price for a drug in a category.

Moreover, under the rationale that discounts on commonly used generic drugs are also typically made available under current industry practice, and that offering discounts on generics improves beneficiary understanding of sources of prescription drug discounts, we are requiring that endorsed sponsors provide discounts on a range of generic drugs. Specifically, sponsors must provide at least one generic drug for a negotiated price in at least 55 percent of the required categories (italicized in Table 2). Fifty-five percent represents about 95 percent of those categories that include a Class A generic drug according to the FDA's Orange Book.

We believe it is important that the Medicare name be associated only with endorsed programs that offer at least the types of drugs commonly needed by Medicare beneficiaries, while still maintaining the ability to negotiate discounts. Thus, we believe that requiring at least one drug per category, including generic drugs, strikes the proper balance between achieving drug discounts for card enrollees and offering some assurance that discounts will be available for the drugs Medicare enrollees most commonly need.

It is important to note that endorsed sponsors have the flexibility to provide negotiated prices on as many drugs as they choose beyond the minimum number and types needed to satisfy this endorsement qualification criterion, and we expect that many endorsed sponsors will choose to do so in order to make their discount cards attractive to beneficiaries.

We employed a contractor to provide technical assistance to develop the list of categories in Table 2.[1] The following set of principles served to guide a comprehensive approach to develop the list of categories:

- The category list is based on covered discount card drugs, as defined in section 1860D–2(e) of the Act, and also represents the types of drugs commonly needed by Medicare beneficiaries, as determined through analyses of survey data from the 2000 Medicare Current Beneficiary Survey, 2002–2003 Scott Levin-Verispan pharmacy data, and Food and Drug Administration information.
- One category list will set minimum requirements for discount card offerings, regardless of whether an enrollee has access to transitional assistance funds. Importantly, provided that the drug is offered at the pharmacy, enrollees with transitional assistance can use these funds to purchase covered discount card drugs for which no discount is provided.
- A given category could not contain only a single drug.
- The list is intended to wrap around rather than represent existing Medicare Part B outpatient drug coverage.[2] As such, drugs, biologicals, and vaccines administered in physician offices, hospital outpatient departments, dialysis centers, or provided outside of retail pharmacies were not reviewed unless they also can generally be obtained through retail pharmacies and appeared in data sources used to identify drugs commonly used by Medicare beneficiaries.
- In compliance with section 1860D–2(e) of the Act, non-covered discount card drugs were excluded from review.

To develop the listing of therapeutic categories of drugs most commonly needed by Medicare beneficiaries, we first analyzed drug utilization and expenditure data from the 2000 Medicare Current Beneficiary Survey (MCBS), a CMS-sponsored continuous, multipurpose survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries, to produce lists of the top 200 drugs used based on number of prescriptions and the top 200 drugs used based on expenditures. Separate lists were compiled for elderly enrollees and disabled enrollees to ensure that important drugs for both populations were captured.

We supplemented the list of commonly used drugs derived from the Medicare Current Beneficiary Survey by analyzing commercial datasets (Scott-Levin/Verispan Source Prescription Audit (SPA) and Physician Drug & Diagnosis Audit (PDDA)) for other commonly used drugs in the elderly populations. These data provide a comprehensive overview of the national performance of all prescription drugs dispensed by retail pharmacies for the 12-month period ending in May 2003. Utilization share percentages for people age 65 and over were applied to the data. Out of this data set, we obtained the top 200 drugs used based on number of prescriptions and the top 200 drugs used based on expenditures for the age 65 and over group. Prescription data is electronically collected on a monthly basis from approximately 35,000 U.S. retail pharmacies, including chains, independents, mass merchandisers, and food stores. It is estimated that SPA data cover approximately 70 percent of all dispensed prescriptions in the U.S. The Scott-Levin PDDA database includes data from approximately 365,000 office-based physicians in 29 specialties. Finally, to ensure that our list of commonly used drugs included new drugs and excluded retired and over-the-counter drugs (where over-the-counter drug is defined in our regulations at § 403.802 to mean non-prescription drug), we consulted current Food and Drug Administration (FDA) materials, including the FDA's ''Additions/Deletions for Prescription and OTC Drug Product Lists'' for June 2002 through July 2003.

After the list of drugs commonly needed by Medicare beneficiaries was

[1] Contract 500–02–0024 Modification #3, AMS, subcontracted to Navigant Consulting and Independent Pharmaceutical Consultants, Inc. *Identification of Baseline Therapeutic Categories for the Medicare Drug Discount Card Program.* December 5, 2003.

[2] Medicare coverage of outpatient drugs under Part B is principally for certain drugs and biologicals used in dialysis, cancer treatment, organ transplantation, certain vaccines and drugs used with DME such as infusion pumps and nebulizers.

finalized, we assigned therapeutic class codes and sorted each drug into therapeutic classes. We accomplished this by using an enhanced classification tool made available from First DataBank. The First DataBank Enhanced Therapeutic Classification System (ETC) [3] provides a method for classifying drugs and drug products into classes and sub-classes using a parent-to-child relationship hierarchy. Using a combination of identifiers and formulation-based and name-based drug concepts, the system provides for maximum flexibility and allows for categorization of drugs into more than one therapeutic classification as necessary. The drugs were assigned to therapeutic categories and sub-categories based on National Drug Code and/or drug short name. The classification tool was then used to sort the listing of commonly used drugs according to therapeutic categories and sub-categories. The category list then underwent the following steps:

- It was reviewed for major therapeutic classes that did not appear in the listing. In addition, non-covered discount card drugs were eliminated and drugs covered under Part B were flagged.
- The revised draft classification and sub-classification system was reviewed by a pharmacy team, external to CMS, consisting of 5 PhD and clinical pharmacists, and two geriatricians/internists, to determine the level of specificity required to ensure that the types of medications required by Medicare beneficiaries are represented. The category list was also compared with several commercial formulary categorization schemes.
- Several non-CMS internal medicine physicians with specialties in geriatrics and several non-CMS specialists with expertise in serving Medicare beneficiaries, reviewed the specifications and drugs listed to ensure that the category list represents types of drugs that are commonly needed by the Medicare population, and to provide the guidance concerning the drugs they routinely prescribe to Medicare beneficiaries in their areas of specialization, for the consideration of sponsors in their development of formularies for the Medicare drug discount card program. A total of 11 physicians took part in this review process.
- CMS clinicians, including 2 pharmacists and a physician, conducted a final review of the categories. We then finalized the categories based on this input.

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[3] According to First DataBank, the following sources were used in the compilation of data for the ETC: American Hospital Formulary Service (AHFS) Drug Information, Pharmacotherapy: A Pathophysiologic Approach, Martindale: The Extra Pharmacopeia, Applied Therapeutics: The Clinical Use of Drugs, Goodman and Gilman's The Pharmacological Basis of Therapeutics, Harrison's Principals of Internal Medicine, The Merck Manual of Diagnosis and Therapy, Current Medical Diagnosis and Treatment, The Merck Index, and manufacturer package inserts.

Table 2 Therapeutic Classes and Subclasses/Groups for Medications Frequently Used by Medicare Beneficiaries

Analgesic, Anti-inflammatory or Antipyretic
- Analgesic, Anti-inflammatory or Antipyretic - Non-Narcotic
  - NSAID's
    - *Cyclooxygenase Inhibitors Non-Selective and Combinations*
    - *Cyclooxygenase-2 (COX-2) Selective Inhibitors and Combinations*
  - *Salicylates and Salicylate Combinations*
  - *Analgesic or Antipyretic Non-Narcotic and Combinations*
  - *Disease Modifying Anti-Rheumatoid Drugs (DMARD)*
- Analgesics - Narcotic
  - Analgesic Narcotic Agonists and Combinations
    - *Analgesic Narcotic Agonists*
    - *Analgesic Narcotic Agonist Combinations*
    - *Analgesic Narcotic Partial/Mixed Agonists and Combinations*

Anorectal Preparations
- *Anorectal - Glucocorticoids*
- *Rectal/Lower Bowel- Glucocorticoids*

Anti-Infective Agents
- Antibacterial Agents
  - *Aminoglycosides*
  - *Antibacterial Folate Antagonists*
  - *Antibacterial Nitrofuran Derivatives and Combinations*
  - Antimycobacterial Agents
    - *Antitubercular Agents*
    - *Antileprotic Agents*
  - BetaLactam Antibiotics
    - *Penicillins*
    - *Cephalosporins*
  - *Glycopeptide Antibiotics (Vancomycin)*
  - *Lincosamides*
  - *Macrolides and Combinations*
  - Quinolones
    - *Fluoroquinolones and Combinations*
  - Tetracyclines and Combinations
    - *Tetracyclines*
- Antifungals
  - *Antifungal - Amphoteric Polyene Macrolides*
  - *Antifungal - Azole Agents*
  - *Antifungal Other*
- Antivirals
  - *Antiretrovirals*
  - *CMV Agents*
  - Hepatitis Agents
    - *Hepatitis B Treatment Agents*
    - *Hepatitis C Treatment Agents*
  - *Herpes Agents*
- Antiparasitics
  - *Antiprotozoal*

Antiprotozoal/Antibacterial Agents
Antiprotozoal/Antibacterial - Nitroimidazole Derivatives
Antineoplastics
Alkylating Agents
Antimetabolites
Antimetabolite - Folic Acid Analogs
Antimetabolite - Purine Analogs
Antimetabolite - Pyrimidine Analogs
Antimetabolite - Urea Derivatives
Antineoplastic - Hormone/Hormone Antagonist Agents
Antineoplastic - Antiandrogens
Antineoplastic - Aromatase Inhibitors
Antineoplastic - Selective Estrogen Receptor Modulators (SERMs)
Antineoplastic - Progestins
Chemotherapy Rescue/Antidote Agents
Cardiovascular Therapy Agents
Angina Therapy
Antianginal - Coronary Vasodilators (Nitrates) and Combinations
Antiarrhythmics
Antiarrhythmic - Class I
Antiarrhythmic - Class I-A
Antiarrhythmic - Class I-C
Antiarrhythmic - Class II
Antiarrhythmic - Class III
Antiarrhythmic - Class IV
Antihyperlipidemics
Antihyperlipidemic - Bile Acid Sequestrants
Antihyperlipidemic - Fibric Acid Derivatives
Antihyperlipidemic - HMG CoA Reductase Inhibitors
Antihyperlipidemic - Nicotinic Acid Derivatives
Antihyperlipidemic Agents Other (including ZETIA)
Beta Adrenergic Blockers
Beta Blockers Cardiac Selective, All
Beta Blockers Non-Cardiac Selective, All
Alpha-Beta Blockers
Calcium Channel Blockers
Calcium Channel Blockers - Benzothiazepines
Calcium Channel Blockers - Dihydropyridines
Calcium Channel Blockers - Phenylakylamines
Cardiac Inotropes
Diuretics
Diuretic - Loop and Combinations
Diuretic - Potassium Sparing Diuretics and Combinations
Diuretic - Potassium Sparing (Single Agent), All
Diuretic - Potassium Sparing in Combination
Diuretic - Thiazides and Related, and Combinations
Antihypertensive Therapy Agents
ACE Inhibitors
Angiotensin II Receptor Blockers (ARBs)
Antihypertensive Therapy Combinations
Central Alpha-2 Receptor Agonists
Peripheral Alpha-1 Receptor Blockers

Pulmonary Antihypertensive Agents
Vasodilators
Direct Acting Vasodilators
Central Nervous System Agents
Attention Deficit-Hyperact Disorder (ADHD) Therapy
Attention Deficit-Hyperactivity (ADHD) Therapy, Stimulant-Type
Antianxiety Agents
Antianxiety Agent - Antihistamine Type
Antianxiety Agent - Non-Benzodiazepine
Anticonvulsant
Anticonvulsant - Carboxylic Acid Derivatives
Anticonvulsant - Hydantoins
Anticonvulsant - Iminostilbene Derivatives
Anticonvulsant Others
Antidepressants
Antidepressant - Alpha-2 Receptor Antagonists (NaSSA)
Antidepressant - Monamine Oxidase (MAO) Inhibitors
Antidepressant - Norepinephrine & Dopamine Reuptake Inhibitors (NDRIs)
Antidepressant - Serotonin-2 Antagonist/Reuptake Inhibitors (SARIs)
(1) *Antidepressant - Selective Serotonin & Norepinephrine Reuptake Inhibitors (SSRIs & SNRIs)*
Antidepressant - Tricyclics & Related (Non-Select Reuptake Inhibitors)
Antidepressant Combinations
Antimanic Agents
Antiparkinson Therapy
Antiparkinson Therapy - Anticholinergic Agents
Antiparkinson Therapy - Dopaminergic
Antiparkinson's Adjuvants
Antiparkinson Combination Agents
Antipsychotics
Antipsychotic - Dopamine Antagonists
Antipsychotic - Dopamine/Serotonin Antagonists
Antipsychotic - Atypical Agents, General
Migraine Therapy
Migraine Therapy - Serotonin Agonists
Migraine Therapy - Carboxylic Acid Derivatives
Sedative/Hypnotics
Chemical Dependency, Agents to Treat
Smoking Deterrents and Combinations
Cognitive Disorder Therapy
Cognitive Disorder Therapy - Antidementia
Antidementia - Cholinomimetics (ACHE Inhibitors)
Dermatological
Acne Therapy
Acne Therapy Topical
Dermatological - Anti-infectives
Dermatological - Antibacterials
Dermatological - Antifungals
Dermatological - Anti-infective Combinations
Dermatological - Antineoplastic or Premalignant Lesions
Dermatological - Antipruritics
Dermatological - Antiseborrheic Products and Combinations
Dermatological - Burn Products

Dermatological - Emollients and Combinations
Dermatological - Glucocorticoids and Combinations
Dermatological - Keratolytics/Antimitotics
Dermatological - Protectants and Combinations
Dermatological - Rosacea Therapy, Topical
Electrolyte Balance/Nutritional Products
Prenatal Vitamins and Combinations
Endocrine
Corticosteroids
Glucocorticoids and Combinations
Androgen-Anabolic
Anabolic Steroids
Estrogens and Combinations
Estrogens
Estrogen Combinations
Progestins
Diabetic Therapy
Insulin
Insulin - Human and Combinations
Oral Antidiabetic Agents
Alpha-Glucosidase Inhibitors
Oral Antidiabetic - Biguanides
Oral Antidiabetic - Insulin-Release Stimulant Type
Insulin Response Enhancers
Oral Antidiabetic Combinations
Hyperglycemic Agents and Combinations
Thyroid Therapy
Thyroid Hormones and Combinations
Anterior Pituitary Hormones and Hormone Antagonists
Calcium & Bone Metabolism Regulators
Posterior Pituitary Hormones
Antidiuretic and Vasopressor Hormones
Prolactin Inhibitors
Gastrointestinal Therapy Agents
Gastrointestinal Antispasmodics
GI Antispasmodic - Belladonna Alkaloids
GI Antispasmodic - Quaternary Ammonium Compounds
GI Antispasmodic - Synthetic Tertiary Amines
GI Antispasmodic Combinations
Peptic Ulcer Therapy
Peptic Ulcer - Antisecretory Agents
Peptic Ulcer - H-2 Antagonists
Peptic Ulcer - Proton Pump Inhibitors
Peptic Ulcer - Cytoprotectives
Peptic Ulcer - Prostaglandin Analogues
Peptic Ulcer Therapy Combinations
Antacids and Combinations
Antidiarrheals
Laxatives
Laxative - Saline and Osmotic
Laxative - Surfactant
Laxative Combinations

Antiemetics
Antiemetic - Antihistamines and Antihistamine Combinations
Antiemetic - Phenothiazines
Antiemetic - Selective Serotonin 5-HT3 Antagonists
Gastrointestinal Prokinetic Agents
Gallstone Solubilizing Agents and Combinations
Colonic Acidifier (Ammonia Inhibitor)
Inflammatory Bowel Agents
Phosphate Binders
Digestive Aids
Genitourinary Therapy
Urinary Anti-infectives
Urinary Antibacterials
Urinary Antibacterial - Quinolones
Urinary Antibacterial - Nitrofuran Derivatives
Urinary Antispasmodics
Urinary Antispasmodic - Anticholinergics
Urinary Antispasmodic - Smooth Muscle Relaxants
Urinary Antispasmodic Combinations
Urinary Ph Modifiers
Urinary Ph Modifier - Alkalinizers
Urinary Analgesics
Prostatic Hypertrophy Agents
Prostatic Hypertrophy Agent - 5-Alpha Reductase Inhibitors
Gout and Hyperuricemia Therapy
Gout - Acute Therapy
Hyperuricemia Therapy
Gout and Hyperuricemia Combination Drugs
Hematological Agents
Anticoagulants
Hematopoietic Agents
Hematopoietic Agents - Hematopoietic Growth Factors
Erythropoietins
Granulocyte Colony-Stimulating Factor (G-CSF)
Granulocyte/Macrophage Colony-Stimulating Factor (GM-CSF)
Hematorheologic Agents
Platelet Aggregation Inhibitors & Combinations
Immunosuppressive Agents

Impotence Agents

Locomotor System
Musculoskeletal Therapy Agents
Skeletal Muscle Relaxants
Skeletal Muscle Relaxant - Central Muscle Relaxants
Skeletal Muscle Relaxant Combinations
Neuromuscular Therapy Agents
Neuromuscular Therapy Agents - ALS Agents
Mouth/Throat/Dental - Preparations
Mouth and Throat - Anti-infectives
Mouth and Throat - Antifungals
Mouth and Throat - Glucocorticoids

Multiple Sclerosis Agents

Ophthalmic Agents
- Ophthalmic - Anti-infectives
  - Ophthalmic Antibacterial
    - *Ophthalmic - Fluoroquinolones*
    - *Ophthalmic - Macrolides*
    - *Ophthalmic - Steroidal Antibiotics*
  - *Ophthalmic Anti-infective Combinations*
- Ophthalmic - Anti-inflammatory
  - *Ophthalmic - Anti-Inflammatory, Glucocorticoids*
  - *Ophthalmic - Anti-Inflammatory, NSAIDs*
- Ophthalmic - Antiallergy
  - *Ophthalmic - Antihistamines*
  - *Ophthalmic - Mast Cell Stabilizers*
- Ophthalmic - Intraocular Pressure Reducing Agents
  - *Ophthalmic - Selective Alpha Adrenergic Agonists*
  - *Ophthalmic - Beta-blockers*
  - *Ophthalmic - Prostaglandin Analogs*
  - *Ophthalmic - Miotics*
  - *Ophthalmic - Carbonic Anhydrase Inhibitors*
  - *Ophthalmic - Intraocular Pressure Reducing Combinations*
- Ophthalmic - Mydriatics and Cycloplegics
  - *Ophthalmic - Anticholinergics*
- Ophthalmic Combinations
  - *Ophthalmic - Anti-infective/Anti-inflammatory Combinations*

Otic
- Otic Combinations
  - *Otic - Anti-infective/Glucocorticoid Combinations*

Respiratory Therapy Agents
- Antihistamines
  - *Antihistamines - 1st Generation*
  - *Antihistamines - 2nd Generation*
- Asthma Therapy Agents
  - *Asthma Therapy - Anticholinergics*
  - *Asthma Therapy - Beta Adrenergic Agents*
  - *Asthma Therapy - Glucocorticoids*
  - *Asthma Therapy - Leukotriene Modulators*
  - *Asthma Therapy - Xanthines*
  - *Asthma Therapy Combinations*
- Nasal Preparations
  - *Nasal Anti-infectives*
  - *Nasal Antiallergy*
  - *Nasal Anticholinergics*
  - *Nasal Corticosteroids*

Vaginal Products
- Vaginal Anti-infectives
  - *Vaginal Antifungals*
- *Vaginal Estrogens*

Footnotes:

(1) Combined category, not part of First DataBank therapeutic classification system.

Notes:

Non-italicized categories represent therapeutic class titles or headings. Endorsed sponsors will not be required to provide drugs in these categories.

Italicized categories represent those categories where an endorsed sponsor must provide at least one prescription drug at a discount within the category.

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In the interest of protecting beneficiaries' health, we believe there are several issues applicants should consider in developing their formularies, if they plan to use one. First, there are several medications that are not widely recommended for use in the elderly population based on their potential to cause adverse outcomes (Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. *Arch Intern Med.* 1997; 157:1531–1536). However, under certain clinical conditions, some of these medications may be appropriate for use in the elderly population. Endorsed sponsors should evaluate whether or not to include these drugs on their formularies, as well as ways in which to help reduce the potential for adverse drug reactions, described further in section II.C.7. of this document.

Second, another key area for consideration by endorsed sponsors is the importance of ensuring that negotiated prices are available to special populations. Certain groups, such as beneficiaries who are HIV positive, beneficiaries with a mental illness, and beneficiaries with cancer may require treatment with a variety of specific medication combinations, which may not be easily substitutable. The medical treatment of these beneficiaries and other special populations may be significantly compromised if discounts are not made available on particular medications that they require.

Finally, we believe endorsed sponsors should consider ensuring that there are appropriate selections and dosage forms of drugs within each class or subclass as needed (for example, long-acting versus short-acting). In some cases, this might require more than one drug to satisfy a single subclass or group. Specifically, there are several therapeutic classes that contain both short-acting and long-acting medications. These medications commonly come in both standard oral dosage forms and time-release dosage forms.

We are requesting that applicants address these issues in their applications if they will use a formulary so that we may have a fuller understanding of how drug discount card programs will address the needs of Medicare beneficiaries.

c. Pricing

As provided in sections 1860D–31(e)(1)(A) and 1860D–31(h)(4) of the Act, and cited in § 403.806(d)(1) of our regulations, each endorsed sponsor will be required to provide card enrollees access to negotiated prices on covered discount card drugs. Section 1860D–31(e)(1)(A)(ii) of the Act defines negotiated prices as taking into account negotiated price concessions (such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations) for covered discount card drugs, and includes any dispensing fees for such drugs. Thus, as a general matter, to the extent discounts, rebates, subsidies or other price concessions are obtained by endorsed sponsors, the negotiated prices must take these concessions into account and some of the concessions should be shared with beneficiaries in the form of lower prices.

In addition, section 1860D–31(i) of the Act specifically requires that endorsed sponsors disclose to us the percentage of manufacturer price concessions or rebates passed on to Medicare beneficiaries, with section 1860D–31(h)(4) of the Act requiring endorsed sponsors to pass these savings on to card enrollees. We interpret these provisions as reflecting Congressional intent that endorsed sponsors meet the threshold of obtaining some level of manufacturer rebates, discounts, or other price concessions on some covered discount card drugs. In addition, we believe requiring endorsed sponsors to obtain manufacturer rebates, discounts, or other price concessions on some covered discount card drugs will promote and protect the interests of Medicare beneficiaries.

Therefore, as stated in § 403.806(d)(6) of our regulations, as a condition of endorsement, endorsed sponsors must obtain manufacturer rebates, discounts, or other price concessions on at least some covered discount card drugs.

In requiring endorsed sponsors to disclose to us the extent to which they pass through to card enrollees manufacturer discounts, rebates or other remunerations or price concessions, section 1860D–31(i) of the Act anticipates that endorsed sponsors might not pass through to card enrollees 100 percent of such manufacturer price concessions. We therefore interpret section 1860D–31(h)(4) of the Act as requiring endorsed sponsors to pass through to card enrollees some, but not necessarily all, of these price concessions. Rather than establish minimum quantitative requirements for either the level of manufacturer rebates, discounts, or other price concessions endorsed sponsors must obtain or the share of such price concessions that must be passed through to card enrollees, we will allow endorsed sponsors to determine this in light of their understanding of consumer preferences and the impact of market forces on their business model. Research conducted for us has shown that pharmacy benefit managers frequently obtain and pass through substantial manufacturer rebates for their commercial populations (BoozAllenHamilton, *Pharmaceutical Industry Scan,* August 6, 2002). In addition, we believe that market competition will encourage endorsed sponsors to pass through to enrollees a high percentage of the rebates, discounts, or other remuneration or price concessions. In particular, our price comparison Web site, discussed in greater detail in section II.E. of this document, will promote competition by allowing beneficiaries to compare maximum negotiated prices for drugs under different endorsed programs. Further, as described below, endorsed sponsors' negotiated prices for covered discount card drugs will not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C) of the Act. We therefore anticipate that endorsed sponsors will pass a substantial share of manufacturer price concessions through to beneficiaries in the form of negotiated prices at the point of sale. We have chosen not to establish minimum threshold levels for manufacturer price concessions because doing so could have the unintended effect of undercutting market competition as endorsed sponsors might cluster their drug price offering around that threshold.

We believe this approach provides endorsed sponsors with maximum flexibility within the basic program requirement in designing their endorsed program and negotiating price concessions with a broad range of manufacturers at levels that are commensurate with the structure of their endorsed programs.

In recognition of current industry practice, we anticipate that the level of discount offered to card enrollees will vary across the full complement of covered discount card drugs offered at negotiated prices. Moreover, as provided in § 403.806(d)(4) of our regulations, prices may vary across pharmacy contracts. We believe it is necessary to permit such price variation in order to provide endorsed sponsors sufficient flexibility to accommodate local market conditions and competition. As part of our educational efforts, we will explain to beneficiaries the possibility of price variation by pharmacy, and expect endorsed sponsors to do the same.

Additionally, we will allow endorsed sponsors to vary prices and formularies by enrollee characteristics, such as transitional assistance eligibility status, to offer lower negotiated prices to low-

income card enrollees, or card enrollees with a particular disease. We believe this flexibility promotes the objective of improving beneficiaries' access to prescription drug discounts by allowing card sponsors to structure formularies and prices for these populations for whom prescription drug expenses are a significant burden. An endorsed sponsor choosing to incorporate this flexibility into its endorsed program must ensure that its alternative offerings do not restrict any card enrollee's access to its basic option should the card enrollee not wish to participate in the alternative offering.

Further, CMS recognizes that endorsed sponsors may change their negotiated prices over time for legitimate business purposes. However, because beneficiaries are generally locked into the endorsed program of their choice for a calendar year, we would not want beneficiaries to enroll in cards with unrealistically low advertised prices, only to see those prices arbitrarily increase in subsequent weeks or months. Therefore, as provided in § 403.806(d)(9) of our regulations, we require that, except during the week of November 15, 2004, (which coincides with the beginning of the annual coordinated election period), endorsed sponsors must ensure that any increase in the negotiated price does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to the changes in the endorsed sponsor's cost structure, including material changes to any discounts, rebates, or other price concessions the endorsed sponsor receives from a pharmaceutical manufacturer or pharmacy. We will monitor whether negotiated prices decline in proportion to decreases in AWP.

As discussed in section II.C.7. of the document, an endorsed sponsor must make available to its card enrollees, over its customer service telephone line, upon request, information about negotiated prices.

Under section 1860D–31(h)(8) of the Act, and as provided in § 403.806(d)(7) of our regulations, endorsed sponsors must ensure that card enrollees are charged at the point of sale the lower of the negotiated price or the pharmacy's usual and customary price for a covered discount card drug. We expect an endorsed sponsor to arrange with its network and mail order pharmacies that if, at time of purchase, a drug's usual and customary price is lower than the negotiated price under the endorsed sponsor's endorsed program, the pharmacy will make available to card enrollees the lower usual and customary price.

Additionally, as provided in section 1860D–31(d)(3) of the Act and stated in § 403.806(d)(8) of our regulations, endorsed sponsors are required to ensure that pharmacies inform card enrollees of any differential between the price of the covered discount card drug to the card enrollee and the price of the lowest priced generic drug that is therapeutically equivalent and bioequivalent and available at that pharmacy. This information must be provided at the time the card enrollee purchases the drug, or in the case of drugs purchased by mail order, at the time of delivery of that drug. As permitted under sections 1860D–31(d)(3)(B) and 1860D–31(g)(5) of the Act, for the reasons discussed in section II.I. of this document, we exempt from this requirement covered discount card drugs obtained from long-term care pharmacies or I/T/U pharmacies.

As provided in section 1860D–31(e)(1)(D) of the Act, the prices negotiated for covered discount card drugs under an endorsed discount card program (notwithstanding any other provision of law) will not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C) of the Act. Section 103(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amends section 1927(c)(1)(C)(i) of the Act by adding a new subparagraph (V) to exclude from best price any negotiated prices charged under an endorsed program. This exemption applies only to prices obtained from a drug manufacturer for the ingredient cost of the drug under the Medicare drug discount card program; prices negotiated for discount cards that are not Medicare endorsed programs would not meet the criteria of the exemption. Furthermore, since this rule relates to the Medicare drug discount card program, the rule does not address application of the best price rules to non-endorsed drug discount cards. We will not codify into regulation the statutory exemption from best price for negotiated prices under endorsed programs because we do not currently have regulations implementing section 1927(c)(1) of the Act.

d. Transitional Assistance

As discussed under section II.A. of this document, certain low-income Medicare beneficiaries enrolled in the Medicare drug discount card program will be eligible to receive transitional assistance of up to $600 per year, which may be applied toward the cost of covered discount card drugs obtained under the program.

Section 1860D–31(h)(1)(C) of the Act requires endorsed sponsors to administer the transitional assistance on our behalf and to demonstrate to the Secretary that they have satisfactory arrangements that account for the transitional assistance provided to transitional assistance enrollees. Therefore, as stated in § 403.806(e) of our regulations, endorsed sponsors must:

- Establish accounting procedures to manage the transitional assistance funds;
- Ensure that transitional assistance is applied toward the lower of a covered discount card drug's negotiated price (if any) or usual and customary price;
- Permit transitional assistance enrollees to apply transitional assistance toward the cost of any covered discount card drug obtained under the endorsed sponsor's endorsed program, regardless of whether that drug is on the endorsed sponsor's formulary (if any) or whether a discount has been negotiated for that drug.
- As required under section 1860D–31(d)(2)(C) of the Act, make available electronically or by telephone at the point-of-sale of covered discount card drugs the amount of transitional assistance remaining available to the transitional assistance enrollee; and
- As required under section 1860D–31(d)(2)(B) of the Act and discussed in section II.C.7. of this document, endorsed sponsors should inform transitional assistance enrollees of the endorsed sponsor's toll-free telephone number where they can obtain information on the amount of transitional assistance available to them.

In tracking the amount of transitional assistance available to transitional assistance enrollees, endorsed sponsors must take into account that any transitional assistance remaining available to a beneficiary on December 31, 2004 should be rolled over to 2005 and applied toward the cost of covered discount card drugs obtained under the program during 2005, and any transitional assistance remaining available to a beneficiary on December 31, 2005 may be applied toward the cost of covered discount card drugs obtained under the program during the transition period.

Endorsed sponsors must maintain a real-time claims adjudication system that, among other capabilities, will—

- Communicate to pharmacies the applicable coinsurance rates— 5 percent or 10 percent;
- Ensure that transitional assistance is applied only toward the cost of

covered discount card drugs obtained under the program; and

• Track the amount of transitional assistance available to each transitional assistance enrollee.

We understand that in some circumstances real-time claims adjudication may not be possible, for instance, due to coordination of benefits issues. To accommodate these circumstances, endorsed sponsors must have the capacity to process claims off-line for transitional assistance.

As discussed below in section II.G. of this document, exclusive card sponsors may permit their transitional assistance enrollees to apply transitional assistance toward any copayments, coinsurance, and deductible amounts for covered discount drug cards obtained under their Medicare managed care plan outpatient drug benefit. Medicare managed care organizations seeking to offer an exclusive card program must indicate in their applications their intent to permit transitional assistance enrollees to apply transitional assistance toward the cost of covered discount card drugs obtained under their Medicare managed care plan and explain their process for doing so.

Applicants must include in their applications details on their proposed methods for managing and accounting for transitional assistance.

As discussed in section II.C.6. of this document, endorsed sponsors will not be permitted to charge their transitional assistance enrollees any annual enrollment fee; rather, we will pay any enrollment fee on their behalf.

Endorsed sponsors will be required to establish procedures for applying transitional assistance toward the cost of covered discount card drugs obtained by transitional assistance enrollees under the Medicare drug discount card program. Such procedures must include applying the coinsurance rules set forth in section 1860D–31(g)(1)(B) of the Act, as stated in § 403.808(e) of our regulations and discussed in section II.A.4.a. of this document. Further, as stated in § 403.806(e)(6) of our regulations, endorsed sponsors must ensure that transitional assistance is not applied to cover the portion of the negotiated price that transitional assistance enrollees are responsible for paying under the coinsurance rules. That is, endorsed sponsors must ensure that the amount of transitional assistance applied toward the cost of covered discount card drugs obtained by transitional assistance enrollees is the negotiated price (or usual and customary price, if lower) minus the coinsurance. For example, if a beneficiary has a $600 transitional assistance balance and he or she obtains a covered discount card drug under the Medicare drug discount card program with a negotiated price of $100, the beneficiary would pay, depending on his or her income, a coinsurance of 5 percent or 10 percent ($5 or $10), the endorsed sponsor would pay the negotiated price minus the coinsurance amount ($95 or $90), and following the transaction, the amount of transitional assistance remaining available to the transitional assistance enrollee would be $505 or $510. In their applications, applicants must describe their approach for applying the coinsurance rules.

Section 101(e)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 exempts from the prohibition under section 1128B(b)(3) of the Act pharmacies who waive or reduce coinsurance for enrollees with transitional assistance provided such waiver or reduction meets the conditions in clauses (i) through (iii) of section 1128A(i)(6)(A). Thus, pharmacies participating in an endorsed program's network could not be criminally prosecuted under section 1128B(b)(3) of the Act for waiving or reducing coinsurance under the Medicare drug discount card program provided the pharmacies comply with the provisions of clauses (i) through (iii) of section 1128A(i)(6)(A) of the Act, which include the following—

• The waiver is not to be advertised;

• The coinsurance is not routinely waived; and

• The coinsurance is waived only after determining (in good faith) that—

• The eligible beneficiary is in financial need; or

• The pharmacy has made reasonable collection efforts but still failed to collect the coinsurance due.

Pharmacies and endorsed sponsors seeking further guidance regarding waivers or reduction of coinsurance may request advisory opinions from the Office of the Inspector General. To request an advisory opinion, entities should submit an original and 2 copies of a written request that contains certain specified information to the following address:

Chief, Industry Guidance Branch, U. S. Department of Health and Human Services, Office of Inspector General, Office of Counsel to the Inspector General, Room 5527, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

For more information on the advisory opinion process and the information included in the request, please refer to *www.oig.hhs.gov/fraud/advisoryopinions.html.*

In addition, as discussed under section II.H. of this document, States may establish arrangements to pay directly to endorsed sponsors some or all of the coinsurance on behalf of transitional assistance enrollees in their State. If a pharmacy waives or reduces a transitional assistance enrollee's coinsurance amount or if the State pays some or all of the coinsurance, the endorsed sponsor must ensure that no more than 90 or 95 percent, as applicable, of the negotiated price is paid using transitional assistance funds.

5. Products and Services Inside and Outside the Scope of the Endorsement

Section 1860D–31(e)(1)(C) of the Act prohibits an endorsed discount card sponsor (and any pharmacy included in the endorsed sponsor's network) from charging card enrollees any amount, other than the annual enrollment fee and negotiated prices (which include dispensing fees), for any items and services required to be provided by the endorsed sponsor under the Medicare drug discount card program. Therefore, our regulations at § 403.806(h)(2) prohibit endorsed sponsors (and their network pharmacies) from charging any amount for required services other than the enrollment fee and negotiated prices. Required services include, for example—

• Conducting enrollment;

• Offering negotiated prices on covered discount card drugs;

• Ensuring convenient pharmacy access;

• Reducing the likelihood of medication errors and adverse drug interactions;

• Providing customer service and information and outreach materials;

• Providing a grievance mechanism; and

• Administering transitional assistance.

Section 1860D–31(h)(7)(A) of the Act allows endorsed sponsors to provide certain non-required services under their endorsements as well, but only if such products or services are directly related to a covered discount card drug, or are discounts for over-the-counter drugs (that is, non-prescription drugs). Thus, endorsed sponsors may voluntarily choose to provide under their Medicare endorsement discounts on over-the-counter drugs, and products or services that are related to covered discount card drugs but which are not required services under the Medicare drug discount card program. For example, an endorsed sponsor might offer discounts on durable medical equipment that is related to a covered

discount card drug. Any product or service that is either not related to a covered discount card drug, or is not a discount for an over-the-counter drug, could not be provided under the endorsement and would be considered outside the scope of a sponsor's Medicare endorsement.

Although an endorsed sponsor (and pharmacies participating in their networks) may provide products and services related to covered discount card drugs and may offer discounts on over-the-counter drugs, our regulations provide at § 403.806(h)(1) that endorsed sponsors (and pharmacies participating in their networks) may not offer any such product or service for an additional fee (nor may any of their subcontractors or pharmacies in the network charge an additional fee for services offered under the endorsement). Endorsed sponsors therefore must fund all such products and services (whether optional or required) through the enrollment fee, and, if necessary, through rebates, discounts, and other price concessions garnered from manufacturers and pharmacies. We believe that we have the authority to recognize as outside the scope of endorsement those products and services offered for an additional fee. Section 1860D–31(h)(8) of the Act charges us with protecting and promoting the interests of Medicare beneficiaries. Were we to allow endorsed sponsors to charge additional fees, we believe beneficiaries might, in effect, be charged annual enrollment fees higher than the $30 limit mandated by section 1860D–31(c)(2)(B) of the Act, especially if endorsed sponsors were to condition enrollment in their endorsed programs on beneficiaries paying these additional fees. In addition, beneficiaries may be unable to access negotiated prices and transitional assistance, as intended by Congress, if endorsed sponsors require that they pay additional fees for optional products and services. Further, we believe permitting endorsed sponsors to charge additional fees could be confusing to beneficiaries. For example, beneficiaries may find it confusing and frustrating that endorsed sponsors can charge a diabetic an additional fee to access discounts on durable medical equipment related to drugs for diabetics when they cannot charge a case management fee related to helping the beneficiary manage his or her diabetes. Our beneficiary research has demonstrated that beneficiaries expect a discount card program to be simple to understand and easy to use (Bearing Point and Sutton Group. CMS Formative Research on Prescription Drug Shopping Habits: Round 1 Findings, Final. April 8, 2003). We believe that the most straightforward and easily understood structure for an endorsed program is one that provides all products and services related to covered discount card drugs and discounts on over-the-counter drugs for the single enrollment fee.

We clarify that we do not intend to prohibit pharmacies from charging beneficiaries for drugs; rather, this policy concerns not the price of a drug itself, but products or services directly related to the drug and access to discounts on over-the-counter drugs. Pharmacies and endorsed sponsors therefore may charge beneficiaries negotiated prices for covered discount card drugs and discounted prices for over-the-counter drugs.

In accordance with section 1860D–31(h)(7)(B) of the Act, our regulations at § 403.813(a) and § 403.806(g)(5)(iv) provide that an endorsed sponsor's information and outreach materials may describe only those products or services within the scope of the Medicare endorsement; the information and outreach materials may not include descriptions of products or services offered by the endorsed sponsor outside the scope of the endorsement. Because only products and services that are both (1) related to a covered discount card drug or are discounts for over-the-counter drugs and (2) offered for no fee (other than the enrollment fee or negotiated prices) are considered within the scope of the Medicare endorsement, an endorsed sponsor's information and outreach materials may not include information on products or services offered for an additional fee. We interpret this to mean that endorsed sponsors may not commingle communications about endorsed sponsors' products or services offered outside the scope of endorsement with information and outreach materials describing products and services within the scope of endorsement. In addition, if endorsed sponsors offer for no additional fee non-required products and services related to covered discount card drugs or they offer discounts on over-the-counter drugs, the endorsed sponsor must describe these products and services in its information and outreach materials, which are subject to our review as described in section II.C.7. of this document.

Finally, as provided in § 403.813(a)(1) and (2) and discussed in section II.C.9. of this document, an endorsed sponsor may not use or disclose a card enrollee's individually identifiable health information created, collected, or maintained under the Medicare drug discount card program for the purpose of marketing products or services offered outside the scope of endorsement.

6. Eligibility and Enrollment Responsibilities

Sections 1860D–31(f)(1)(A) and (c)(1) of the Act direct the Secretary to establish procedures for determining beneficiaries' eligibility for the Medicare drug discount card program and transitional assistance and for enrolling eligible beneficiaries in endorsed programs. Sections 403.810 and 403.811 of our regulations set forth these procedures, which are discussed in part in section II.A. of this document. Endorsed sponsors are expected to implement these requirements as provided in § 403.806(k) of the regulations. This section discusses the obligations of endorsed sponsors related to eligibility determinations and enrollment. Section 1860D–31(c)(1)(B) of the Act also requires endorsed sponsors to use a standard enrollment form, and section 1860D–31(c)(2) of the Act permits endorsed sponsors to charge an annual enrollment fee up to, but no more than, $30 per year. This section also discusses our rules pertaining to the standard enrollment form and annual enrollment fee.

a. Eligibility and Enrollment Process

An endorsed sponsor may enroll a Medicare beneficiary in its endorsed program only after we verify the beneficiary's eligibility. We require endorsed sponsors to interact with CMS's enrollment systems to ensure that only eligible beneficiaries enroll in the Medicare drug discount card program; that beneficiaries enroll in only one endorsed program at a time and with few exceptions, in only one endorsed card program per year, as required under section 1860D–31(c)(1)(C)(i) of the Act and § 403.811(a)(6) and (a)(7) of our regulations; and that members of a Medicare managed care plan offering an exclusive card program do not enroll in other endorsed programs.

Medicare beneficiaries seeking to enroll in an endorsed sponsor's program must submit information to the endorsed sponsor by completing the standard enrollment form or by providing the necessary information to the sponsor via other means (for example, telephone, internet, or facsimile), as specified by CMS and permitted by the endorsed sponsor. Beneficiaries who wish to receive transitional assistance must complete the standard enrollment form for transitional assistance and submit this

form to their endorsed sponsor. We expect endorsed sponsors to promptly transmit to us all standard data elements captured on a beneficiary's completed enrollment form.

Prior to transmitting to us any standard data elements, we expect that the endorsed sponsor will ensure that the beneficiary's enrollment form is complete. If a beneficiary's enrollment form is incomplete, the endorsed sponsor must promptly contact the beneficiary or return the beneficiary's incomplete application to him or her to obtain the missing information.

In addition to reviewing an enrollment form for completeness, endorsed sponsors are expected to review whether an enrollment form on its face indicates that the beneficiary is ineligible for the Medicare drug discount card program or, if applicable, transitional assistance. Specifically, if the beneficiary is applying to enroll in the endorsed sponsor's endorsed program, the endorsed sponsor should review the enrollment form to determine whether:

- The beneficiary resides within the endorsed program's service area; and
- The beneficiary has any outpatient drug coverage under a State Medicaid plan (including a 1115 waiver).

If the beneficiary is applying for transitional assistance, the endorsed sponsor must review the enrollment form to determine whether:

- The beneficiary has signed the form;
- The beneficiary's income as listed on the enrollment form exceeds 135 percent of the poverty line applicable to the beneficiary's family size;
- The beneficiary has coverage for outpatient covered discount card drugs under one or more of the following sources: (a) TRICARE, (b) a Federal Employee's Health benefit plan, or (c) a group health plan or health insurance coverage other than a Part C plan or a group health plan consisting solely of excepted benefits, such as Medigap; and
- The beneficiary does not reside in one of the 50 States or the District of Columbia.

We also expect endorsed sponsors to determine the appropriate coinsurance level for each transitional assistance enrollee based on the income information he or she provides on the standard enrollment form.

If the endorsed sponsor determines that the beneficiary is ineligible for its endorsed program or, if applicable, transitional assistance, the endorsed sponsor should promptly notify the beneficiary that he or she is not eligible. The endorsed sponsor may wish to discuss with the beneficiary whether the individual wishes to make any changes to his or her enrollment form. Otherwise, the endorsed sponsor is expected to issue a notice of negative eligibility determination, as discussed in greater detail below.

As discussed in section II.A.3. of this document, if a beneficiary applies for transitional assistance when he or she applies for an endorsed program, the endorsed sponsor may not enroll the beneficiary in their endorsed program if the beneficiary is determined ineligible for transitional assistance. This requirement is specified in § 403.811(a)(3) of our regulations.

We will inform an endorsed sponsor of beneficiaries' eligibility for the sponsor's endorsed program and, if applicable, transitional assistance. If a beneficiary is determined ineligible for the endorsed sponsor's program and/or transitional assistance, we will inform the endorsed sponsor of the reasons for the negative determination. We expect endorsed sponsors to promptly notify a beneficiary in writing of any negative eligibility determination made either as a result of the endorsed sponsor's initial review of an individual's complete enrollment form (or information submitted as part of the enrollment process) or of CMS' verification process. If the beneficiary has been determined ineligible for the sponsor's endorsed program and/or transitional assistance, the notice must communicate to the beneficiary—

- The reason for the negative eligibility determination;
- The beneficiary's right to request reconsideration of the eligibility determination and the process for doing so; and
- If not determined eligible for transitional assistance, the beneficiary's option of enrolling in the endorsed program without access to transitional assistance.

The model information and outreach materials that will accompany information and outreach guidelines referenced in section II.C.7. of this document will include model language for these notices, as discussed under section II.C.7. of this document. Our reconsideration process is discussed in greater detail under section II.A.5. of this document.

The determination process for this program relies on self-certification and verification. As discussed above in section II.A.2. of this document, if, as part of our verification process for transitional assistance , we are unable to verify a beneficiary's ability to meet the income threshold specified in § 403.810(b)(3) of our regulations, we may direct endorsed sponsors to request that the beneficiary submit additional income information. Section 403.810(f)(2) of our regulations provides that CMS can require such beneficiaries to fulfill this request as one condition of eligibility for transitional assistance.

Under section 1860D–31(c)(1)(A)(i) of the Act, and as provided in § 403.811(a)(10) of our regulations, a discount card eligible individual may enroll only in an endorsed program serving residents of the State in which he or she resides. Therefore, an endorsed sponsor may only enroll in its endorsed program beneficiaries that are residents of a State within the endorsed program's service area. We expect the endorsed sponsor to advise beneficiaries that those who change their address to an address outside the endorsed program's service area during the year must disenroll from the endorsed program and request a special election period if they wish to enroll in a new card program whose service area includes their new address. The model information and outreach materials to be provided with the information and outreach guidelines will include model language addressing this issue. We also plan to educate beneficiaries that any discount card eligible individual planning to change residence during the year should enroll in a national endorsed program.

As discussed under sections II.A.3. and II.G. of this document, Medicare managed care organizations may group enroll, into their exclusive card programs, eligible beneficiaries enrolled in those Medicare managed care plans that include access to an exclusive card program as part of the plan's benefit package. Prior to doing so, these organizations must notify affected plan members of their intent to enroll eligible beneficiaries as a group into their exclusive card program and grant beneficiaries ample opportunity to decline enrollment in the exclusive card program. We encourage organizations offering exclusive card programs to inform affected plan members that, if they decline enrollment in the exclusive card program, they will not be permitted to enroll in any other endorsed program.

Under § 403.814(b)(5)(iii) of our regulations, we permit exclusive endorsed sponsors electing to group enroll their plan members into their exclusive card program to use a modified version of the standard enrollment form provided such form has been submitted and approved by us along with the exclusive endorsed sponsor's other information and outreach materials. If a Medicare managed care organization group enrolls its plan members into its exclusive card

program, any transitional assistance eligible beneficiary must be afforded the opportunity to apply for transitional assistance.

Section 1860D–31(c)(3) of the Act requires that endorsed sponsors issue a discount card to all of its discount card enrollees for use as proof of enrollment and to facilitate identification of the discount card enrollee and the appropriate endorsed program at the point of sale. Section 1860D–31(c)(3) of the Act gives the Secretary the discretion to specify a standard format for the discount cards. We require in § 403.806(g)(4) of our regulations that all discount cards follow a standard format that complies with National Council for Prescription Drug Programs standards. We will further discuss this format in our information and outreach guidelines.

b. Standard Enrollment Form

Section 1860D–31(c)(1)(B) of the Act requires endorsed sponsors to use a ''standard'' enrollment form that is specified by the Secretary. The standard enrollment form will collect eligibility data elements in a standard format for use by the endorsed sponsor and CMS in determining the beneficiary's eligibility for the Medicare drug discount card program and, if applicable, transitional assistance. We interpret the requirement for a standard enrollment form to mean that, although such forms do not have to be identical, an endorsed sponsor's enrollment form must contain certain data elements and language. These data elements will be specified in the information and outreach materials that accompany the solicitation, but will include:

- Information on eligibility criteria for the Medicare drug discount card program and transitional assistance;
- Documentation of a beneficiary's request for a determination of his or her eligibility for the Medicare drug discount card program and enrollment in the endorsed sponsor's endorsed program;
- Documentation (in the form of a signature) of a beneficiary's request for a determination of his or her eligibility for transitional assistance and request for enrollment assuming eligibility determination is positive;
- Beneficiary's income level and family size;
- Authorization to verify the information reported on the enrollment form, including the beneficiary's income, if applicable; and
- Certification of whether the beneficiary has outpatient prescription drug coverage under one or more of the following sources: (a) TRICARE, (b) a Federal Employee's Health benefit plan, or (c) a group health plan or health insurance coverage other than a Part C plan or a group health plan consisting solely of excepted benefits, such as Medigap.

We have developed a standard enrollment form that is as easy to understand as possible. Endorsed sponsors may customize the layout, graphics, and language of their enrollment form so long as the form conforms to the requirements of this section and the information and outreach guidelines referenced in section II.C.7. of this document. An endorsed sponsor must submit to us its enrollment form along with its other information and outreach materials for our review and approval.

As specified in § 403.814(b)(5)(iii) of our regulations, a Medicare managed care organization offering an exclusive card program that wishes to group enroll its plan members into its exclusive card program may use a modified version of the standard form. Any such modifications must conform to the requirements we will specify in the information and outreach guidelines (see § 403.806(g)(5)(i) of our regulations).

c. Transition Period

As discussed in section II.B.2. of this document, we require endorsed sponsors to continue operating their endorsed program during the transition period, including providing its discount card enrollees access to negotiated prices during this period. In accordance with section 1860D–31(a)(2)(C)(ii)(II) of the Act, § 403.811(c)(6) of our regulations specifies that endorsed sponsors may not charge an annual enrollment fee during the transition period. In addition, as provided in § 403.808(f), endorsed sponsors must permit transitional assistance enrollees to apply any transitional assistance remaining available to them on December 31, 2005 toward the cost of covered discount card drugs obtained under the program during the transition period. Endorsed sponsors may not enroll any beneficiaries in their endorsed programs during the transition period.

d. Enrollment Fee

Section 1860D–31(c)(2) of the Act provides that endorsed sponsors may charge an annual enrollment fee up to, but no more than, $30 per year.

Section 1860D–31(c)(2)(c) of the Act requires that an endorsed sponsor charge all beneficiaries residing in the same State the same enrollment fee. As specified in § 403.811(c)(4) of our regulations, for endorsed programs with service areas larger than a State, the endorsed sponsor may charge a different annual enrollment fee in each State of up to, but not more than, $30.

Section 1860D–31(c)(2)(G) provides that the Secretary may establish special rules with respect to payment of any annual enrollment by discount card enrollees who enroll in a new endorsed program during a calendar year. As provided in § 403.811(b)(7) of our regulations, when a discount card enrollee enrolls in a new endorsed program during a special election period, the endorsed sponsor of the new endorsed program may charge the discount card enrollee its annual enrollment fee. We allow the new endorsed sponsors to charge their annual enrollment fee because we believe that much of the enrollment fee covers the start-up costs of enrolling a beneficiary into an endorsed program.

Section 1860D–31(c)(2)(G) of the Act allows the Secretary to provide special rules regarding payment of the enrollment fee for discount card eligible individuals, which include transitional assistance enrollees who enroll in a new endorsed program during the calendar year. For transitional assistance enrollees who change endorsed programs during a special election period, we will pay any annual enrollment fee charged by the new endorsed program. Further, section 1860D–31(c)(2)(C) of the statute and § 403.811(c)(4) of the regulations provides for a uniform enrollment fee for all discount card enrollees. The requirement means that the Secretary will pay the same enrollment fee (if any) for individuals receiving transitional assistance that the endorsed sponsor is charging those not receiving transitional assistance and residing in the same State.

Section 1860D–31(c)(2)(A) of the Act, as reflected in § 403.811(c)(3) of our regulations, prohibits an endorsed sponsor from prorating its annual enrollment fee for portions of a calendar year. Accordingly, an endorsed sponsor that charges an enrollment fee must charge its discount card enrollees the same enrollment fee in a given calendar year, regardless of when during the calendar year the discount card enrollee enrolls in the endorsed sponsor's endorsed program.

Section 403.811(a)(2) of our regulations provides that if the beneficiary indicates on the enrollment form that he or she only seeks to enroll in the endorsed sponsor's endorsed program and is not seeking transitional assistance, the endorsed sponsor may charge the beneficiary an annual

enrollment fee in a form and manner determined by the endorsed sponsor.

As discussed above in section II.A.3. of this document, and provided in § 403.811 (a)(3) of our regulations, beneficiaries may not enroll in an endorsed sponsor's endorsed program when they also apply for transitional assistance, unless they are determined eligible for transitional assistance at the time of application. To ensure that a beneficiary does not pay any enrollment fee prior to a determination of his or her eligibility for transitional assistance, § 403.811(c)(2) of our regulations provides that endorsed sponsors may not charge beneficiaries applying for transitional assistance any annual enrollment fee at the time of application. Should a beneficiary be determined eligible for transitional assistance and enrolled in the endorsed program, the endorsed sponsor may then charge CMS any enrollment fee. Beneficiaries determined ineligible for transitional assistance may apply for enrollment in an endorsed drug discount card program and, if found eligible to enroll in the endorsed program, must pay the annual enrollment fee (if any) in a form and manner determined by the endorsed sponsor.

As required in section 1860D–31(c)(2)(E) of the Act, and specified in § 403.808(c) of our regulations, we will pay any annual enrollment fee on behalf of transitional assistance enrollees. Should a discount card enrollee be determined eligible for transitional assistance after already enrolling in an endorsed program, we will pay the annual enrollment fee and the endorsed sponsor must immediately refund to the discount card enrollee, or any State that has paid the enrollment fee on behalf of the card enrollee, any annual enrollment fee for the calendar year previously paid by the discount card enrollee or State. If the discount card enrollee is first determined eligible for transitional assistance in 2005, we will not pay any enrollment fee for 2004 and the endorsed sponsor will not be required to refund to the discount card enrollee any enrollment fee paid by him or her in 2004. This policy is incorporated into § 403.811(c)(5) of our regulations.

As discussed in greater detail in section II.H.2. of this document, under section 1860D–31(c)(2)(F) of the Act and § 403.815(a) of our regulations, a State may pay some or all of any enrollment fee for some or all discount card enrollees (other than transitional assistance enrollees) residing in the State. As specified in § 403.815(a)(1) of our regulations, these payment arrangements should be negotiated directly between the State and the endorsed sponsor.

e. Disenrollment

Section 1860D–31(c)(1)(D)(ii) of the Act and § 403.811(b)(6) of our regulations permit an endorsed sponsor to involuntarily disenroll any discount card enrollee, other than a transitional assistance enrollee, who fails to pay the annual enrollment fee charged by the endorsed sponsor. We expect endorsed sponsors to provide discount card enrollees prior written notice before involuntarily disenrolling them for failure to pay the enrollment fee.

Under section 1860D–31(c)(1)(D)(i) of the Act, a discount card enrollee also may voluntarily disenroll from an endorsed program at any time. Discount card enrollees generally must notify an endorsed sponsor of their desire to disenroll from the endorsed sponsor's endorsed program. We expect endorsed sponsors to promptly submit to CMS all disenrollment requests they receive. In addition, if an endorsed sponsor involuntarily disenrolls one of its discount card enrollees for failure to pay any enrollment fee, we expect the endorsed sponsor to promptly notify us of such disenrollment. As discussed above in section II.A.6. of this document, discount card enrollees who disenroll from a Medicare managed care plan offering an exclusive card program are no longer eligible for that exclusive card program. The exclusive endorsed sponsor must disenroll these beneficiaries from its exclusive card program.

If a discount card enrollee contacts the endorsed sponsor in order to disenroll from an endorsed program, the endorsed sponsor is responsible for—

- Disenrolling the discount card enrollee from its endorsed program and promptly notifying us of such disenrollment;
- Determining whether the discount card enrollee is eligible for a special election period based on the reason provided for the disenrollment, if any; and
- If the endorsed sponsor determines that a discount card enrollee is eligible for a special election period, promptly notifying us of this determination.

7. Information and Outreach, and Other Customer Service

a. Information and Outreach

Section 1860D–31(d)(2)(A) of the Act requires that each prescription drug card endorsed sponsor that offers an endorsed discount card program will make available to eligible beneficiaries for the discount card program (through the Internet and otherwise) information that the Secretary identifies as being necessary to promote informed choice among endorsed discount card programs including information on enrollment fees and negotiated prices for covered discount card drugs. Furthermore, section 1860D–31(h)(7)(A) of the Act limits drug card endorsed sponsors to providing under their endorsements only (1) products and services directly related to covered discount card drugs, or (2) discounts on over-the-counter drugs. Section 1860D–31(h)(7)(B) then prohibits endorsed sponsors from marketing—under their endorsements—any products and services other than those described in section 1860D–31(h)(7)(A).

Under the above authority, we have drafted regulations which condition endorsement on card sponsors providing information and outreach according to our rules. To further explain these regulations and provide guidance to endorsed sponsors, we plan to publish information and outreach guidelines on our Web site at the same time we release the solicitation for applications. These information and outreach guidelines will provide further interpretations of our regulations and will contain the procedures endorsed sponsors can use to apply for and receive approval of their information and outreach materials.

Our regulations at § 403.806(g) contain our requirements for the information to be included in materials. Endorsed sponsors must provide to Medicare beneficiaries in their service area(s) information and outreach materials on the endorsed program, including discounts on over-the-counter drugs, if offered. Our regulations also incorporate the statutory requirement that information and outreach materials promote informed choice and contain information on enrollment fee and negotiated prices.

As we will explain further in the information and outreach guidelines, we will implement and interpret these statutory and regulatory requirements by requiring endorsed sponsors to disclose to Medicare beneficiaries (prior to enrollment, after enrollment, and upon request) the following information at a minimum—

(1) A detailed description of the program that includes information on how to become enrolled in a program, eligibility qualifications for transitional assistance, and how transitional assistance works;

(2) A description of the services the sponsor provides for no additional fee,

such as drug interaction counseling or allergy alerts;

(3) The availability of a grievance process and how it works;

(4) If applicable, any special rules for beneficiaries in long term care facilities, American Indians/Alaska Natives who use I/T/U pharmacies, as well as residents of the U.S territories;

(5) The toll-free telephone numbers described in § 403.806(g)(6) of our regulations;

(6) A list of contracted pharmacies and prescription drugs offered for a negotiated price, how coinsurance works, and a guarantee that contracted pharmacies will provide the lower of the negotiated price or the usual and customary price;

(7) Enrollment fees (if any);

(8) A notice that drugs and prices may change or vary and a description of how the enrollee can obtain information regarding those changes and variations;

(9) A clear description of the service area in which the endorsed program is available;

(10) A privacy notice for protected health information. Further guidance will be provided in the information and outreach guidelines on the notice of privacy practices for protected health information; and

(11) A description of any circumstances and special procedures that relate to potential transitional assistance enrollee liabilities stemming from procedures endorsed sponsors have in place to manage transitional assistance against an enrollee's cap or transitional assistance balance transfer to a newly elected endorsed program.

Endorsed sponsors must also make available, upon request, the negotiated prices for prescription drugs.

In addition to the above information, section 1860D–31(d)(2)(B) of the Act provides that an individual's transitional assistance balance must be available and provided as requested by toll-free line. Because this provision also requires that the toll-free line is publicized, we will require in the information and outreach guidelines that the toll-free number be included in all media through which the sponsor communicates with beneficiaries (for example, magazines, television, newspapers, billboards, radio, pre-enrollment, or post-enrollment materials).

Section 1860D–31(d)(2)(C) of the Act requires endorsed sponsors to make available, at the point of sale, information on the remaining balance of transitional assistance. Endorsed sponsors, therefore, must explain in their information and outreach materials that, at the point of sale, enrollees can request that network pharmacies determine—either electronically or by telephone—how much of the enrollee's transitional assistance remains. Endorsed sponsors must also include information in the member handbook or summary of program features on how an enrollee can obtain his or her transitional assistance balance.

Additionally, in accordance with section 1860D–31(d)(3) of the Act, information and outreach materials must explain how enrollees will be informed of the differential between the price of the drug to the enrollee and the price of the lowest priced therapeutically equivalent and bioequivalent generic covered discount card drug available at that pharmacy. Our forthcoming information and outreach guidelines will provide further detail on the method for communicating this information to beneficiaries, including to beneficiaries who purchase drugs through mail order.

All information required to be included in information and outreach materials, must, as required under section 1860D–31(d)(2)(A) of the Act, be provided both through the Internet and through some tangible medium, such as mailings (see § 403.806(g)(1) of our regulations). For information provided on the Internet, endorsed sponsors must establish a process for informing members when the web page was last updated, for example, by putting a date and disclaimer on the web page to promote beneficiary understanding that the information could be dated. In their applications, we require endorsed sponsors to demonstrate how they will maintain Web sites that provide information and outreach.

In II.C.5. of this document, we discuss products and services considered inside and outside the scope of endorsement, and explain that products or services outside the endorsement may not be offered or marketed under the endorsement. We further explain in section II.C.9. of this document that marketing related to non-endorsed services will be prohibited, even if the endorsed sponsor obtains beneficiary consent to receive such marketing. In keeping with these rules, our information and outreach provisions provide that any communication provided by sponsors that would concern services outside the endorsement may not be co-mingled with information and outreach materials relating to endorsed items or services. Therefore, when endorsed sponsors are acting in their capacity as endorsed sponsors, and are using data or information they collected through the operation of their endorsed program, they may not co-mingle information and outreach materials on endorsed features with any materials on non-endorsed features. This, however, would not prohibit entities, when they are not acting in their capacity as endorsed sponsors, from publicizing their endorsed programs or providing information about such programs. Thus, for example, an exclusive card sponsor could describe its endorsed program in its Medicare managed care plan marketing materials if those materials are CMS-approved, but it could not describe its Medicare managed care plan general features in materials which are directed solely toward its endorsed program enrollee population.

Our forthcoming information and outreach guidelines also will provide certain rules regarding the proper procedures for conducting information and outreach. For example, the guidelines will provide that, in conducting information and outreach, endorsed discount card sponsors may not engage in activities that could mislead or confuse beneficiaries or provide cash or other monetary rebates (for example, coupons or discounts on pharmacy products and services) as an incentive for enrollment.

Section 1860D–31(c)(3) of the Act provides that each endorsed sponsor must issue to each enrollee a card in a standard format specified by the Secretary that establishes proof of enrollment and that can be used in a coordinated manner to identify the endorsed sponsor, program, and beneficiary (*see also* § 403.806(g)(4) of our regulations). We will, in the information and outreach guidelines, provide guidance according to the requirements of the National Council for Prescription Drug Programs (NCPDP) for pharmacy identification cards. NCPDP is recognized as the industry standard for current prescription drug programs. We will review and approve pharmacy identification cards.

Our information and outreach guidelines will also include standards for use of a Medicare endorsement emblem. Use of the emblem may occur only after written notification of endorsement. Endorsed discount card sponsors may use the emblem on information and outreach materials such as newsletters, discount cards, stationery, and other promotional items designed to inform Medicare beneficiaries about the program.

Finally, as a condition of endorsement, we will require endorsed sponsors to file with us all information and outreach materials (*See also* § 403.806(g)(5)). These materials will require our review and approval (within

the time period discussed below) prior to the endorsed sponsor being able to disseminate them. We believe there is sufficient authority in section 1860D–31 of the Act for us to require prior submission and review of information and outreach materials. For example, section 1860D–31(d)(2) of the Act gives the Secretary the authority to identify the information necessary to be included in information and outreach materials to ''promote informed choice among endorsed discount card programs.'' In order to ensure that information and outreach materials are, in fact, promoting informed choice, we believe prior filing and review is necessary. Additionally, section 1860D–31(h)(8) of the Act authorizes us to craft conditions for endorsement that we believe would ''protect and promote the interests of Medicare beneficiaries.'' We believe that ensuring that marketing materials contain the necessary information, adequately reflect the drug discount card program, and do not violate any of our conditions for endorsement will protect Medicare beneficiaries. Our review of these materials will ensure that beneficiaries are not misled or confused about the services offered by drug discount card programs, that beneficiaries receive the information necessary to make informed choices in their selection of a drug discount card program, and that the Medicare name is not misused—for example, to advertise services unrelated to this program.

Therefore, we require in § 403.806(g)(5) of our regulations that information and outreach materials must have our review and approval (within the time period discussed in § 403.806(g)(5)(iii)) in order for them to be disseminated. We define information and outreach materials to include the same kinds of materials described in 42 CFR § 422.80(b) as well as enrollment forms, eligibility determination forms, membership cards, Web site content and any information on over-the-counter drugs (*see also* § 403.806(g)(5)(v) of our regulations). Examples of information and outreach materials that will be reviewed include, but are not limited to—

- General audience materials;
- Telephone or sales scripts for presentations;
- Presentation materials and slides;
- Membership communications, such as member handbooks and letters regarding contractual changes in benefits, procedures, or enrollment fee;
- Enrollment forms, eligibility determination forms, and membership cards;
- Information regarding over-the-counter drugs offered for a discount; and
- All forms of advertising, including television, radio, print, and Internet.

In order for us to conduct our review, our regulations provide that all information and outreach materials must be submitted to us for approval 30 days before dissemination. We will include model language in our guidelines, and materials that use that model language will receive a streamlined review process and will be approved in fewer than 30 days. Our guidelines will also include a File and Use Program, which will be another approach for streamlining the review process. Further guidance will be provided in the information and outreach guidelines regarding the criteria for the File and Use Program.

The endorsed sponsor may disseminate the information and outreach materials if we do not disapprove the initial submission of these materials by the end of the 30-day period. This rule applies only to the initial submission of materials. Resubmission of materials (that is, submissions made after receiving comments or questions on the initial submission) will not be subject to the deemed approval rule in § 403.806(g)(5)(iii) of our regulations.

Exclusive card sponsors will have a modified review process that will facilitate the coordination of their information and outreach materials with the Medicare managed care plan marketing materials. Further details on the review process will be provided in the Information and Outreach Guidelines, the solicitation, and also in the pre-application conference that will be announced in the solicitation.

b. Call Center

As stated in section 1860D–31(d)(2)(B) of the Act, each endorsed sponsor must have a mechanism (including a toll-free telephone number) for providing, upon request, specific information (such as negotiated prices and the amount of transitional assistance remaining available through the program) to their enrollees. Therefore, in § 403.806(g)(6), we are requiring that, as a condition of endorsement, each endorsed card endorsed sponsor must maintain a toll-free customer call center to assist beneficiaries in understanding the drug discount card program offered. The call center must be open during regular business hours and must 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 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 will be operated in accordance with standard business practices to mean that—

- 70 percent of customer service representatives' time while on the job 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
- There will be an explicit process for handling customer complaints.

These standards are required or exceeded by the 1–800 Medicare call center contractors.

As stated earlier and included in § 403.806(e)(5) of our regulations endorsed sponsors are required to provide through their toll-free numbers information on the amount of available transitional assistance (section 1860D–31(d)(2)(B) of the Act).

Endorsed sponsors must also have in place a reliable means for accommodating pharmacy inquiries regarding the endorsed sponsor's program. We believe this requirement promotes and protects beneficiaries by ensuring that pharmacists can have their questions answered about the card program's drug offering on behalf of the beneficiary. Endorsed 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 endorsed 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 permit individual endorsed sponsors to decide on methods for effectively addressing pharmacy inquiries.

Endorsed discount card programs may establish additional mechanisms for communicating with enrollees and pharmacies, such as e-mail or fax.

c. Reduction of Medication Errors and Adverse Drug Reactions

In our regulations at § 403.806(g)(7), we require that each endorsed discount

card program must provide a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use (section 1860D–31(e)(2) of the Act). Endorsed sponsors have flexibility to design their own individual systems to accomplish these goals. We will require applicants to describe their systems and discuss how these goals will be accomplished. Published scientific and clinical literature should support the proposed approaches. If applicants have experience using their proposed systems to accomplish these goals, applications should describe past achievements in reducing medication errors and adverse drug interactions and in improving medication use.

8. Grievance Process

Section 1860D–31(h)(5) of the Act specifies that endorsed sponsors must establish and maintain a grievance process to track and address in a timely manner enrollees' complaints about any aspect of the endorsed sponsor's operations. The grievance process does not include the reconsideration process, described in section 1860D–31(f)(4) of the Act and discussed in section II.A.5. of this document, which affords beneficiaries an opportunity to seek review of an initial determination that they are ineligible to receive transitional assistance or enroll in an endorsed program.

A grievance is any card enrollee's complaint or dispute expressing dissatisfaction with the manner in which he or she has received services under an endorsed program. The subjects of a grievance may include the timeliness, appropriateness, access to, and/or setting of services provided by the endorsed sponsor, such as waiting times, demeanor of pharmacy or customer service staff, or disrespect shown a card enrollee. A grievance may also include a dispute concerning the endorsed sponsor's failure to offer discounts on particular covered discount card drugs, ensure its pharmacies charge a certain price for covered discount card drugs, apply transitional assistance toward the cost of a covered discount card drug obtained by a transitional assistance enrollee under the program, or correctly calculate the correct coinsurance amount for a covered discount card drug obtained by a transitional assistance enrollee.

In § 403.806(j) of our regulations, we require endorsed sponsors to maintain meaningful procedures for timely review and resolution of their card enrollees' grievances. We will publish more specific guidelines on grievance procedures in our solicitation. These guidelines will include the following features—

(1) Endorsed sponsor's ability to collect information concerning the grievance;

(2) Timely transmission of grievances to appropriate decision-making levels within the endorsed sponsor's organization, including to any subcontractors;

(3) Taking prompt and appropriate action to address a grievance, including conducting a full investigation of the grievance if warranted; and

(4) Communication of the results of an investigation to all concerned parties, consistent with applicable State law.

9. HIPAA Administrative Simplification Provisions and Other Marketing and Security Provisions

a. General

Section 1860D–31(h)(6)(A) of the Act provides that for the purpose of the Medicare drug discount card program, the operations of an endorsed program are covered functions and an endorsed sponsor is a covered entity for purposes of applying Part C of title XI and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We therefore provide in § 403.812(a) of our regulations that endorsed sponsors are covered entities and must comply with the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164 as set forth in § 403.812 of our regulations. Section 403.812(a) of our regulations also provides that those functions of an endorsed sponsor the performance of which are necessary or directly related to the operations of the endorsed discount card program are covered functions for purposes of applying to endorsed sponsors the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164.

Section 1860D–31(h)(7)(B) of the Act provides that an endorsed sponsor only may market those products and services under its endorsed program that are directly related to a covered discount card drug, or discounts on non-prescription drugs to the extent such marketing is otherwise permitted under the Medicare discount drug card program, and the use of beneficiary information for such communications is permitted by the HIPAA Privacy Rule.

b. Overview of HIPAA Administrative Simplification Regulations

The HIPAA Administrative Simplification Regulations are a suite of regulations that provide for the standardization of certain electronic financial and administrative health care transactions, as well as for the privacy and security of individually identifiable health information.[4] The regulations apply to three types of entities, which collectively are termed ''covered entities''—health care providers who transmit protected health information in electronic form in connection with a transaction for which the Secretary has adopted a standard, health plans, and health care clearinghouses. Section 1860D–31(h)(6)(A) of the Act essentially specifies a fourth type of covered entity, the endorsed sponsors. Therefore, as a condition of endorsement, endorsed sponsors must comply with the HIPAA Administrative Simplification regulations in the manner described in § 403.812 of our regulations.

Section 1860D–31(h)(6)(A) of the Act provides that only the endorsed sponsor's operations of an endorsed program are covered functions. Consequently, activities performed by an endorsed sponsor outside of the scope of its endorsement under the Medicare drug discount card program are not made covered functions by the Act. However, if these other activities would make the endorsed sponsor a health plan, covered health care provider, or health care clearinghouse, as currently defined by HIPAA, then the endorsed sponsor may otherwise be a covered entity that is subject to the Administrative Simplification regulations. An endorsed sponsor performing non-covered functions may declare itself a hybrid entity in accordance with 45 CFR 164.105, with its health care component including any component performing operations that make the entity an endorsed sponsor.

As provided in § 403.812(f) of our regulations, nothing in this discussion or § 403.812 of our regulations should be considered a modification of the HIPAA Administrative Simplification regulations or as otherwise affecting the applicability of the Administrative Simplification regulations to covered entities other than endorsed sponsors. Moreover, as provided in § 403.812(f) of our regulations, if an endorsed sponsor is also a health plan, covered health care provider, or health care clearinghouse, the Administrative Simplification

[4] The suite includes regulations for the electronic health care transactions and code sets, unique health identifiers for health plans, health care providers, and employers, and security and privacy.

regulations as set forth in parts 160, 162, and 164 will still govern the performance of those functions which make it a health plan, health care clearinghouse, or covered health care provider.

c. HIPAA Privacy Rule

As covered entities, endorsed sponsors are responsible for complying with the HIPAA Privacy Rule. The Privacy Rule limits the uses and disclosures a covered entity may make with individually identifiable health information (known as protected health information), requires that safeguards be applied to the information to protect it, and gives individuals rights with respect to the protected health information about them, including rights to access and correct the information. Thus, endorsed sponsors are responsible for safeguarding the protected health information of beneficiaries of the program, and must limit the uses and disclosures made with the information to only those permitted by the Privacy Rule and these regulations. In addition, under the program, beneficiaries have certain rights to be informed of the uses and disclosures the endorsed sponsor is permitted or required to make with their protected health information, to access their records, and to have corrections made to their records, among other rights. *See* 45 CFR part 160 and subparts A and E of part 164 for the full set of standards, implementation specifications, and requirements of the Privacy Rule.

1. Endorsed Sponsors To Be Treated in Same Manner as Health Plans

The standards, implementation specifications, and requirements in the HIPAA privacy regulations do not apply uniformly to all covered entities; rather, certain provisions apply only to one or two of the different types of covered entities. We believe we have the discretion to prescribe the manner in which the regulations will apply to endorsed sponsors, as section 1860D–31(h)(6)(A) is silent on this issue. Although endorsed sponsors are not by definition health plans under HIPAA, we believe that the HIPAA privacy regulations should apply to endorsed sponsors in the same manner as applicable to health plans because endorsed sponsors' operations more closely resemble those of health plans than health care clearinghouses or providers.

Health plans are organizations that provide, or pay the cost of, ''medical care,'' which is defined in section 2791(a)(2) of the Public Health Service Act (42 U.S.C. 300gg–91(a)(2)) as amounts paid for (1) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body; (2) amounts paid for transportation primarily for and essential to such medical care; or (3) amounts paid for insurance covering such medical care or transportation. As endorsed sponsors do not themselves provide or pay the cost of medical care, they are not by this definition health plans under HIPAA. However, endorsed sponsors resemble health plans in several respects.

Whereas health plans typically negotiate discount rates for health care products and services, endorsed sponsors similarly will negotiate discounted prices for covered discount card drugs. In addition, health plans coordinate health care for its enrollees, in part by assessing the interaction of various modalities of treatment, which endorsed sponsors also provide albeit on a more limited basis by assessing and avoiding adverse drug interactions and providing educational activities that resemble some of a health plan's care coordination activities. Endorsed sponsors' processing payment for covered discount card drugs provided to transitional assistance enrollees is also somewhat similar to a health plan's payment infrastructure and processes, although unlike health plans, generally speaking, endorsed sponsors would not be bearing capitated risk under this program.

In contrast, the functions performed by endorsed sponsors do not resemble the functions performed by health care providers or health care clearinghouses. A health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), or any other person or organization who furnishes, bills, or is paid for health care in the normal course of business. Under the Medicare discount drug card program, endorsed sponsors will not provide medical or health services to beneficiaries, but instead will arrange for discount card enrollees to have access to negotiated prices and related products and services. A health care clearinghouse is a public or private entity that processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction or receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity. Endorsed sponsors, however, will not be required to perform such services. Accordingly, except as otherwise provided and discussed below, § 403.812(b) of our regulations provide that the HIPAA privacy regulations will apply to endorsed sponsors in the same manner as they apply to health plans.

2. Waiver by the Secretary

Section 1860D–31(h)(6)(B) provides that, in order to promote participation of endorsed sponsors in the Medicare drug discount card program, the Secretary may waive portions of the HIPAA Privacy Rule for a limited period of time as the Secretary deems appropriate. While the Secretary expects endorsed sponsors to be able to comply with the Privacy Rule and, therefore, does not at this time anticipate a need to exercise his waiver authority, the Secretary reserves the right to do so at a later time, if such waiver is deemed necessary to promote participation of endorsed sponsors in the Medicare drug discount card program.

3. Administering the Drug Card Program

The Privacy Rule permits covered entities to use or disclose protected health information without individual authorization for health care treatment and payment activities, as well as for certain legal, financial, and administrative functions—known as health care operations—that support treatment and payment activities. To carry out their obligations under the Medicare drug discount card program, endorsed sponsors will have to conduct a number of activities pertaining to products and services offered under the endorsement that may involve the use or disclosure of beneficiary information. These activities and services will include processing beneficiary applications and enrollment in the program, reducing the likelihood of medication errors and adverse drug interactions, providing customer service and information and outreach materials, and administering transitional assistance. (For a description of the services required as part of the endorsement, see section II.C.5 of this document.) The use or disclosure of beneficiary protected health information for these activities are encompassed within the Privacy Rule's definition's of ''payment'' and ''health care operations'' and, thus, may be conducted without beneficiary authorization.

4. Special Marketing Restrictions for Endorsed Sponsors

Under the Medicare drug discount card program, as explained above, endorsed sponsors will be required to provide information and outreach about products and services offered under the endorsement. Section 1860D–31(h)(7)(B) of the Act provides that an endorsed sponsor may only market those products and services directly related to a covered discount card drug, or discounts for non-prescription drugs to the extent such marketing is otherwise permitted under the Medicare drug discount drug card program and the Privacy Rule. Accordingly, § 403.813(a)(1) provides that an endorsed sponsor may only market those products and services offered within the scope of its endorsement, that is, products and services directly related to a covered discount card drug, and discounts for non-prescription drugs. Thus, only products and services offered by an endorsed sponsor within the scope of its endorsement may be included in an endorsed sponsor's information and outreach materials.

As discussed in section II.C.5. of this document, products or services offered by an endorsed sponsor following termination of its endorsement or termination of the Medicare drug discount card program are considered outside the scope of endorsement. Therefore, § 403.813(b)(4) of our regulations provides that individually identifiable health information created, collected or maintained by an endorsed sponsor may not be used to market any product or service following termination of an endorsed sponsor's endorsement or the program.

Under the Privacy Rule, most uses or disclosures of protected health information to make marketing communications require individual authorization. The Privacy Rule at 45 CFR 164.501, however, defines the term ''marketing'' to mean the making of a communication about a product or service that encourages the recipient of the communication to purchase or use the product or service, with the exception of communications that—

(1) Describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication;

(2) Are for treatment of the individual; or

(3) Are for case management or care coordination, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

Since information and outreach under the Medicare drug discount program is limited to communicating about products and services offered within the scope of endorsement, these activities fall within the exception to the definition of marketing under the Privacy Rule for describing health-related products or services provided by the covered entity. Thus, using or disclosing beneficiary protected health information to provide information and outreach is not marketing under the Privacy Rule, but rather, as described above, is permitted without beneficiary authorization as part of the endorsed sponsor's health care operations.

To use or disclose protected health information to make communications that do not fall within the exceptions to the definition of ''marketing'' under the Privacy Rule at 45 CFR 164.501, a covered entity must obtain individual authorization in accordance with 45 CFR 164.508(a)(3). However, section 1860D–31(h)(7)(B) of the Act limits the marketing that may be conducted by endorsed sponsors to only that which pertains to products and services offered under the Medicare drug discount program or discounts on over-the-counter drugs. For purposes of this marketing prohibition, we will consider a communication to be marketing if the communication is about a product or service and encourages recipients of the communication to purchase or use the product or service. Thus, a sponsor may not market if the marketing involves products or services falling outside the endorsed sponsor's endorsement, that is, services that do not directly relate to a covered discount card drug, or to discounts for a non-prescription drug. Section 403.813(a)(2) of our regulations expressly provides that an endorsed sponsor may not request of a drug card applicant or enrollee the use or disclosure of protected health information to market any products or services not offered under the program. Thus, endorsed sponsors may not market such products or services under § 403.806(d)(3) of our regulations even if they obtain authorization from discount card enrollees to do so, as permitted by the Privacy Rule. Due to this prohibition, endorsed sponsors are not permitted, at the time of enrollment or any other time, to ask beneficiaries if they would be interested in receiving marketing materials related to products and services offered outside the program. Similarly, endorsed sponsors may not commingle any information and outreach materials that describe their endorsed program with any marketing materials related to products and services offered outside the program.

This prohibition applies regardless of whether the marketing of products or services outside the program involves the use or disclosure of protected health information of discount card enrollees. Accordingly, marketing of a product or service outside the program that does not involve the use of discount card enrollees' protected health information, such as advertising for contact lenses or travel on an endorsed sponsor's Web site, is not permitted under the Medicare drug discount card program, even though such marketing would not involve the use of protected health information.

Many entities that sponsor an endorsed program also may engage in activities outside the Medicare drug discount card program. For example, a Part C organization may be both a sponsor of an endorsed program and operate a Part C plan. The marketing prohibition set forth under section 1860D–31(h)(7)(B) of the Act only applies to entities when acting in their capacity as an endorsed sponsor. Accordingly, although an entity in its endorsed sponsor capacity may not commingle with other marketing materials any information and outreach materials related to products and services offered under its endorsed program, it may commingle such materials when acting in another capacity, to the extent otherwise permitted under law. For example, a Part C organization which sponsors an endorsed program may, in its role as a Part C plan, commingle information and outreach materials describing its endorsed program with Part C plan marketing materials to the extent permitted under the Privacy Rule and the Part C marketing rules under Medicare Part C. We will deem an entity as acting in its capacity as an endorsed sponsor when it either (1) uses beneficiaries' information created, collected or maintained under its endorsed program to conduct marketing, or (2) targets its marketing to all or a subset of its discount card enrollees (or potential discount card enrollees). We will deem an entity as acting in another capacity when it (1) does not use beneficiaries' information created, collected or maintained under its endorsed program to conduct marketing, and (2) does not target its marketing to all or a subset of its discount card enrollees (or potential discount card enrollees). For example, we will consider a Part C organization as acting in its endorsed sponsor capacity if it targets its marketing to members of its

Part C plan who are also enrolled in its endorsed program, to the exclusion of other plan members. In contrast, we will consider a Part C organization as acting in its capacity as a Part C plan if it directs its marketing to all or a subset of its Part C plan membership, including those not enrolled in its endorsed program, and, to the extent it uses individual information, such information was not collected or maintained under the Part C organization's endorsed program. Similarly, we will consider an organization's Web site listing its full range of products and services, including but not limited to its endorsed program, as targeted to the public at-large; however, we will consider its web pages specifically describing its endorsed program as targeting potential discount card enrollees, and therefore such web pages may not include information related to products and services offered outside the scope of endorsement.

Section 403.813(a) of our regulations is not enforceable under HIPAA but will be enforced by CMS under the Medicare drug discount card program.

5. Other Uses and Disclosures Without Authorization

Under 1860D–31(i)(1) of the Act and as discussed in section II.A., II.C., and II.F. of this document, endorsed sponsors are required to disclose to the Secretary certain information, some of which may contain protected health information. The Privacy Rule at 45 CFR 164.512(a) permits covered entities to use or disclose protected health information without individual authorization where the use or disclosure is required by other law. Thus, the Privacy Rule permits endorsed sponsors to make the required disclosures to the Secretary without beneficiary authorization. Similarly, the Privacy Rule at 45 CFR 164.512(d) permits covered entities to use or disclose protected health information without individual authorization to a health oversight agency for oversight activities that are authorized by law. Both of these provisions would permit endorsed sponsors to provide CMS with the information needed for the Secretary's oversight and reporting requirements.

6. Uses and Disclosures Requiring an Authorization

For uses and disclosures of protected health information that are not otherwise permitted under the Privacy Rule, an endorsed sponsor must obtain a beneficiary's written authorization for such uses or disclosures in accordance with 45 CFR 164.508. For example, a Medicare beneficiary may authorize the endorsed sponsor to disclose his/her protected health information to a third party, such as an employer. However, as explained above and provided for in § 403.813(a)(2) of our regulations, an endorsed sponsor may not market products or services outside the scope of its endorsement under the Medicare drug discount card program even if it obtains from discount card enrollees authorization to do so. Additional information about this marketing prohibition can be found above in this section and also in section II.C.5 of this document.

7. Notice of Privacy Practices

In accordance with the Privacy Rule at 45 CFR 164.520, prior to enrolling a beneficiary in its endorsed program, or at the time of enrollment, an endorsed sponsor must notify each beneficiary as to how the endorsed sponsor is permitted or required to use and disclose the beneficiary's protected health information, as well as of the beneficiary's rights and the endorsed sponsor's duties with respect to that information. The notice must be in plain language and clearly explain these rights and the uses and disclosures permitted or required under this rule and other applicable law, including that the endorsed sponsor may use or disclose protected health information to communicate about products and services offered by an endorsed sponsor inside, and only inside, the scope of its endorsement. The notice may be combined with other information and outreach materials, provided that the content requirements of the Privacy Rule are fully met.

8. Endorsed Sponsors as Business Associates

As defined in the Privacy Rule, a business associate is a person or entity that performs or assists in the performance of certain functions or activities on behalf of, or provides certain services to, a covered entity, that involve the use or disclosure of individually identifiable health information. The Privacy Rule requires that the covered entity obtain satisfactory assurances, usually in the form of a written contract, from the business associate that the business associate will appropriately safeguard the protected health information it creates or receives on behalf of the covered entity. The contract or other written arrangement between the covered entity and its business associate must meet the requirements at 45 CFR 164.504(e).

For purposes of administering transitional assistance, endorsed sponsors are business associates of CMS under the Privacy Rule. Transitional assistance will be a benefit offered and paid for by the Medicare program, a health plan, with CMS contracting with endorsed sponsors to administer transitional assistance on behalf of CMS in conjunction with their other responsibilities under the Medicare drug discount card program. As such, the contract between CMS and endorsed sponsors will include the terms necessary to satisfy the requirements of the Privacy Rule at 45 CFR 164.504(e).

The application of the Privacy Rule to endorsed sponsors under our regulations does not affect business associate arrangements or requirements between the endorsed sponsor and one or more covered entities for activities that are outside of the endorsed drug card program. However, because an endorsed sponsor is also a covered entity, when an endorsed sponsor is acting as a business associate of another covered entity, the endorsed sponsor will violate the Privacy Rule if it violates its business associate contract with the other covered entity (*see* 45 CFR 164.502(e)(1)(iii)).

9. Enforcement by the HHS Office for Civil Rights

The HHS Office for Civil Rights (OCR) is responsible for implementing and enforcing the HIPAA Privacy Rule. OCR has authority to investigate complaints and to conduct compliance reviews, and may impose civil money penalties on covered entities for violations where appropriate. Thus, any violations by an endorsed sponsor with respect to its obligations under the Privacy Rule as a covered entity are subject to such enforcement by OCR. OCR maintains a Web site with Frequently Asked Questions and other compliance guidance at *http://hhs.gov/ocr/hipaa*.

OCR's enforcement authority pertains only to the HIPAA Privacy Rule. Thus, any violations with respect to compliance with the other HIPAA Administrative Simplification Rules or proper operation of an endorsed program will be enforced by CMS. In addition, if an endorsed sponsor's actions also violate the requirements of the Medicare drug discount card program, such actions also may be sanctioned under § 403.820(a) of our regulations. See section II.F. of this document for further information about CMS oversight and monitoring of endorsed sponsors.

d. Administrative Data Standards

As covered entities, endorsed sponsors must comply with any applicable standards, implementation specifications, and requirements set forth in 45 CFR part 162, subparts I *et seq.*, when conducting a transaction (as that term is defined under section 1173 (a) of the Act and 45 CFR 160.103) as of the compliance date of a final rule issued under that Part. In addition, such sponsors are business associates of the Medicare program (a health plan covered entity), as they perform certain administrative functions related to transitional assistance on our behalf. We will, therefore, require in our contracts with endorsed sponsors that, when conducting all or part of a transaction on our behalf, they comply with, and require their agents and subcontractors to comply with, all requirements under 45 CFR part 162 applicable to CMS as a covered entity.

e. National Identifiers

As covered entities, endorsed sponsors must comply with the standards, implementation specifications, and requirements of 45 CFR parts 160 and 162, relating to the use of national identifiers, as of the compliance date of any final rule issued under part 162.

f. Security

As covered entities, endorsed sponsors must comply with the standards, implementation specifications, and requirements of the HIPAA Security Rule (''Security Rule'') set forth in 45 CFR parts 160 and 164, subparts A and C to ensure the confidentiality, integrity, and availability of all electronic protected health information they create, receive, maintain or transmit as of the compliance date of the final Security Rule (April 15, 2005). In addition, endorsed sponsors as covered entities must have appropriate administrative, technical and physical safeguards in place to protect the privacy of beneficiary information under 45 CFR 164.530(c) of the Privacy Rule. An applicant must include in its application the following:

- An attestation that as of the date upon which it will begin enrollment activities, appropriate administrative, technical and physical safeguards will be in place to protect the privacy of protected health information in accordance with 45 CFR 164.530(c); and
- An attestation that it will meet the standards, requirements, and implementation specifications as set forth in the Security Rule as of the date it begins enrolling beneficiaries in its endorsed programs, or, if the endorsed sponsor will be unable to provide this attestation, the applicant's plan for coming into compliance with the specifications as set forth in the Security Rule as of the compliance date for the Security Rule.

Endorsed sponsors are encouraged, but not required, to use Information Security Program references as provided by the National Institute of Standards and Technology (NIST), in documenting their efforts to implement reasonable security measures.

We believe these attestation requirements are critical to beneficiary confidence in the Medicare drug discount card program and their decision to enroll in an endorsed program. Furthermore, as endorsed sponsors are using the Medicare name and acting on our behalf in administering transitional assistance, we believe these requirements are important to promoting the continued confidence of beneficiaries in the Medicare program. We specifically require that applicants attest that they will be in compliance with the Security Rule as of their initiation of enrollment activities, or provide their plan for coming into compliance as of the compliance date. This approach will allow us to evaluate whether their information security measures will comply with the Privacy Rule standard under 45 CFR 164.530(c) and whether they will adequately protect the confidentiality, integrity, and availability of discount card enrollees' electronic protected health information.

10. Document Retention

Section 403.813(b) of our regulations requires endorsed sponsors to retain records that they or their subcontractors create, collect, or maintain while participating in the Medicare drug discount card program for at least six years following termination of the transition period. This retention period may be extended by the Secretary if an endorsed sponsor's records relate to an ongoing investigation, litigation, or negotiation by the Secretary, the OIG, the Department of Justice, or a State, or such documents otherwise relate to suspicions of fraud and abuse or violations of Federal or State law.

We recognize that under the Privacy Rule, CMS, as a covered entity, must require its business associates, upon termination of the contract, to return or destroy protected health information created or received in their capacity as business associates, or if such return or destruction is not feasible, to extend the contract protections to the retained information and limit further uses and disclosures to the purposes that made the return or destruction infeasible. Our record retention policy will make it infeasible for endorsed sponsors to return or destroy protected health information, as they will be required to retain all program information for at least six years after termination of the program. Therefore, as required by the Privacy Rule, the business associate contract protections for the retained information will continue to be applied and any further use or disclosure of the information will be limited to health care operations and health oversight activities that made return or destruction of the information infeasible, as well as other uses or disclosures that may be required by law.

In addition, our record retention policy will require endorsed sponsors to continue to apply security and privacy protections to the record and the information contained therein to the same extent endorsed sponsors are required to do so prior to termination. We establish this requirement under the authority granted the Secretary under section 1860D–31(h)(8) of the Act to protect and promote the interests of beneficiaries. The interests of beneficiaries are furthered by continuing to protect the confidentiality, integrity, and availability of their protected health information for so long as these records are retained by an endorsed sponsor.

We believe our retention policy is necessary to preserve our ability and that of other Federal and State agencies to exercise appropriate oversight over endorsed sponsors and protect the interests of beneficiaries. We believe six years represents an appropriate time period for this requirement because there is a six year statute of limitations on bringing actions for civil monetary damages under section 1860D–31(i)(3) of the Act against endorsed sponsors that knowingly engage in conduct that violates the requirements of section 1860D–31 or our regulations. Our record retention policy is subject to enforcement under § 403.820(a) of our regulations.

11. Endorsed Sponsor Reporting

Section 1860D–31(h)(4) of the Act provides that endorsed sponsors shall pass on negotiated prices to discount card enrollees, including discounts with pharmacies and manufacturers, to the extent disclosed to the Secretary. Further, section 1860D–31(i)(1) of the Act provides that endorsed sponsors shall disclose to the Secretary (in a manner specified by the Secretary) information relating to program

performance, use of prescription drugs by discount card enrollees, the extent to which discounts, rebates or other remunerations or price concessions made available to the endorsed sponsor by a manufacturer are passed through to discount card enrollees through pharmacies or otherwise, and such other information as the Secretary may specify. As provided under these authorities and in order to promote and protect the interests of beneficiaries, endorsed sponsors are required to maintain for auditing purposes, data and other information that will accomplish oversight objectives.

Additionally, we will collect information as part of our education and outreach efforts described in Section II.E, to provide beneficiaries comparative prices on covered discount card drugs across all endorsed programs.

To meet these objectives, we specifically require in § 403.806(i) of our regulations that endorsed sponsors report certain types of information. Examples include:

- Savings obtained through rebates, discounts, and other price concessions from pharmacies and manufacturers;
- Savings shared with discount card enrollees by manufacturer, by all retail pharmacies, by all mail order pharmacies, and by all brand name and generic covered discount card drugs;
- Dispensing fees;
- Certified (by the chief financial officer) financial accounting records on transitional assistance used by the transitional assistance enrollees in each month;
- Participant utilization and spending statements;
- Performance on customer service metrics such as call center performance;
- Grievance logs;
- Compliance with the pharmacy network access standards; and
- Notice of, and the rationale for, negotiated price increases, except for increases during the week of November 15, 2004, due to reasons other than changes in average wholesale price (AWP), including submission of an attestation that, based on best knowledge, information, and belief, the rationale for the price increase is accurate, complete, truthful, and supportable.

In addition, to support our education and outreach efforts endorsed sponsors must report the following—

- Customer service hours,
- Customer service contact information,
- Endorsed program Web site address,
- Annual enrollment fee, and
- Negotiated prices (including any applicable dispensing fee) for every covered discount card drug included in the endorsed program's offering.

This is not an exhaustive list of the types of card program performance we will monitor and evaluate, as we will, as described in section II.F. of the preamble, also conduct activities independent of this information to, for example, monitor whether marketing materials are properly used; evaluate beneficiary experience under the endorsed programs; and conduct program integrity activities.

The data and information that endorsed sponsors will be required to report consist of performance measures and indicators typically provided by third party administrators of pharmacy benefits in the current drug industry. Endorsed sponsors must certify the validity and completeness of the data and other information they report.

Further, during the endorsement period, endorsed sponsors will be required to notify us of any material modifications to their endorsed programs if the modification could put them at risk of no longer meeting any of the terms of the endorsement.

Section 1860D–31(i)(1) of the Act provides that section 1927(b)(3)(D) of the Act, which guides the protection of proprietary pricing information under the Medicaid program, shall also apply to the drug pricing data (other than aggregated data) under the Medicare drug discount card program. Consistent with the requirements of 1927(b)(3)(D) of the Act, we will handle any non-aggregated pricing information in a manner that ensures that the non-aggregated discounts or rebates or other remuneration or price concessions from manufacturers to endorsed sponsors, and reported by the endorsed sponsors, will not be made available in a format that discloses the identity of particular drugs, manufacturers, or wholesalers. However, the information may be disclosed in the circumstances described in section 1927(b)(3)(D)—

(1) As the Secretary deems necessary to carry out section 1860D–31 of the Act;

(2) To permit the Comptroller General to review the information provided; and

(3) To permit the Director of the Congressional Budget Office to review the information provided.

We will provide a reporting tool to ensure consistent and comparable reporting by endorsed sponsors. In developing the tool, we will make an effort to minimize the reporting burden on endorsed sponsors.

D. CMS Reimbursement of Transitional Assistance

All endorsed sponsors must enter into an agreement with CMS that will provide for reimbursement from CMS to endorsed sponsors for any transitional assistance applied toward the cost of covered discount card drugs obtained by transitional assistance enrollees in accordance with section 1860D–31(g)(3) of the Act. Under the contract, sponsors will submit requests to debit each enrollee's transitional assistance balance via the Department of Health and Human Services' Payment Management System. These amounts will be reported to CMS and used to reconcile payments, as provided in § 403.822(c) of our regulations.

Endorsed sponsors will be required to submit monthly reports detailing the total amount of transitional assistance applied toward the cost of covered discount card drugs obtained by transitional assistance enrollees. These reports will be reconciled against transitional assistance balance reports used to authorize payments to endorsed sponsors.

Endorsed sponsors will only be reimbursed for transitional assistance applied toward the cost of covered discount card drugs for claims that are fully adjudicated for payment; we will not reimburse endorsed sponsors for pending claims. Further, as provided in § 403.822(e) of our regulations, Federal funding in excess of the amount of the balance included in CMS' systems is not permitted.

We also expect endorsed sponsors to establish a process for holding pharmacies harmless, that is reimbursing pharmacies for their costs if the endorsed sponsor erroneously informs the pharmacy that the amount of transitional assistance remaining available to a transitional assistance enrollee is more than the amount actually available to the transitional assistance enrollee.

As discussed above in section II.C.6. of this document, should a discount card enrollee be determined eligible for transitional assistance after already enrolling in an endorsed program, we will pay the annual enrollment fee and the endorsed sponsor must immediately refund to the card enrollee, or any State that has paid the enrollment fee on behalf of the discount card enrollee, any annual enrollment fee for the calendar year previously paid by the discount card enrollee or State. The endorsed sponsor would include this payment in its report to us for our reimbursement.

Endorsed sponsors will be required to have a process for managing payment

against an individual's transitional assistance cap to ensure that not more than the amount of transitional assistance available is provided to the individual. Additionally, endorsed sponsors will need to have a process for managing transitional assistance in the event a transitional assistance enrollee switches endorsed discount card programs with a transitional assistance balance remaining. In this case, the endorsed sponsor must ensure that the amount of transitional assistance reported to CMS as remaining available for transfer to the new endorsed program is a final number; that is, CMS will not adjust the number at a later date to account for outstanding claims at the time the amount was reported, nor will CMS provide additional reimbursement to the endorsed sponsor to make up any difference. In their applications, applicants must describe their processes for (1) managing payment against transitional assistance caps, and (2) managing payment such that remaining transitional assistance balances reported to CMS at the time of an enrollee's disenrollment represent final amounts. If processes that endorsed sponsors put in place to manage payment in these cases could create a financial liability for a transitional assistance enrollee, endorsed sponsors will be required to inform these enrollees of such circumstances and any special procedures.

Our procedures for reimbursing endorsed sponsors for transitional assistance will be discussed in further detail in the solicitation and pre-application conference.

E. CMS-Provided Beneficiary Education

1. General

In accordance with section 1860D–31(d)(1) of the Act, we plan to disseminate to beneficiaries eligible for the discount card general information about the availability of the program and general program features, such as the limitation of enrollment to only one discount card at a time, the initial enrollment date, and the potential use of formularies containing the drugs on which discounts are available. We also plan to disseminate general information about the availability of transitional assistance and the qualifying standards for the assistance. In addition to the general information, we plan to disseminate specific comparison information to promote informed consumer choice among endorsed discount card programs, including—

- Enrollment fee;
- Customer service hours;
- Contact information;
- Program Web site; and
- Negotiated prices, to include the dispensing fee.

Finally, we plan to develop messages that are understandable and meaningful for beneficiaries to support specific information about the program in order to increase beneficiary knowledge about and motivation to consider this program.

Section 1860D–31(d)(1)(C) of the Act states that both the general information and the specific comparative information should, ''to the extent practicable,'' be disseminated so that ''discount card eligible individuals are provided such information at least 30 days prior to the initial enrollment date.'' We will make available general program information and a subset of comparison information for each card program 30 days before the initial enrollment date and will coordinate later information dissemination activities with our annual coordinated education campaign on Medicare options. The provided comparison information will not contain negotiated prices. Provision of ''price comparison'' information to the public requires populating a database with data files from each endorsed sponsor, with a standard format and terminology, of negotiated prices, to include dispensing fee information for each covered discount card drug. To ensure the accuracy of prices on the Web site, endorsed sponsors must be allowed to validate their submitted price information. These activities cannot be completed before the start of the initial enrollment date. In the 30 days prior to the initial enrollment date, discount card eligible individuals will be able to access specific prices by contacting endorsed sponsors through the contact information we will provide.

2. Medicare Web site and Toll-free Information Line

Both general and comparison information will be made available to Medicare beneficiaries on our Web site, *http://www.medicare.gov,* as well as through the toll-free Medicare information line (1–800–MEDICARE), which is available 24 hours per day, 7 days a week. To generate awareness about the program and resources available to answer consumer questions, we plan to use paid advertising, including television, to reach the general audience and the Hispanic market. We also expect a Medicare publication describing program features will be available on *http://www.medicare.gov* and through 1–800 Medicare 30 days prior to the initial enrollment date. We also expect to include an overview of this program in the 2005 *Medicare & You* handbook, which will reach beneficiaries in time to elect a new drug card for 2005. In addition, we will strive to disseminate information to community level organizations, State Health Insurance Assistance Programs, and our other partners that represent the needs and the interests of the diverse Medicare beneficiary population.

To report on negotiated prices, as requested in section 1860D–31(d)(1)(B)(i) of the Act, we will provide, through *http://www.medicare.gov,* a price comparison Web site that will include maximum, and possibly ranges of, negotiated prices, including the dispensing fee, in actual dollars for the purpose of comparing across endorsed discount card programs. These prices will reflect an estimate of the maximum price charged at the point of sale. This Web site should also include information about generic substitutes. All of this comparative information will assist beneficiaries in deciding which Medicare discount card will offer them the greatest financial advantage. We will provide education that drugs and prices may vary over time.

As described in § 403.806(i)(4)(v), to support the price comparison Web site, drug card sponsors may submit updated data files on a weekly basis to include information on customer service hours, contact information, program Web site, enrollment fee, and negotiated prices, including the dispensing fee. We will specify a standard file format and timing for submitting these data elements to us in the solicitation for endorsed sponsors. At a minimum, each file will include the maximum negotiated price for every covered discount card drug under the card program. As required in § 403.806(d)(5) of our regulations, maximum negotiated prices available under the endorsed discount card program must match those reported on the price comparison Web site. We believe that a weekly update of information is frequent enough to allow endorsed sponsors to adjust to fluctuating supply prices, but also ensures that accurate price information is available to discount card eligible individuals and card enrollees at all times. The effort to allow more frequent updates is not practical because we must coordinate creating a new database of prices from all endorsed sponsors.

As discussed in section II.C.7. of this document, in order to communicate the Secretary's endorsement of a prescription drug discount card program, as required in section 1860D–31(a)(1)(A) of the Act, 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 develop standards for use of the emblem to be included in the Information and Outreach Guidelines.

In addition to answering beneficiary questions about the drug discount card program, the 1–800 MEDICARE call center will also log and help triage discount card members' complaints for resolution through the complaints tracking process discussed in greater detail under section II.F. of this document.

Physicians and pharmacists are an important source of information for discount card eligible beneficiaries. Although not required by the legislation, we also plan to conduct provider outreach activities through a variety of channels to make physicians and pharmacists aware of this program and to educate them about the specific features. We hope that increased physician and pharmacist awareness will bolster beneficiary awareness and improve the quality of their card choice and their ultimate cost-savings. We also believe that physician and pharmacist promotion of the program will encourage low-income individuals to enroll and access the available transitional assistance.

F. CMS Oversight and Monitoring

1. General

Consistent with section 1860D–31(i)(2) of the Act, we will develop a drug discount card program oversight system to ensure compliance with program requirements.

We will develop and operate a complaint (also referred to as ''grievance'') tracking system to monitor and manage complaints that are not satisfactorily resolved through the endorsed sponsors' customer complaints process. In accordance with section 1860D–31(d)(1)(D) of the Act, we will develop a system for collecting beneficiary complaints through our 1–800–MEDICARE toll-free telephone number. This system will likely be augmented by a system for gathering and responding to complaints acquired through the *http://www.medicare.gov* Web site as well as through Congressional and other types of correspondence. We will also analyze the reports provided by endorsed sponsors on their program performance. In addition, we plan to conduct mystery shopping and a beneficiary satisfaction survey. We plan to use these various sources of information to observe possible trends that indicate less than satisfactory performance, significant departures from the marketed card program offering, or fraud or other violations of State and Federal laws. We anticipate tracking complaints related to—

- Deceptive marketing and enrollment practices;
- Violations of the confidentiality provisions;
- Persistent inconsistencies in formulary or pricing information compared to those available at the point of sale;
- Inadequate endorsed sponsor customer service;
- Persistent problems with pharmacy network services or providers;
- Denying transitional assistance to qualified beneficiaries;
- Arbitrary variations in negotiated prices offered; and
- Any additional changes that put the endorsed sponsor at risk of failing to continue to meet the endorsement requirements.

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

a. Marketing and Enrollment Policies

We will also review information from our own enrollment systems for data that may indicate endorsed sponsors' failure to comply with the program's marketing or enrollment policies. We will examine claims and pricing data reported by endorsed sponsors to determine whether enrollees are receiving the savings promised through their discount cards. Finally, we will review the grievance logs submitted by each of the endorsed sponsors to examine trends in types of complaints and to ascertain whether endorsed sponsors are responding appropriately to enrollee service complaints.

b. Transitional Assistance Payments

We will also monitor the allocation and tracking of the annual transitional assistance payments for eligible enrollees. As a qualification for endorsement, under section 1860D–31(h)(1)(C) of the Act, endorsed sponsors are required to have satisfactory arrangements to account for the transitional assistance. To ensure that transitional assistance is made available on behalf of the proper beneficiaries and that it is used only to purchase covered discount card drugs, we will contract with auditors to analyze select claims and other information maintained by the sponsors related to the payment and tracking of the transitional assistance. As necessary, we will exercise our authority, under section 1860D–31(i)(2) of the Act, to conduct audits and to inspect the records of endorsed sponsors related to the operation of the drug discount card program.

2. Intermediate Sanctions

Under section 1860D–31(i)(3) of the Act, we may impose intermediate sanctions against endorsed sponsors in the form of suspended marketing and enrollment activities in a manner similar to the sanctioning process under Part C. In § 403.820(a)(3), we have identified the following bases related to significant performance requirements for the imposition of intermediate sanctions—

(1) Substantial failure to maintain an adequate contracted retail pharmacy network;

(2) Substantial failure to comply with our information and outreach guidelines;

(3) Substantial failure to provide enrollees with negotiated prices consistent with information provided on our price comparison Web site and/or reported by the sponsor;

(4) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), substantial failure to ensure that the negotiated price for a covered discount card drug does not exceed an amount proportionately greater than the change in the drug's average wholesale price (AWP), and/or an amount proportionate to changes in the endorsed sponsor's cost structure (including material changes to any discounts, rebates, or other price concessions the endorsed sponsor receives from a pharmaceutical manufacturer or pharmacy);

(5) Charging card program enrollees additional fees beyond the $30 enrollment fee;

(6) Charging transitional assistance enrollees any enrollment fee;

(7) Charging a coinsurance rate higher than 10 percent for those above 100 percent of the poverty line and up to 135 percent of the poverty line, or charging a coinsurance rate higher than 5 percent for those at or below 100 percent of the poverty line;

(8) Substantial failure to properly administer the transitional assistance funding for transitional assistance enrollees;

(9) Substantial failure to provide us or our designees with requested information related to the endorsed sponsor's drug card operations;

(10) Substantial failure to comply with the requirements of the

endorsement, including failing to perform the operational requirements of this program, or the failure to submit an acceptable plan of correction within the time frame specified by CMS; and

Upon determining that at least one basis exists for imposing an intermediate sanction, our regulations at § 403.820(a)(4) provide that we will notify the non-compliant endorsed sponsor of our intent to impose sanctions. The endorsed sponsor will have 15 days to challenge the accuracy of our finding. If the endorsed sponsor does not challenge the finding, the sanctions will go into effect 15 days after the endorsed sponsor received the sanction notice from us. If the endorsed sponsor does challenge the finding, we will notify the sponsor of the effective date in the reconsideration determination notice that we will send to the endorsed sponsor. Once intermediate sanctions are imposed, the endorsed sponsor will be required to demonstrate to us that it has come into compliance with card program requirements before the sanctions are lifted.

3. Civil Monetary Penalties

Section 1860D–31(i)(3) of the Act authorizes the imposition of civil monetary penalties (CMP) against endorsed sponsors that knowingly engage in conduct that violates the requirements of section 1860D–31 of the Act or engage in false or misleading marketing practices. In § 403.820(b) of our regulations, we interpret this to mean that those endorsed sponsors that knowingly engage in conduct that violates the conditions of their endorsement agreement with us or that constitutes false or misleading marketing practices may be subject to CMPs.

We have divided the sanction authority between CMS and the Department of Health and Human Services Office of the Inspector General (OIG). As in Part C, where CMP authority is shared between these two agencies, we have assigned sanction authority to OIG for those violations that concern misleading or defrauding a beneficiary. We have also assigned sanction authority to the OIG for misuse of transitional assistance funds. On the other hand, we will have the authority to impose CMPs in those instances where the endorsed sponsor's conduct constitutes non-compliance with an operational requirement not directly related to beneficiary protection. Accordingly, as provided in § 403.820(b)(1) of our regulations, OIG will have the authority to impose CMPs against an endorsed sponsor whom it determines has knowingly—

(1) Misrepresented or falsified information in information and outreach or comparable material provided to a program enrollee or other persons;

(2) Charged a program enrollee in violation of the terms of the endorsement contract; or

(3) Used transitional assistance funds in any manner that is inconsistent with the purpose of the transitional assistance program.

As provided in § 403.820(b)(2) of our regulations, we will have the authority to impose CMPs for an endorsed sponsor's—

(1) Substantial failure to maintain an adequate retail pharmacy network;

(2) Substantial failure to comply with our information and outreach guidelines;

(3) Substantial failure to provide us or our designees with requested information related to the endorsed sponsor's drug card operations;

(4) Substantial failure to provide enrollees with levels of discounts or prices consistent with information provided in its marketing materials;

(5) Charging card program enrollees additional fees beyond an enrollment fee, charging transitional assistance-qualified enrollees any enrollment fee, charging a co-payment higher than 10 percent for those above 100 percent of the poverty line and up to 135 percent of the poverty line, or charging a co-payment higher than 5 percent for those at or below 100 percent of the poverty line;

(6) Substantial failure to administer properly the transitional assistance, including the charging of coinsurance, for the endorsed sponsor's eligible enrollees;

(7) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), substantial failure to ensure that the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP) and/or an amount proportionate to the changes in the endorsed sponsor's cost structure (including materials changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy); or

(8) Any other failure to substantially comply with the requirements of the endorsement, or the failure to submit an acceptable plan of correction within the timeframe specified by CMS.

The CMS and the OIG may impose CMPs of up to $10,000 per violation. We will impose CMPs and afford endorsed sponsor appeal rights according to the procedures stated in 42 CFR parts 1003 and 1005.

We note that in addition to the sanctions described above, a card sponsor's misuse of the Medicare name or emblem may subject them to the penalties stated at 42 U.S.C. 1320b-10, which prohibits the misuse of the Medicare name or emblem. In general, the statute authorizes the OIG to impose penalties on any person who misuses the term, ''Medicare,'' or other names associated with DHHS in a manner which the person knows or should know gives the false impression that it is approved, endorsed, or authorized by DHHS. Offenders are subject to fines of up to $5000 per violation or, in the case of a broadcast or telecast violation, $25,000.

4. Termination by CMS

Pursuant to section 1860D–31(i)(3) of the Act, and as provided in § 403.820(c) we may terminate the contract of any endorsed sponsor upon a determination that the sponsor no longer meets the requirements for participation in the Medicare drug discount card program or that the sponsor has engaged in false or misleading marketing practices (for example, use of non-CMS-approved marketing materials, marketing outside the approved service area, use of beneficiary information to market services not directly related to the endorsed sponsor's Medicare card program). The bases stated above for the imposition of intermediate sanctions also serve as the bases for termination for failure to meet the requirements for participation in the Medicare drug discount card program. Prior to terminating a contract, we will afford the endorsed sponsor an opportunity to develop and execute a CMS-approved corrective action plan.

We will afford an endorsed sponsor the opportunity to appeal our decision to terminate an endorsement contract as well as our decision not to enter into a contract with an entity that applied for endorsement. In each case, we will provide notice to the endorsed sponsor stating the reasons for terminating the contract or failing to endorse the program. These sponsors will have 15 days from the date of the notice to file a request in writing for reconsideration to us. We will then designate a hearing officer who is impartial and has no interest in the matter pending for decision. CMS and the sponsor will have the opportunity to submit evidence and participate in a hearing convened by the hearing officer. The hearing officer will issue a decision as soon as

practicable after the hearing. This decision is final and binding on the parties and, as provided in § 403.820(f)(11) of our regulations, is not subject to judicial review.

Endorsed sponsors whose endorsement we terminate must notify all of their card program enrollees in writing within 10 days of receiving our notice of termination.

5. Termination by Endorsed Sponsor

An endorsed sponsor may terminate its contract with us in the event that we substantially fail to perform our obligations related to this program, as provided in § 403.820(d). These obligations would include, but are not limited to, our operation of the drug card enrollment system, price comparison Web site, and reimbursement for transitional assistance, as well as payment of enrollment fees for beneficiaries eligible for transitional assistance and timely review of marketing materials. An endorsed sponsor entering into a contract with us has a reasonable business expectation that we will adequately support the operation of the discount card program and that it will not be held to the contract in the event that we are in significant breach of that contract. Accordingly, we are adopting this termination provision to promote the efficient administration of the Medicare drug discount card program, consistent with section 1102 of the Act.

The endorsed sponsor will be required to provide a notice of termination to us 90 days prior to its intended effective date and to its enrollees by mail 60 days prior to the same date. The notice will provide affected enrollees with a description of remaining endorsed discount card programs available in its own area and the process for enrolling in a new endorsed discount card program.

6. Termination by Mutual Consent

As provided in § 403.820(e) of our regulations, CMS and an endorsed sponsor may agree to terminate or modify an existing contract. If a contract is terminated by mutual consent, the endorsed sponsor must follow the enrollee notice procedures as required in the case of a termination of the contract by an endorsed sponsor. We have adopted the provision, as specified in § 403.820(e), for mutual modification or termination to address those circumstances when both parties may agree that a contract termination is in the best interests of the endorsed sponsor, taxpayers, Medicare beneficiaries, and the Medicare program, allowing us to terminate an endorsed sponsor's endorsement contract before its term expires. This is also a contracting provision that we are adopting to promote the efficient administration of the Medicare drug discount card program, consistent with section 1102 of the Act.

G. Special Rules Concerning Medicare Managed Care Organizations

1. General Requirements for Medicare Managed Care Organizations

As discussed in section II.C.1 of this document and codified in §§ 403.804(b) and 403.804(c) of our regulations, section 1860D–31(h)(1)(A)(iv) of the Act provides that a Part C organization is eligible to be an endorsed sponsor if it meets the requirements for endorsement either individually or in combination with one or more other entities. Sections 403.804(b) and 403.804(c) of our regulations also make reasonable cost reimbursement plans eligible to be endorsed sponsors provided they meet the requirements for endorsement. Medicare managed care organizations—organizations offering coordinated care plans as described in section 1851(a)(2)(A) of the Act and reasonable cost reimbursement plans under section 1876(h) of the Act—qualifying for endorsement may offer their endorsed program to all discount card eligible individuals residing in their service area(s) or only to those discount card eligible individuals enrolled in one or more of the Medicare managed care organization's plan(s). All other Part C organizations qualifying for endorsement must offer their endorsed program to all discount card eligible individuals residing in their service area(s). Part C organizations and reasonable cost reimbursement contracts that offer an endorsed program to all discount card eligible individuals must meet the requirements for endorsement applicable to all other applicants endorsed sponsors. However, as discussed below in section II.G.2.a of this document, special rules apply to Medicare managed care organizations that limit enrollment in their endorsed program to members of one or more of their Medicare managed care plans.

Under section 1860D–31(g)(7) of the Act, any nonuniformity in benefits offered by a Part C organization to its Part C plan members resulting from implementation of the Medicare drug discount card program, including payment or waiver of any enrollment fee for an endorsed program and limiting transitional assistance to transitional assistance enrollees, will not be taken into account in applying the requirement, set forth in section 1854(f)(1)(D) of the Act that any additional benefits offered by a Part C organization be provided uniformly to all Part C plan members. Accordingly, as provided in § 403.814(c) of our regulations, a Part C organization will not be violation of this uniformity of benefits rule if it:

- Pays the annual enrollment fee, if any, for its Part C plan members choosing to enroll in an endorsed program—whether operated by the Part C organization or another endorsed sponsor—provided that any such benefit is reflected in the Part C plan's Adjusted Community Rate (ACR) filing;
- Waives the annual enrollment fee for its Part C plan members enrolling in its endorsed program, provided that any such benefit is reflected in the Part C plan's Adjusted Community Rate (ACR) filing;
- Provides transitional assistance to transitional assistance enrollees.

Although section 1860D–31 of the Act does not explicitly state that it is creating an exception to the uniform premium rule under section 1854(c) of the Act and 42 CFR 422.100(d)(2), it authorized Part C plans to offer non-uniform benefits that would be inconsistent with the rule. For the reasons set forth below, we believe that in doing so, Congress created a new implicit statutory exception to the uniform premium rule. Under the uniform premium rule, as implemented in regulations, a Part C organization must offer its Part C plan at a uniform premium, with uniform benefits and cost-sharing levels throughout the plan's service area (or segment of the plan's service area as provided in 42 CFR 422.304(b)(2)). Absent an exception to this rule, a Part C organization offering its endorsed program to members of its Part C plan as an optional supplemental benefit would be required to offer the benefit to all of its members within the plan's service area (or segment of the service area), and charge them the same annual enrollment fee. However, as discussed above in section G.1. of this document, a Part C organization is prohibited by statute from offering its endorsed program to members of its Part C plan(s) that are not eligible for the Medicare drug discount card program. Similarly, a Part C organization offering an endorsed program may not collect an annual enrollment fee from transitional assistance enrollees, but instead must collect this fee from CMS. Consequently, a Part C organization offering an endorsed program to members of its Part C plan(s) cannot comply with the requirements of section 1860D–31 without violating the uniform premium rule.

As discussed in Norman J. Singer's *Statutes and Statutory Construction* (6th ed.), where two statutory provisions irreconcilably conflict, courts generally hold that the more recently enacted statutory provision prevails. Applying this principle, we believe that in enacting the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress intended implicitly to except from the uniform premium rule under Part C any non-uniformity resulting from a Part C organization's implementation of its endorsed program. We further note that in section 1860D–31(g)(7) of the Act Congress clearly indicated its intent to allow non-uniformity in benefits among a Part C plan's members as a result of a Part C organization's implementation of its endorsed program. Accordingly, as provided in § 403.814(c) of our regulations, a Part C organization would not be violation of the uniform premium rules under section 1854(c) of the Act and 42 CFR 422.100(d)(2) if it:

- Offers its endorsed program to members of its Part C plan who are discount card eligible individuals, to the exclusion of those members who are not discount card eligible individuals; or
- Collects an annual enrollment fee only from discount card enrollees who are not eligible for transitional assistance.

Section 18060D–31(a)(3) provides that discount card eligible individuals cannot be required to enroll in an endorsed program. In keeping with the voluntary nature of the Medicare discount drug card program, and as specified in § 403.814(a) of our regulations, a Part C organization or reasonable cost reimbursement plan may not require enrollment in any endorsed program, whether operated by the organization or another entity, as a condition of enrollment in any of its Part C or reasonable cost reimbursement plans.

In addition, a Part C or reasonable cost reimbursement organization may not require transitional assistance enrollees enrolled in its Part C or reasonable cost reimbursement plan to exhaust their transitional assistance prior to obtaining covered discount card drugs under any drug benefit offered by its Part C or reasonable cost reimbursement plan. We believe this policy is consistent with the Part C rules under 42 CFR 422.100(d)(2) and section 1876(g)(2) of the Act which require that any additional benefit offered by a Part C or reasonable cost reimbursement plan must be offered uniformly to all plan members. Requiring transitional assistance enrollees to utilize their transitional assistance prior to obtaining covered discount card drugs under their Part C or reasonable cost reimbursement plan drug benefit would violate these uniformity of benefits rules because non-transitional assistance enrollees would be entitled to obtain covered discount card drugs under the Part C or reasonable cost reimbursement plan drug benefit while transitional assistance enrollees would be prohibited from doing so until they exhaust their transitional assistance. In other words, non-transitional assistance enrollees would receive more generous drug coverage under the Part C or reasonable cost reimbursement plan than transitional assistance enrollees. (Section 1860D–31(g)(7) of the Act waives the uniformity of benefits rule under Part C only for purposes of implementing the Medicare drug card program; that is, when non-uniformity directly results from implementation of the drug card statutory provisions. Because any requirement that transitional assistance enrollees first exhaust their transitional assistance would stem not from implementation of the Medicare drug discount card program but from the benefits package offered under a Part C plan, the uniformity of benefits waiver under section 1860D–31(g)(7) of the Act would not apply.) We also note that our prohibiting Part C organizations from requiring their transitional assistance enrollees to first exhaust their transitional assistance prior to utilizing their drug benefit under their Part C plan means Part C plans will not need to take transitional assistance into account in their annual ACR filings.

As discussed in II.A.6. of this document and provided in our regulations at § 403.811(b)(2)(iii), discount card enrollees may disenroll from their endorsed program and enroll in a new endorsed program during a special election period when enrolling in or disenrolling from a Part C or reasonable cost reimbursement plan offering an endorsed program, irrespective of whether the Part C or reasonable cost reimbursement plan offers an endorsed program of any kind. We will automatically disenroll card enrollees from their endorsed program when they enroll in or disenroll from a Medicare manage care plan offering an exclusive card program. Further, in accordance with our regulations at § 403.808(f)(3), any transitional assistance remaining available to a transitional assistance enrollee electing to switch to a new endorsed program following his or her enrollment in or disenrollment from a Part C or reasonable cost reimbursement plan offering an endorsed program will follow the transitional assistance enrollee to his or her new endorsed program.

2. Special Rules for Applicants Seeking To Offer Exclusive Card Programs

a. Endorsement Requirements for Applicants Seeking To Offer Exclusive Card Programs

Applicants seeking to offer an exclusive card program must indicate their intent to do so on their applications. For Medicare managed care organizations seeking to offer an exclusive card program, if the Medicare managed care organization combines with one or more other entities eligible to meet the requirements of endorsement, the Medicare managed care organization must be the applicant, as required under § 403.814(b)(1) of our regulations. We require this because we want to ensure that our endorsed sponsor contract—and, ultimately, accountability for an endorsed program—is with the Medicare managed care organization itself, and not with any of the entities with which it combines to offer an endorsed program. If a Medicare managed care organization will not offer an exclusive card program, we will permit another entity with which the Medicare managed care organization combines to be the applicant.

We will not require Medicare managed care organizations operating more than one Medicare managed care plan to offer its exclusive card program to members of all of its Medicare managed care plans; rather, the Medicare managed care organization may limit enrollment in its exclusive card program to members of only certain Medicare managed care plans it operates. Members of the organization's other Medicare managed care plans are free to enroll in any other endorsed program, including any non-exclusive endorsed program offered by the Medicare managed care organization, provided they meet the eligibility criteria for the program.

Section 1860D–31(h)(9)(B) of the Act exempts exclusive card sponsors from certain requirements generally applicable to endorsed sponsors, including: (1) The requirement set forth in section 1860D–31(h)(3) of the Act and § 403.806(f)(1) and § 403.806(f)(2) of our regulations concerning minimum service areas; and (2) the pharmacy access standard under section 1860D–31(e)(1)(B) of the Act and § 403.806(f)(3) of our regulations.

Although a Medicare managed care organization may limit enrollment in its

exclusive card program to members of one or more of its Medicare managed care plans that include the exclusive card program as part of the plans' benefit package, the Medicare managed care organization must offer its exclusive card program to all discount card eligible individuals enrolled in those specific Medicare managed care plan(s). A Medicare managed care organization may not limit enrollment in its exclusive card program to only some discount card eligible individuals enrolled in those Medicare managed care plan(s) to the exclusion of other discount card eligible individuals because this would violate the uniformity of benefits provisions under section 1854(f)(1)(D) of the Act and 42 CFR 422.100(d)(2).

We also implement the exception from pharmacy access standards in section 1860D–31(h)(9)(B)(ii) of the Act and § 403.814(b)(3)(i) of our regulations by deeming exclusive card sponsors as having met such standards if—

- The network is not limited to mail-order pharmacies; and
- The network is equivalent to the pharmacy network under any outpatient drug benefit offered under the Medicare managed care organization's Medicare managed care plan which was previously approved by us under the Medicare Part C or Section 1876 rules.

If the Medicare managed care organization does not offer a drug benefit under its Medicare managed care plan, we will evaluate whether the network provides sufficient access to covered discount card drugs at negotiated prices for discount card enrollees using the same considerations we currently use to evaluate Medicare managed care plans' other provider networks under 42 CFR 422.112.

We are not applying the standards of § 403.806(f)(3) of our regulation because these standards may be impracticable for exclusive card sponsors. Medicare managed care organizations currently do not have to follow these standards in establishing their pharmacy networks. We presume that many exclusive card sponsors will wish to use the same pharmacy networks under their endorsed program as they currently use to provide prescription drugs under any prescription drug benefit they may offer to their Medicare managed care plan members. Moreover, given the size of exclusive card sponsors' service areas relative to the statewide service areas of other sponsors, the pharmacy access standards contained in § 403.806(f)(3) of our regulation may be too restrictive. In addition, Medicare managed care organizations that use plan-owned pharmacy networks would have a difficult time meeting these access standards.

In addition to the requirements Congress specifically waived in section 1860D–31(h)(9)(B) of the Act, section 1860D–31(h)(9)(B)(iii) authorizes the Secretary to waive other endorsed sponsor requirements if those requirements are duplicative of or conflict with requirements applicable to Medicare managed care organizations under Part C (and the regulations promulgated thereunder) or section 1876 (and the regulations promulgated thereunder), as the case might be, or if waiver of the requirements would improve coordination of the benefits available under the Medicare drug discount card program and Medicare managed care plan programs. We believe the following requirements, discussed in section II.C of this document, are duplicative of, or conflict with, requirements applicable to Medicare managed care organizations under Medicare managed care plan programs, or that waiver of such requirements would improve coordination of the Medicare drug discount card program with Medicare managed care plan benefits—

(1) The covered lives requirement in § 403.806(a)(3) of the regulations;

(2) The requirement set forth in § 403.806(e)(2) of our regulations that transitional assistance be applied only toward costs incurred for covered discount card drugs obtained through the Medicare drug discount card program. Instead, we also permit transitional assistance to be used to pay for coinsurance, copayments, or other cost-sharing charged under a Medicare managed care plan drug benefit when beneficiaries purchase covered discount card drugs.

In addition, although applicants seeking to offer an exclusive card program must meet the business integrity and financial stability requirements in § 403.806(b) of our regulations, we will not require their applications to include the documentation we generally require of applicants to demonstrate compliance with this requirement, as described in section II.C.1. of this document, because such documentation would be duplicative of what these organizations already must demonstrate to us under the provisions of Part C and section 1876 of the Act.

We believe it is appropriate to waive the 1 million covered lives requirement for exclusive card programs because 1 million covered lives is more than most Medicare managed care organizations currently enroll in their Medicare managed care plans and is far higher than the minimum enrollment requirements for Medicare managed care organizations under 42 CFR 422.514 and 42 CFR 417.413(b). Moreover, the service area for exclusive card programs will be limited to the affiliated Medicare managed care plan service area, which could be as low as several thousand individuals for some plans. Therefore, the 1 million covered lives standard potentially would conflict with the minimum enrollment requirements for Medicare managed care plans and pose challenges for certain Medicare managed care organizations seeking to coordinate benefits under their Medicare managed care plans and newly created endorsed programs. Our failure to waive the 1 million covered lives requirement for exclusive card programs likely would have the effect of excluding from the Medicare drug discount card program small Medicare managed care organizations that might otherwise meet the endorsement requirements.

We believe it is appropriate to waive the transitional assistance requirements in § 403.806(e)(2) of our regulations. We believe exclusive card sponsors should be permitted to apply transitional assistance toward any copay, coinsurance, and deductible amounts incurred by transitional assistance enrollees for covered discount card drugs obtained under their Medicare managed care plan's outpatient drug benefit in order to improve coordination between the benefits provided under their endorsed programs and Medicare managed care plans. Because of differences between the cost-sharing structure under a Medicare managed care plan's outpatient prescription drug benefit and the coinsurance requirements under the Medicare drug discount card program, as required under section 1860D–31(g)(1)(B) of the Act, transitional assistance enrollees could be responsible for a larger portion of a drug's costs if obtained under the Medicare managed care plan drug benefit than under the Medicare drug discount card program. Allowing transitional assistance enrollees to apply transitional assistance toward any cost-sharing amounts incurred for covered discount card drugs obtained under their Medicare managed care plan drug benefit would address this problem while allowing for more seamless drug coverage.

Although applicants seeking to offer an exclusive card program must meet the business integrity and financial stability requirements under § 403.806(b) of our regulations, we believe the process for demonstrating compliance with this requirement, as

described in section II.C.1 of this document, is duplicative of aspects of the qualification process that already exists under Part C and section 1876 of the Act. Medicare managed care organizations are currently required, under 42 CFR 422.400 or 42 CFR 417.120 and 42 CFR 417.122, to be licensed under State law as risk-bearing entities or, alternatively, to obtain certification from a State that they meet the financial solvency and other standards that the State may require for the entity to operate as a managed care plan. Under these licensure or certification requirements, Medicare managed care organizations must demonstrate a level of business stability and integrity that generally exceeds our standards for endorsed program applicants. Because exclusive card sponsors already demonstrate business stability and integrity through alternative processes, neither they nor their subcontractors will be required to present documentation demonstrating they meet the business stability and financial stability requirement set forth in § 403.806(b) of our regulations.

In addition to the aforementioned waivers, we will allow applicants seeking to offer exclusive card programs to request in their applications for endorsement that we waive or modify additional requirements applicable to endorsed sponsors. Applicants making such requests must demonstrate that the requirements at issue are duplicative of, or conflict with, requirements applicable to Medicare managed care organizations under Part C, or that they interfere with coordination of the benefits offered under the Medicare drug discount card program with benefits provided under Part C. If we determine that waiver of any additional requirements applicable to endorsed sponsors would be appropriate with respect to exclusive card sponsors, the waivers will apply to all similarly situated exclusive card sponsors.

We are considering providing a streamlined application process for applicants seeking to offer exclusive card programs that parallel the discount cards currently offered under their Medicare managed care plans. We will provide further guidance on this issue in the solicitation.

b. Enrollment and Enrollment Fees in Exclusive Card Programs

As discussed in section II.A.3 of this document, and under section 1860D–31(c)(1)(E) of the Act, discount card eligible individuals enrolled in a Medicare managed care plan offering an exclusive card program may *only* enroll in the exclusive card program and may not enroll in another endorsed sponsor's endorsed program. Discount card eligible individuals enrolled in Medicare managed care plans that *do not* offer an exclusive card program may enroll in any endorsed program available in their service area.

As discussed above in section II.A.3 of this document and as described in § 403.814(b)(5) our regulations, we will allow Medicare managed care organizations offering exclusive card programs to group enroll their eligible Medicare managed care plan members into their exclusive card programs—defined as simultaneous enrollment of all or many members of a Medicare managed care plan into an exclusive card program. However, prior to doing so, an exclusive card sponsor must disclose to its Medicare managed care plan members its intent to group enroll them into its exclusive card program and provide them the opportunity to actively decline such enrollment.

c. Application Process

Section 403.804(a) of our regulations provides that only those applicants submitting their applications for endorsement of their prescription drug discount card programs by the deadline announced in the solicitation will be eligible for endorsement. However, in recognition of the advantages to members of Medicare managed care plans from improved coordination between the benefits available under the Medicare drug discount card program and their Medicare managed care plans, we will permit certain Medicare managed care organizations to apply for endorsement of their prescription drug card programs after the official application deadline.

As discussed above, section 1860D–31(h)(9)(B)(iii) of the Act authorizes the Secretary to waive requirements applicable to endorsed sponsors for exclusive card sponsors if such waiver would improve coordination of the benefits available under the Medicare drug discount card program and Medicare managed care plan programs. One of the major features of the Medicare discount drug card program is that it allows Part C organizations to offer members in their plans a prescription drug plan that integrates access to negotiated prices and transitional assistance available under a drug card with the unique package of benefits available in that Part C plan, including any prescription drug benefit. Beneficiaries who choose to enroll in a new Medicare managed care plan should have the same access to these coordinated discount card programs as members of existing Part C plans. Therefore, as provided under § 403.804(a)(2) of our regulations, we will permit an entity that is applying to enter into a new contract with CMS under Part C to offer a new coordinated care plan or plans, as described in section 1851(a)(2)(A) of the Act, to simultaneously apply to offer an exclusive card program. We will approve such organization's application to offer an exclusive card program provided we approve its Part C application, the Part C organization demonstrates to CMS that it meets all applicable requirements for endorsement, and the Part C organization is ready to initiate enrollment in and fully operate its exclusive card program upon approval of its Part C and endorsement applications.

H. Special Rules Concerning States

1. State Pharmacy Assistance Programs

As described above in section II.A.1. of this document, under section 1860D–31(b)(1)(A)(ii) of the Act and § 403.810(a)(2) of this regulation, beneficiaries with outpatient prescription drug coverage under Title XIX (Medicaid) or a section 1115 waiver demonstration are ineligible for the Medicare drug discount card program. Conversely, beneficiaries with outpatient prescription drug coverage under certain other sources may be eligible for the program provided they meet all other eligibility criteria. For example, many State and local governments provide outpatient prescription drug coverage to individuals through State pharmacy assistance programs (SPAP). Because these programs are operated separately from Title XIX and section 1115 waiver demonstrations and are funded in whole or in part by the State or local governments, without any Federal financial participation, individuals enrolled in these programs still may be eligible for the Medicare drug discount card program. The SPAPs have flexibility in deciding how to work in partnership with endorsed programs. For example, if a State has an SPAP operated by an entity that meets the requirements for endorsement under § 403.800 through § 403.822 of our regulations, that entity could apply to become an endorsed sponsor. However, the entity would be required to meet all requirements for endorsement, including the requirement that an endorsed sponsor offer its endorsed program to all discount card eligible individuals residing in the endorsed program's service area, which may include individuals not eligible for the

SPAP. Should this or any other requirement for endorsement conflict with the endorsed sponsor's arrangement with the State under its SPAP, the endorsed sponsor and State would have to resolve this conflict. Alternatively, a State could coordinate its SPAP with the Medicare drug discount card program by contracting with an endorsed sponsor to administer the SPAP and designing the SPAP benefits so as to wrap around the benefits offered under the Medicare drug discount card program, provided that the endorsed sponsor complies with all applicable requirements of section 1860D–31 of the Act and our regulations. Coordination between a SPAP and an endorsed program could promote their offering a seamless outpatient drug benefit to beneficiaries enrolled in both the SPAP and Medicare drug discount card program.

2. Optional State Payment of Enrollment Fee

Section 1860D–31(c)(2)(F)(i) of the Act specifies that the Secretary will establish an arrangement under which a State voluntarily may provide for payment of some or all of the enrollment fee for some or all discount card enrollees in the State who are not transitional assistance enrollees. The portion of the enrollment fee paid by the State and the category of discount card enrollees (other than transitional assistance enrollees) entitled to State payment of all or some of their enrollment fees is left to a State's discretion. Any enrollment fee paid in whole or part by a State must be paid directly to the endorsed sponsor. We want to provide States flexibility in designing these arrangements to address circumstances particular to that State. Therefore, rather than prescribe a single, specific method for States to work in partnership with endorsed sponsors to pay the enrollment fee on behalf of discount card enrollees, we simply provide at § 403.815(a)(1) of our regulations that States may enter into payment arrangements with endorsed sponsors to provide payment of some or all of the enrollment fee for discount card enrollees, provided the enrollment fee is paid directly by the State to the endorsed sponsor.

Section 1860D–31(c)(2)(F)(ii) of the Act specifies that Federal matching payments will not be available under titles XIX and XXI for State expenditures for enrollment fees under the Medicare drug discount card program. To implement this requirement, we are setting forth a new provision at § 403.815(a)(2) of our regulations that mirrors the statutory provision.

3. Optional State Payment of Coinsurance

As discussed above, under section 1860D–31(g)(1)(B) of the Act, available transitional assistance may be applied toward 90 or 95 percent of the cost of a covered discount card drug obtained under the Medicare drug discount card program, with the transitional assistance enrollees responsible for a 5 or 10 percent coinsurance amount, depending on their income, unless the pharmacy waives those coinsurance amounts. Section 1860D–31(g)(4)(B)(i) of the Act specifies that the Secretary must establish an arrangement under which a State may provide for payment of some or all of these coinsurance amounts for some or all transitional assistance enrollees residing in the State. If a State will pay all or some of these coinsurance amounts, the payment must be paid directly by the State to the pharmacy involved. We want to allow States flexibility in the design of these arrangements to address circumstances particular to that State. Therefore, rather than prescribe a single, specific method for States to work in partnership with pharmacies to pay coinsurance on behalf of transitional assistance enrollees, we are providing at § 403.815(b)(1) of our regulation that States may enter into payment arrangements with pharmacies to provide payment of some or all of the coinsurance for transitional assistance enrollees, provided the coinsurance is paid directly by the State to the pharmacy involved. We leave it to the State's discretion whether it will pay all or a portion of these coinsurance amounts, as well as the category of transitional assistance enrollees entitled to State payment of all or some of their coinsurance.

Under section 1902(a)(10)(E)(i) of the Act, States are required to pay the coinsurance obligations (as defined in section 1905(p)(3)(B) of the Act) for certain Medicare beneficiaries, with the Federal government, in turn, reimbursing States for a portion of these payment amounts. However, section 1860D–31(g)(4)(B)(ii) of the Act provides that any State expenditures for the coinsurance of transitional assistance enrollees will not be considered State expenditures for which Federal matching payments are available under titles XIX and XXI. To implement this requirement, we are setting forth a provision at § 403.815(b)(2) of our regulations that mirrors the statutory provision.

Section 1860D–31(g)(4)(B)(iii) of the Act provides that the coinsurance liability of transitional assistance enrollees is not a cost-sharing obligation set forth in section 1905(p)(3)(B) of the Act. This means that States are not required to pay the coinsurance liability incurred by transitional assistance enrollees who are also Qualified Medicare Beneficiaries (QMBs) (as defined in section 1905(p)(1) of the Act) under the Medicaid program. To implement this requirement, we are setting forth a provision at § 403.815(c) of our regulations that mirrors the statutory provision.

4. State Data

As discussed in section II.A.1. of this document, under section 1860D–31(b)(1) of the Act and § 403.810(a)(2) of our regulations, beneficiaries residing in the 50 States or the District of Columbia with outpatient prescription drug coverage under Title XIX (Medicaid) or a section 1115 waiver demonstration are ineligible for the Medicare drug discount card program. As discussed in section II.A.2 of this document, we will verify beneficiaries' eligibility for the program. To perform this function, we require data from the 50 States and the District of Columbia that will allow us to identify those Medicare beneficiaries eligible under Medicaid or a section 1115 waiver demonstration for outpatient drug coverage. Section 1860D–31(f)(3)(C)(ii) of the Act provides the 50 States and the District of Columbia must provide to us information relating to our verification process under the program, in the manner specified by us, as a condition of the provision of Federal financial participation to a State under Title XIX. Section 1935(a)(1) of the Act similarly conditions receipt of Federal financial assistance under Title XIX upon a State's provision this data. Finally, section 1902(a)(66) of the Act provides that a State plan under Title XIX must provide for making eligibility determinations under section 1935(a) of the Act, which as previously noted includes the provision of eligibility data to us. We will specify the data we require and the manner in which states should provide us the data in a future communication to the State Medicaid directors.

Section 1935(a)(3) of the Act provides that amounts expended by a State in carrying out 1935(a) of the Act, including the provision of data related to our eligibility process, are State expenditures reimbursable under the ''appropriate paragraph'' of section 1903(a) of the Act, which sets forth the Federal share of State expenditures

under a State plan under Title XIX. As States' expenditures related to the provision of this data do not fall within the activities covered under sections 1903(a)(1) through (6) of the Act, we believe the only paragraph under section 1903(a) of the Act that would capture these expenditures is section 1903(a)(7) of the Act. Section 1903(a)(7) of the Act provides for a federal share of 50 percent for State expenditures ''found necessary by the Secretary for the proper and efficient administration of the State plan'' that are not already covered under sections 1903(a)(1) through (6) of the Act. Because States are required to provide us the eligibility data under their State plan, we believe related State expenditures are necessary for the proper administration of the State plan. Section 403.815(d)(2) of our regulations therefore provides that expenditures made by a State in connection with providing us eligibility data will be treated as State expenditures for which Federal matching payments are available under section 1903(a)(7) of the Act. Accordingly, States will be reimbursed 50 percent of these expenditures.

I. Special Rules Concerning Pharmacies Serving Long Term Care Residents or Operated by the Indian Health Service, Indian Tribes and Tribal Organizations, and Urban Indian Organizations

Section 1860D–31(g)(5)(A) of the Act provides that the Secretary shall establish procedures and may waive requirements as necessary to negotiate arrangements with sponsors to provide arrangements with pharmacies that support long term care facilities in order to ensure access to transitional assistance for transitional assistance eligible individuals who reside in long term care facilities.

Further, section 1860D–31(g)(5)(B) provides that the Secretary shall establish procedures and may waive requirements to ensure that, for purposes of providing transitional assistance, Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies have the opportunity to participate in the pharmacy networks of at least two endorsed discount card programs in each of the 50 States and the District of Columbia where such a pharmacy operates.

In the United States, there are approximately 16,380 Medicare and Medicaid certified skilled nursing facilities and nursing facilities (source: On-Line Survey and Certification and Reporting (OSCAR) System, August, 2003). About 1.3 million Medicare beneficiaries are residents of extended-stay skilled nursing facilities and nursing facilities (Source: 2001 Medicare Current Beneficiary Survey). Among the 1.3 million, the vast majority of these individuals (72 percent) are enrolled in both Medicare and Medicaid, and therefore will be ineligible for the Medicare endorsed discount card program if they have drug coverage through Medicaid. Of the remaining approximately 400,000 Medicare nursing home residents, some portion—perhaps as many as 200,000—may be eligible for transitional assistance under this program. Approximately 3,000 pharmacies support these facilities (source: American Society of Consultant Pharmacists, verbal communication, August 2003.).

Generally speaking, long term care pharmacies provide access to prescription drugs to residents of skilled nursing facilities and nursing facilities through medical benefits that are coordinated by the long term care facilities in cooperation with the long term care pharmacies. Further, the medications provided are often specially packaged to provide quality control. These, among other circumstances, contribute to such pharmacies not being well integrated into the private networks maintained by the pharmacy benefit management industry. The provisions of section 1860D–31(g)(5)(A) of the Act provide an opportunity for long term care pharmacies to provide prescriptions to residents of long term care facilities through the usual distribution channels established by these facilities, while offsetting the cost borne by such residents when their medical coverage either does not apply or has been exhausted.

We estimate that there are approximately 87,000 AI/ANs over the age of 65 who use the services of the Indian Health Service, and another 20,000 or so such individuals who are under the age of 65 years and eligible for Medicare by virtue of a disability (source: Indian Health Service). Of the total, about 36,000 are covered by Medicaid and we estimate that a total of about 18,000 may be eligible for transitional assistance. There are 201 I/T/U pharmacies in 27 States, with 152 operating in ambulatory settings and 49 operating in hospitals. Table 3 depicts the number of these pharmacies by State.

Generally speaking, I/T/U pharmacies provide access to prescription drugs off of the Federal Supply Schedule to AI/ANs, and these pharmacies are not well integrated into the private networks maintained by the pharmacy benefit management industry. The provisions of section 1860D–31(g)(5)(B) of the Act provide an opportunity for I/T/U pharmacies to provide prescriptions to AI/ANs at the low Federal Supply Schedule rate, whereby coverage of the cost of such drugs would in Part Come from transitional assistance funds, and in part from Indian Health Service funds.

To meet the requirements of section 1860D–31(g)(5) of the Act, we are strongly encouraging endorsed sponsors to offer a plan in their application for endorsement to include long term care and/or I/T/U pharmacies in their networks for the purpose of administering transitional assistance. As will be provided in greater detail in the solicitation, CMS intends to employ a competitive process to select for ''special endorsement,'' among interested applicants, in each of the 50 States and the District of Columbia, at least two applicants that, in accordance with § 403.816(b)(2) of our regulations, agree to contract with any willing long term care pharmacy provider in the endorsed sponsors' service areas seeking to participate in their pharmacy networks. Similarly, CMS intends to select at least two applicants for ''special endorsement'' in each of the 50 States and the District of Columbia where I/T/U pharmacies operate, in accordance with § 403.816(d)(2) of our regulations, to contract with any I/T/U pharmacy in the endorsed sponsors' service areas seeking to participate in their networks.

Selection criteria will be further discussed in the solicitation and will include understanding and accommodation of, as well as prior experience with, the unique circumstances of these special pharmacies, the percent of all long term care and/or I/T/U pharmacies within the proposed service areas to be provided contracts, the expansiveness of the proposed service area, completeness and feasibility of the plan for favorable access, and timeliness of implementation. The selected applicants, also called special endorsed sponsors, will provide for terms in these special pharmacy contracts to accommodate certain unique attributes of these pharmacies, described below, which are intended to improve access to needed prescription drugs and transitional assistance by long term care residents and AI/ANs. Also, as described below, we will work closely with interested applicants and special endorsed sponsors to provide technical assistance and other incentives.

As described above, the Secretary must ensure that transitional assistance-

eligible residents of long term care facilities have access to transitional assistance. Additionally, the Secretary must ensure that I/T/U pharmacies utilized by AI/ANs have the opportunity to participate in the pharmacy networks of at least two discount cards for the purpose of providing transitional assistance. We believe the best way to ensure that AI/ANs and residents of long term care facilities have the opportunity to receive transitional assistance is to promote a competition for ''special endorsement'' to serve these beneficiaries. We believe a competition among interested sponsors will encourage better, more thoughtful plans for access to a market generally untapped by the pharmacy benefit management industry.

As discussed previously, pharmacies supporting long term care facilities and AI/ANs are not generally included in the traditional pharmacy networks of the pharmacy benefit management industry, thus representing potentially new lines of business for some applicants, or possibly leveraging an existing niche market for some pharmacy benefit management organizations. The competition will guarantee to the special endorsed sponsors additional covered lives, an opportune business strategy to grow enrolled lives and subsequent utilization, leading to additional revenues. A ''guaranteed'' volume of new covered lives would be needed to cover the fixed costs associated with starting up the special provisions of these special pharmacy contracts. We believe that the promise of a guaranteed volume for the winning applicant will be a critical factor in whether the applicant decides to submit a plan that covers long term care and/or I/T/U pharmacies. Without the competition, we think that there is a high risk of drug discount card program applicants not offering a plan. Literally speaking, we believe the competition is necessary to assure these populations will have access to any endorsed card program. Further, the competition will provide to the special endorsed sponsors a ''special endorsement'' they can market.

An added benefit of the competition to beneficiaries is that the negotiations between these pharmacies and special endorsed sponsors to accommodate these pharmacies' special circumstances, along with technical assistance provided by CMS, can be accomplished relatively quickly compared to the process necessary if all endorsed sponsors had to accommodate these special circumstances. This will lead to a timely implementation of these special provisions, improving access to prescription drugs. In the case of long term care pharmacies, if interested pharmacy benefit management organizations with niche expertise in this area are able to meet our requirements and compete successfully for the special endorsement, then participation may also improve the timeliness of implementation and access to transitional assistance for long term care residents.

The applicants selected for special endorsement will receive assistance and support from CMS in setting up special contracting arrangements with these pharmacies as needed. We intend to hold a special break out session at the pre-application conference and, to the extent that this would be useful to interested applicants and, if feasible, CMS would arrange for the participation of the long term care pharmacy industry and the Indian Health Service, to the extent possible, provide a list of all pharmacies that support long term care facilities and I/T/U pharmacies; provide for an expedited marketing review to the extent possible; and provide special recognition for these special endorsed sponsors on the CMS Web site that describes their programs.

Additionally, as discussed in section II.C.1. of this document, endorsed sponsors must provide us with sample copies of their contracts with pharmacies participating in their network prior to commencing outreach and enrollment activities. Because the arrangements between special endorsed sponsors and long-term care and I/T/U pharmacies will present unique challenges and represent new types of arrangements for most special endorsed sponsors, special endorsed sponsors must only make a good faith effort to finalize these arrangements as soon as practicable; we will not require that these arrangements be finalized and approved by us prior to the start of the special endorsed sponsor's commencement of outreach and enrollment activities under its general endorsement, if applicable.

One of the goals of the technical assistance will be to help special endorsed sponsors understand the operations of these pharmacies which may require that special contracting provisions be included in the contracts between the special endorsed sponsors and these pharmacies. Both types of pharmacies have a number of unique characteristics that distinguish them from other retail pharmacies that will be participating in the drug discount card program. For instance, I/T/U pharmacies purchase drugs off the Federal supply schedule; generally can only serve AI/ANs; are required by law to waive copayments; and generally stock a more limited range of drugs compared to other retail pharmacies. Further, a few may not have point of sale technology.

Long term care pharmacies generally provide the drugs directly to the skilled nursing facilities and nursing facilities where the patient resides, not directly to the patient, under a medical benefit. They also engage in a significant coordination of benefits effort that would require at least some claims processed against the transitional assistance to be processed off-line, not in real time.

Thus, as cited in § 403.816 of our regulations, we may require of special endorsed sponsors certain contracting provisions. First, we will require that these sponsors contract with any willing provider of these types in their service areas (§ 403.816(b)(2) and § 403.816 (d)(2) of our regulations). Other likely special provisions in the contracts between special endorsed sponsors and these pharmacies include (§ 403.816(b)(4) and § 403.816(d)(3) of our regulations):

- For long term care: Long term care pharmacies are permitted to provide covered discount card drugs only to transitional assistance enrollees of the special endorsed sponsor's endorsed program who reside in long term care facilities served by the pharmacy; special endorsed sponsor may need to process special transaction type depending on whether the pharmacy is recognized under HIPAA as a retail pharmacy (that is, X12 versus NCPDP); and the special endorsed sponsor must agree to process ''late'' claims without penalty as payer of last resort after other insurance has been processed first.
- For I/T/U pharmacies: the pharmacy generally can only serve AI/ANs (special endorsed sponsor must structure network and educate enrollees so that non-AI/ANs understand these pharmacies generally are not available to them); and pharmacy is not required to stock all drugs.

An additional requirement, as provided in § 403.816(b)(3) of the regulation, special endorsed sponsors for long term care residents will be required to process claims from any out-of-network long term care pharmacies that supply covered discount card drugs to long term care facility residents enrolled in the drug discount card program when such beneficiaries have a transitional assistance balance remaining. As residents in skilled nursing facilities and nursing facilities are generally required by these entities to use the facility's selected long term care pharmacy, this provision will

accommodate long term care pharmacies in the event they do not decide to join the special endorsed sponsor's network.

Section 1860D–31(g)(5) of the Act grants the Secretary the authority to waive requirements of the Medicare drug discount card program as necessary to ensure that transitional assistance may be applied toward covered discount card drugs obtained from long-term care and I/T/U pharmacies. In recognition of the unique challenges facing special endorsed sponsors who agree to include these pharmacies in their pharmacy networks, we will waive application of certain requirements if doing so is necessary to: (1) Ensure that a sufficient number of applicants seek special endorsement; (2) enable the Medicare drug discount program to start within 6 months of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and (3) accommodate the unique needs of long-term care and I/T/U pharmacies.

Section 403.806(e)(4) of our regulations require endorsed sponsors to ensure that their pharmacies make available to transitional assistance enrollees at the point of sale, either electronically or by telephone, the amount of transitional assistance remaining available to them. Because long-term care pharmacies may process claims off-line due to coordination of benefit issues, there may be a lag in updating the transitional assistance amount to reflect recent transactions involving transitional assistance funds. Consequently, transitional assistance enrollees could be informed that they have more transitional assistance available to them than actually available if prior claims are still pending. Because I/T/U pharmacies do not charge AI/ANs for drugs obtained by them, AI/ANs obtaining drugs from these pharmacies will not have any out-of-pocket expenditures, and therefore their drug purchasing decisions will not be influenced by the amount of transitional assistance remaining available to them. Therefore, as provided in § 403.816(c)(ii) and § 403.816(e)(ii) of our regulations, special endorsed sponsors are not required to ensure that their long-term care and I/T/U pharmacies make available to transitional assistance enrollees at the point of sale the amount of transitional assistance remaining available to them.

In addition, section 1860D–31(g)(5) requires the availability of transitional assistance to long-term care residents and those using I/T/U pharmacies, but it does not discuss negotiated prices. Therefore, under §§ 403.816(c) and 403.816 (e) of our regulations, we provide that special endorsed sponsors will not be required to provide card enrollees access to negotiated prices at long-term care and I/T/U pharmacies. Special endorsed sponsors will be required to provide AI/ANs access to negotiated prices through non-I/T/U pharmacies included in the endorsed sponsor's network. We believe that waiving this provision is consistent with the statute as provided in section 1860D–31(g)(5) of the Act, and the resultant reduction in administrative burden is necessary so that applicants will be more likely to apply to become a special endorsed sponsor.

As permitted under section 1860D–31(g)(5) of the Act, we will allow applicants seeking special endorsement to request that we waive application of one or more of the other requirements of the Medicare drug discount card program. For instance, an applicant that intends to solely contract with long term care pharmacies for the purpose of administering transitional assistance through special endorsement, but who is not interested in otherwise becoming an endorsed sponsor under the Medicare drug discount card program, might request general waivers of certain requirements pertaining to endorsement. In its application, the applicant must cite the statutory or regulatory provision(s) it wishes us to waive, and explain why: (1) Such waiver is necessary to enable the applicant to either initiate enrollment activities within six months of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 or accommodate the unique needs of long-term care and/or I/T/U pharmacies; or (2) compliance with the requirement(s) in question would be impracticable or inefficient. Applicants also must provide an assessment of the impact of waiving the requirement(s) in question on long-term care residents and/or AI/ANs. If we grant the waiver, we will waive the applicable requirement(s) for all similarly situated applicants seeking special endorsement.

TABLE 3.—I/T/U PHARMACIES BY STATE

Alaska	14
Alabama	1
Arizona	21
California	11
Colorado	2
Connecticut	1
Idaho	3
Kansas	3
Maine	3
Michigan	5
Minnesota	6
Mississippi	1

TABLE 3.—I/T/U PHARMACIES BY STATE—Continued

Montana	13
North Carolina	1
North Dakota	6
Nebraska	3
New Mexico	20
Nevada	8
New York	3
Oklahoma	37
Oregon	7
South Dakota	11
Texas	1
Utah	1
Washington	11
Wisconsin	6
Wyoming	2
Total	201

J. Special Rules Concerning Territories

1. Background

As discussed above in section II.A. of this document, Medicare beneficiaries residing in the territories may be eligible for the Medicare drug discount card program, but are not eligible for transitional assistance under the program. However, as provided for under section 1860D–31(j)(2) of the Act, the territories may establish their own programs providing transitional assistance to low-income beneficiaries. This section first discusses special rules for applicants seeking to offer endorsed programs in the territories, followed by a discussion of the transitional assistance available to beneficiaries residing in the territories under programs established by the territories. As background, Table 4 provides the total number of Medicare beneficiaries in each of the U.S. Territories.

TABLE 4.—MEDICARE BENEFICIARIES BY U.S. TERRITORY

Territory	Total Medicare beneficiaries as of 07/01/2003
American Samoa	2,977
Commonwealth of the Northern Mariana Islands	1,257
Guam	9,372
Puerto Rico	573,468
Virgin Islands	11,797

Source: Medicare Enrollment Database

2. Discount Card

Medicare beneficiaries residing in the U.S. territories, which include American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and Virgin Islands, are eligible to enroll in the Medicare drug discount card program. Whereas Medicare beneficiaries residing in the 50 States or

the District of Columbia are ineligible for the program if they have outpatient prescription drug coverage under Medicaid or a section 1115 waiver demonstration, section 1860D–31(j)(1) of the Act grants the Secretary the discretion to find Medicare beneficiaries residing in the territories eligible for the program even if they receive outpatient prescription drug coverage under Medicaid or a section 1115 waiver demonstration. As provided in § 403.817(d) of our regulations, beneficiaries residing in the territories who have outpatient prescription drug coverage under these sources will be eligible for the program.

To ensure that eligible individuals residing in the territories have access to endorsed programs offering negotiated prices, we will select for special endorsement at least one applicant to provide discounts for covered drugs in the territories. In accordance with § 403.817(a) of our regulations, these applicants must agree to offer endorsed programs to residents of all the territories. Section 1860D–31(j)(1) of the Act allows us to waive the requirement for two endorsed sponsors per State in section 1860D–31(h)(2)(D) of the Act, if necessary to secure access to negotiated prices for beneficiaries in the territories. Therefore, we will elect to limit the number of special endorsed sponsors operating in each of the territories to at least one in order to assure that a sufficient number of beneficiaries will enroll in special endorsed sponsors' endorsed programs in the territories, thereby justifying from a business perspective their offering such programs. We believe these volume considerations will be a critical factor in whether an applicant seeks special endorsement in the territories.

We are concerned that in the absence of a competitive process for special endorsement in the territories, an insufficient number of applicants will seek to offer endorsed programs in the territories and we therefore will be unable to ensure that residents of the territories have access to negotiated prices.

Selection criteria for special endorsement in the territories will include understanding, as well as prior experience with, the unique challenges of providing a drug discount card in the territories, the extensiveness of an applicant's pharmacy network in the territories, the feasibility of the applicant's plan for offering an endorsed program in the territories, and timeliness of implementation of its plan. We will further discuss the selection criteria and the competitive process for special endorsement in the solicitation.

As permitted by section 1860D–31(j)(1) of the Act, we will waive certain sponsor requirements of the Medicare drug discount card program in the territories if doing so is necessary to: (1) Ensure that a sufficient number of applicants seek special endorsement in the territories; (2) enable the Medicare drug discount card program to start within six months of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and (3) accommodate the unique challenges faced by special endorsed sponsors in the territories.

As provided in § 403.817(c)(2) of our regulations, special endorsed endorsed sponsors in the territories will not be required to meet the pharmacy network access standard set forth in § 403.806(f) of our regulations and as explained in section II.C.3 of this document. In addition, special endorsed sponsors are not required to maintain a service area covering an entire territory if it proves impracticable to do so, as otherwise required in § 403.806(f)(2) of our regulations. The pharmacy access standard provides that the pharmacies included in an endorsed sponsor's network may not dispense drugs solely by mail-order and must be located within certain distances of most beneficiaries. We waive the distance requirement because in some territories there are few retail pharmacies, and relative to pharmacies in the 50 States and the District of Columbia, these pharmacies generally are less inclined to participate in pharmacy networks established by pharmacy benefit managers, discount drug cards, and similar programs. Special endorsed sponsors therefore may be unable to secure the participation of a sufficient number of pharmacies in the territories to meet our pharmacy access standard. For this reason, if after a good faith effort a special endorsed sponsor in the territories is unable to secure the participation of a retail pharmacy in a particular locale, they may offer a mail-order only pharmacy in that locale. Because it may be impracticable to provide drugs by mail to residents in more remote areas within a territory, we do not require special endorsed sponsors to provide residents of these particular areas with access to mail-order pharmacies, but the special endorsed sponsor must demonstrate that a good faith effort has been made to provide residents of these remote areas with discounts through retail pharmacies, and must explain the reason why mail order is impracticable. Provided endorsed sponsors make a good faith effort to secure the participation in their networks of retail and mail-order pharmacies throughout a territory, we will deem the service area requirement set forth in § 403.806(f)(2) and the network access requirement set forth in § 403.806(f)(3) of our regulations to be met, as provided in § 403.817(c)(2) of our regulations.

In recognition of the special challenges involved in delivering mail-order drugs to residents of the territories, special endorsed sponsors will need to educate their card enrollees in the territories about any considerations they need to take into account to assure that they receive safe and timely access to their prescription drugs, such as the need to order their drugs in advance of their need for such drugs. We recognize that in some cases special packaging needs (for example, refrigeration) for particular covered discount card drugs may make it impracticable to ship specific medications to the territories. Card enrollees should be made aware of these limitations.

As provided in § 403.817(c)(1)(ii) of our regulations, special endorsed sponsors in the territories will not be required to comply with § 403.806(d)(8) of our regulations requiring that retail pharmacies inform card enrollees of any differential between the price of the drug to the card enrollee under their endorsed program and the price to the card enrollee of the lowest priced generic covered discount card drug that is therapeutically equivalent and bioequivalent under the program. In recognition that few discount drug cards currently have contractual relationships with retail pharmacies in the territories, we are waiving this requirement to reduce the administrative complexity of special endorsed sponsors' contracts with participating retail pharmacies in the territories, which we believe we will enhance applicants' willingness to apply for special endorsement in the territories. However, mail-order drugs sent to residents in the territories should include this price differential information in the same manner such information is provided to card enrollees in the 50 States and District of Columbia who obtain mail-order drugs under the program.

Because the arrangements between special sponsors and pharmacies in the territories represent new types of arrangements for most special endorsed sponsors, as with special endorsed sponsors agreeing to include long-term care and for I/T/U pharmacies in their networks, we only require that special endorsed sponsors in the territories make a good faith effort to finalize these arrangements as soon as practicable; we

will not require that these arrangements be finalized and approved by us within 6 months after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

As permitted under section 1860D–31(j)(1) of the Act, we will allow applicants seeking special endorsement in the territories to request that we waive application of one or more of the other requirements of the Medicare drug discount card program. In its application the applicant must cite the statutory or regulatory provision(s) it wishes us to waive, and explain why: (1) Such waiver is necessary to enable the applicant to either initiate enrollment activities in the territories within six months of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 or accommodate the unique needs of pharmacies in the territories; or (2) compliance with the requirement(s) in question would be impracticable or inefficient. Applicants also must provide an assessment of the impact of waiving the requirement(s) in question on beneficiaries residing in the territories. If we grant the waiver, we will waive the applicable requirement(s) for all similarly situated applicants seeking special endorsement.

We will provide technical assistance to applicants seeking to offer endorsed programs in the territories, including holding a special break-out session at the pre-application conference. In addition, as additional incentives to encourage applicants to offer endorsed programs in the territories, we will, to the extent possible, provide expedited marketing review of special endorsed sponsors' information and outreach materials, and provide special recognition for these sponsors on the Medicare drug discount card Web site.

Applicants should note that special endorsed sponsors in the territories will not be asked to administer transitional assistance on behalf of CMS; rather, transitional assistance provided to residents in the territories will be a separate program independently operated by each territory, as described below.

3. Transitional Assistance

Section 1860D–31(j)(2)(A) of the Act provides that a territory may provide transitional assistance to some or all individuals residing in the territory who are entitled to benefits under part A or enrolled under part B with incomes no more than 135 percent of the poverty line for their family size, regardless of whether the individual receives an outpatient drug benefit under Medicaid or any other coverage sources (such as FEHBP, Tricare, or employer-sponsored health insurance). In accordance with section 1860D–31(j)(2)(B) of the Act, a territory wishing to provide transitional assistance to eligible beneficiaries must submit to CMS for our approval a plan describing its proposed transitional assistance program, including:

- The territory's criteria and process for determining beneficiaries' eligibility for transitional assistance (including its definition of income and family size) for individuals who reside in the territories, who are entitled to benefits under Medicare Part A or enrolled under Medicare Part B, and who have income at or below 135 percent of the poverty line for the contiguous United States; and
- The process for ensuring that allotment provided to the territory under section 1860D–31(j)(2) of the Act will be used only to provided covered discount card drugs to those individuals determined eligible for transitional assistance; and
- The territory's assurance that it will operate its transitional assistance plan as approved.

Section 1860D–31(j)(2)(C) of the Act provides that territories with approved transitional assistance plans will receive in the aggregate $35 million for the duration of the Medicare drug discount card program, which will be allocated among such territories in the manner described below. Territories must submit their plans to CMS within 90 days of the publication of this rule so as to allow us adequate time to review and approve their plans and determine each territory's allocated share of the $35 million.

CMS may request reports or information to substantiate that the territories have administered the program consistent with the territory's approved transitional assistance plan.

Section 1860D–31(j)(2)(D) of the Act provides that the Secretary shall calculate the portion of the $35 million allocated to a territory with an approved plan for transitional assistance by multiplying $35,000,000 by the ratio of—

(1) The number of individuals who are entitled to benefits under part A or enrolled under part B and who reside in the territory (as determined by the Secretary as of July 1, 2003), to

(2) The sum of such number for all territories with an approved plan under this program.

Section 1860D–31(j)(2)(D) provides that amounts made available to a territory for transitional assistance which are not used to provide transitional assistance will be added to the amount available to that territory for purposes of carrying out the Medicare Part D drug benefit.

K. Special Rules and Part B Premium and Appropriations

1860D–31(k)(2)(B) states that amounts payable from the Transitional Assistance Account shall not be taken into account in computing the actuarial rates or premium amounts under section 1839 of the Act. Similarly, section 105(a) amends section 1839(g) of the Act by ensuring that any estimations used to calculate the Part B monthly premium rate shall exclude estimates attributable to the Medicare prescription drug discount card and transitional assistance program under section 1860D–31 of the Act. We have accordingly made changes to the regulations in 42 CFR 408.20 to reflect these statutory provisions.

IV. Regulatory Impact Analysis and Regulatory Flexibility Act Analysis

A. Overall Impact

We have examined the impacts of this rule under 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 of this program will depend upon the final designs of endorsed discount card sponsors' programs, our estimate is that this rule is economically significant as measured by the $100 million standard. The savings to beneficiaries from discount card activities, including negotiated prices on prescription drugs and education about generic substitution by endorsed sponsors, will represent an economic impact ranging from $1.4 billion to $1.8 billion in the last nine months of 2004 (assuming for the purposes of this impact analysis implementation beginning second quarter 2004), $2.0 billion to $2.7 billion in 2005, and $0.4 billion to $0.6 billion in the first four and one-half months of 2006. This impact would not affect the

Federal budget, but would be a transfer of money due to a decrease in the revenues of entities providing the supply of drugs to consumers. This represents at most 1.18 percent of projected total retail prescription drug spending during the respective periods of 2004 ($153.5 billion for the last nine months of the year), 2005 ($228.6 billion), and 2006 ($95.3 billion for the first four and one-half months of the year), based on the most recent published National Health Expenditures projections (released in February 2003).

In addition to savings from discount card activities, a subset of discount card enrollees—those who qualify for transitional assistance—are projected to save an additional $2.4 billion in 2004, $2.6 billion in 2005, and up to $0.1 billion in 2006 due to the annual $600 transitional assistance. Beneficiary savings from transitional assistance are funded through the Federal budget, so these savings are a transfer from budget revenue to beneficiaries.

This rule also generates costs and benefits for drug sponsors in the new market created by the Medicare-endorsed drug discount card programs. Net benefits in this new market are generally projected to be positive but small relative to the savings generated for beneficiaries. The net present value benefits range from near zero to approximately $10 million.

This 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 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 and take certain other actions before issuing a 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. The UMRA stipulates that this is a requirement before an agency promulgates a notice of proposed rulemaking or promulgates a final rule for which a notice of proposed rulemaking had previously been issued. Since Congress specifically authorized us to dispense with a notice of proposed rulemaking, we believe that the UMRA requirements do not apply to this rule. Regardless, we do not anticipate that this rule would impose costs approaching the $110 million UMRA threshold.

While this rule does include a data reporting requirement for States, the State costs associated with this activity are expected to be relatively small. As discussed in this document, States will be required to provide data to CMS that will allow us to identify those beneficiaries who would be ineligible for the Medicare prescription drug discount card program due to the receipt of drug coverage through Medicaid or a section 1115 waiver demonstration. Aggregate State costs associated with this data reporting, including expenses related to data transmissions, quality assurance, and any needed systems changes, are expected to be substantially less than the $110 million UMRA threshold. Furthermore, as discussed in this document, States will receive Federal reimbursement for a share of these expenditures at the Federal matching rate for administrative expenses under 1903(a)(7).

In terms of territories and tribal governments, this rule imposes no mandatory requirements for these entities, while offering them an additional source of funding that they can elect to take advantage of. As discussed in this document, funds are available for a territory to provide prescription drug assistance to eligible low-income beneficiaries in the territory, if they elect to do so and submit a plan to CMS about how they intend to do it. For tribal governments (specifically pharmacies operated by Indian Tribes and Tribal Organizations, and Urban Indian Organizations (as defined in section 4 of the Indian Health Care Improvement Act)), the rule makes special provisions for these pharmacies to have the opportunity to participate in the networks of at least two endorsed programs in each of the 50 States and the District of Columbia where such pharmacies operate.

In addition, we have determined that this rule would not be an unfunded mandate related to the private sector 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.

C. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. As noted earlier in this document, a State may choose, on a voluntary basis, to partner with private drug card sponsors to coordinate its State Pharmacy Assistance Program with the Medicare prescription drug discount card program. States also have the option of paying for some or all of the enrollment fee for some or all non-transitional assistance eligible beneficiaries and the option of paying for some or all of the beneficiary coinsurance liability for some or all transitional assistance enrollees in a State. In addition, some States may decide to educate beneficiaries, particularly dual eligibles who would qualify for transitional assistance (that is, QMBs, SLMBs, & QIs without Medicaid drug coverage) and beneficiaries in State Pharmacy Assistance Programs, about benefits available through the Medicare prescription drug discount card program. All of these are voluntary opportunities for States, and have no Federalism implications. In addition, States with State Pharmacy Assistance Programs may realize savings related to the Medicare prescription drug discount card program to the extent that they provide for coordination of their program with the new Medicare program.

We have also determined that this rule would not impose substantial direct requirement costs on State and local governments. As discussed above, States would likely incur some costs related to data submission activities, but these costs are expected to be small and substantially less than the $110 million UMRA threshold. Furthermore, CMS has taken a number of steps to minimize the costs related to this program for States. CMS has consulted with State Medicaid Directors on the data submissions process and what mechanisms would be least burdensome and costly to States. In addition, CMS has already held and plans to hold additional information sessions for State officials to help them anticipate and prepare for implementation of this program. Further, we are taking measures to ensure that States are provided with training materials and beneficiary resources so that States can have ready access to materials that they can use if they receive questions from beneficiaries about the program.

D. Limitations of Our Analyses

The following analyses present projected effects of this rule on Medicare beneficiaries, the Medicare program, total national retail prescription drug spending, small entities, and endorsed sponsors. This section discusses limitations of the analyses conducted in especially sections E and I of this regulatory impact analysis.

Because this will be the first year of the Medicare prescription drug discount card program, we do not have the benefit of the experience of prior years. Therefore, we present a range rather than a single estimate for the amount of beneficiary savings resulting from negotiated prices obtained by endorsed sponsors. 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 2000 Medicare Current Beneficiary Survey (MCBS). The MCBS is a continuous multipurpose survey of a representative sample of the Medicare population. We have adjusted the data for projected growth in drug spending and for under reporting.

Another limitation of our analysis is that we make no adjustments to the savings estimates to take into account that some beneficiaries who enroll in this program already receive sizable discounts on drugs, and thus the savings potential from this program may be overstated for these individuals. For example, estimated savings from discount card activities may be overstated for beneficiaries enrolled in Medicare managed care organizations and beneficiaries participating in manufacturer discount card programs, since both are likely to already receive significant discounts.

As we discuss later in this document, other limitations to our analysis include that we have made no adjustments to take into account: possible effects of the program on beneficiary drug utilization and possible changes in the type of outlets through which beneficiaries purchase prescription drugs. We did not believe that we had adequate data to inform assumptions concerning these issues.

Additional limitations of the analysis relate to our estimate of the number of beneficiaries who enroll in the Medicare prescription drug discount card program. First, our estimate of the number of beneficiaries with standardized Medigap drug coverage who will enroll in the Medicare prescription drug discount card program may be somewhat imprecise. As discussed in more detail later in the analysis, we believe some beneficiaries who have drug coverage through standardized Medigap policies are likely to enroll in the Medicare prescription drug discount card program. 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 (M+C) but also report having individually purchased supplemental insurance. Therefore, we also excluded from the estimate of the number of beneficiaries with Medigap drug coverage anyone who was also enrolled in M+C during at least one month of the year since we believe that the drug coverage was more likely to come from a M+C plan than from a Medigap plan.

Second, our enrollment estimates do not factor in the possibility that some Medicare managed care plans that are exclusive card sponsors may decide to group enroll all of their members into an endorsed discount card program that they are sponsoring. If this occurs, overall enrollment in the Medicare prescription drug discount card program may be somewhat higher than we have estimated. However, given that we are uncertain about the frequency with which this might occur, we have taken a conservative approach and used the same assumptions concerning enrollment rates for beneficiaries in M+C and Medicare Fee-For-Service. Savings estimates from discount card activities are unlikely to be affected by group enrollment since beneficiaries who might be recipients of group enrollment into an endorsed discount card program by a Medicare managed care organization are likely to have already been obtaining discounts on prescription drugs through their plan, so this would not represent new savings for these beneficiaries. However, it is possible that estimated savings from the $600 transitional assistance may be slightly understated due to this issue.

Third, while we are able to exclude most beneficiaries who have drug coverage through Medicaid from our enrollment estimates (since these beneficiaries are ineligible for the drug card), difficulties with identifying those beneficiaries who have drug coverage through Medicaid via 1115 Pharmacy Plus Waivers means that some of these beneficiaries may not have been excluded from our enrollment estimates. Similarly, difficulties with precisely identifying in the data the source of a beneficiary's drug coverage, particularly TRICARE and employer-sponsored individually purchased Medigap coverage, means that some beneficiaries not eligible for transitional assistance (that is, those with TRICARE drug coverage) may not have been fully excluded from transitional assistance enrollment estimates, while some beneficiaries eligible for transitional assistance (that is, those with employer-sponsored individually purchased Medigap drug coverage) may not have been fully incorporated into the transitional assistance enrollment estimates.

Finally, as discussed later in this document, we did not make any differential assumptions concerning program uptake for beneficiaries currently enrolled in manufacturer discount card programs—that is, we assumed beneficiaries currently participating in manufacturer card programs will enroll in the Medicare prescription drug discount card program at the same rate as other beneficiaries. It is difficult to predict how both manufacturer card programs and beneficiaries currently enrolled in those programs will behave in terms of participation in the Medicare prescription drug discount card program. Consequently, it is possible that our enrollment estimates for this group of beneficiaries could be overstated or understated. Furthermore, as noted previously in this document, for beneficiaries currently enrolled in manufacturer card programs there are not likely to be significant additional savings beyond what they currently obtain; thus we may be overstating savings on their behalf to some extent. However, it should be noted that the manufacturer card programs generally cover a limited set of drugs, and the Medicare prescription drug discount card program may offer these beneficiaries discounts on a wider set of drugs.

E. Anticipated Effects on Medicare Beneficiaries

1. Enrollment Assumptions

Although the Medicare prescription drug discount card program will be available to all Medicare beneficiaries except for those with drug coverage

through Medicaid, we anticipate that the discount card will have the highest uptake among those eligible for transitional assistance. As discussed in this document, beneficiaries are eligible for transitional assistance if their income does not exceed 135 percent of the official poverty line and they do not have drug coverage through Medicaid, employer sponsored insurance (except for employer purchased coverage under a Part C plan or employer purchased individual Medigap policies), the U.S. Office of Personnel Management, or TRICARE. Based on data on drug coverage and income from the MCBS and the Current Population Survey, we estimates that there will be about 7.2 million beneficiaries eligible for transitional assistance in 2004. Of the 7.2 million, we assume that 65 percent, or 4.7 million, would enroll in an endorsed discount card program in 2004. This uptake assumption was developed considering a variety of factors including: uptake rates in similar means-tested programs, the nature and duration of this program, and the eligibility and enrollment processes involved in this program.

Among those beneficiaries not eligible for transitional assistance, we anticipate that those most likely to benefit from the program will be those without drug coverage. There are projected to be about 6.1 million beneficiaries with incomes greater than 135 percent of the official poverty line and without drug coverage in 2004. We anticipate that the rate at which these beneficiaries enroll in the Medicare prescription drug discount card program will vary by their level of drug spending. In addition, we expect that the maximum $30 annual enrollment fee and the interim nature of this program (with implementation of a Medicare drug benefit scheduled to occur in less than 2 years) will factor into these beneficiaries' enrollment decision.

In Table 5, we show the specific assumptions regarding the percentage of these beneficiaries enrolling in an endorsed discount 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. For example, we assume a 5 percent enrollment rate among beneficiaries with spending not exceeding $200—the point at which the maximum $30 annual enrollment fee could be recouped assuming 15 percent savings. For beneficiaries with the highest levels of drug spending—more than $600—we assume a 50 percent enrollment rate. Based on the assumptions in Table 5 and the distribution of drug spending among these beneficiaries without drug coverage, we estimate that about 35 percent of them will enroll in the Medicare prescription drug discount card program.

Another group of beneficiaries likely to benefit from the Medicare prescription drug discount card program will be those 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 $1,250 (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.

We project that there will be about 2.1 million beneficiaries who have incomes greater than 135 percent of the official poverty line and have drug coverage from a Medigap policy in 2004. Table 6 shows the assumptions regarding the percentage of these beneficiaries enrolling in an endorsed discount card program. Similar to the enrollment assumptions for beneficiaries without drug coverage, we assume that the enrollment rate for these beneficiaries with Medigap drug coverage varies by the level of drug spending. For beneficiaries with the highest levels of drug spending, we assumed a slightly higher uptake rate (60 percent) among those with Medigap drug coverage than among those without drug coverage (50 percent). We believe that beneficiaries with Medigap coverage for prescription drugs will be more risk averse than the average beneficiary and will therefore have a somewhat higher propensity to enroll.

We assume that beneficiaries with Medigap drug coverage would use the drug card for spending exceeding the Medigap benefit cap. Thus, the table shows enrollment rate assumptions by the level of drug spending involved in the Medicare prescription drug discount card program (not by the level of total drug spending). Based on the assumptions in Table 6 and the distribution of drug spending for these beneficiaries, we estimate that about 24 percent of these beneficiaries will enroll in the Medicare prescription drug discount card program. The 24 percent average enrollment rate stems from the fact that most beneficiaries with Medigap drug coverage have low levels of spending above the Medigap benefit cap, and thus we assume a low uptake rate for these individuals for this time limited program with an annual enrollment fee of up to $30.

These estimates of Medicare beneficiary enrollment in the Medicare prescription drug discount card program are one of the elements in our estimates of the impact of the program.

TABLE 5—ESTIMATED ENROLLMENT RATE OF MEDICARE BENEFICIARIES WITH NO DRUG COVERAGE AND WITH INCOME GREATER THAN 135 PERCENT OF THE OFFICIAL POVERTY LINE 2004 TO 2005

Annual drug spending	Percent enrolling
0–200.00	5
200.01–300.00	10
300.01–400.00	20
400.01–500.00	30
500.01–600.00	40
600.01+	50

TABLE 6—ESTIMATED ENROLLMENT RATE OF MEDICARE BENEFICIARIES WITH MEDIGAP DRUG COVERAGE AND WITH INCOME GREATER THAN 135 PERCENT OF THE OFFICIAL POVERTY LINE 2004 TO 2005

Annual drug spending subject to the Medicare drug discount card	Percent enrolling
$0–200.00	5
200.01–300.00	10
300.01–400.00	20
400.01–500.00	30
500.01–600.00	40
600.01–700.00	50
700.01+	60

As discussed previously in this document, we assume the same uptake rate in the Medicare prescription drug discount card program for beneficiaries currently participating in manufacturer discount card programs as for other beneficiaries. 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. Eli Lilly, Novartis, and Pfizer have each established co-pay cards. Eight drug manufacturers (Abbott Laboratories, AstraZeneca, Aventis, Bristol-Myers Squibb Company, GlaxoSmithKline, Janssen Pharmaceutical Products, L.P., Novartis, and Ortho-McNeil Pharmaceutical, Inc.) have established Together Rx, a discount card. In addition,

GlaxoSmithKline—one of the participants in Together Rx—also operates a separate discount card program. The income limits of the manufacturer cards vary, ranging from $18,000 to $30,000 for individuals and from $24,000 to $40,000 for couples. In terms of enrollment, Together Rx is the largest of these programs, reporting more than 1 million enrollees (as of September 2003). Enrollment for the other manufacturer card programs is reported to be more than 355,000 in the Pfizer card (as of May 2003), about 100,000 in the Eli Lilly card (as of October 2002), about 100,000 in the GlaxoSmithKline card (as of November 2002), and about 15,000 in the Novartis card (as of April 2002).

Many beneficiaries who might benefit from the Medicare prescription drug discount card program may currently be enrolled in or eligible for manufacturer card programs. We use the same uptake assumptions for these beneficiaries as for the general beneficiary population, since it is difficult to predict how both manufacturer card programs and beneficiaries currently enrolled in those programs will behave in terms of participation in the Medicare prescription drug discount card program. For example, 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 prescription drug discount card program. On the other hand, if manufacturer card programs do not seek Medicare endorsement, some beneficiaries may opt to enroll in both the manufacturer cards and a Medicare endorsed discount card program. For example, we would expect that many low-income beneficiaries currently enrolled in manufacturer card programs would likely also enroll in an endorsed discount card program to take advantage of the $600 transitional assistance. In addition, since the manufacturer cards provide savings only on specific drugs and endorsed programs have a low annual enrollment fee, we believe that some beneficiaries, depending on the mix of prescription drugs they use and their income levels, may find it beneficial to enroll in both types of programs as well.

While we expect there will be a phase-in of beneficiary enrollment in the Medicare prescription drug discount card program, we believe that because of the recognition and acceptance of the Medicare name, the educational efforts undertaken, and the proration policy for the $600 transitional assistance discussed in this document, beneficiaries wishing to enroll will do so over a relatively short period of time. For the purposes of this impact analysis, we assume that the program is implemented beginning second quarter (April) 2004 and that all beneficiaries expected to enroll in 2004 do so at the program outset. For beneficiaries who become eligible for Medicare between April 2004 and December 2005, we assume enrollment at the time they become Medicare eligible.

2. Beneficiary Savings Assumptions

The Medicare prescription drug discount card program will generate two types of savings from the perspective of beneficiaries. First, beneficiaries enrolled in an endorsed discount card program will derive savings from discount card activities undertaken by endorsed sponsors, such as negotiating lower prices on prescription drugs and educating beneficiaries about generic equivalents. Second, for the subset of Medicare prescription drug discount card enrollees who qualify for the transitional assistance, they will also derive savings from the government funded $600 transitional assistance. For ease of reference in the remainder of the regulatory impact analysis, we will refer to these two different types of savings as ''savings from discount card activities'' and ''savings from transitional assistance,'' respectively.

a. Savings From Discount Card Activities

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.

A March 2003 study by the Brandeis University Schneider Institute for Health Policy, entitled ''PBM-Administered Prescription Drug Discount Cards: Savings for Uninsured Seniors,'' examined administrative data on eight national drug discount card programs operated by 3 PBMs to analyze the level of discounts available through these types of discount programs. Looking at drugs most commonly used among individuals age 65 and over, the study found that on average the card programs provided discounts (over and above any other discounts uninsured individuals received at retail pharmacies) of 14 percent for brand drugs, 26 percent for generic drugs, and 15 percent overall.

We anticipate that the estimated savings for Medicare beneficiaries from discount card activities, such as negotiated prices and education about generic substitution, under the Medicare drug discount 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 endorsed programs will save as a result of discount card activities, on average, between 10 and 15 percent of their total drug costs compared to their spending in the absence of this program. While savings of 10 to 15 percent are anticipated on total drug expenditures, the discounts on individual drugs will vary and may be substantially higher for certain products, particularly generics, due to their lower prices. If endorsed discount card programs rely heavily on the use of formularies, we expect that manufacturer rebates or discounts will be greater in response.

The beneficiary savings from discount card activities 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 program. For purposes of estimating beneficiary savings from discount card activities, we assume average overall savings of 15 percent off of drug spending. These estimates do not take into account the possible increased use of prescription drugs by Medicare beneficiaries resulting from paying reduced out-of-pocket amounts due to savings from discount card activities. They also do not take into account the likelihood that use of prescription drugs will increase somewhat in response to the $600 transitional assistance.

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. In September 2003, GAO issued another report entitled ''Prescription Drug Discount Cards: Savings Depend on Pharmacy and Type of Card Used.'' For 9 drugs (7 brand and 2 generic) commonly used by Medicare beneficiaries, the report provided the median price for each drug across five PBM-administered discount card programs and comparison data on the median retail pharmacy price for each drug in 3 geographic areas. In these studies, pharmacy prices were inclusive of senior discounts for those pharmacies that offered them. The GAO simply reported prices on each drug; 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 15 percent savings off total beneficiary drug spending for several reasons.

First, savings for the program 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 program, drug-specific discounts comparable to insured products, which are often 25 to 30 percent, or sometimes more, per prescription.

Second, 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.

Finally, the Medicare prescription drug discount card program requires that endorsed discount card sponsors obtain manufacturer rebates or discounts and pass a share of the rebates or discounts through to beneficiaries in the form of lower prices. We believe that this differs from the practices of some of the discount card programs in the GAO studies. Two of the five programs in the 2003 GAO study reported that the pharmacy is not paid for any of the difference between the pharmacies' usual price and the price the cardholder pays.

Because the endorsed discount 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 endorsed 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. To the extent that endorsed discount card sponsors design formularies to mimic those of insured products, the ability to garner manufacturer rebates or discounts will increase.

For purposes of estimating beneficiary savings, it is necessary to make some assumptions concerning the portion of spending that will be affected by discount card activities by endorsed sponsors such as negotiating lower prices and promoting generic substitution. 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 endorsed programs probably will provide discounts on more than one drug per grouping and be highly likely to provide discounts on commonly used drugs.

We have 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 2000 MCBS data (including a special analysis related to disabled beneficiaries). As of 2000, the drugs most commonly used or having the greatest spending by Medicare beneficiaries accounted for approximately 72 percent of total drug spending for beneficiaries without drug coverage.

The drug classification listing in Table 2, for which endorsed sponsors must include at least one drug, is more extensive than the specific top drug list that was used to estimate 72 percent. In addition, we assume that many endorsed 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 program at 75 percent.

We also assume that it is possible that endorsed 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 prescription drug discount card program. We note, however, that we have made no adjustment to take into account that some beneficiaries currently receive discounts and that some of the savings to beneficiaries will come from generic substitution and not just price reductions.

b. Savings From Transitional Assistance

Those drug card enrollees who qualify for transitional savings will realize savings from the annual $600 transitional assistance. The aggregate amount of savings from the transitional assistance depends in part on the level of drug spending among these beneficiaries. Many of these beneficiaries will exhaust the $600 transitional assistance each year; however, those who do not will be allowed to roll over any unspent funds from one year to the next. While those beneficiaries with transitional assistance dollars remaining at the end of 2005 will be able to roll over the funds through the first four and one-half months of 2006 or up to the point that they enroll in Medicare Part D (whichever is earlier), it is likely that a small portion will not exhaust the transitional assistance dollars fully by the end of the program. Our estimates of total transitional assistance savings in each year take into account both this roll-over phenomenon and the likelihood that a small portion of beneficiaries will not exhaust the full transitional assistance by the end of the program. In estimating savings from the transitional assistance, we also factor in the proration policy and the tiered coinsurance.

3. Projection Assumptions

Since our data on Medicare beneficiary prescription drug spending are based on 2000 MCBS data, it is necessary to make several adjustments in order to prepare 2004 estimates. In order to trend 2000 spending to 2004 dollars, we use prescription drug spending projections based on per capita drug expenditure growth from the National Health Expenditure (NHE) Projections 2002 to 2012. These projections can be found on our Web site at: *http://www.cms.hhs.gov/statistics/nhe/projections-2002/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 rule, the spending data from the MCBS has been increased by 20.5 percent to adjust for under reporting that has been identified through our research thus far. It is also necessary to adjust for future growth in the Medicare beneficiary population. The adjustments are made based on the assumptions about growth in the overall Medicare population from the 2003 Medicare Trustees Reports and assumptions about growth in the dual eligible population (that is, the group of beneficiaries not eligible for the program).

These assumptions are detailed in Table 7, which shows the projected increase in Medicare enrollment and per capita drug expenditures from 2000 to 2004, and annually from 2004 to 2006, using 2000 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 program, beneficiary savings from discount card activities (both upper bound and lower bound estimates), the impact of beneficiary savings from discount card activities as a percent of total national aggregate retail drug sales, and estimated total beneficiary savings resulting from the transitional assistance.

To estimate the impact of the program 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 2001, 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 these projections for prescription drug spending are the most appropriate to use for analysis of the impact of this program on prescription drug revenues. These 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 7.—ESTIMATED IMPACT

	2000 (Baseline)	2004 (Apr–Dec)	2005 (Jan–May)	2006 (Jan–Dec)
Increase in Medicare Enrollment		4.6%*	1.4%	1.3%
Increase in Per Capita Drug Expenditures		62.7%*	10.8%	10.2%
Total National Aggregate Retail Drug Expenditures ($ billions)	$121.5	$153.5	$228.6	$95.3
Discount Card Enrollees Who Qualify for Transitional Assistance				
Projected Number of Enrollees (millions)		4.7	4.7	4.7
Projected Prescription Drug Spending Under the Drug Discount Card Programs (billions)	6.2	8.0	11.9	2.5
Lower & Upper Bound Beneficiary Savings from Discount Card Activities (billions)		0.9–1.2	1.3–1.8	0.3–0.4
Estimated Beneficiary Savings From Transitional Assistance (billions)		2.4	2.6	0.1
Discount Card Enrollees Who Do Not Qualify for Transitional Assistance				
Projected Number of Enrollees (millions)		2.6	2.7	2.7
Projected Prescription Drug Spending Under the Drug Discount Card Programs (billions)	3.2	4.1	6.1	1.3
Lower & Upper Bound Beneficiary Savings from Discount Card Activities (billions)**		0.5–0.6	0.7–0.9	0.1–0.2
Total—All Discount Card Enrollees				
Projected Number of Enrollees (millions)		7.3	7.4	7.4
Projected Prescription Drug Spending Under the Drug Discount Card Programs (billions)	9.4	12.0	18.0	3.7
Lower & Upper Bound Estimated Beneficiary Savings from Discount Card Activities (not including savings from $600 transitional assistance) (billions)**		1.4–1.8	2.0–2.7	0.4–0.6

TABLE 7.—ESTIMATED IMPACT—Continued

	2000 (Baseline)	2004 (Apr–Dec)	2005 (Jan–May)	2006 (Jan–Dec)
Lower & Upper Bound Impact of Beneficiary Savings from Discount Card Activities as a Percent of National Aggregate Retail Drug Expenditures		0.88%–1.18%	0.89%–1.18%	0.44%–0.59%

*For 2004, the increase in Medicare enrollment and per capita drug expenditures shown in the table reflect the percent change between 2000 and 2004.

**These savings estimates do not take into account the costs associated with beneficiary enrollment fees. Beneficiary savings may be up to $0.08 billion lower in 2004 and 2005 due to the maximum annual enrollment fees of $30 that card sponsors may charge enrollees in those years who do not qualify for transitional assistance.

Note: Numbers may not sum due to rounding.

4. Impact Estimates

We estimate that 7.3 million Medicare beneficiaries will be enrolled in endorsed discount card programs in the last nine months of 2004 and 7.4 million in 2005. In addition, depending on when beneficiaries choose to enroll in Medicare Part D, it is possible that up to 7.4 million beneficiaries may be enrolled in endorsed discount card programs during at least some portion of the first four and one-half months of 2006. For 2006, we assume that enrollees remain in the Medicare prescription drug discount card program on average for two and one-quarter months in 2006. Of the 7.3 million beneficiaries estimated to enroll in the Medicare prescription drug discount card program, an estimated 4.7 million would qualify for transitional assistance (as well as discount card savings) while an estimated 2.6 million would receive standard discount card services only.

As discussed previously, we assume that Medicare beneficiaries enrolled in an endorsed discount card program will save between 10 and 15 percent of their total drug costs as a result of savings from discount card activities (with 15 percent savings being assumed in the impact estimates). 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 endorsed sponsors. It is also possible, as discussed previously in this document, that savings from discount card activities could be lower for some beneficiaries. For example, beneficiaries who currently may receive a sizeable discounts under manufacturer discount card programs may not experience additional discounts for those same drugs under the Medicare prescription drug discount card program.

As shown in Table 7, for the estimated 7.3 million beneficiaries who will be enrolled in an endorsed discount card program in the last nine months of 2004 and the 7.4 million who are estimated to be enrolled in 2005 and the first part of 2006, the base for total drug expenditures involved in the Medicare prescription drug discount card program is projected to be $12.0 billion in the last nine months of 2004, $18.0 billion in 2005, and $3.7 billion in the transition period in 2006 before the savings achieved through the program. Total estimated savings for these beneficiaries from discount card activities range from $1.4 billion to $1.8 billion in the last nine months of 2004, $2.0 billion to $2.7 billion in 2005, and $0.4 billion to $0.6 billion in the transition period in 2006. Furthermore, the subset of enrolled beneficiaries (an estimated 4.7 million) who qualify for transitional assistance are estimated to save an additional $2.4 billion in 2004 (last nine months), $2.6 billion in 2005, and $0.1 billion in 2006 (first four and one-half months) from the annual $600 transitional assistance. Savings from transitional assistance in 2006 are very small because they only reflect carryover spending for beneficiaries with low drug spending who do not exhaust the full transitional assistance during 2005.

Beneficiaries may be required to pay an annual enrollment fee of up to $30 to join an endorsed discount card program. The Federal government pays the enrollment fee for beneficiaries who qualify for transitional assistance. If all of the non-transitional assistance eligible Medicare beneficiaries who are projected to enroll in the Medicare prescription drug discount card program (2.6 million beneficiaries in 2004 and 2.7 million in 2005) pay the maximum $30 annual enrollment fee, the total beneficiary savings overall and specifically for this group of beneficiaries will be reduced by roughly $78 million in 2004 and $81 million in 2005.

Regardless of whether or not endorsed sponsors charge the full $30 enrollment fee, this is a voluntary program. Beneficiaries have a choice of which program to enroll in, or not to join a program at all. Therefore, beneficiaries will only join a program if their expected gain is greater than the enrollment fee. In addition, those who choose to enroll in an endorsed program will still be free to buy a drug at any price outside of the program, so they can only be helped by the estimated savings and educational efforts from the program.

F. Anticipated Effects on the Medicare Program

Beneficiary savings from transitional assistance are funded through the Federal budget, while beneficiary savings from discount activities do not affect the Federal budget. We estimate that Medicare program spending will increase by $2.5 billion in calendar year (CY) 2004, $2.7 billion in CY 2005, and $0.1 billion in CY 2006, due to the transitional assistance. The vast majority of this spending is for the $600 transitional assistance ($2.4 billion in 2004, $2.6 billion in 2005, and 0.1 billion in 2006), with the remaining spending, $0.14 billion in 2004 and 2005, for payment of the enrollment fee for transitional assistance eligible beneficiaries. In addition, we estimate that CMS' administrative expenses to implement this program will be $134 million.

We also expect that the Medicare prescription drug discount card program will have several positive effects on the Medicare program. While not quantifiable, a positive impact of the rebate and discount reporting requirements of the program will be to provide us with experience in understanding issues in the pharmaceutical industry before implementation 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.

G. Anticipated Effects on National Retail Prescription Drug Spending

Total national retail spending (spending for the total population, not just Medicare beneficiaries) on prescription drugs is projected to be $153.5 billion in 2004 (last nine months), $228.6 billion in 2005, and $95.3 billion in 2006 (first four-and-one-half months). *(http://www.cms.hhs.gov/statistics/nhe/projections-2002/t11.asp).*

In the last nine months of 2004, the total economic impact of savings from discount card activities under the Medicare prescription drug discount card program is estimated to range from $1.4 billion to $1.8 billion, representing 0.88 percent to 1.18 percent of total national aggregate retail prescription drug expenditures during that period. In 2005, the total impact is estimated to range from $2.0 billion to $2.7 billion, or 0.89 percent to 1.18 percent of total national aggregate retail expenditures for prescription drugs. In the first four-and-one-half months of 2006, we estimate the total impact to range from $0.4 to $0.6 billion, or 0.44 percent to 0.59 percent of total national aggregate retail drug expenditures during that period. Thus, the economic impact is estimated to be at most 1.18 percent of total retail prescription drug spending.

One of the factors underlying these estimates of economic impact is our assumptions concerning enrollment in this program. While we believe that our uptake assumptions are reasonable estimates of the likely level of enrollment in this program, we have conducted an additional analysis to provide a sense of how these impact estimates would change if actual program uptake differed somewhat from the assumed levels. In the first 9 months of 2004, if program uptake was anywhere between 15 percent below to 15 percent above the assumed levels, estimated savings from discount card activities would range from $1.2 billion to $2.1 billion (assuming capita spending among enrollees remained unchanged), with these savings representing between 0.75 percent to 1.35 percent of national retail prescription drug sales in 2004.

We expect that the various sectors involved in the prescription drug industry will adjust to the impact of this program 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 a 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 prescription drug discount card program 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.

It is also possible that the requirements of 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 program 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, we do not expect that this program will have any impact on the number of Medicare beneficiaries with drug coverage through employer-sponsored health insurance. Since this program is short-term and it provides $600 transitional assistance only to a subset of beneficiaries (those with incomes that do not exceed 135 percent of the official poverty line), we do not anticipate that employers will alter their drug coverage in response to this program.

H. Analysis of Effects on Small Entities

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. However, the RFA stipulates that these requirements are applicable to a notice of proposed rulemaking or a rule for which an agency has published a notice of proposed rulemaking. Since Congress specifically authorized us to dispense with a notice of proposed rulemaking, we believe that a regulatory flexibility analysis is not required for this rule. Nevertheless, a regulatory flexibility analysis follows.

The Medicare prescription drug discount card program 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 program 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 program may not be significantly different than current practice for some pharmacies.

The role of individual pharmacies, including small pharmacies, in this program is a critical one: they will be an integral part of the pharmacy networks of endorsed discount card programs, serving Medicare beneficiaries at the point of retail sale. The objectives of the program and the related design requirements will preclude an individual pharmacy or drug store from operating the full scale of contemplated activities that will be necessary to obtain an endorsement. Individual pharmacies could participate in the program 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 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 program. As discussed elsewhere in this 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 urban areas served by the program live within 2 miles of a contracted pharmacy (90/2), at least 90 percent of Medicare beneficiaries in suburban areas served by the program live within 5 miles of a contracted pharmacy (90/5), and at least 70 percent of Medicare beneficiaries in rural areas served by the program live within 15 miles of a contracted pharmacy (70/15). These access ratio requirements, which are based on the Department of Defense TRICARE Retail Pharmacy (TRRx) program, are similar to the access standards in many commercial insured products and we believe they will require endorsed sponsors to support an extremely broad network of retail pharmacies.

Given the access ratio requirements and the provision that 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 endorsed programs' networks, particularly small pharmacies in rural areas. This is generally the case in the current insured market and the TRRx program, and we do not anticipate significantly narrower networks in the endorsed 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. Similarly, the Department of Defense reports that the TRRx program has more than 40,000 pharmacies in its network (as of June 2003). Furthermore, the PWC study 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 broad pharmacy networks, lead us to believe that a very large number of small pharmacies and drug stores will be included in the networks of endorsed discount card programs. Further, we believe that small entities in rural areas especially will be included in order to meet the rural 70/15 standard for endorsement.

1. 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 prescription drug discount card program 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 prescription drug discount card program. These analyses found that while the program 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 prescription drug discount card program does not have a significant economic impact on a substantial number of small entities.

As a result, even if the RFA applied to this rule (which as discussed previously, we believe it does not) we would still not be required to perform a regulatory flexibility analysis. Nevertheless, due to the possibility that concerns may be voiced by some about the potential effects of the rule on small businesses, we have included in this section or in other sections of this document 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 this document, we have included a description of the program and its objectives. In this and subsequent sections of this document, we include an estimate of the number of small entities affected; an estimate of the economic impact on small pharmacies including a sensitivity analysis assessing the potential for differential distributional effects on small pharmacies; a discussion of reporting, recordkeeping, and other compliance requirements; and a description of the alternatives considered to minimize the economic impact on small pharmacies.

2. 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 program, 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 2002, NACDS reports 55,200 community retail pharmacy outlets, of which 19,749 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 IMS' National Prescription Audit data obtained 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 the data obtained by OACT, it is possible to estimate the portion of sales occurring through independent and chain pharmacies. The data 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 2002, the data indicate that 23.5 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 analysis of the Prescription Drug Audit for 2002.

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. Analysis of 1997 data from the Prescription Drug Audit indicates that $8.8 billion in prescription drug sales occurred through food stores, or 2.5 percent of total product sales. Similarly, the 1997 Census data indicate that total product sales for the two categories of mass merchants, as defined by NAICS, were $208 billion. Since data from the Prescription Drug Audit 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 $9.6 billion in 1997, or 4.6 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.

3. 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 program on prescription drug retail sales associated with small pharmacies and drug stores, we take our national estimates in Table 7 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 endorsed discount card program enrollees.

Assuming that 23.5 percent of total retail pharmacy sales are through small pharmacies (based on analysis of data from IMS' Prescription Drug Audit on the share of total retail sales through independent pharmacies in 2002), the share of total national prescription drug sales through small pharmacies and drug stores will be $36.1 billion in the last nine months of 2004, $53.7 billion in 2005, and $22.4 billion in the first four and one-half months of 2006. If we assume that the population most likely to enroll in the Medicare prescription drug discount card program splits its purchases between large and small pharmacies in the same proportion as the total population, then the estimated sales involved in the Medicare prescription drug discount card program through small pharmacies and drug stores will be $2.8 billion in the last nine months of 2004, $4.2 billion in 2005, and $0.9 billion in the first four and one-half months of 2006, accounting for less than 8 percent of prescription drug sales through small pharmacies. Consequently, the portion of the estimated beneficiary savings

from discount card activities occurring through sales in small pharmacies and drug stores ranges from: $0.32 to $0.42 billion in 2004 (last nine months), $0.48 to $0.64 billion in 2005, and from $0.10 billion to $0.13 billion in 2006 (first four and one-half months). These amounts, as a share of the national retail prescription drug sales occurring through small pharmacies and drug stores, represent a range of 0.88 percent to 1.18 percent in 2004, from 0.89 to 1.18 percent in 2005, and from 0.44 to 0.59 percent in 2006.

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. Endorsed sponsors will be required to obtain 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 endorsed 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 educational aspects of the program, 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 prescription drug discount card program on beneficiary drug use. It is likely that the transitional assistance will lead to somewhat greater use of prescription drugs, resulting in a smaller impact on pharmacy revenues. In addition, it is possible that lower drug prices may lead to greater use of prescription drugs, possibly further reducing the impact on pharmacy revenues. On the other hand, it is 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.

4. 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 prescription drug discount card program will comprise, on average, less than 8 percent of revenues, with the economic impact of the discount card activities on total revenues related to prescription drugs estimated to be at most 1.18 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 program account for at least 20 percent of a business's revenues. In the sensitivity analysis, we developed a hypothetical geographic locality skewed to contain a large Medicare beneficiary population with a large share of the beneficiary population having characteristics making them likely to enroll in this program. Under this highly skewed assumption, we estimated a maximum share of 15.7 percent of a business's total prescription drug revenues would be associated with the Medicare prescription drug discount card program, with the program having an economic impact of 2.36 percent of prescription drug sales.

As noted previously, this economic impact will not be borne entirely by pharmacies, because endorsed 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. Nevertheless, 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 program and the consequent impact resulting from the Medicare prescription drug discount card program. 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 13.8 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 Medicare prescription drug discount card programs. As discussed previously, we think that the beneficiaries most likely to enroll in the program will be those beneficiaries with income less than or equal to 135 percent of the official poverty line who are eligible for the $600 transitional assistance, beneficiaries not eligible for transitional assistance who do not have insurance coverage for prescription drugs (including those with supplemental insurance coverage that does not include prescription drugs), and beneficiaries not eligible for transitional assistance who have Medigap drug coverage. To develop upper bound estimates for the percent of Medicare beneficiaries in an area who might fall into one of these three groups of potential enrollees, we use the prevalence rates of beneficiaries with these characteristics in non-metropolitan areas. Based on analysis of MCBS data for non-metropolitan areas, we assume that 21 percent of beneficiaries in the hypothetical geographic area were eligible for the $600 transitional assistance (compared with 18 percent nationally). We also assume that among beneficiaries in the hypothetical area, 20 percent had no drug coverage and were ineligible for the transitional assistance (compared with 15 percent nationally), while another 8 percent had Medigap drug coverage and were ineligible for the transitional assistance (compared with 5 percent nationally).

Nationally, we estimate that more than 7 million Medicare beneficiaries will enroll in Medicare prescription drug discount card programs in 2004, accounting for an estimated 2.5 percent of the total U.S. population. Adjusting the data, using the population and drug coverage weighting factors for the sensitivity analysis and using the overall uptake assumptions (65 percent uptake among transitional assistance eligible beneficiaries, 35 percent uptake among beneficiaries not eligible for transitional assistance who do not have drug coverage, and 24 percent uptake among beneficiaries not eligible for transitional assistance who have Medigap drug coverage), results in the hypothetical area having approximately 8.15 percent of its total population participating in the Medicare prescription drug discount card program. Therefore, about 91.85 percent

of the total hypothetical area's population will not participate in the program, including both Medicare beneficiaries and non-Medicare beneficiaries.

To estimate the impact of the program on prescription drug revenues in the hypothetical locality, we estimated the per capita drug spending for program participants and non-participants in the hypothetical area. We estimated per capita drug spending to be $2187 for participants and $1039 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 prescription drug discount card program, the per capita value consists of the estimated total spending for enrolled transitional assistance eligible beneficiaries, plus estimated total spending for enrolled beneficiaries not eligible for transitional assistance who do not have drug coverage, plus the share of spending for the Medigap enrollees that is purchased through the program, divided by the total number of participants.

For purposes of calculating the per capita spending for non-participants in the Medicare prescription drug discount card program, 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 program. These two per capita values for non-participants 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 estimate 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 Medicare prescription drug discount card program (that is, the portion of drug spending covered by Medigap plans) to yield an estimate of total drug spending outside of the program. 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 program, we used the upper bound figure of all drug spending being effected by the program as a high-end assumption.

The results of the sensitivity analysis are shown in Table 8. For the hypothetical area that is skewed to have a large Medicare beneficiary population with a large share of that beneficiary population having characteristics making them likely to enroll in this program, the negative impact on prescription drug revenues reached 2.36 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 2.36 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. Similar to the additional analyses performed earlier in this document looking at how varying the uptake assumptions by 15 percent would affect the impact on national retail prescription drug spending, we performed additional analyses here further skewing enrollment in this hypothetical area to assume 15 percent higher uptake rates among beneficiaries. Even under those assumptions, the economic impact on prescription drug revenues in the hypothetical area would still be below the HHS standard for significant impact of 3 to 5 percent of revenues.

We recognize that reliance of the sensitivity analysis 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. However, lacking such pharmacy level data, this sensitivity analysis represents our best estimate of the maximum potential effect of the program on small pharmacies and drug stores in a hypothetical area with substantially higher than average program enrollment.

TABLE 8.—NATIONAL AVERAGE VERSUS SENSITIVITY ANALYSIS—HYPOTHETICAL EXAMPLE

2004	Discount card participants (percent)	Discount card Non-participants (percent)	Total population (percent)
National Average for Comparison Purposes:			
Percent of Total Population	2.49	97.51	100.00
Percent of Total Prescription Drug Sales	7.84	92.16	100.00
Estimated Beneficiary Savings From Discount Card Activities as a Percent of Drug Sales	15.00	0.00	1.18
Hypothetical Example:			
Percent of Total Population	8.15	91.85	100.00
Percent of Total Prescription Drug Sales	15.73	84.27	100.00
Estimated Beneficiary Savings From Discount Card Activities as a Percent of Drug Sales	15.00	0.00	2.36

5. Reporting, Recordkeeping, and Other Compliance Requirements for Small Pharmacies

Requirements related to reporting, recordkeeping, and other compliance activities for small pharmacies under this program are minimal. There are only two requirements of this type for pharmacies that participate in an endorsed discount card sponsor's network. Pharmacies are required to notify the beneficiary at the point of sale of the differential between the price of the drug to the beneficiary and the lowest priced generic covered drug under the program that is therapeutically equivalent and bioequivalent and available at the

pharmacy. While it is possible that this requirement could represent some burden, we anticipate that the burden would be at most marginal. The pharmacy community routinely indicates that it is common practice for pharmacies to promote the use of generic drugs. Thus, this requirement is unlikely to represent a change in current practice for most pharmacies. The costs of the systems infrastructure required to furnish this pricing information will be borne by endorsed sponsors. The only cost to pharmacies would be the time involved in conveying the information to the beneficiary, which we anticipated would be small.

Pharmacies are also required upon request from the beneficiary to determine—either electronically or by telephone—how much of the beneficiary's transitional assistance dollars remain. The costs associated with this activity for pharmacies are expected to be small for several reasons. First, we anticipate that the costs associated with the development of the infrastructure for providing the balance of the transitional assistance dollars at the point of sale will be borne by endorsed sponsors, not network pharmacies. Second, we expect that the time involved in pharmacies determining the balance either electronically or by phone will be small. Finally, providing to beneficiaries the transitional assistance balance is not required to occur at the point of every sale, only at the beneficiary's request. Beneficiaries will have other options for accessing their card balances outside of the retail pharmacy, including through the endorsed sponsor's toll free line, which is likely to lessen the extent to which beneficiaries request balance determinations by pharmacies.

6. 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 rule will not affect small rural hospitals since the program 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.

7. Alternatives Considered for, Especially, Small Pharmacies

In developing this program, we recognized that the statute already provided for a number of major program features that act to mitigate the potential effects of this program on retail pharmacies, including small pharmacies. First, we interpret the statute as reflecting Congressional intent that endorsed sponsors obtain manufacturer rebates, discounts, or other price concessions on some covered discount card drugs and that endorsed sponsors pass through some of these price concessions to enrollees in the form of lower prices. In addition, as discussed elsewhere in this rule, prices under this program will not be taken into account for the purposes of establishing ''best price.'' Together, these program features relieve pressure from pharmacies, by ensuring that manufacturer rebates and discounts will be an important component of savings in this program and that endorsed sponsors will not rely solely on pharmacy discounts to compete for customers.

Second, the statute prohibits a mail order-only option. Mail order programs have some popularity and may be a convenient option for some beneficiaries. However, the prohibition of mail order only programs ensures that strong access to retail pharmacies will be an important feature of this program.

Finally, the program includes broad network access requirements that ensure that convenient access to retail pharmacies, including small pharmacies, will be a critical component of this program. Endorsed sponsors are required to have a pharmacy network of sufficient size to demonstrate that at least 90 percent of beneficiaries in urban areas served by the program live within 2 miles of a network pharmacy, at least 90 percent of beneficiaries in suburban areas served by the program live within 5 miles of a network pharmacy, and at least 70 percent of beneficiaries in rural areas served by the program live within 15 miles of a network pharmacy. Given these network access requirements, coupled with the industry norm for broad pharmacy networks, and the prohibition of a mail order only option, we anticipate that a very large number of small pharmacies and drug stores will be included in the networks of endorsed sponsors.

In addition to these statutory-related features of the program that mitigate its potential effects on pharmacies, we considered whether or not to require that endorsed sponsors negotiate discounts on all drugs. We decided to only require that endorsed sponsors offer a discount on at least one drug in the therapeutic categories representing the drugs most commonly needed by beneficiaries. Since endorsed sponsors are less likely to negotiate manufacturer discounts on every drug dispensed, we believe our decision not to require discounts on every drug relieves pressure on pharmacies to provide discounts.

I. Estimated Administrative Costs and Anticipated Revenues of Endorsed Card Sponsors

1. Introduction

The statutory requirement that this program be provided by private, endorsed card sponsors places program success in providing savings and transitional assistance to Medicare beneficiaries on the participation of potential card sponsors. In light of this, we estimated the administrative costs and revenues faced by potential card sponsors to assess the willingness of private organizations to participate in the Medicare prescription drug discount card program. There are several incentives for organizations with pharmacy benefit management experience to choose to participate as endorsed card sponsors. We know that Medicare beneficiaries trust the Medicare name and are more confident about product offerings when they are Medicare approved or backed by the Medicare name. Receiving a Medicare endorsement will give potential card sponsors credibility with Medicare beneficiaries. In light of this, we believe that Medicare's endorsement of a discount program, and especially the availability of transitional assistance, will result in much greater enrollment with these organizations than the same entities might achieve if they decided to offer a discount program on their own. Greater enrollment means revenue from enrollment fees and more lives with which to negotiate manufacturer rebates. In addition, participation in the Medicare prescription drug discount card program may offer organizations the opportunity to gain experience working with Medicare beneficiaries and contracting with CMS prior to implementation of Medicare Part D.

The following cost and benefit analysis reflects the estimated major administrative costs and benefits incurred by an endorsed sponsor to implement the Medicare prescription drug discount card program. The administrative costs include start-up and program implementation activities, the production and distribution of

information and outreach materials, eligibility determination and enrollment processing of beneficiaries, processing claims for retail and mail-order prescriptions, operation of a customer service call center, account maintenance, and logging and responding to beneficiary complaints and grievances. This analysis provides a range for each cost component, from low to high, that reflect possible endorsed sponsor differences in the level of technical efficiency and business investment decisions for offering the discussed initiative. For purposes of this analysis, estimated benefits are limited to the legislated enrollment fee, a maximum of $30 per year in 2004 and 2005. This analysis demonstrates that a maximum annual enrollment fee of $30 can cover all or almost all administrative costs over the life of the program. Finally, we believe that the low costs estimated in this analysis maybe more accurate because CMS received many applications from potential card sponsors during our previous attempts to enact a fairly comparable program, suggesting that these organizations believed expected returns to be positive.

2. Sources of Administrative Cost Estimates

We used several sources in estimating administrative costs for this analysis. First, CMS has extensive experience pricing and contracting for some of the activities we require of endorsed sponsors, specifically call center operations for the Medicare population and producing and mailing printed information and outreach materials. We thoroughly explored internal sources to estimate costs for information and outreach, and for call center and customer service activities.

Early this year, 2003, as the President's plan for Medicare reform was being considered by Congress, CMS contracted for research of discount drug card call center operations to better inform our understanding of endorsed sponsor customer service and possible impacts on 1–800 Medicare.[5]

Other administrative costs of this program, such as account management and claims processing costs for pharmacy benefit management services, are not publicly available in a standardized format. In part, this is due to a general lack of transparency in the financial reporting of the pharmacy benefit management industry. Administrative cost information is considered proprietary by the industry and is not clearly itemized in financial reports.

Of the information that is available, most is not standardized, and therefore, not readily compared across discount card programs. A pharmacy benefit management firm's administrative costs are unique to its business structure. The structure of pharmacy benefit management contracts also reduces the standardization of cost information. When bidding on a Request for Proposal by an employer or health insurer to provide pharmacy benefit management services, pharmacy benefit management firms typically offer a package of administrative costs, negotiated pricing for reimbursing drug costs, and rebate-sharing arrangements. The package approach often includes a comprehensive administrative fee that covers many bundled services, the content of which vary by organization and proposal. The multifarious rebate-sharing arrangements unique to each pharmacy benefit management firm and other revenue flows mask the cost of some activities, contributing even more to reduced comparability. In short, payments for costs taken from multiple pharmacy benefit manager contracts cannot be readily compared. For example, a recent investor report by Credit Suisse First Boston demonstrates the impact of rebate-sharing arrangements on administrative costs. The authors cite variation in per claim processing costs paid by purchasers of $0.0 to $0.70.[6]

In order to best estimate these administrative costs, CMS contracted with an independent, management-consulting firm to provide technical support in developing estimates of administrative costs.[7] For each of the major activities required to implement the Medicare prescription drug discount card program, we identified seven categories of economic costs that potential endorsed sponsors might incur in implementing this program. These costs are discussed in detail later in this analysis and presented in Table 9.

The consulting firm's analysis is based on interviews with officials representing State senior discount card programs and commercial organizations representing various categories of firms that provide drug card program administration, throughout the United States. These organizations include pharmacy benefit management firms (independent and owned by managed care organizations) and other commercial discount card program operators. In addition to conducting interviews, the consulting firm also consulted industry experts on purchasing pharmacy benefit management services.

The consulting firm interpolated costs from more generalized cost information gathered in interviews about required labor and resources, in some instances, in order to estimate specific, comparable costs for all activities. This was necessary, in part, because commercial organizations were cautious about sharing costs and uncertain about the programmatic requirements of this regulation, which were not publicly available at the time that these interviews were conducted. Also, States and other purchasers did not always have the specific costs of components included in bundled administrative fees.

3. General Assumptions, Limitations, and Scope

This program has two full operational years beginning in April 2004 and ending mid-May 2006. Although the program does not start in January, we estimate costs for each calendar year of operation because calendar years correspond to the source of revenue, the annual enrollment fee, and to the coordination of the enrollment process with the Annual Coordinated Election Period for Medicare. We refer to the first nine months of 2004 as Year One, to 2005 as Year Two, and to the first four and one-half months of 2006 as the Transition Period. For Year One estimates, we adjust the costs associated with ongoing program operations, including claims processing, account maintenance, and responding to discount card enrollee complaints and grievances, to reflect the nine-month operating period.

The four and one-half month transition period is a carryover period during the initial open enrollment period for the new Medicare Part D prescription drug benefit. During this period, no new enrollment is allowed in the Medicare prescription drug discount card program, no new transitional assistance is available, and endorsed sponsors may not charge an annual enrollment fee. Current discount card enrollees retain access to negotiated prices and transitional assistance enrollees may, in most instances, use the balance of transitional assistance funds not expended in Year Two to

[5] The Health Strategies Consultancy LLC. Call Center Parameters and Regulatory Authority for Drug Discount Cards. May 20, 2003.

[6] Berg, Kevin and Noah Yosha. July 14, 2003. *Pharmacy Benefit Managers and Specialty Pharmacies.* Credit Suisse Equity Research for First Boston: 5.

[7] Booze, Allen, and Hamilton. December 2003. *Discount Card Administrative Costs to Support the Medicare Drug Discount Card Program.* CMS contract number 500–97–0437, Task Order 2006.

assist with covering the costs of their covered discount card drugs obtained during the transition period. Therefore the costs reflected for this period include claims processing, account maintenance, customer service and call center operations, and responding to discount card enrollee complaints and grievances. We adjust all costs incurred in this period for an average enrollment length of two and one-quarter months, which is the same assumption made earlier in the beneficiary impact estimates to reflect declining enrollment in the Medicare prescription drug discount card program as individuals move to Part D.

We assume that all endorsed sponsors, or at least one of their contractors, are experienced in pharmacy benefit management and have the infrastructure in place to implement this program. The applicant, or one of its subcontractors, at the time of application for endorsement must have three years experience in adjudicating and processing claims at the point of sale, negotiating with prescription drug manufacturers and others for rebates and discounts on prescriptions drugs, and administering an individual enrollee health care subsidy or benefit in real time. Further, the applicant, or at least one of its subcontractors, must serve at least 1 million covered lives. For this reason, some requirements of this program are part of standard business practices for administering a prescription drug benefit or assistance program and are associated with negligible additional costs.

Activities already conducted as standard business practice include creating typical reports on discounts, pricing, and utilization for the client, providing counseling on generic substitution, establishing a pharmacy network, reimbursing network pharmacies for drugs covered by transitional assistance, drug utilization review, formulary management, and negotiating manufacturer and retail rebates. We assume marginal cost incurred for these activities, if any, will be captured in our estimates for account maintenance. Further, we believe that endorsed sponsors will be compliant with HIPAA because their other lines of business require such compliance. Regarding the HIPAA security rule, which is not enforceable until 2005, based on our discussions with potential endorsed sponsors, we assume they are already in compliance with these provisions under the privacy rule and are preparing to complete compliance with the security rule 2005 deadline for their other lines of business.

We assume that total program enrollment is equal to 100 percent of the number of beneficiaries that the impact analysis estimates will be enrolled in each year of operation: 7.3 million in Year One, and 7.4 million in Year Two and the Transition Period. We used a growth estimate of 1.4 percent to estimate enrollment in Year Two, which is the estimate for growth in Medicare Part B enrollment. Part E of this section discusses estimated program enrollment in greater detail. For some of our enrollment application, and information and outreach estimates, we assume that new enrollment in Year Two consists of those individuals the impact analysis anticipates enrolling in the program in Year Two and those individuals switching card programs. With regard to the latter, we assume that roughly 10 percent of enrollees will disenroll during Year One. As a simplifying assumption, we also assume that this same number re-enrolls in a different card in Year Two. We chose 10 percent as a modification of the 2001 Medicare managed care disenrollment rate of 13 percent because the rate reflects a continuous open enrollment policy. Our regulations limit enrollment to one endorsed program each year, with the option to elect another endorsed programs during the Annual Coordinated Election Period.

Exclusive card sponsors are Medicare managed care organizations that limit their card program membership to their health plan membership. We have chosen not to present separate cost estimates for exclusive card sponsors for two reasons. First, we assume that we will largely be endorsing existing card programs already in operation by these organizations for their Medicare enrollees. Second, we believe that the costs for exclusive card sponsors will be lower than those incurred by other endorsed sponsors. Exclusive card sponsors can group enroll their Medicare managed care organization enrollees, a known population. They also will have lower costs for information and outreach since they already engage in marketing activities for their plan and can achieve efficiencies by including their discount card information with other outreach efforts. Since the costs of enrollment, and information and outreach are some of the highest cost components in Year One, we expect exclusive endorsed sponsors will have costs substantially lower than the maximum $30 enrollment fee.

We estimate that 812,637 individuals will be enrolled in a discount drug card offered by an exclusive card sponsor in 2004, and 824,201 individuals will be enrolled in an exclusive card program in Year 2005 and the Transition Period. We derived this estimate by applying the proportion of individuals enrolled in a Medicare managed care plan (that is, Section 1876 cost plans, M+C plans, and preferred provider and most other managed care demonstrations) in the Medicare population, 12 percent, to the number of individuals estimated to enroll in this initiative who are not enrolled in Medigap, 6.8 million in 2004 and 6.9 million in 2005. Because we are not estimating costs for endorsed sponsors that are also managed care organizations, we removed these individuals from all enrollment assumptions made in this analysis.

Throughout the discussion of individual costs, we present estimated costs for the whole program, by discount card enrollee, and for the average fee-for-service (FFS) endorsed sponsor (meaning a endorsed sponsor whose enrollment is made up mostly of beneficiaries in the original Medicare program) whose average enrollment is based on the total enrollment level calculated above divided by the number of FFS programs we expect will apply and meet the requirements for endorsement, as described below. In part, this is because our research on administrative costs suggests that experienced administrators of prescription drug benefits have comparable per discount card enrollee and per prescription variable costs for programs of different sizes that meet minimum endorsement requirements. However, endorsed sponsors have the option of proposing a program for a service area as small as a State.

The remainder of this analysis examines the impact on endorsed sponsors that must comply with all components of this regulation and serve primarily beneficiaries in fee-for-service. This includes the few organizations that we expect may choose to offer a card for all Medicare beneficiaries rather than limit enrollment to their health plan membership. Only the latter are exclusive endorsed sponsors. Having removed individuals in exclusive card programs, we estimate per endorsed sponsor costs based on an average endorsed sponsor enrollment of 431,865 in Year One and 438,010 in Year Two and the Transition Period. We derived these numbers by dividing estimated enrollment less our estimates for exclusive card program enrollment by 15, or 6,477,973 divided by 15 in Year One, and 6,570,150 divided by 15 in Year Two. In 2001, we received 28 applications, with approximately one-half appearing to meet all of the

endorsement criteria to operate a discount card program.[8]

This analysis estimates a range of high and low annual costs per discount card enrollee, per endorsed sponsor, and for the whole program, for each type of administrative cost incurred to implement this program. The ranges serve to illustrate the sensitivity of differences in possible administrative costs that are the result of various levels of industry experience and technological efficiency, and of business decisions about the level of investment for discretionary activities, such as information and outreach. For example, efficient pharmacy benefit management organizations with modern information systems that are currently operating a card program and that selectively target their marketing efforts are anticipated to have much lower costs than organizations that must program older mainframe systems, have less experience with direct enrollment, and make greater investments in information and outreach materials. Further, some organizations other than pharmacy benefit management firms that could qualify to be endorsed sponsors may have less experience in some areas of pharmacy management or may choose to outsource or partner with another organization for some activities, resulting in alternative, and possibly higher, cost structures.

The following estimates were made in 2003 dollars and have been updated by 1.041 percent in Year One to reflect 2004 dollars, 1.085 percent in Year Two to reflect 2005 dollars, and 1.132 percent to reflect 2006 dollars during the transition period. All dollar figures discussed in greater detail in the next section and presented in Table 9 reflect the inflated rate for that identified year. Inflation estimates are based on those for labor in the general population from table III.A.1 of the 2003 Annual Report of the Board of Trustees, *see http://www.cms.hhs.gov/publications/trusteesreport/2003/.*

TABLE 9.—ADMINISTRATIVE COSTS AND BENEFITS BY PERIOD

[Year one (nine months) administrative costs in 2004 dollars]

	Costs per endorsed sponsor (431,865 enrolled)		Dollars per discount card enrollee	
	Low	High	Low	High
Program Implementatioon	$1,561,500	$3,123,000	$3.62	$7.23
Information and Outreach	1,807,771	4,300,194	4.19	9.96
Eligibility Determination and Enrollment Processing	2,261,793	2,945,591	5.24	6.82
Customer Service Operations	2,899,735	4,366,461	6.71	10.11
Claims Processing and Claims Adjudication	541,677	1,764,862	1.25	4.09
Account Maintenance	1,294,765	1,348,714	3.00	3.12
Logging and Responding to Grievances	30,346	40,461	0.07	0.09
Total Administrative Costs	10,397,588	17,889,284	24.08	41.42
Maximum Revenue Stream from Enrollment Fee	12,955,945	12,955,945	30.00	30.00
Net Benefits	2,558,357	(4,933,339)	5.92	(11.42)

[Year two administrative costs in 2005 dollars]

	Costs per endorsed sponsor (438,010 enrolled)		Dollars per discount card enrollee	
	Low	High	Low	High
Program Implementation	$0	$0	$0.00	$0.00
Information and Outreach	858,543	1,513,041	1.96	3.45
Eligibility Determination and Enrollment Processing	302,577	393,446	0.69	0.90
Customer Service Operations	574,370	864,894	1.31	1.97
Claims Processing and Claims Adjudication	763,474	2,173,771	1.74	4.96
Account Maintenance	1,824,925	1,900,963	4.17	4.34
Logging and Responding to Grievances	42,772	57,029	0.10	0.13
Total Administrative Costs	4,366,661	6,903,144	9.97	15.76
Maximum Revenue Stream from Enrollment Fee	13,140,301	13,140,301	30.00	30.00
Net Benefits	8,773,640	6,237,156	20.03	14.24

[8] On November 5, 2001, the Federal Court for the District of Columbia preliminarily enjoined CMS from proceeding with the administration's proposal for a Medicare-Endorsed Prescription Drug Discount Card program. In accordance with the court order, we withdrew the solicitation, all work on the initiative ceased. CMS did not make any Medicare endorsements on the basis of applications received. However, we had, at that time, completed our review of all applications and knew how many proposed programs would have been endorsed.

[Transition period (five and one-half months) administrative costs in 2006 dollars*]

	Costs per endorsed sponsor (438,010 enrolled)		Dollars per discount card enrollee	
	Low	High	Low	High
Program Implementation	$0	$0	$0.00	$0.00
Information and Outreach	0	0	0.00	0.00
Eligibility Determination and Enrollment Processing	0	0	0.00	0.00
Customer Service Operations	107,694	162,168	0.25	0.37
Claims Processing and Claims Adjudication	149,352	305,325	0.34	0.70
Account Maintenance	356,996	371,871	0.82	0.85
Logging and Responding to Grievances	8,367	11,156	0.02	0.03
Total Administrative Costs	622,410	850,519	1.42	1.94
Maximum Revenue Stream from Enrollment Fee	0	0	0.00	0.00
Net Benefits	(622,410)	(850,519)	(1.42)	(1.94)

* Costs assume an average of 2.25 months enrollment to match assumptions in section on beneficiary impact analysis.

4. Specific Assumptions For Administrative Cost Estimates

In the following paragraphs, we discuss our assumptions for the estimates provided in Table 9 for the 7 major types of administrative costs anticipated for this program.

(a) Start-up, program implementation costs for infrastructure enhancements, including software and hardware upgrades, programming for many operations, and systems integration;

(b) Information and outreach activities, for example the production and distribution of pre-enrollment application materials and a post-enrollment welcome kit with a discount card;

(c) Eligibility determination and enrollment processing;

(d) Call center and customer service operations, including handling calls asking for information and outreach materials and enrolling, where applicable;

(e) Claims processing for administrating and adjudicating claims transactions;

(f) Account maintenance, including staff time to run the program and updates to various systems, to provide typical industry data reports, including providing data to support the price comparison Web site; and

(g) Logging and responding to beneficiary complaints and grievances for reasons other than eligibility.

a. Program Implementation

Program implementation costs are those associated with setting up the necessary infrastructure, mostly information systems, to run the Medicare prescription drug discount card program.

We do not believe that endorsed sponsors will need to purchase entirely new hardware or software. We believe that those organizations, with their subcontractors, that will be eligible for the endorsement already maintain the information system infrastructure, including hardware and software, necessary to house the information systems needed for this program. This infrastructure includes enrollment databases, claims processing and adjudication, third-party reimbursement, and call center operations. One exception is our requirement that endorsed sponsors pay to install CMS software and test connect with CMS data systems for exchanging eligibility and enrollment information. However, CMS will pay for the program sponsor T1 connection and provide the ''connection software''. For this software, we estimate installation costs of no more than $1,500 per endorsed sponsor, or less than $0.01 per discount card enrollee, in 2003 dollars.

Endorsed sponsors will incur program implementation costs for programming or enhancing current software systems and conducting the systems integration necessary to accommodate the specific parameters of this program. Impacted software systems include current enrollment systems, drug price database, formulary management, pharmacy network database, call center software, accounting systems to track expenditures by beneficiary for the transitional assistance program, updates to claims processing to provide rebates at the point-of-sale, and setting up other data files associated with CMS reporting requirements.

One representative of the pharmacy benefit management industry interviewed for CMS, anticipated information system enhancement costs, including upgrading and programming call center software, for a Medicare prescription discount card program, to between $4 million and $6 million for a program of 500,000 enrollees. Using our estimates of 431,865 enrolled per endorsed sponsor, these fixed costs become an estimated per discount card enrollee annual cost between $9.26 and $13.89 dollars. These estimates reflect costs known to this organization as well as additional dollars to account for the uncertainty of making estimates without programmatic specifics.

Interviews with other State and commercial discount card programs, provided estimates of labor type and time required to program software systems. Using the information, the consulting firm estimated start-up program implementation costs for information systems between $54.5 and $250 thousand in 2003 dollars. As an annual per discount card enrollee cost for the average endorsed sponsor, this program implementation estimate is negligible, ranging from $0.13 to $0.58. This program has unique aspects whose costs are not fully known. So as to accommodate for this and the limited experience that some types of firms may have with programming specific software systems and new programming, such as tracking beneficiary expenditure of transitional assistance, CMS has chosen to estimate program implementation costs that are a compromise of the higher cost estimates for program implementation anticipated by one organization and the lower costs estimated by the consulting firm. Specifically, we have chosen a per endorsed sponsor range between 1.5 million and $3 million dollars for program implementation for Year One in 2003 dollars. We reduced the lowest industry number of $2 million by a rough $500 thousand for upgrading call center software, as the estimates for that

cost per call is reflected in section (d). We estimate that the aggregate program implementation cost across all endorsed sponsors in Year One is between $23 million and $47 million in 2004 dollars, with a per endorsed sponsor cost between $1.6 million and $3.1 million. This translates into a per discount card enrollee cost between $3.62 and $7.23. There are no program implementation costs for Year Two or the Transition Period.

b. Information and Outreach

Under this initiative, there will be costs associated with information and outreach materials for each new discount card enrollee in Year One and costs associated with distribution of program materials to current discount card enrollees as well as to a small percentage of new discount card enrollees and disenrollees choosing to reenroll in Year Two. There are no information and outreach costs for the Transition Period as no new enrollment is allowed after December 31, 2005. We assume that individuals will be notified that the Medicare prescription drug discount card program will end in 2006 through the annual notice of change mailed at the end of 2005.

We develop a range of estimates that reflect the production and mailing of five types of information and outreach materials: a pre-enrollment application kit with the standard enrollment form, a post-enrollment welcome kit with the drug card, an annual notice of change, an eligibility determination, and mailing back incomplete applications that cannot be processed. These estimates do not include costs for information and outreach through mass media as this is not a requirement for endorsement.

Information and outreach is an area where endorsed sponsors can choose to spend an extensive amount of money, depending on their long-term business interests and plans. In their interviews with potential endorsed sponsors and comparable State programs, the consulting firm found large differences in information and outreach expenditures. For example, expenditure for mass media advertising quickly increases costs beyond those discussed here. The decision to invest in mass media advertising is ultimately that of the endorsed sponsor.

CMS intends to assist endorsed sponsor information and outreach efforts by launching an education campaign about the new Medicare prescription drug discount card program. We plan on both television and print advertising. Further, we expect 1–800 MEDICARE to serve as the first source of information about the program. 1–800 MEDICARE provides interested individuals with decision support, helping them identify the programs that they are eligible to join. 1–800 MEDICARE also will mail interested individuals a booklet describing the Medicare prescription drug discount card program, transitional assistance, and how to enroll. For these reasons, we expect that at least some of the financial burden of generating awareness and educating Medicare beneficiaries about the program will not fall on endorsed sponsors, reducing costs for information and outreach.

For low estimates, we used production costs based on prices from Federal contractors available through the General Services Administration and in-house mail estimates. We priced simple, low-end, serviceable materials with some color and limited design. For the high estimates, we substituted the costs quoted for application kits (overview materials and standard enrollment form) and welcome kits (member handbook and drug card) by organizations interviewed for CMS, for our in-house estimates. We assume these materials to be higher-end commercial products. Both low and high estimates include postage and use our in-house estimates for producing and mailing the other information and outreach materials: mailing eligibility determination notices, mailing back incomplete applications, and an annual notice of program changes for each year.

Low and high estimates for producing and mailing a welcome kit to a new member were $1.20, the Government's estimate, and $2.00, which was based on costs reported by organizations interviewed for CMS. Organization estimates for providing a welcome kit ranged from $0.12 to $2.70 in 2003 dollars. However, most reported costs hovered between $1.00 and $1.50. The $2.70 cost was for a kit compiled on demand with few economies of scale, an approach we do not expect nor require endorsed sponsors to take. We chose an estimate of $2.00 because it was higher than most reported commercial costs but low enough to reflect the expected requirements of this program. We also believe that we have reduced the time endorsed sponsors may need to spend drafting marketing materials by providing model information and outreach materials with the solicitation.

We used the same approach in our low and high estimates of application kits. Our government sources reported a cost of $0.65 to produce and mail an application kit to interested individuals. Commercial and State estimates for providing an application kit to interested individuals ranged from a low of $0.45 to $2.12. We chose a high estimate for the application kit of $2.00.

We have assumed that the total number of pre-enrollment application kits mailed by endorsed sponsors will be three and one-half times the number of new beneficiaries enrolling in the program each year. This estimate is based on the midpoint of estimates gathered during interviews by the consulting firm. The firm found that card programs mailed applications to between two and five times the number of individuals enrolled in their program. For Year Two, this number is three and one-half times the number of individuals who are newly eligible for Medicare and the individuals reenrolling in Year Two after disenrolling in Year One.

Because the standard enrollment form in the application kit has several required elements and because the Medicare population has lower literacy levels and greater cognitive difficulties than some populations, individuals may not properly complete the form for their first submission. The regulation requires endorsed sponsors to ensure the completeness of submitted applications. We have assumed information and outreach costs also include an estimate for mailing back 30 percent of applications.

We assume that 100 percent of beneficiaries who would actually enroll in each year will receive a post-enrollment welcome kit. And, we assume that 100 percent of enrolled beneficiaries will receive an annual notice of change prior to the Annual Coordinated Election Period in each year. In 2005, this notice will inform discount card enrollees that the program is ending and direct them to information on Part D.

We assume that 30 percent of all individuals will request an eligibility determination for transitional assistance and will not immediately enroll in an endorsed card program because they are not determined eligible for transitional assistance. This regulation requires that endorsed card sponsors not immediately enroll individuals who request transitional assistance at the time of enrollment if they are not determined eligible for such assistance. We chose 30 percent to capture a proportion of individuals ultimately choosing to enroll in the discount card after finding that they are not eligible for transitional assistance and a proportion of those never enrolling in the program who request transitional assistance, but are determined ineligible. In Year Two, we estimate that 30 percent of new discount card enrollees will request an eligibility determination, and we estimate an

additional five percent of those currently enrolled and not receiving transitional assistance will request an eligibility determination because their financial circumstances have changed during the year. For this 30 percent of individuals, this regulation requires endorsed sponsors to mail them a negative eligibility determination, and to inform them of access to the reconsideration process.

We estimate a total information and outreach cost in Year One between $27 million and $65 million. We estimate a per endorsed program cost between $1.8 million and $4.3 million, and we estimate a per discount card enrollee cost between $4.19 and $9.96. These cost ranges are comparable to those estimated by the consulting firm for all marketing activities except mass media, between $0.84 and $7.02 per new member.

We estimate a total Year Two cost for information and outreach between $12.9 and $22.7 million. We estimate a cost per endorsed sponsor between $0.86 million and $1.5 million, and a per discount card enrollee cost between $1.96 and $3.45. Reduced costs for information and outreach in Year Two reflect information and outreach to a more limited pool of individuals, those changing plans or becoming eligible for the Medicare program, spread across the entire enrollment of the endorsed program. Information and outreach activities are not required during the Transition Period.

c. Eligibility Determination and Enrollment Processing

Endorsed discount endorsed sponsors will incur costs in administering the eligibility determination and enrollment processes as outlined in this regulation, but CMS has significantly reduced their potential role by assuming much of the burden of these activities. Specifically, we will develop an on-line enrollment and eligibility system against which endorsed sponsors can check the eligibility of individuals and enroll them in their endorsed programs. We also will handle any grievances about eligibility determinations and address requests for reconsideration of eligibility.

As our own eligibility determination process for transitional assistance is means-tested, we believe that means-tested State senior discount card programs are the best source of information about the costs of conducting eligibility determination activities. The interviews of several State programs and their contracted pharmacy benefit management firms gathered actual cost information and/or labor time to estimate costs of eligibility and enrollment.

To assess the sensitivity of our estimates, the consulting firm interviewed State programs that differed in the amount of documentation they required for an eligibility determination and in the level of verification activity required. Enrollment and eligibility activities for means-tested programs generally require some manual entry of information from an application or manual correction of scanned enrollment forms. Verification occurs either electronically or through manual review of multiple sources of income, family size, State residence, and health insurance. Some States require multiple forms of income documentation and manual review, while others accept the applicant's verbal certification that they meet income requirements. Sometimes States conduct these activities, and sometimes this activity is delegated to a private contractor providing pharmacy benefit management services.

Endorsed sponsor responsibilities will include reviewing applications, ensuring that applications are complete, screening initial applications for transitional assistance, entering eligibility information into a database, electronically requesting a determination on eligibility and enrollment for an individual through CMS systems, maintaining an enrollment database, and issuing eligibility determination notices that refer individuals to the reconsideration process as appropriate. We assume that endorsed sponsors will ensure that submitted applications are complete, either by recontacting individuals submitting incomplete applications, or by mailing incomplete applications back to the applicant. We have accounted for these mailing and telephone costs under estimates for information and outreach, and for customer service.

For those individuals applying for transitional assistance, we will require endorsed sponsors to first review applications for an individual's prescription drug coverage and the income level that the individual has certified as accurate, and identify individuals that need to be checked against CMS' eligibility and enrollment databases. The endorsed sponsor then will submit batch jobs of eligibility and enrollment requests through a telecommunications data connection with CMS, update their enrollment database with the results, and issue notices of eligibility determination and enrollment. The costs of mailing these notices are included in marketing estimates.

We assume that endorsed sponsors will process a total of 8.34 million applications in Year One. This application pool reflects 100 percent of program enrollment (6.4 million), plus an estimated additional 30 percent of enrollment to capture costs for processing reapplications to enroll in the discount card after receiving a negative eligibility determination for transitional assistance. We use the same 30 percent assumption when we estimate the number of eligibility determination notices that endorsed sponsors will mail. We chose 30 percent to capture a proportion of individuals ultimately choosing to enroll in the discount card program after finding that they are not eligible for transitional assistance and a proportion of those never enrolling in the program who request transitional assistance, but are determined ineligible. We assume that endorsed sponsors will process a total 1.6 million applications in Year Two. This application pool consists of 100 percent of individuals choosing to disenroll in Year One and all newly eligible enrollees in Year Two, plus an additional 30 percent of this total for reapplications and individuals choosing not to enroll. We also assume an additional 5 percent of discount card enrollees who are not receiving transitional assistance will request an eligibility determination because their financial status changed during the previous year.

From their interviews with State programs, the independent consulting firm estimates the cost of eligibility processing costs for a new application ranges from $3.87 to $16.68 in 2003 dollars. The low cost is from a State program that has self-certification of income and age, does not require review of any documentation for eligibility, and requires reporting of limited data elements on its enrollment form. The high cost is from a program that has a very complex eligibility process including requiring a breakdown of income and assets into categories, prospective adjustment of income for the coming year, and review of multiple documents demonstrating income, residency, health insurance, and age.

We chose to use $3.87 as our low estimate of conducting eligibility determination and processing enrollment for a new application, because the process CMS has created does not require labor-intensive processes such as review of documents verifying income or family size or prospective adjustment of income, however, it is not a simple attestation process. We chose $5.04 as our high estimate because our requirements on

endorsed sponsors are significantly less burdensome than the manual processing implied by the $16.68 estimate and because the estimate of $5.04 reflects the proportion of the high cost that accounts for data entry and eligibility determination activities that CMS would require of endorsed card sponsors.

We use the same cost estimate to approximate processing eligibility and enrollment requests for individuals applying for transitional assistance and those only applying to enroll in an endorsed program. We believe the amount of effort required to process applications for both populations is fairly comparable. If anything, we have slightly overestimated the cost of processing enrollment for individuals not applying for transitional assistance.

Combining our assumptions about the number of applications in each year with our estimates of the costs to process a new application, we estimate an aggregate eligibility determination and enrollment processing cost across all sponsors for Year One between $34 million and $44 million. We estimate a per endorsed sponsor cost for Year One between $2.3 million and $3 million. This translates to a per discount card enrollee cost between $5.24 and $6.82. In Year Two, we estimate an aggregate program eligibility cost between $4.6 million and $5.9 million, with a per endorsed sponsor cost between $303 thousand and $393 thousand. This translates to a per discount card enrollee cost between $0.69 and $0.90. As with other cost elements, Year Two costs are less because the cost to enroll the limited number of new discount card enrollees is spread across total program enrollees. We assume that there are no costs for eligibility determination and enrollment in the Transition Period.

d. Customer Service Call Center

The following estimates reflect costs for both an interactive voice-response system and access to live customer service representatives by telephone. To accurately represent an endorsed sponsor's call center costs, we rely on interviews conducted for CMS by the independent consulting firm as well as the research on discount drug card call center operations that CMS sponsored earlier this year. We also rely on literature reflecting call volume within similar program offerings.

We expect that Medicare beneficiaries will call an endorsed sponsor's customer service center for a variety of reasons. First, we believe that the majority of Medicare beneficiaries will call to gather additional information about the program and with questions about completing the enrollment form, especially those applying for transitional assistance. Our research on discount drug card call center operations also suggest that a small proportion of discount card enrollees call for more mundane reasons, including locating a network pharmacy, ordering a replacement card, and asking how to use the card when purchasing drugs. In addition to these reasons, we also expect that discount card enrollees will call to check drug prices, to disenroll, to file a grievance, and for those receiving transitional assistance, to check the balance of remaining funds.

With regard to call volume, we assume that endorsed sponsors will receive calls equal to 1.5 times new enrollment in Year One. We believe that the majority of call volume will be the result of initial enrollment activities. Our research indicates that endorsed sponsors expect Medicare beneficiaries who are considering enrolling in a card to call around for price information prior to enrolling. The recent report on the Pfizer Share Card program indicates call volume of roughly 6 times total enrollment during the first year of operation. Although this call volume includes income eligibility pre-screening for all applicants.[9] Further, both the independent consulting firm, Pfizer, and our own experience with 1–800 Medicare indicate that call volume increases after publicity and after information and outreach activities. We assume that endorsed sponsors will have call volume greater than enrollment but less than that documented by Pfizer for the following reasons.

First, we assume that CMS' education efforts and the availability of 1–800 Medicare and *http://www.Medicare.gov* will help reduce call volume to endorsed sponsors. Specifically, we believe that the availability of pre-screening tools through *http://www.Medicare.gov* and through 1–800 Medicare will attract calls requesting pre-screening for information and eligibility that might otherwise be addressed to individual endorsed sponsors. We also believe CMS' provision of a price comparison Web site will reduce call volume to endorsed sponsors because it will help individuals to check prices before they choose a card and, after they are enrolled, to check for changes in discounted prices.

We also assume that endorsed sponsors will take proactive measures to manage inquiries by discount card enrollees and others through communication channels other than the telephone. Our research on discount card call center operations suggests that endorsed sponsors can take several steps to preempt calls, including repetitive messaging, newsletters, Web sites, direct mail, and extensive FAQs (frequently asked questions) in information and outreach materials.

In Year Two, we assume call volume will be 1.5 times new enrollment. We also assume that 30 percent of those receiving transitional assistance will call for reasons other than enrollment and that 20 percent of those enrolled only in the discount card will call for reasons other than enrollment. Research on drug card call centers conducted for CMS indicate much lower call volume, less than 10 percent of membership, from individuals enrolled in a discount drug card than call volume in a funded benefit, roughly 30 percent of membership.

We assume that the endorsed sponsor's 1–800 customer service line will include an interactive voice-response system (IVR). An IVR system achieves call-savings by providing standard information without using the more expensive resources of a live customer service representative. If properly utilized, an IVR connected to various back office systems for immediate automated information retrieval, may help reduce significant call center costs to the sponsor. This allows for a good customer service tool, by giving callers responses to simple questions and easy access to various information. Many of the questions received by drug discount cards are questions that can be handled in the IVR, including requesting basic information about the program and enrollment, services, ordering replacement cards, checking for a network pharmacy, checking the discounted price of a specific drug, and checking account balances. We believe that the IVR will not be able to handle complex eligibility questions, questions regarding the balance of transitional assistance, and a range of other questions, such as a request for disenrollment.

We assume that an endorsed sponsor's IVR system can handle 50 percent of all incoming calls. We base this assumption on several sources. First, it has been CMS experience with 1–800 MEDICARE that traditionally 32 percent of all calls are handled in the IVR. Because 1–800 Medicare handles a range of questions about the Medicare program, these calls are more likely, on average, to be time consuming as 1–800 MEDICARE customer service

[9] Pfizer U.S. Pharmaceuticals. *Report to America.* September 2003.

representatives support beneficiaries in understanding their options among endorsed cards and other pharmacy assistance alternatives. In addition, the research conducted for CMS on discount drug card call centers provides some information on the percentage of calls moving from the IVR to a customer service representative. Two large call centers reported that 30 and 60 percent of calls were handled in their IVR respectively.[10] We believe 50 percent of calls reflects the simplicity of calls, other than those related to eligibility and transitional assistance, that endorsed sponsors will receive. We assume 50 percent of calls are handled in the IVR for both years.

We estimate the cost of a completed call in the IVR to range between $0.10 and $.35 cents. These estimates reflect a range of differences in IVR structure and time.[11] The independent consulting firm also estimated completed calls in the IVR to cost between $0.22 and $0.30. These estimates are fully loaded and reflect the marginal cost of each additional call, as we assume that each endorsed sponsor or its subcontractor will already have the basic call center infrastructure for IVR in place.

Using call volume assumptions and IVR cost information, we estimate aggregate interactive voice-response system costs to range between $1 million to 3.5 million dollars, with a per endorsed sponsor cost of $67 thousand to $236 thousand dollars. The estimated per new discount card enrollee cost is between $0.16 and $0.55 dollars.

For Year Two, we estimate aggregate interactive voice-response system costs range between $200 thousand and $701 thousand dollars, with a per endorsed sponsor cost of $13 thousand to $47 thousand dollars. The estimated per discount card enrollee cost is between $0.03 and $0.11 dollars.

We assume that calls to a customer service representative will average seven minutes in length. Interviews conducted by the independent consulting firm suggests that average talk-time for the senior population ranges from six to eight minutes. Our own internal experience with 1–800 Medicare confirms this analysis. Based on our assumptions about calls handled in the IVR, above, we assume that 50 percent of all calls are passed through. In Year One, this represents a total of approximately 4.9 million calls, across all card programs. In Year Two, applying 50 percent to our total call volume estimates suggests that 924 thousand calls will be passed through to a customer service representative. As mentioned earlier, we assume that most of the first calls made by individuals will come into the Medicare 1–800, thereby reducing the call volume and thus costs to the endorsed sponsors.

We estimate the fully loaded cost of a call to a live customer service agent per minute to range between $1.20 and $1.75. These estimates reflect a range of differences in IVR structure and time as well as CMS' experience contracting with call centers.[12] These costs include the costs of overhead and labor for conducting call center operations. We assume these costs also include start-up costs, such as programming call center software, increasing seat licenses, computers, phones, phone lines and training customer service representatives. To avoid double counting, we do not include costs for setting up call-center operations in our estimates of program implementation.

The estimated Year One customer service representative costs across all endorsed sponsors is between $42 million to $62 million dollars with a per endorsed sponsor cost of $2.8 million to $4.1 million dollars. This translates to a per discount card enrollee cost of $6.56 to $9.56 dollars. The estimated Year Two cost across all sponsors will be $8.4 million to $12.3 million dollars, with a per endorsed sponsor cost of $561 thousand to $818 thousand dollars. This translates to per discount card enrollee costs between $1.28 and $1.87 dollars.

The total IVR and customer representative service costs for Year One are between $44 million and $66 million across all sponsors, $2.9 million to $4.4 million per endorsed sponsor, and $6.71 to $10.11 per discount card enrollee. This range of costs is slightly higher than the per member estimates captured by the consulting firm in their interviews with comparable drug card programs. They estimated between $1.44 and $8.04 per member. The total IVR and customer representative service costs for Year Two are between $8.6 million and $13 million across all endorsed sponsors, $574 to $865 thousand, and $1.31 to $1.97 per discount card enrollee. For the Transition Period, the total IVR and customer representative service costs are estimated between $1.6 million and $2.4 million across all endorsed sponsors, $108 thousand to $162 thousand per endorsed sponsor, and $0.25 to $0.37 per discount card enrollee.

e. Claims Processing

The following estimates reflect costs for claims processing by the endorsed sponsors. Claims processing is the process performed by an endorsed sponsor to adjudicate a claim. It includes checking an eligibility database for program information, such as balance of transitional assistance; verifying prices; and conducting Drug Utilization Review (DUR). Consumer purchasing at a retail pharmacy is almost always an automated process, with adjudication happening at the point of sale. We anticipate that endorsed sponsors will use their computerized management information systems to perform claims processing. For purposes of this analysis, we assume that claims-processing costs apply to processing all transactions, whether providing a discount or processing an actual claim against transitional assistance. Although processing a discount is generally less burdensome because it does not require financial reimbursement and associated reconciliation against third party payor funds, we have not reduced our transaction estimates to account for this difference. Research conducted for us concluded that the cost difference between these two types of claims would be negligible.

Costs for processing claims in the literature range from $0.00 to $.70.[13] But, as already noted, these costs are not the true economic cost of processing claims because they include the cost of other services, such as account maintenance, and rebate-sharing arrangements. Estimates of the cost of claims processing obtained through the interviews conducted for CMS revealed true costs ranging from $0.05 to $0.14 for electronic processing of a prescription in 2003 dollars. We used this same range for our estimates of processing electronic claims. Lastly, endorsed sponsors may choose to promote mail prescription services for their enrollees. Some mail prescription fulfillments may be as high as a 90-day supply and thus utilize one prescription. This results in one prescription processing cost, instead of three claims being processed, at a 30-day supply each, thereby substantially reducing the overall cost component on the endorsed sponsor's expense

[10] The Health Strategies Consultancy LLC. Call Center Parameters and Regulatory Authority for Drug Discount Cards. May 20, 2003.

[11] Personal communication with Elizabeth Herrell, Vice President, Customer Experience, Forrester Research. October 29, 2003.

[12] Personal communication with Elizabeth Herrell, Vice President, Customer Experience, Forrester Research. October 29, 2003.

[13] Berg, Kevin and Noah Yosha. July 14, 2003. *Pharmacy Benefit Managers and Specialty Pharmacies.* Credit Suisse Equity Research for First Boston.

structure. We do not figure this into pricing the claims processing cost described here.

Some claims may be submitted on paper. Approximately one percent of all claims processed for a funded benefit are paper claims.[14] In our estimates, we assume that any one endorsed sponsor will have to process one percent of their claims manually for their endorsed program. To process a paper claim, the endorsed sponsor must manually enter the information into the claims processing system. Cost estimates for processing paper claims range from $1.00 to $1.50 per claim.[15] We used this same range of costs for our estimates of processing paper claims.

Section 1860D–31(g)(5) of the Act requires that transitional assistance through the endorsed sponsor be made available to beneficiaries who qualify for transitional assistance and reside in skilled nursing facilities and nursing facilities. These claims will be more difficult to process than electronic claims because they are likely to be submitted by pharmacies that are not in the endorsed sponsor's pharmacy network and with whom the endorsed sponsor may not have a formal relationship or electronic data exchange. We make this assumption because we believe that pharmacies in long-term care and skilled nursing facilities may not participate in an endorsed discount card program; institution-based pharmacies have less incentive than those in the community to join a discount card network.

To address the specific structure of the long-term care pharmacy market, this regulation provides for CMS to award a ''special endorsement'' to endorsed sponsors competing for the opportunity to process claims from long-term care pharmacies. This competition limits the processing of claims from pharmacies serving long-term care and skilled nursing facilities to a few endorsed sponsors who have experience processing such claims and who can garner economies of scale. We expect that endorsed sponsors receiving a special endorsement will have some pharmacies serving long-term care and skilled nursing facilities in their pharmacy network. For purposes of this analysis, we assume that two of the anticipated fifteen endorsed sponsors receive a special endorsement from CMS. For each of these two ''special endorsed sponsors,'' we assume that they continue to enroll the average number of enrollees in a card program: 431,865 in Year One, and 438,010 in Year Two and Transition Period, but that a sizable proportion of those enrollees is institutionalized.

We estimate that roughly 200 thousand institutionalized individuals will qualify for transitional assistance and use that transitional assistance at the pharmacy in their facility. This estimate is derived from the Medicare Current Beneficiary Survey (MCBS) and is used earlier in this document. We also estimate that this enrollment is split across the two special endorsed sponsors, thereby allocating 100 thousand enrollees to each special endorsed sponsor. This means that, roughly, one-quarter of the 430 thousand enrollees in a special card program are institutionalized. With regard to cost, we estimate that each of the special endorsed sponsors will receive about one-third of their claims for the institutionalized from long-term care pharmacies in their networks and that the cost per claim will be the same as processing any electronic in-network claim. Also, we assume that each card sponsor will achieve efficiencies in processing out-of-network claims from long-term care pharmacies. Without better estimates of the burden of processing out-of-network claims, we assume that the cost of processing such claims is similar to that for processing paper claims, between $1.00 to $1.50 per claim. In light of our assumption about available economies of scale, we assume a cost estimate of $1.00 for processing claims from out-of-network long-term care pharmacies.

We make a base assumption that beneficiaries using a discount card will fill 27 prescriptions a year. We base this assumption on findings from CMS Office of the Actuary, which obtains data on prescription drug sales and prescription utilization from a variety of sources, including the National Prescription Audit conducted by IMS Health. These are the same numbers used in the Impact Analysis. In light of the nine-month operating period for Year One, we assume that discount card enrollees will fill an average of 20 prescriptions using their discount card in Year One. We assume they will fill all 27 prescriptions during Year Two and fill 5 prescriptions during the Transition Period.

For the purpose of claims submitted against transitional assistance for beneficiaries in skilled nursing facilities and nursing facilities, we estimate that institutionalized individuals will fill an average of nine prescriptions for Year One and eight prescriptions for Year Two. This assumes that their long-term care pharmacy will only process claims against the balance of available transitional assistance. When the balance of transitional assistance becomes depleted for the year, we assume claims processing through the card program will cease. We derived nine and eight prescriptions by dividing $600 by an average prescription cost of $66 and $72, which is an average total prescription price of $46.99 (derived from self-reported beneficiary expenditures in MCBS 2000), adjusted to 2004 and 2005 dollars. We assume that institutionalized enrollees will not use their card during the Transition Period because they will have expended all of their transitional assistance in Year Two.

Twenty prescriptions for each non-institutionalized enrollee and nine prescriptions for each institutionalized care enrollee translates to a total of 129 million prescriptions in Year One, with each of the 13 endorsed sponsors processing 8.7 million prescriptions and each of the two special endorsed sponsors processing 7.6 million prescriptions. In Year Two, twenty-seven prescriptions per non-institutionalized enrollee and eight for institutionalized enrollees means a total of 174 million prescription across all beneficiaries, with each of the 13 endorsed sponsors processing 11.8 million prescriptions and each of the two special endorsed sponsors processing 10 million prescriptions. Five prescriptions for non-institutionalized enrollees in the Transition Period means a total of 32 million prescriptions for all enrollees will be processed, with each of the 13 endorsed sponsors processing 2.2 million prescriptions and each of the two special endorsed sponsors processing 1.7 million prescriptions.

We used the cost and prescription utilization estimates listed above to estimate costs for each of the 13 endorsed sponsors not processing claims from long-term care pharmacies. We assume that these endorsed sponsors only process in-network claims, both paper and electronic. For Year One, we estimate a per endorsed sponsor cost between $542 thousand and $1.4 million and a per enrollee cost between $1.25 and $3.24. For Year Two, we estimate a per endorsed sponsor cost between $763 thousand and $2 million and a per enrollee cost between $1.74 and $4.50. For the Transition Period, we estimate a per endorsed sponsor cost between $149 thousand and $386 thousand and a per enrollee cost between $0.34 and $0.88.

We used the costs and prescription utilization estimates discussed above to

[14] Price Waterhouse Coopers. June 2001. *Study of Pharmaceutical Benefit Management,* CMS contract number 500–97–0399 Task Order 0097: 76.

[15] Ibid.

estimate costs for each of the two special endorsed sponsors. We assume that these special endorsed sponsors process in-network claims, both paper and electronic, and process out-of-network claims for two-thirds of their institutionalized enrollees. For Year One, we estimate a per endorsed sponsor cost between $1 million and $1.8 million and a per enrollee cost between $2.48 and $4.09. For Year Two, we estimate a per endorsed sponsor cost between $1.2 million and $2.2 million and a per enrollee cost between $2.75 and $4.96. For the Transition Period, we estimate a per endorsed sponsor cost between $120 thousand and $305 thousand and a per enrollee cost between $0.28 and $0.70.

To accurately represent the full range of possible costs faced by an endorsed sponsor, for our final estimates of claims processing, we use the lowest per sponsor cost estimate, the low costs faced by each of the 13 endorsed sponsors, as our low estimate. Similarly, we used the highest per endorsed sponsor cost estimate, the high costs faced by each of the two special endorsed sponsors, as our high estimate of claims processing costs.

We estimate the total claims processing costs, including claims from pharmacies in long-term care facilities and paper claims, across all sponsors for Year One to be between $8 million and $22 million dollars, with a per endorsed sponsor cost between $542 thousand and $1.8 million dollars. This translates to a per discount card enrollee cost between $1.25 and $4.09 dollars. For Year Two, the total program cost is between $11.5 million and $30 million dollars, with a per endorsed sponsor cost between $763 thousand and $2.2 million dollars. This translates to a per discount card enrollee cost between $1.74 and $4.96 dollars. For the Transition Period, we estimate the total cost across all sponsors to be between $2.2 million and $5.6 million dollars, with a per endorsed sponsor cost between $149 thousand and $305 thousand dollars. This translates to a per discount card enrollee cost between $0.34 and $0.70 dollars.

f. Account Maintenance

Endorsed programs generally require ongoing account maintenance to maintain and update eligibility databases, input changes to the formulary database, provide technology support, provide typical industry data reports, and manage customer service for the purchaser. Account maintenance does not include call center or information and outreach activities. The cost of account maintenance is fairly minimal and is often rolled into other costs, such as a claims-processing fee. This clarifies, in part, the higher observed claims processing costs observed in the literature than we are using in this analysis.

The independent consulting firm gathered estimates of current account maintenance costs across commercial and State programs ranging from $2.28 per discount card enrollee per year to $3.84 per discount card enrollee per year in 2003 dollars. One firm that the consulting firm interviewed believed account maintenance costs for this program would be closer to $4.00 per discount card enrollee per year in 2003 dollars. For purposes of these estimates, we used $3.84 per discount card enrollee for our low estimate and $4.00 per discount card enrollee as our high estimate.

We believe these estimates capture the costs of producing data files for price comparison and the type of reporting that CMS requires to support monitoring. Further, the consulting firm found that most data related reports provided by sponsors to their clients, based on their clients' business needs, are negligible in cost. An example provided by the consulting firm includes a data file of all claims for a week long period. They Stated that the cost of such a report would be between $100 to $200 and would include the retail purchase price actually paid, the coded name and address of the store, and the name of the drug. The consulting firm indicated that some of the types of reporting likely to be required by CMS under the Medicare prescription drug discount card program would, in the private sector, be treated as a revenue generating product offering by sponsors. As such, sponsors would typically charge their clients according to the value, not cost that this data provides. In cases where the owner/producer of the data is providing the data reports as a subcontractor to a client of CMS, then whether the subcontractor chooses to charge the sponsor, at cost or profit, is a business and contract decision for these two entities, where, for example, the subcontractor is competing among other possible subcontractors for the volume of business that the name of the front organization may provide.

Adjusting account maintenance for the nine-month operating period in Year One and for inflation, we estimate a per discount card enrollee cost for Year One ranging from $3.00 to $3.12. This translates to a total cost between $19.4 million and $20.2 million dollars for all endorsed sponsors in Year One, with a per endorsed sponsor cost between $1.3 million and $1.4 million. In Year Two, an aggregate account maintenance cost is between $27 million and $29 million dollars with a per endorsed sponsor cost between $1.8 million and $1.9 million dollars. This translates to a per discount card enrollee cost between $4.17 and $4.34 for Year Two. For the Transition Period, we estimate a total program cost between $5.4 million and 5.6 million dollars, with a per endorsed sponsor cost between $357 thousand and $372 thousand dollars and a per discount card enrollee cost between $0.82 and $0.85 dollars.

g. Grievances

We anticipate that endorsed sponsors will incur minimal costs providing an internal grievance mechanism to document and address discount card enrollee complaints. Our endorsement criteria require that endorsed sponsors maintain a grievance process dedicated to complaints by discount card enrollees only about program operations, not about requests for reconsideration of a negative eligibility determination. Within a traditional benefit, medical-related grievances are usually related to prior approval, medical necessity, or a previous complaint. In means-tested prescription assistance programs, appeals for negative eligibility determinations are also a common source of complaints.

For this discount card program, discount drug endorsed sponsors will not need to address the traditional appeals of a funded benefit, those related to medical necessity determinations, or to address appeals for means-tested programs, those of eligibility determination. We expect grievances to be limited to programmatic issues such as pharmacy participation and the size of discounts. These issues are not complex and are straightforward to address.

The consulting firm gathered estimates of grievance processing in State programs and reports and estimated that costs were less than $0.01 per discount card enrollee per month. In light of this information, we estimate a low of $0.09 and a high of $0.12 per discount card enrollee per year in 2003 dollars.

For the nine-month operating period in Year One, we estimate a range of total program costs between $455 thousand and $606 thousand dollars. We estimate a per endorsed sponsor cost for grievances in Year One between $30 thousand and $40 thousand and a per discount card enrollee cost between $0.07 and $0.09. In Year Two, we estimate a total costs between $642 thousand and $855 thousand, a per

endorsed sponsor costs between $43 thousand and $57 thousand, and a per discount card enrollee cost between $0.10 and $0.13. For the Transition Period, we estimate a total cost between $126 thousand and $167 thousand, a per endorsed sponsor cost between $8 and $11 thousand, and a per discount card enrollee cost between $0.02 and $0.03.

TABLE 10.—NET PRESENT VALUE ANALYSIS BY AVERAGE ENDORSED SPONSOR

	Net present value	Year 1	Year 2	Transition period
Low.				
Net Benefits from Table 9 in 2003 dollars	NA	$2,457,596	$8,086,304	($549,832)
Discounted by 3%	9,790,107	2,457,596	7,850,781	(518,269)
Discounted by 7%	9,534,645	2,457,596	7,557,293	(480,244)
High.				
Net Benefits from Table 9 in 2003 dollars	NA	(4,739,038)	5,748,531	(751,342)
Discounted by 3%	133,848	(4,739,038)	5,581,098	(708,212)
Discounted by 7%	(22,830)	(4,739,038)	5,372,459	(656,251)

TABLE 11.—COST BENEFIT RATIOS BY ENDORSED SPONSOR

	Year 1	Year 2	Transition period
Benefits.			
From Table 9 in 2003 Dollars	$12,445,673	$12,110,876	$0
Discounted by 3%	$12,445,673	$11,758,132	$0
Discounted by 7%	$12,445,673	$11,318,576	$0
Costs.			
Low.			
Cost Stream from Table 9 in 2003 Dollars	9,988,077	4,024,572	549,832
Discounted by 3%	9,988,077	3,907,352	518,269
Discounted by 7%	9,988,077	3,761,282	480,244
High.			
Cost Stream from Table 9 in 2003 Dollars	17,184,711	6,362,345	751,342
Discounted by 3%	17,184,711	6,177,034	708,212
Discounted by 7%	17,184,711	5,946,117	656,251
Present Value Benefit/Cost Ratios.			
Low—3%	1.68	.....	.....
Low—7%	1.67	.....	.....
High—3%	1.01	.....	.....
High—7%	1.00	.....	.....

Table 9, which appears earlier in this document at the beginning of the discussion about individual administrative cost categories, presents cost estimates for endorsed sponsors for each cost component in nominal dollars, at both the program and per discount card enrollee levels, relative to the maximum annual enrollment fee of $30. The total low cost range represents the costs to a card sponsor incurring all low administrative costs, and the total high cost range represents the costs to a card sponsor incurring the highest administrative costs, including those associated with claims processing for special endorsed sponsors. We use the maximum annual enrollment fee as the only source of revenue for endorsed sponsors in this analysis to demonstrate that endorsed sponsors can cover their administrative costs with enrollment fee revenue. These estimates do not account for any costs of producing services that are not required for endorsement, but which could be offered to distinguish a drug card offering, such as disease-specific counseling or using mass media for information and outreach.

In Year One, we estimate that endorsed sponsors with low costs can easily cover their costs if they charge the maximum annual enrollment fee of $30. An average endorsed sponsor with 431,865 beneficiaries enrolling and participating for nine-months, and low administrative costs could collect revenue of $12,955,945 and incur costs of $10,397,588 resulting in a profit of $2,558,357. We estimate that endorsed sponsors with high administrative costs and an average of 431,865 beneficiaries enrolling and participating for nine-months could collect revenue of $12,955,945 and incur administrative costs of $17,889,284, resulting in a net loss of $4,933,339. Costs are higher than revenue for these endorsed sponsors because the costs associated with information and outreach, enrollment, and program implementation activities are loaded into Year One.

In Year Two, we estimate that all endorsed sponsors will cover their administrative costs. We estimate that endorsed sponsors with low costs and an average of 438,010 enrolled could earn revenue of $13,140,301, if they charge the maximum annual enrollment fee, and will incur administrative costs of $4,336,661. This results in net revenue of $8,773,640. For the same year, we estimate that endorsed sponsors with high costs and an average of 438,010 enrolled could earn revenue of $13,140,301, if they charge the maximum annual enrollment fee, and will incur administrative expenses of $6,903,144. This results in net revenue of $6,237,156. For the Transition Period, we estimate that endorsed sponsors with low costs and 438,010 enrolled for an average of 2.25 months will lose $622,410 and that endorsed sponsors with high costs and 438,010 enrolled for an average of 2.25 months will lose $850,519. Endorsed sponsors cannot charge an annual enrollment fee during the Transition Period.

A present value calculation is appropriate when costs and benefits are realized in different years in order to standardize costs and benefits for the time-value of money. Table 2 calculates the net present value (NPV) of these streams of net benefits (provided in Table 9), over the life of the program. In

their circular A–4, the Office of Management and Budget requires all benefit-cost analyses to use a 7 percent discount rate (r), which is the rate used to adjust cost and benefit streams for the time-value of money.[16] We also calculated net benefits using a 3 percent discount rate. The Office of Management and Budget has indicated that a 3 percent discount rate better approximates the individual rate of time preference.

As noted in the introduction to this analysis, we believe that potential card sponsors will find it profitable to participate in this program. The cost of capital to a private firm choosing to implement this program is the interest rate of a corporate bond. Lehman Brothers estimate that AAA and A average corporate bond yields to maturity are 2.89 percent and 3.93 percent respectively.[17] These low rates also reflect the return on capital for such a short investment. The program will last roughly 24 months. In order to avoid the influence of inflation on nominal interest rates, in Tables 10 and 11 we have removed all inflation adjustments from cost estimates, adjusted the nominal benefit stream of enrollment fee revenue for inflation in 2004 and 2005, and calculated present values in 2003 dollars. Net present value in Table 10 is calculated:

$$NPV = Year1Net + [Year2Net/(1+r)] + [Transition\ PeriodNet/(1+r)^2]$$

As shown in Table 10, a positive net present value exists for both the low and high cost estimates when discounted by 3 percent. A positive net present value exists for the low cost estimate when discounted by 7 percent, and a slightly negative net present value exists for the high cost estimate when discounted by 7 percent. Endorsed sponsors with modern information systems and experience administering pharmacy benefits, who also selectively target their information and outreach efforts will realize a large economic profit if they choose to charge the maximum enrollment fee of $30. We estimate that these endorsed sponsors could, in total, realize a net present value of approximately $9.5 million to $9.8 million over the life of the program. At a endorsed sponsor's option, to distinguish its endorsed program's offering, these profits could be channeled to deeper discounts on drugs or to additional drug-related products and services to benefit discount card enrollees.

Endorsed sponsors using older mainframe systems, or who have less experience with direct enrollment, and who make greater investments in information and outreach materials, and who have chosen to be a special endorsed sponsor, can cover all or almost all of their costs if they choose to charge the maximum annual enrollment fee of $30. We stated earlier that we believe 3 percent to be an appropriate discount rate for this program. Using a 3 percent discount rate, we estimate that endorsed sponsors with the highest administrative costs could realize a net present value of $134 thousand with an annual enrollment fee of $30. However, using the higher discount rate of 7 percent results in a slight loss for endorsed card sponsors with the highest costs. Such a finding does not preclude these potential card sponsors from participating because they can choose to cover their administrative costs by passing less rebate and other price concession revenues on to their discount card enrollees in the form of higher negotiated prices.

The highest cost estimates are for sponsors who receive a special endorsement to process claims for long-term care pharmacies. Sponsors with high administrative costs, excluding the effect of claims processing for LTC pharmacies, and dealing only with non-institutionalized enrollees could easily cover their costs, realizing a net present value of $442 thousand to $601 thousand with an annual enrollment fee of $30. We also believe that endorsed sponsors stand to further benefit from the amortization of certain cost components, thereby yielding a more attractive net present value in both the low and high ranges.

Calculating Benefit-Cost ratios is another means of assessing the profitability of a program. In Table 11 we estimate present value benefit-cost ratios. These are calculated by discounting costs and benefits for each year, summing over the years of the program and setting total present value benefits over total present value costs. As with the net present value calculations, we removed the effect of inflation from these estimates and calculate benefit-cost ratios in 2003 dollars. For endorsed sponsors with low administrative costs, we estimate a benefit-cost ratio of approximately 1.68 for the 3 percent discount rate and 1.67 for the 7 percent discount rate, and for endorsed sponsors with high administrative costs, we estimate a benefit-cost ratio of 1.01 and 1.00 respectively. In both instances, the benefit-cost ratio equals or exceeds one, demonstrating the feasibility of programs offered by each type of endorsed sponsor relative to anticipated revenue.

We have estimated costs for an average endorsed sponsor of 430 thousand enrolled individuals. Realistically, enrollment may not be evenly distributed when this program is implemented. We expect that some national endorsed programs will garner a large proportion of discount card enrollees, and that their participation will fulfill the geographic requirement that discount card eligible individuals have access to at least 2 programs. We also expect that other endorsed programs will enroll the remainder. The benefit-cost ratio for high estimated costs at 430 thousand enrolled equals or exceeds one, indicating that profitability for a endorsed sponsor with very high administrative costs will depend on enrolling all anticipated enrollment. There is very little room to absorb the impact of reduced enrollment through enrollment fees alone. This is not because fixed costs are large, the endorsement criteria require endorsed sponsors to already have most of the infrastructure needed to offer a drug discount card. Rather it is because very high variable costs leave little room to spread these minimal fixed costs across a reduced level of enrollment.

On the other hand, the benefit-cost ratios for low estimated costs, 1.67 and 1.68, clearly demonstrates enough room to absorb the costs of reduced enrollment. We believe that efficient endorsed sponsors can easily reach profitability with a moderate level of enrollment. Efficiencies are not necessarily due to economies of scale and can be achieved through new technology and smarter business practices. Finally, if, for some reason, endorsed sponsors enroll fewer individuals than anticipated, costs could be recouped through rebate and other price concessions.

This analysis has demonstrated that the maximum enrollment fee of $30 in Years One and Two gives endorsed sponsors with very different operating environments, levels of commitment, technological efficiency, and business investment strategies the flexibility to recoup their costs through enrollment revenue. Endorsed sponsors with the highest administrative costs can collect sufficient enrollment revenue to cover all or almost all of their expenditures. Card sponsors experiencing any minimal net loss can cover these costs with earnings from rebate dollars. Endorsed sponsors with lower administrative costs can easily collect sufficient enrollment revenue to cover

[16] Office of Management and Budget, Circular A–4, September 17, 2003.

[17] Lehman Brothers Credit Index, Yield by Quality, September 30, 2003.

their administrative expenses and may be able to charge a lower enrollment fee or pass greater savings onto their discount card enrollees.

J. Conclusion to Impact Analysis

In summary, more than 7 million Medicare beneficiaries are projected to enroll in the Medicare prescription drug discount card program. Savings to these beneficiaries from discount card activities are estimated to range from $1.4 billion to $1.8 billion in the last nine months of 2004, $2.0 billion to $2.7 billion in 2005, and $0.4 billion to $0.6 billion in the transition period in 2006. About 4.7 million of these beneficiaries are also expected to be enrolled in the transitional assistance program, with savings realized by these beneficiaries from transitional assistance estimated to be about $2.4 billion in 2004, $2.6 billion in 2005, and $0.1 billion in the transition period in 2006.

The Medicare prescription drug discount card program is not expected to have a significant economic impact on a substantial number of small pharmacies and drug stores. On average, estimated savings from discount card activities represent at most 1.18 percent of retail prescription drug revenues. Results from the sensitivity analysis found that even in a hypothetical geographic area with a larger than average proportion of residents likely to enroll in the Medicare prescription drug discount card program, savings from discount card activities represented less than 3 percent (2.36 percent) of total retail prescription drug sales.

Furthermore, this economic impact will not be borne entirely by pharmacies, because endorsed sponsors will be required to obtain manufacturer rebates or discounts that will defray the cost of pharmacies providing discounts on retail drug prices.

Finally, the analysis of administrative costs and revenue demonstrated that endorsed discount card sponsors with varied levels of administrative costs, ranging from low to high, would be able to recoup all or almost all of their costs through enrollment revenue (a maximum $30 enrollment fee in Years One and Two) alone. Furthermore, this analysis found that endorsed sponsors with lower administrative costs can easily collect sufficient enrollment revenue to cover their administrative expenses, and as a result may be able to charge a lower enrollment fee or pass greater savings onto their enrollees.

K. Alternatives Considered

Most of the provisions related to the Medicare prescription drug discount card program are statutorily specified; however, there were a few policy areas where the Secretary was provided discretion and we considered alternatives to the proposed features. A number of the areas where we considered alternatives relate to applicant qualifications. The statute specifies that the Secretary may determine the types of non-governmental entities that are appropriate to act as endorsed sponsors, and these entities may include pharmacy benefit management companies, wholesale or retail pharmacy delivery systems, insurers (including insurers offering Medicare supplemental policies), and Part C plans. Although we have the authority to limit the types of entities that may act as endorsed sponsors, the only specific structural requirement for a sponsor is that it be a non-governmental, single legal entity doing business in the United States. We chose not to impose other structural requirements at this time because we believe our other conditions for endorsement ensure that applicants, either individually or through subcontracts, will have the necessary experience and integrity to act as endorsed sponsors. We did this to provide flexibility for a wider variety of applicants using combined capabilities to become card sponsors than are specifically identified in the statute.

Another provision of the statute related to applicant qualifications is that an applicant is eligible for endorsement under the Medicare prescription drug discount card program if the applicant by itself, or together with subcontractors, demonstrates experience and expertise in operating a drug discount card or similar program and meets certain requirements related to business stability and integrity. We considered alternatives for how to interpret this provision. As discussed earlier in this document, we decided to interpret this provision to mean that applicants, together with their subcontractors, must have certain qualifications. First, is the qualification of demonstrating 3 years of private sector experience in pharmacy benefit management, including adjudication and processing of claims at the point of sale, negotiating with prescription drug manufacturers and others for rebates and discounts on prescription drugs, and administration and tracking of an individual subsidy or benefit in real time. All of these administrative functions are features that must be performed as part of this program. We did consider both shorter and longer periods of experience. We believe, however, that the 3 years prior experience strikes an appropriate balance to ensure that endorsed sponsors are able to quickly establish their endorsed programs, thereby promoting the statutory mandate to implement the Medicare drug discount card program within 6 months of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. In addition, the 3 years prior experience requirement ensures that endorsed sponsors have the necessary experience and capacity to offer card enrollees quality discounts and customer service. Moreover, given the relative newness of the drug card industry and high market turnover, we believe requiring less than 3 years experience would create an untenable risk of having the Medicare name associated with less than stable and reputable organizations. Alternatively, requiring more than 3 years experience might be too limiting in terms of an applicant pool.

In addition to requiring 3 years of relevant experience, we decided to require that a single entity which is either the applicant or a subcontractor operate a pharmacy benefit program, a drug discount card, a low-income drug assistance program, or a similar program that serves at least 1 million covered lives. We decided not to link the 1 million covered lives requirement with the 3-year experience requirement in order to provide entities the flexibility to combine their capabilities. For example, an entity with the requisite experience may not have the enrollment capacity, but may acquire this capacity by contracting with another entity for purposes of administering the endorsed program. As discussed previously in this document, given the potential level of enrollment in this program, we believe it is necessary that endorsed sponsors have the capacity to accept a large volume of enrollees. Furthermore, our 6-month statutorily mandated implementation timeline necessitates that endorsed sponsors be able to quickly accommodate a potentially large influx of enrollees over a relatively short period of time. Current levels of covered lives provides evidence of an applicant's immediate capacity to do so. 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 strikes a balance between ensuring a competitive marketplace with a number of different endorsed programs available to Medicare beneficiaries and ensuring that endorsed sponsors have the capacity to handle a large influx of card enrollees.

Another area where we considered alternatives relates to proration of the $600 transitional assistance. Section 1860D–31(g)(2)(A) of the Act provides that transitional assistance beneficiaries may receive up to $600 each year in transitional assistance. However, section 1860D–31(g)(2)(B) of the Act permits us to prorate the amount of transitional assistance available to beneficiaries applying for transitional assistance. We considered whether or not to exercise this authority. We decided not to prorate transitional assistance amounts in 2004 in recognition that it may take time for our education campaign to reach all beneficiaries and that beneficiaries need sufficient opportunity to learn about the Medicare prescription drug discount card program without penalty. We did, however, decide to prorate the transitional assistance available to eligible enrollees applying for transitional assistance in 2005. We decided to prorate transitional assistance in 2005 because we believe that, by 2005, beneficiaries will have had ample time to learn about the Medicare prescription drug discount card program. In addition, prorating transitional assistance encourages transitional assistance eligible beneficiaries to enroll in the Medicare prescription drug discount card program as early as possible in order to maximize their transitional assistance amount, which in turn will increase the volume of covered discount card drugs obtained under an endorsed program and enhance an endorsed sponsor's ability to negotiate deeper discounts for discount card enrollees.

We also considered alternatives related to the requirements for the Secretary to establish procedures and negotiate arrangements with sponsors regarding pharmacies that support long term care facilities and I/T/U pharmacies. We considered whether to require all card sponsors to integrate pharmacies that support long term care facilities and, for sponsors serving the relevant states, I/T/U pharmacies into their networks. As discussed in greater detail previously in this document, we decided the best way to ensure that AI/ANs and residents of long term care facilities have the opportunity to receive transitional assistance is to promote a competition for ''special endorsement'' to serve these beneficiaries and to select at least two of the best plans for including each type of pharmacy, one type associated with long term care facilities, and the other being I/T/U pharmacies. We believe a competition among interested sponsors will encourage better, more thoughtful plans for access to a market generally untapped by the pharmacy benefit management industry. Pharmacies supporting long term care facilities and AI/ANs are not generally included in the traditional pharmacy networks of the pharmacy benefit management industry. To require that all sponsors provide for their inclusion would represent a significant new burden and could undermine the business case for participation by some potential applicants considering participation in the broader program. A similar set of considerations also applied to how to deal with the territories and our decision to limit the number of special endorsed sponsors operating in each of the territories to at least one in order to assure that a sufficient number of beneficiaries will enroll in special endorsed sponsors' endorsed programs in the territories. We were concerned that in the absence of this decision, an insufficient number of applicants would seek to offer endorsed programs in the territories and we therefore would be unable to ensure that residents of the territories have access to negotiated prices.

List of Subjects

42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 408

Medicare.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, as follows:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Subpart H is revised to read as follows:

Subpart H—Medicare Prescription Drug Discount Card and Transitional Assistance Program

Sec.

403.800 Basis and scope.
403.802 Definitions.
403.804 General rules for solicitation, application and Medicare endorsement period.
403.806 Sponsor requirements for eligibility for endorsement.
403.808 Use of transitional assistance funds.
403.810 Eligibility and reconsiderations.
403.811 Enrollment, disenrollment, and associated endorsed sponsor requirements.
403.812 HIPAA privacy, security, administrative data standards, and national identifiers.
403.813 Marketing limitations and record retention requirements.
403.814 Special rules concerning Part C organizations and Medicare cost plans and their enrollees.
403.815 Special rules concerning States.
403.816 Special rules concerning long-term care and I/T/U pharmacies.
403.817 Special rules concerning the territories.
403.820 Sanctions, penalties, and termination.
403.822 Reimbursement of transitional assistance and associated sponsor requirements.

Subpart H—Medicare Prescription Drug Discount Card and Transitional Assistance Program

§ 403.800 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–31 of the Social Security Act (the Act).

(b) *Scope.* This subpart sets forth the standards and procedures CMS uses to implement the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

§ 403.802 Definitions.

For purposes of this subpart, the following definitions apply:

Annual coordinated election period means the period beginning on November 15, 2004 and ending on December 31, 2004, during which a discount card enrollee may elect to disenroll from their current endorsed discount card program and elect enrollment in another endorsed discount card program effective January 1, 2005.

Applicant means the non-governmental, single legal organization or entity doing business in the United States that is applying for Medicare endorsement of its prescription drug discount card program, as described in its application, to be operated by itself or in coordination with subcontractors.

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

Authorized representative means a person with legal authority to act on behalf of an individual in making decisions related to the individual's health care or the individual's

enrollment in, disenrollment from, and access to negotiated prices and transitional assistance under the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

Covered discount card drug means any of the following: a drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act; a biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act; insulin described in section 1927(k)(2)(C) of the Act; the following medical supplies associated with the injection of insulin: syringes, needles, alcohol swabs, and gauze; a vaccine licensed under section 351 of the Public Health Service Act; or any use of a covered discount card drug for a medically accepted indication (as defined in section 1927(k)(6) of the Act). The definition of covered discount card drug excludes the following: agents when used for anorexia, weight loss, or weight gain; agents when used to promote fertility; agents when used for cosmetic purposes or hair growth; agents when used for the symptomatic relief of cough and colds; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; nonprescription drugs; outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; barbiturates; and benzodiazepines.

Discount card enrollee or enrollee or card enrollee means an individual described in § 403.810(a) who elects to enroll in a Medicare-endorsed prescription drug discount card program.

Effective date means the date on which an enrollment or disenrollment transaction becomes effective.

Enrollment period means the period beginning on the initial enrollment date and ending on December 31, 2005.

Exclusive card program means an endorsed discount card program that is offered by an exclusive card sponsor.

Exclusive card sponsor means an endorsed sponsor that also operates one or more Medicare managed care plans and limits enrollment in its endorsed discount card program to individuals described in § 403.810(a) who are enrollees in one of the Medicare managed care plans it offers.

Family size means one for individuals who are single, and two for individuals who are married.

Federal Employee's Health Benefits Program plan means a plan under chapter 89 of title 5 of the United States Code including the Retired Federal Employee's Health Benefits Program.

Formulary means the list of specific drugs from among covered discount card drugs for which an endorsed sponsor offers negotiated prices to Medicare beneficiaries enrolled in its Medicare-endorsed prescription drug discount card program.

Group enrollment means simultaneous enrollment of all or some of the individuals described in sectioin 403.810(a) who are members of a Medicare managed care plan into the exclusive card program offered by the Medicare managed care organization.

HIPAA means the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d and section 264 of Public Law 104–191.

Income means the components of an individual's adjusted gross income (AGI), as defined under 26 U.S.C. section 62, and, to the extent not included in the components of AGI, retirement and disability benefits, or, if he or she is married, the sum of such income for the individual and his or her spouse.

Initial enrollment date means the date established by the Secretary on which endorsed sponsors may begin accepting beneficiaries' standard enrollment forms.

Initial enrollment year means the period beginning on the initial enrollment date and ending on December 31, 2004.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility, as defined in section 1819(a) of the Act, or nursing facility, as defined in section 1919(a) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Medicare cost plan means an organization that offers enrollment under a reasonable cost reimbursement contract under section 1876(h) of the Act.

Medicare managed care organization means a Part C organization offering a Part C plan described in section 1851(a)(2)(A) of the Act or a Medicare cost plan.

Medicare managed care plan means a plan described in section 1851(a)(2)(A) of the Act offered by a Part C organization or a Medicare cost plan.

Medicare Prescription Drug Discount Card and Transitional Assistance Program or Medicare Drug Discount Card Program means the program established under section 1860D–31 of the Act.

Medicare-endorsed prescription drug discount card program, or endorsed program, or endorsed discount card program means any prescription drug discount card program that has received Medicare endorsement and whose endorsed sponsor has entered into a contract with CMS.

Medicare-endorsed prescription drug discount card sponsor, or endorsed sponsor, or endorsed discount card sponsor means any applicant that has received endorsement from Medicare and entered into a contract with CMS to operate an approved Medicare-endorsed discount card program.

Negotiated price means the discounted price for a covered discount card drug offered by an endorsed sponsor, including any dispensing fee, which takes into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations.

Network pharmacy means a licensed pharmacy that is not a mail order pharmacy and that is under contract with an endorsed sponsor to provide negotiated prices to its card enrollees and accept transitional assistance as payment for covered discount card drugs provided to its transitional assistance enrollees.

New Medicare managed care organization means an entity applying for approval to enter into a new contract with CMS to offer a new, coordinated care plan or plans as described in section 1851(a)(2)(A) of the Act under Medicare Part C and an exclusive card program under the Medicare Drug Discount Card Program.

Over-the-counter drug means a non-prescription drug.

Part C organization means an organization offering a Part C plan.

Part C plan means a plan described in section 1859(b)(1) of the Act.

Pharmacy network means the group of network pharmacies under contract with an endorsed sponsor.

Poverty line means the income level defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), including any revision required by such section, applicable to the family size involved.

Rural means a five-digit zip code in which the population density is less than 1000 persons per square mile.

Second enrollment year means the period beginning on January 1, 2005 and ending on December 31, 2005.

Solicitation means the application materials identified in the notice CMS publishes in the **Federal Register** announcing its intention to accept and consider applications from applicants seeking Medicare endorsement for their prescription drug discount card programs.

Special election period means the period beginning the day after the effective date of an individual's disenrollment from an endorsed discount card program for one of the reasons listed in § 403.811(b)(2). The length of any given election period will be specified by CMS in a form and manner that supports the goals of the Medicare Drug Discount Card Program.

Special endorsed sponsor means an endorsed sponsor who has received special endorsement by CMS.

Special endorsement means an endorsement granted under § 403.816 or § 403.817.

Standard enrollment form means an enrollment form or other approved process for enrolling individuals into an endorsed program that incorporates the standard elements provided by CMS.

Subcontractor means an organization or entity doing business in the United States with which an applicant or endorsed sponsor enters into a contract or other legal arrangement in connection with the operation of a prescription drug discount card program.

Suburban means a five-digit zip code in which the population density is between 1000 and 3000 persons per square mile.

Transition period means the period beginning on January 1, 2006 and ending, for individuals enrolled for coverage under Part D, on the effective date of the individual's coverage, and for individuals not so enrolled, on the last day of the initial Part D open enrollment period.

Transitional assistance means a subsidy that transitional assistance enrollees may apply toward the cost of covered discount card drugs in the manner described in § 403.808(d).

Transitional assistance effective date means the date on which a transitional assistance enrollee can access transitional assistance.

Transitional assistance enrollee means an individual described in § 403.810(b) who has applied for and been determined eligible for transitional assistance and has enrolled in a discount card program.

Urban means a five-digit zip code in which the population density is greater than 3000 persons per square mile.

§ 403.804 General rules for solicitation, application and Medicare endorsement period.

(a) *Application.* (1) Except as provided in paragraph (a)(2) of this section, an applicant must submit an application to CMS by the deadline announced in the solicitation to be eligible for Medicare endorsement of its prescription drug discount card program. The applicant must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

(2) A new Medicare managed care organization may simultaneously apply to offer a new Part C plan or plans and an exclusive card program after the deadline announced in the solicitation. New Medicare managed care organizations seeking endorsement of their prescription drug discount card programs must submit an application to CMS at the time that they submit their Part C applications. New Medicare managed care organizations will be eligible for endorsement provided CMS approves their Part C application, the new Medicare managed care organizations demonstrate to CMS that they meet the criteria under paragraph (b) of this section, and the new Medicare managed care organizations demonstrate that they will meet the requirements of paragraph (e)(2) of this section.

(b) *Eligibility to receive endorsement.* Except as specified in §§ 403.814, 403.816 and 403.817, an applicant will be eligible for endorsement if its application demonstrates to CMS's satisfaction that the applicant meets the requirements of § 403.806(a) and § 403.806(b)(1) and that it would operate its endorsed program in a manner consistent with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m). An applicant that submits a complete application that meets all of the requirements of this subpart will be eligible to enter into a contract with CMS to operate a Medicare-endorsed prescription drug discount card program. Following the receipt of its Medicare endorsement, an endorsed sponsor must comply with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m) through the end of the transition period.

(c) *Ability to subcontract with other organizations and entities.* (1) An applicant for endorsement may demonstrate that it meets the requirements of this subpart by combining with subcontractors.

(2) Any subcontracts must be in final form satisfactory to CMS, signed by all applicable parties, and filed with CMS before an endorsed sponsor will be permitted to engage in any enrollment or information and outreach.

(3) Once endorsed, an endorsed sponsor must ensure that its subcontractors comply with all applicable requirements of this subpart.

(d) *Period of endorsement.* An applicant eligible to receive endorsement will be required to sign a contract with CMS agreeing to operate its approved Medicare-endorsed prescription drug discount card program(s) until the end of the transition period.

(e)(1) Except as provided in paragraph (e)(2) of this section, we expect an endorsed sponsor to be ready by June 8, 2004, to initiate enrollment and fully operate its endorsed program in compliance with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m).

(2) A new Medicare managed care organization must be ready to initiate enrollment and fully operate its exclusive card program in compliance with the requirements of §§ 403.806(b)(2) and (b)(3) through § 403.806(m) upon approval of its Part C application and application for Medicare endorsement of its prescription drug discount card program.

§ 403.806 Sponsor requirements for eligibility for endorsement.

Except as specified in § 403.814, § 403.816, and § 403.817, an endorsed sponsor must meet the following requirements:

(a) *Applicant experience.* (1) An applicant must be a non-governmental, single legal entity doing business in the United States.

(2) An applicant must have 3 years of private sector experience in the United States in pharmacy benefit management, which is defined to mean—

(i) Adjudicating and processing claims for drugs at the point of sale;

(ii) Negotiating with prescription drug manufacturers and others for discounts, rebates, and/or other price concessions on prescription drugs; and

(iii) Administering and tracking individuals' subsidies or benefits in real time.

(3) A single legal entity which is either the applicant or a subcontractor must, at the time of application for Medicare endorsement, operate a pharmacy benefit program, a prescription drug discount card program, a low-income drug assistance program, or a similar program that serves at least 1 million covered lives.

(b) *Financial stability and business integrity.* (1) An applicant must

demonstrate a satisfactory record of the financial stability and business integrity of itself, any subcontractors on whom the applicant relies to satisfy the 3 years experience requirement in paragraph (a)(2) of this section and the 1 million covered lives requirement in paragraph (a)(3) of this section, and any subcontractors engaged by the applicant to perform the following activities: develop the pharmacy network; negotiate with manufacturers or pharmacies for rebates, discounts, or other price concessions; handle eligibility for or enrollment in the endorsed sponsor's endorsed discount card program and/or transitional assistance; and administer transitional assistance.

(2) An endorsed sponsor and any subcontractors described in paragraph (b)(1) of this section must maintain a satisfactory record of financial stability and business integrity during the term of the endorsed program.

(3) Medicare endorsement of a discount card program shall not be construed to express or imply any opinion that an endorsed sponsor or any subcontractor of an endorsed sponsor is in compliance with or not liable under the False Claims Act, anti-kickback statute (section 1128B(b) of the Act), or other legal authorities for any improper billing, claims submission, or related conduct.

(c) *Compliance with applicable law.* An endorsed sponsor must comply with all applicable Federal and State laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).

(d) *Prescription drug offering.* An endorsed sponsor must comply with the following discount, rebate, and formulary requirements:

(1) Offer all of its discount card enrollees negotiated prices on covered discount card drugs, which may be limited to those covered discount card drugs included on the endorsed sponsor's formulary.

(2) If the endorsed sponsor uses a formulary, offer a negotiated price on at least one covered discount card drug in each of the lowest level categories for each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS. A specific covered discount card drug may not be used to fulfill this requirement for more than one category.

(3) Offer a negotiated price on a generic drug in at least 55 percent of the lowest level categories in each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS.

(4) In setting negotiated prices under this section, an endorsed sponsor may vary its prices and the drugs included on the formulary by pharmacy contract and enrollee characteristics, such as transitional assistance eligibility status.

(5) Synchronize changes in the list of, and negotiated prices for, covered discount card drugs included in the endorsed sponsor's formulary with formulary and negotiated prices published on a price comparison Web site, as described in paragraph (i)(4)(v) of this section.

(6) Obtain rebates, discounts, or other price concessions from manufacturers on covered discount card drugs and pass a share of such concessions to enrollees through negotiated prices.

(7) Guarantee that network and mail order pharmacies provide the lower of the negotiated price or usual and customary price when a covered discount card drug for a negotiated price is available at the point of sale.

(8) Guarantee that a network pharmacy, at the point of sale, inform a discount card enrollee of any differential between the price of a prescribed drug (if it is a covered discount card drug) and the price of the lowest priced generic covered discount card drug that is therapeutically equivalent and bioequivalent and available at such pharmacy. Mail order pharmacies are to provide this information at the time of delivery of the drug.

(9) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), ensure that any increase in the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to the changes in the endorsed sponsor's cost structure, including material changes to any discounts, rebates, or other price concessions the endorsed sponsor receives from a pharmaceutical manufacturer or pharmacy.

(e) *Transitional assistance administration.* An endorsed sponsor must administer transitional assistance funds, including any roll-over funds as described in § 403.808(f), for transitional assistance enrollees, through the following procedures:

(1) Establish accounting procedures to manage the transitional assistance funds for each transitional assistance enrollee.

(2) Ensure that transitional assistance funds are applicable to, and only to, all covered discount card drugs available at the endorsed sponsors' network and mail order pharmacies, regardless of formulary.

(3) Ensure that, at network and mail order pharmacies, transitional assistance funds are applied at the lower of negotiated price (if any) and the pharmacy's usual and customary price.

(4) Ensure that network pharmacies make available to the transitional assistance enrollee, electronically or by telephone, at the point-of-sale of covered discount card drugs, the amount of transitional assistance remaining available to the transitional assistance enrollee. Mail order pharmacies are to make this information available by telephone.

(5) Maintain a toll-free telephone number that discount card enrollees may use to determine their transitional assistance balances.

(6) Enforce coinsurance requirements described in § 403.808(e) and ensure that the portion of the price paid through coinsurance is not deducted from the total transitional assistance funds available to the discount card enrollee.

(f) *Service area and pharmacy access.* An endorsed sponsor must meet the following requirements for its service area and its pharmacy network:

(1) The service area must cover one or more States.

(2) The endorsed sponsor's discount card program must be available to all eligible individuals residing in each State in the endorsed sponsor's service area and may not be offered to individuals residing outside of the United States.

(3) The endorsed sponsor must have a contracted pharmacy network, consisting of pharmacies other than mail-order pharmacies, sufficient to ensure that for beneficiaries residing in the endorsed sponsor's service area the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the endorsed program, live within 2 miles of a network pharmacy;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the endorsed program, live within 5 miles of a network pharmacy; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the endorsed program, live within 15 miles of a network pharmacy.

(4) The endorsed sponsor's pharmacy network may be supplemented by pharmacies offering home delivery via mail-order, provided the requirements of paragraph (f)(3) of this section are met.

(g) *Information and outreach and customer service.* (1) An endorsed

sponsor must provide through the Internet and some other tangible medium (such as a mailing) to Medicare beneficiaries information and outreach materials describing its endorsed drug card program, including the following information—

(i) The enrollment fee;

(ii) Negotiated prices offered for covered discount card drugs;

(iii) If offered, discounts on over-the-counter drugs;

(iv) Any other products or services offered under the endorsement; and

(v) Any other information that CMS determines is necessary for a full description of the endorsed discount drug card program.

(2) An endorsed sponsor must include on a Web site the following:

(i) Information regarding when the Web site was last updated; and

(ii) A disclaimer that the information on the Web site may not be current.

(3) An endorsed sponsor must use the following forms which incorporate standard elements provided by CMS:

(i) An enrollment form (except as may be modified for an exclusive card sponsor as discussed in § 403.814(b)(5)(iii); and

(ii) An eligibility determination notice.

(4) An endorsed sponsor must provide to each enrollee a card that complies with National Council for Prescription Drug Programs standards.

(5) An endorsed sponsor must meet the following requirements for the review and approval of information and outreach materials:

(i) Comply with the Information and Outreach Guidelines published by CMS; and

(ii) Except as provided in paragraph (g)(5)(iii) of this section, not distribute any information and outreach materials until or unless they are approved by CMS.

(iii) If CMS does not disapprove the initial submission of information and outreach materials within 30 days of receipt of these materials, then the materials will be deemed approved under paragraph (g)(5)(ii) of this section.

(iv) Information and outreach materials may discuss only products or services inside the scope of endorsement, as described in paragraph (h) of this section.

(v) Information and outreach materials include the same kinds of materials described in 42 CFR 422.80(b), as well as the enrollment form, eligibility determination form, and membership card described in paragraphs (g)(3) and (g)(4) of this section, Web site content, and information regarding discounts for over-the-counter drugs.

(6) An endorsed sponsor must 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. The endorsed sponsor must inform enrollees that the toll-free telephone number provides information on the amount of remaining transitional assistance, in accordance with paragraph (e)(5) of this section.

(7) An endorsed sponsor must provide a system to reduce the likelihood of medical errors and adverse drug interactions and to improve medication use.

(h) *Products and services inside and outside the scope of the endorsement.* (1) An endorsed sponsor may provide, under the endorsement, only those products and services inside the scope of the endorsement, including conducting enrollment. An endorsed sponsor must ensure that discount card enrollees are not charged any additional fee (other than the enrollment fee allowed under § 403.811(c)) for products or services inside the scope of the endorsement.

(2) Products and services inside the scope of the endorsement are limited to—

(i) Products or services offered for no additional fee, other than the enrollment fee allowed under § 403.811(c), that are directly related to a covered discount card drug; or

(ii) A discounted price for an over-the-counter drug.

(i) *Reporting.* (1) An endorsed sponsor must report to CMS on a periodic basis information on the major features of the endorsed sponsor's programs that correspond to the qualifications for endorsement, including, but not limited to, information concerning—

(i) Savings from pharmacies and manufacturers obtained through rebates, discounts, and other price concessions;

(ii) Savings shared with discount card enrollees by manufacturer, by all retail pharmacies, by all mail order pharmacies, and by all brand name and all generic covered discount card drugs;

(iii) Dispensing fees;

(iv) Certified (by the chief financial officer) financial accounting records on transitional assistance used by the transitional assistance enrollees in each month;

(v) Participant utilization and spending statements;

(vi) Utilization and spending for selected drugs;

(vii) Performance on customer service metrics such as call center performance;

(viii) Grievance logs; and

(ix) Endorsed sponsor's compliance with the pharmacy network access standards.

(2) An endorsed sponsor must provide notice of, and the rationale for, negotiated price increases, except for increases during the week of November 15, 2004, due to reasons other than changes in average wholesale price (AWP).

(3) An endorsed sponsor must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

(4) Through a price comparison Web site, an endorsed sponsor must report the following information:

(i) Customer service hours;

(ii) Customer service contact information;

(iii) Endorsed program Web site address;

(iv) Annual enrollment fee; and

(v) Negotiated prices (including any applicable dispensing fee), for every covered discount card drug included in the discount card program's offering.

(5) CMS may require endorsed sponsors to submit, in standard terminology, descriptions of other discount card related services they provide, such as pharmacist services.

(j) *Grievance process.* An endorsed sponsor must establish and maintain a grievance process. This process must be designed to track and appropriately address in a timely manner enrollees' complaints about any aspect of their endorsed program for which the endorsed sponsor is responsible.

(k) *Eligibility, enrollment, and disenrollment.* (1) An endorsed sponsor must make preliminary eligibility determinations in accordance with § 403.810 and conduct enrollment and disenrollment in accordance with § 403.811.

(l) *Authorized representative.* An endorsed sponsor must treat an individual's authorized representative as the individual, if under applicable law, the authorized representative has the legal authority to act on behalf of the individual with respect to the action at issue.

(m) *Other.* An endorsed sponsor must meet the requirements of §§ 403.812, 403.813, and 403.822 of this subpart.

§ 403.808 Use of transitional assistance funds.

(a) *Individuals determined eligible for transitional assistance in 2004.* Subject to paragraph (d) of this section, an individual who, in calendar year 2004, is determined eligible for transitional assistance under § 403.810(b) is entitled to the following:

(1) $600 in calendar year 2004; and

(2) $600 in calendar year 2005.

(b) *Individuals determined eligible for transitional assistance in 2005.* Subject to paragraph (d) of this section, an individual who, in calendar year 2005, is determined eligible for transitional assistance under § 403.810(b) is entitled to one of the following amounts for calendar year 2005:

(1) If the complete application for the individual's transitional assistance eligibility is received on or after January 1, 2005 and before April 1, 2005, $600.

(2) If the complete application for the individual's transitional assistance eligibility is received on or after April 1, 2005 and before July 1, 2005, $450.

(3) If the complete application for the individual's transitional assistance eligibility is received on or after July 1, 2005 and before October 1, 2005, $300.

(4) If the complete application for the individual's transitional assistance eligibility is received on or after October 1, 2005 and on or before December 31, 2005, $150.

(c) *Payment of enrollment fee.* An individual found eligible for transitional assistance is entitled to have CMS pay the annual enrollment fee to the endorsed sponsor on his or her behalf.

(d) *Conditions on use of transitional assistance.* A transitional assistance enrollee may access the transitional assistance described in paragraphs (a) and (b) of this section only if the following conditions are met:

(1) Except as provided in § 403.814(b)(3)(v), the transitional assistance funds are applied toward the cost of a covered discount card drug obtained under the Medicare Prescription Drug Discount Card and Transitional Assistance Program;

(2) The individual pays a coinsurance amount in accordance with § 403.808(e);

(3) The individual purchases the covered discount card drug on or after the individual's transitional assistance effective date; and

(4) The individual is enrolled in the Medicare Prescription Drug Discount Card and Transitional Assistance Program on the date the individual's claim for the covered discount card drug is adjudicated.

(e) *Coinsurance.* If sufficient transitional assistance funds are available, transitional assistance funds must be expended in accordance with the following:

(1) For beneficiaries with incomes at or below 100 percent of the poverty line, 95 percent of the price of a covered discount card drug must be paid from the available transitional assistance funds.

(2) For beneficiaries with incomes greater than 100 percent but at or below 135 percent of the poverty line, 90 percent of the price of a covered discount card drug must be paid from the available transitional assistance funds.

(f) *Rollover.* An individual with transitional assistance retains access to any balance of transitional assistance not expended in a calendar year during the next calendar year, up to and including the transition period, if the individual—

(1) Remains in his or her current endorsed discount card program;

(2) Elects a new endorsed program in an Annual Coordinated Election Period; or

(3) Is eligible for a Special Election Period under § 403.811(b)(2) and elects a new endorsed discount card program during such Special Election Period.

§ 403.810 Eligibility and reconsiderations.

(a) *Eligibility for an endorsed discount card program.* An individual is eligible to enroll in an endorsed discount card program only if such individual meets the following conditions:

(1) The individual is entitled to benefits, or enrolled, under Medicare Part A or enrolled under Medicare Part B; and

(2) The individual, at the time of applying to enroll in an endorsed discount card program, is not enrolled in a State medical assistance program under Title XIX of the Act or under a waiver pursuant to section 1115 of the Act, under which the individual is entitled to any medical assistance for outpatient prescribed drugs as described in section 1905(a)(12) of the Act, except as allowed in § 403.817(d).

(b) *Eligibility for transitional assistance.* An individual is eligible to receive transitional assistance if, at the time of applying for transitional assistance, the individual meets the following conditions:

(1) The individual meets the conditions in paragraph (a) of this section;

(2) The individual resides in one of the 50 States or the District of Columbia;

(3) The individual's income is not more than 135 percent of the poverty line applicable to the individual's family size;

(4) The individual does not have coverage for covered discount card drugs under one or more of the following sources:

(i) A group health plan or health insurance coverage, as these terms are defined under section 2791 of the Public Health Service Act, other than a Part C plan or a group health plan consisting solely of excepted benefits (such as a Medigap plan) as the term is defined under section 2791 of the Public Health Service Act;

(ii) Coverage provided under Chapter 55 of Title 10, United States Code, including TRICARE; or

(iii) A Federal Employee's Health Benefits Program plan; and

(5) The individual (or the individual's authorized representative) completes a standard enrollment form and signs and dates the form in accordance with § 403.811(a)(4). By signing the form, the individual (or the individual's authorized representative) certifies, under penalty of perjury, that, to the best of the individual's knowledge, the information he or she provides on the form is accurate.

(c) *Special rule for QMBs, SLMBs and QIs.* An individual is deemed to meet the income requirements in paragraph (b)(3) of this section if the individual is enrolled under Title XIX of the Act as a—

(1) Qualified Medicare Beneficiary (QMB);

(2) Specified Low-Income Medicare Beneficiary (SLMB); or

(3) Qualified Individual (QI).

(d) *Duration of eligibility determinations.* An individual determined eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, in the case of transitional assistance enrollees, for transitional assistance, shall remain eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, in the case of transitional assistance enrollees, for transitional assistance for the duration of the individual's enrollment in the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

(e) *Drug card and transitional assistance benefits not treated as benefits under other Federal programs.* Any benefits received under the Medicare Prescription Drug Discount Card and Transitional Assistance Program must not be taken into account in determining an individual's eligibility for, or the amount of benefits under, any other Federal program.

(f) *Verification of eligibility.* (1) CMS will verify eligibility to enroll in an endorsed discount card program or to receive transitional assistance.

(2) If CMS is unable to verify an individual's eligibility or ineligibility for transitional assistance, CMS can require the individual to provide additional income information in a form and manner specified by CMS as one condition of eligibility for transitional assistance.

(g) *Reconsideration.* (1) If an individual is determined ineligible to enroll in an endorsed discount card program under paragraph (a) of this section or determined ineligible to receive transitional assistance under paragraph (b) of this section, the individual (or the individual's authorized representative) has a right to request that an independent review entity under contract with CMS reconsider the determination.

(2) Reconsideration requests must be filed within 60 days from date of notice of an ineligibility determination, unless the individual (or the individual's authorized representative) can demonstrate good cause for why the 60-day time frame should be extended.

(3) An individual (or the individual's authorized representative) may submit additional documentary evidence or an explanation about his or her eligibility in writing to the independent review entity, as part of the reconsideration process.

(4) Reconsideration decisions shall be issued by the independent review entity in writing and contain an explanation of the reasoning of the decision.

§ 403.811 Enrollment and disenrollment and associated endorsed sponsor requirements.

(a) *Enrollment process.* (1) An individual (or an individual's authorized representative) applying to enroll in an endorsed discount card program must complete a standard enrollment form or other method allowed by CMS and provide such information to the endorsed discount card program in which the individual wishes to enroll.

(2) An individual electing to join an endorsed discount card program that charges an annual enrollment fee, and who is not applying for transitional assistance, must agree to pay the annual enrollment fee, if any, in a form and manner determined by the endorsed card sponsor.

(3) An individual applying for transitional assistance at the time that they apply for enrollment in an endorsed discount card program may only enroll in the endorsed discount card program at that time if CMS determines that the individual is eligible for transitional assistance. Individuals not found eligible for transitional assistance may enroll in an endorsed discount card program without applying for transitional assistance after being notified of their ineligibility for transitional assistance.

(4) An individual applying for transitional assistance must complete a standard enrollment form and sign and date the form, certifying, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the standard enrollment form.

(5) Except as provided in § 403.811(b)(4), an individual who is not currently enrolled in an endorsed card program seeking to enroll in the Medicare Prescription Drug Discount Card and Transitional Assistance Program may do so at any time during the enrollment period.

(6) An individual may not be enrolled in more than one endorsed discount card program at a time.

(7) An individual may enroll in only one endorsed discount card program per year during the enrollment period. An individual enrolling during the initial enrollment year, with the exception of the circumstances under paragraph (b)(2) of this section, may change election for the second enrollment year during the annual coordinated election period. During the second enrollment year, an individual may enroll in only one endorsed discount card program, unless the individual meets the circumstances described in paragraph (b)(2) of this section.

(8) An individual remains enrolled in an endorsed discount card program elected unless—

(i) The individual is disenrolled under paragraph (b) of this section;

(ii) The individual elects a new program during the Annual Coordinated Election Period; or

(iii) The endorsed sponsor terminates its endorsed discount card program, or is terminated.

(9) No new enrollment in an endorsed discount card program or changing election of an endorsed discount card program is allowed during the transition period.

(10) Except as specified in § 403.814(b)(6)(i), an individual may enroll in any endorsed discount card program, and only those endorsed discount card programs, offered in the individual's State of residence.

(11) In order to access negotiated prices or transitional assistance, if applicable, an individual must be enrolled in an endorsed discount card program. Access to negotiated prices begins with the effective date of enrollment and ends with disenrollment. Access to transitional assistance begins with the transitional assistance effective date and ends for claims finalized on the date of disenrollment.

(12) Except as provided in paragraph (b)(5) of this section, an individual may apply for transitional assistance at any time during the enrollment period.

(b) *Disenrollment process.* (1) An enrollee may voluntarily disenroll at any time by notifying (or by having his authorized representative notify) the endorsed sponsor.

(2) An enrolled individual who disenrolls during the enrollment period under the following circumstances is granted a Special Election Period in which the individual may enroll in another endorsed discount card program during the enrollment period:

(i) A move of residence outside the service area of the current program;

(ii) A change in residence to or from a long-term care facility;

(iii) Enrollment in or disenrollment from a Part C plan or Medicare cost plan;

(iv) An individual's current endorsed discount card program is terminated or terminates; or

(v) Other exceptional circumstances, as defined by the Secretary.

(3) Notification in order to effect a disenrollment is not required for an individual disenrolling from a terminating endorsed discount card program or enrolling in or disenrolling from a Medicare managed care plan offering an exclusive card program, or for individuals changing endorsed discount card programs during the Annual Coordinated Election Period.

(4) A drug discount card enrollee who disenrolls from an endorsed discount card program other than for one of the reasons listed in paragraph (b)(2) of this section will no longer be determined eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, if he or she disenrolls in 2004, must re-apply for the Medicare Prescription Drug Discount Card and Transitional Assistance Program should he or she wish to enroll in another endorsed discount card program for the second enrollment year.

(5) An individual receiving transitional assistance who voluntarily disenrolls from an endorsed discount card program other than for one of the reasons listed in paragraph (b)(2) of this section will forfeit any transitional assistance remaining available to the individual on the date of disenrollment, and, if he or she disenrolls in 2004, must re-apply for transitional assistance for 2005 in order to receive transitional assistance in 2005.

(6) A discount card enrollee other than a transitional assistance enrollee may be involuntarily disenrolled from his or her endorsed discount card program for failure to pay the annual enrollment fee on a timely basis.

(7) A discount drug card enrollee other than a transitional assistance enrollee may be charged another annual

enrollment fee each time the individual disenrolls from one endorsed discount card program and enrolls in another endorsed discount card program during the calendar year.

(c) *Enrollment fees.* (1) An endorsed sponsor may charge an annual enrollment fee of no more than $30 to each individual enrolled in its endorsed discount card program.

(2) An endorsed sponsor may not collect an enrollment fee from any individual applying for or receiving transitional assistance.

(3) The annual enrollment fee must not be prorated for portions of the year.

(4) An endorsed sponsor must charge a uniform enrollment fee to every discount card eligible individual, or to the Secretary in the case of individuals receiving transitional assistance, residing in a State.

(5) An endorsed sponsor must refund any enrollment fee collected from a discount card enrollee, or any State that has paid the enrollment fee on behalf of the discount card enrollee, during the calendar year during which the individual is determined eligible to receive transitional assistance.

(6) An endorsed sponsor may not charge an annual enrollment fee during the transition period.

§ 403.812 HIPAA privacy, security, administrative data standards, and national identifiers.

(a) *HIPAA covered entities.* An endorsed sponsor is a HIPAA covered entity and must comply with the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164 as set forth in this section. Those functions of a endorsed sponsor the performance of which are necessary or directly related to the operations of the endorsed discount card program are covered functions for purposes of applying to endorsed sponsors the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164.

(b) *HIPAA privacy requirements.* An endorsed sponsor must comply with the standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information, 45 CFR parts 160 and 164, subparts A and E, in the same manner as a health plan, except to the extent such requirements are temporarily waived by the Secretary.

(c) *Security requirements.* (1) *Standard.* An endorsed sponsor must comply with the applicable standards, implementation specifications, and requirements in the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C, in the same manner as other covered entities as of the compliance date of such Rule.

(2) *Attestation.* An applicant in its application shall—

(i) Attest that, as of the initial enrollment date, it will have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information in accordance with 45 CFR 164.530(c); and

(ii) Attest that its information security measures will meet the standards, implementation specifications, and requirements of 45 CFR part 164 subparts A and C as of the initial enrollment date, or, if unable to make this attestation, provide a plan for coming into compliance with these requirements by the compliance date of the Security Rule set forth in 45 CFR part 164, subpart C.

(d) *Administrative data standards.* An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR parts 160 and 162 subparts I through R.

(e) *Unique identifiers.* An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements regarding standard unique identifiers under 45 CFR parts 160 and 162 as of the compliance date of any final rule for standard unique identifiers.

(f) *Applicability of other regulations.* Nothing in this paragraph or in § 403.813 shall be deemed a modification of parts 160, 162 and 164 of title 45, Code of Federal Regulations or otherwise modify the applicability of such regulations to other organizations or covered entities independently subject to the mandates of HIPAA. If an endorsed sponsor is also a health plan, health care provider, or health care clearinghouse, nothing is this paragraph shall impair or otherwise affect the application of HIPAA or parts 160, 162 and 164 of title 45, Code of Federal Regulations to such entity and its performance of those functions which make such entity a health plan, health care provider, or health care clearinghouse.

§ 403.813 Marketing limitations and record retention requirements.

(a) *Marketing limitations.* (1) An endorsed sponsor may only market those products and services offered under its endorsed program that are inside the scope of endorsement as defined in § 403.806(h) and permitted under § 403.812(b).

(2) An endorsed sponsor may not request that a drug card enrollee or an individual seeking to enroll in its endorsed discount card program authorize the endorsed sponsor to use or disclose individually identifiable health information for purposes of marketing any product or service not allowed under paragraph (a)(1) of this section.

(3) An endorsed sponsor may not co-mingle any materials related to the marketing of products and services allowed under paragraph (a)(1) of this section with other marketing materials.

(4) Following termination of an endorsed sponsor's endorsement under §§ 403.820(c), (d) or (e) or termination of the Medicare Drug Discount Card and Transitional Assistance Program, a drug card enrollee's individually identifiable health information collected or maintained by an endorsed sponsor may not be used or disclosed for purposes of marketing any product or service.

(b) *Record retention standard.* (1) An endorsed sponsor must retain records that it creates, collects, or maintains while participating in the Medicare Drug Discount Card and Transitional Assistance Program as part of its operations of an endorsed program for at least 6 years following termination of such program, or, in the event the endorsed sponsor's endorsement is terminated under § 420.820(c), (d), or (e) of this chapter at least 6 years following termination of such endorsement. The Secretary may extend the six-year retention period if an endorsed sponsor's records relate to an ongoing investigation, litigation, or negotiation by the Secretary, the Department of Health and Human Services Office of Inspector General, the Department of Justice, or a State, or such documents otherwise relate to suspicions of fraud and abuse or violations of Federal or State law.

(2) For the period during which an endorsed sponsor retains records as specified in paragraph (b)(1) of this section, an endorsed sponsor must continue to apply security and privacy protections to such records and the information contained therein to the same extent endorsed sponsors are required to do so under § 403.812(b) and § 403.812(c)(1) prior to termination.

§ 403.814 Special rules concerning Part C organizations and Medicare cost plans and their enrollees.

(a) *General requirements.* (1) A Part C organization and Medicare cost plan may not require enrollment in an endorsed discount card program as a condition for enrollment in its Part C plan or Medicare cost plan.

(2) A Part C organization may subsidize the enrollment fee for an endorsed discount card program, whether operated by the Part C organization or another endorsed sponsor, for individuals described in § 403.810(a), provided that any such benefit is reflected in the Part C organization's Adjusted Community Rate filing.

(b) *Exclusive card sponsors.* (1) A Medicare managed care organization may elect to become an exclusive card sponsor by limiting enrollment in its endorsed discount card program to individuals described in § 403.810(a) who are enrolled in any of its Medicare managed care plans. The Medicare managed care organization must be the applicant for endorsement in order to offer an exclusive card program. Such an election must be made at the time of application for endorsement.

(2) Except as noted in paragraphs (b)(3) and (b)(4) of this section, an exclusive card sponsor must comply with all requirements for endorsed sponsors noted in § 403.804 and § 403.806.

(3) An exclusive card sponsor is deemed to meet or is exempt from certain specific requirements listed in § 403.806 as follows:

(i) An exclusive card sponsor is deemed to meet the pharmacy network requirement in § 403.806(f)(3) if its pharmacy network is not limited to mail-order pharmacies and is equivalent to the pharmacy network used in its Medicare managed care plan and such pharmacy network has been approved by the Secretary, or, if its Medicare managed care plan does not use a pharmacy network, the Secretary determines that the pharmacy network provides sufficient access to covered discount card drugs at negotiated prices for discount card enrollees under the standard set forth under 42 CFR 422.112 for a Part C organization described in section 1851(a)(2)(A) of the Act, or under 42 CFR 417.416(e) for a Medicare cost plan.

(ii) An exclusive card sponsor is deemed to meet the service area requirements in § 403.806(f)(1) and (f)(2) if it operates in a service area equivalent to its Medicare managed care plan's service area.

(iii) An exclusive card sponsor is deemed to meet the requirement for financial stability and business integrity in § 403.806(b) through compliance with § 422.400 of this chapter (if a Part C organization described in section 1851(a)(2)(A) of the Act) or compliance with § 417.120 and § 417.122 of this chapter (if a Medicare cost plan).

(iv) An exclusive card sponsor is deemed to meet the covered lives requirement in § 403.806(a)(3).

(v) An exclusive card sponsor is deemed to meet the requirements of § 403.806(e)(2) if it ensures that transitional assistance funds are applied to, and only to, the cost to transitional assistance enrollees of any covered discount card drugs obtained from a network or mail order pharmacy included in the exclusive card sponsor's pharmacy network, and at the option of the exclusive card sponsor, any covered discount card drug obtained under an outpatient prescription drug benefit offered under the affiliated Medicare managed care plan, including any deductibles, co-payments, coinsurance, and other cost-sharing amounts for which transitional assistance enrollees are responsible under the Medicare managed care plan's outpatient prescription drug benefit.

(4) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in § 403.804 and § 403.806, except for the requirements in § 403.812 and § 403.813, may be waived or modified on behalf of an exclusive card sponsor if:

(i) The requirements are duplicative of or conflict with the requirements that a Medicare managed care organization must meet either under Part C or under section 1876 of Title XVIII of the Act; or

(ii) The waiver or modification is necessary to improve coordination between benefits under the Medicare Prescription Drug Discount Card and Transitional Assistance Program and the benefits either under Part C or under section 1876 of Title XVIII of the Act.

(iii) The applicant seeking to become an exclusive card sponsor requests such waivers or modifications in writing in a manner required by the Secretary.

(5) An exclusive card sponsor may conduct group enrollment according to the following rules:

(i) The exclusive card sponsor must seek CMS verification that its Medicare managed care members are individuals described in § 403.810(a) and enroll such individuals as a group into its exclusive card program.

(ii) The exclusive card sponsor must give all individuals it is enrolling as a group the opportunity to decline enrollment, and the opportunity to apply for transitional assistance.

(iii) The exclusive card sponsor may use a modified version of the standard enrollment form described in § 403.806(g)(3) or other CMS-approved process for group enrollment in its endorsed discount card program.

(6) An individual enrolled in a Medicare managed care plan offered by a Medicare managed care organization offering an exclusive card program to individuals enrolled in such Medicare managed care plan is subject to the following requirements:

(i) The individual may enroll only in the endorsed discount card program offered by his or her Medicare managed care organization.

(ii) If the exclusive card sponsor group elects to group enroll into an exclusive card program members of the Medicare managed plan, the individual must actively decline enrollment to avoid enrollment in the exclusive card program.

(c) *Non-uniformity of Benefits.* Implementation of the Medicare Prescription Drug Discount Card and Transitional Assistance Program, including the provision of transitional assistance and the payment or waiver of any enrollment fee by a Part C organization, will not be taken into account in applying the uniform premium and uniform benefits requirement in sections 1854(c) and 1854(f)(1)(D) of the Act and 42 CFR 422.100(d)(2) and 42 CFR 422.312(b)(2).

§ 403.815 Special rules concerning States.

(a) *Optional State payment of enrollment fee.* (1) A State may enter into payment arrangements with endorsed sponsors to provide payment of some or all of endorsed discount card programs' enrollment fees for some or all of the State's individuals described in § 403.810(a) who are not transitional assistance enrollees, provided the enrollment fees are paid directly by the State to the endorsed sponsor.

(2) Expenditures made by a State for enrollment fees described in paragraph (a)(1) of this section must not be treated as State expenditures for which Federal matching payments are available under titles XIX or XXI of the Act.

(b) *Optional State payment of coinsurance.* (1) A State may enter into payment arrangements with pharmacies to provide payment of some or all of coinsurance amounts described in § 403.808(e) for some or all of the State's transitional assistance enrollees, provided the coinsurance amounts are paid directly by the State to the pharmacy.

(2) Expenditures made by a State for coinsurance described in paragraph (b)(1) of this section must not be treated as State expenditures for which Federal matching payments are available under titles XIX or XXI of the Act.

(c) *Coinsurance for Qualified Medicare Beneficiaries.* For transitional assistance enrollees who are qualified

Medicare beneficiaries, any coinsurance liability under § 403.808(e) must not be treated as Medicare cost-sharing coinsurance, under section 1905(p)(3)(B) of the Act, for which a State would otherwise be required to pay.

(d) *State data.* (1) A State must provide data on a monthly basis in an electronic format as determined necessary by the Secretary to effectuate the verification of beneficiary eligibility for the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

(2) Expenditures made by a State in complying with the requirements of paragraph (d)(1) of this section will be treated as State expenditures for which Federal matching payments are available under section 1903(a)(7) of the Act.

§ 403.816 Special rules concerning long-term care and I/T/U pharmacies.

(a) *In general.* (1) An applicant for endorsement may submit an application to become a special endorsed sponsor for long-term care and/or for I/T/U pharmacies.

(2) Of qualified applicants, the Secretary will select at least two of the best-qualified applicants for special endorsement for long-term care and at least two of the best-qualified applicants for special endorsement for I/T/U pharmacies.

(3) Applicants for special endorsement for long-term care must demonstrate in their applications that they meet the requirements in paragraph (b) of this section.

(4) Applicants for special endorsement for I/T/U pharmacies must demonstrate in their applications that they meet the requirements in paragraph (d) of this section.

(b) *Long-term care.* A special endorsed sponsor for long-term care must—

(1) Apply transitional assistance toward the cost of covered discount card drugs obtained by transitional assistance enrollees who reside in long-term care facilities and who receive such prescription drugs through long-term care pharmacies;

(2) Offer contractual arrangements to any long-term care pharmacy seeking reimbursement from transitional assistance for covered discount card drugs provided by such pharmacy to transitional assistance enrollees who reside in long-term care facilities;

(3) Process any submitted claims from network pharmacies and out-of-network long-term care pharmacies that supply covered discount card drugs to transitional assistance enrollees who reside in long-term care facilities, when such enrollees have unspent transitional assistance remaining;

(4) Include special terms and conditions in its contracts with network pharmacies that are long-term care pharmacies to facilitate access to and the administration of transitional assistance to transitional assistance enrollees residing in long-term care facilities, including, but not limited to the following—

(i) Waiving penalties against long-term care pharmacies for submitting late claims to the special endorsed sponsor due to the pharmacy's coordination of benefits activities; and

(ii) Permitting a long-term care pharmacy to limit its services to only transitional assistance enrollees who reside in a long-term care facility served by the long-term care pharmacy.

(5) Except as noted in paragraph (c) of this section, comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(c) *Waiver of requirements.* (1) The following requirements will not apply to or will be waived for special endorsed sponsors providing transitional assistance to long-term care residents:

(i) Section 403.806(d) (relating to the prescription drug offering) shall not apply to long-term care pharmacies in the special endorsed sponsor's network; and

(ii) Section 403.806(e)(4) (requiring information about the amount of transitional assistance remaining) shall not apply to long-term care pharmacies in the special endorsed sponsor's network.

(2)(i) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for long-term care if the waiver or modification is—

(A) Necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D–31 of the Act, or accommodate the unique needs of long-term care pharmacies; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for long-term care must request such waivers or modifications in writing in a manner required by the Secretary.

(d) *I/T/U pharmacies.* A special endorsed sponsor for I/T/U pharmacies must—

(1) Apply transitional assistance toward the cost of covered discount card drugs obtained by transitional assistance enrollees who are American Indians and Alaska Natives and who receive prescription drugs through I/T/U pharmacies as allowed under paragraph (d)(2) of this section;

(2) Offer contractual arrangements to any I/T/U pharmacy that is in the special endorsed sponsor's service area and seeking reimbursement from transitional assistance for covered discount card drugs provided by such pharmacy to transitional assistance enrollees who are also American Indians/Alaska Natives;

(3) Include special terms and conditions in its contracts with network I/T/U pharmacies to facilitate access to and the administration of transitional assistance for transitional assistance enrollees who are American Indians/Alaska Natives, including, but not limited to the following:

(i) Permitting an I/T/U pharmacy to limit its services to only those transitional assistance enrollees who are American Indians/Alaska Natives, and

(ii) Allowing an I/T/U pharmacy to select which drugs to stock, which may be a more limited set than other retail pharmacies.

(4) Except as noted in paragraph (e) of this section, comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(e) *Waiver of requirements.* (1) The following requirements will not apply to or will be waived for special endorsed sponsors providing transitional assistance through I/T/U pharmacies:

(i) Section 403.806(d) (relating to the prescription drug offering) shall not apply to I/T/U pharmacies in the special endorsed sponsor's network; and

(ii) Section 403.806(e)(4) (requiring information about the amount of transitional assistance remaining) shall not apply to I/T/U pharmacies in the special endorsed sponsor's network.

(2)(i) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for I/T/U pharmacies if the waiver or modification is—

(A) Necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D–31 of the Act, or accommodate the unique needs of I/T/U pharmacies; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for I/T/U pharmacies must request such waivers or modifications in writing in a manner required by the Secretary.

§ 403.817 Special rules concerning the territories.

(a) *In general.* (1) An applicant for endorsement may submit an application to become a special endorsed sponsor for all of the territories.

(2) Of qualified applicants, the Secretary will select at least one of the best-qualified applicants to receive a special endorsement for the territories.

(3) Applicants for special endorsement for the territories must demonstrate in their applications that they meet the requirements in paragraph (b) of this section.

(b) *Requirements.* (1) *Negotiated prices.* A special endorsed sponsor for residents of the territories must provide access to negotiated prices in the territories.

(2) *Transitional assistance.* Any transitional assistance in the territories must be in accordance with paragraph (e) of this section.

(3) *Requirements, exception.* Except as specified in paragraph (c) of this section, a special endorsed sponsor for the territories must meet the requirements of §§ 403.804 and 403.806.

(c) *Waiver of requirements and alternative requirements.* (1) Section 403.806(d)(8) (requiring information about price differentials) shall not apply to pharmacies located in the territories and which are in the special endorsed sponsor's pharmacy network.

(2) Sections 403.806(f)(2) and (f)(3) will be deemed met if the special endorsed sponsor makes a good faith effort to secure the participation of retail and mail order pharmacies throughout a territory.

(3)(i) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for the territories if—

(A) Such waiver is necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D–31 of the Act, or accommodate the unique needs of pharmacies in the territories; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for the territories must request such waivers or modifications in writing in a manner required by the Secretary.

(d) *Other exceptions.* A special endorsed sponsor for the territories may enroll in its endorsed discount card program Medicaid enrollees with coverage for outpatient prescription drugs, as described in § 403.810(a)(2).

(e) *Transitional assistance provided by Territories.* (1) Transitional assistance in the territories may be administered only according to a plan submitted by a territory and approved by CMS.

(2) Territories choosing to provide transitional assistance must submit a plan to CMS within 90 days of the publication of this regulation. The plan must—

(i) Describe how funds allocated to the territory are to be used to cover the cost of covered discount card drugs obtained by individuals who reside in the territory, who are entitled to benefits under Medicare Part A or enrolled under Medicare Part B, and who have income at or below 135 percent of the poverty line for the contiguous United States; and

(ii) Describe how the territory will ensure that amounts received under the allotment are to be used only to provide covered discount card drugs to those individuals determined eligible for transitional assistance, as described in paragraph (e)(2)(i) of this section, and

(iii) Provide such written assurance for the requirements in paragraph (e)(2)(ii) of this section.

(3) CMS will review and approve plans submitted and make allotments to territories with approved plans.

(4) CMS may request reports or information to substantiate that the territories have administered the program consistent with the territory's approved transitional assistance plan.

§ 403.820 Sanctions, penalties, and termination.

(a) *Intermediate sanctions.* (1) For the violations listed in paragraph (a)(3) of this section, the following intermediate sanctions may be imposed on any endorsed sponsor:

(i) Suspension of enrollment of Medicare beneficiaries.

(ii) Suspension of information and outreach activities to Medicare beneficiaries.

(2) *Duration of sanctions.* The intermediate sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to recur.

(3) *Sanctionable violations.* The violations for which intermediate sanctions may be imposed are as follows:

(i) Substantial failure to maintain a contracted retail pharmacy network meeting the requirements of § 403.806(f);

(ii) Substantial failure to comply with CMS Information and Outreach Guidelines;

(iii) Substantial failure to provide discount card enrollees with negotiated prices consistent with information reported to CMS for the price comparison Web site and/or reported by the endorsed sponsor;

(iv) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), substantial failure to ensure that the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to changes in the card sponsor's cost structure (including material changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy);

(v) Charging drug card enrollees additional fees beyond a $30 enrollment fee;

(vi) Charging transitional assistance enrollees any enrollment fee;

(vii) Charging a coinsurance more than 5 percent for those at or below 100 percent of the poverty line, or 10 percent for those above 100 percent but at or below 135 percent of the poverty line;

(viii) Substantial failure to administer properly the transitional assistance funding for transitional assistance enrollees;

(ix) Substantial failure to provide CMS or its designees with requested information related to the endorsed sponsor's endorsed discount card operations; or

(x) Failure to otherwise substantially comply with the requirements of this subpart, including failing to perform the operational requirements of this program or the failure to submit an acceptable plan of correction within the timeframe specified by CMS.

(4) *Written notice of proposed sanctions.*

(i) Prior to imposing sanctions, CMS will send a written notice to the endorsed sponsor stating the nature and basis of the proposed sanction.

(ii) CMS will send a copy of the notice in paragraph (a)(4)(i) of this section to the Office of the Inspector General.

(iii) CMS will allow the endorsed sponsor 15 days from the receipt of notice to provide evidence that it has not committed an act or omission that

may fairly be characterized as a basis for sanction.

(iv) Should an endorsed sponsor present evidence described in paragraph (a)(4)(iii) of this section and by the time limit described in that paragraph, a CMS official not involved in the original sanction determination shall review the evidence and provide the endorsed sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(5) *Effective date of sanction.*

(i) A sanction is effective 15 days after the date that the endorsed sponsor is notified of the sanction or, if the endorsed sponsor timely seeks reconsideration of that sanction decision, on the date specified in the notice of CMS's reconsideration determination.

(ii) The sanction remains in effect until CMS notifies the endorsed sponsor that CMS is satisfied that the basis for imposing the sanction has been corrected and is not likely to recur.

(b) *Civil monetary penalties.* (1) *OIG penalties.* The Office of the Inspector General (OIG) may impose civil monetary penalties in accordance with 42 CFR parts 1003 and 1005 in addition to, or in place of, sanctions that CMS may impose, as described in paragraph (a) of this section, against an endorsed sponsor whom it determines has knowingly—

(i) Misrepresented or falsified information in information and outreach or comparable material provided to program enrollee or other persons;

(ii) Charged a program enrollee in violation of the terms of the endorsement contract; or

(iii) Used transitional assistance funds in any manner that is inconsistent with the purpose of the transitional assistance program.

(2) *CMS penalties.* If CMS determines that an endorsed sponsor has engaged in conduct that it knows or should know constitutes a violation as described in paragraph (a)(3) of this section, where the failure to perform involves the operational requirements of the program, CMS may impose civil monetary penalties in accordance with 42 CFR parts 1003 and 1005 in addition to, or in place of, the sanctions that CMS may impose, as described in paragraph (a) of this section.

(3) CMS or the OIG may impose civil monetary penalties of no more than $10,000 for each violation.

(c) *Termination of endorsement by CMS.* (1) CMS may terminate the endorsement contract at any time with notice on the following bases:

(i) Any of the bases for the imposition of intermediate sanctions as stated in paragraph (a)(3) of this section; or

(ii) The endorsed sponsor engaged in false or misleading information and outreach practices; or

(iii) The endorsed sponsor fails to comply with the requirement of § 403.804(e).

(2) CMS shall provide the endorsed sponsor written notice of termination 30 days prior to the CMS-determined effective date of the termination at which time the endorsed sponsor must do the following:

(i) Provide its discount card enrollees notice of the termination within 10 days of receiving notice from CMS;

(ii) Continue to provide services to its discount card enrollees for 90 days after the discount card enrollees were sent the notice of termination from the endorsed sponsor; and

(iii) Suspend all information and outreach and enrollment activities once enrollees have received the notice of termination.

(3) *Corrective action plan.* Before terminating a contract, CMS shall provide the endorsed sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(d) *Termination by endorsed sponsor*—(1) *Cause for termination.* The endorsed sponsor may terminate its endorsement contract if CMS fails substantially to carry out the terms of the contract.

(2) *Card sponsor notice.* The endorsed sponsor must give advance notice as follows:

(i) To CMS, at least 90 days prior to the intended date of termination. This notice must specify the reasons why the endorsed sponsor is requesting contract termination; and

(ii) To its discount card enrollees, by mail, at least 60 days prior to the termination effective date. This notice must include a written description of alternative endorsed discount card programs that serve the discount card enrollee's address.

(3) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the endorsed sponsor's notice of intent to terminate.

(e) *Termination by mutual consent.* (1) A contract may be modified or terminated at any time by written mutual consent.

(2) If the contract is terminated by mutual consent, the endorsed sponsor must provide notice to its discount card enrollees as provided in paragraph (d)(2) of this section.

(3) If the contract is modified by mutual consent, the endorsed sponsor must provide notice to its discount card enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(f) *Appeal of contract determinations.* (1) *Scope.* This section establishes the procedures for reviewing the following contract determinations:

(i) A determination that an applicant is not qualified to enter into a contract with CMS under section 1860D–31 of the Act; and

(i) A determination to terminate a contract with an endorsed sponsor in accordance with paragraph (c) of this section.

(2) *Notice of determination.* When CMS makes an initial contract determination, it gives the endorsed sponsor or applicant written notice specifying—

(i) The reasons for the determination; and

(ii) The endorsed sponsor's or applicant's right to request reconsideration.

(3) *Effect of contract determination.* The contract determination is final and binding unless a timely request for a reconsideration hearing is filed under this section.

(4) *Right to reconsideration.* An endorsed sponsor whose contract is terminated or an applicant denied endorsement may request a hearing for reconsideration of the CMS contract determination.

(5) *Method and place for filing a request.* A request for a reconsideration hearing must be made in writing and filed with the CMS Central Office.

(6) *Time for filing a request.* The request for a reconsideration hearing must be filed within 15 days from the date of the notice of the initial determination.

(7) *Appointment of hearing officer.* CMS shall appoint a hearing officer to conduct the reconsideration. The hearing officer shall be a representative of the Administrator and not otherwise a party to the contract determination.

(8) *Conduct of hearing.* The endorsed sponsor or applicant may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings will be made and transcribed.

(9) *Reconsideration determination.* A reconsideration determination is a new determination that—

(i) Is based on a review of the contract determination, the evidence and findings upon which it was based, and

any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the endorsed sponsor subsequent to the contract determination; and

(ii) Affirms, reverses, or modifies the initial contract determination.

(10) *Notice of reconsidered determination.* As soon as practicable after the close of the hearing, the hearing officer issues a written reconsideration determination that contains the following:

(i) Findings with respect to the applicant's qualifications to enter into or an endorsed sponsor's qualifications to remain under a contract with CMS under section 1860D–31 of the Act;

(ii) A statement of the specific reasons for the reconsidered determination.

(11) *Effect of reconsidered determination.* A reconsidered determination is final and binding on the parties and is not subject to judicial review.

(g) *Compliance with HIPAA.* Failure of an endorsed sponsor to comply with HIPAA and/or the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164, as established in § 403.812, shall be a violation of HIPAA and may be enforced under sections 1176 and 1177 of the Act.

§ 403.822 Reimbursement of transitional assistance and associated sponsor requirements.

(a) A Transitional Assistance Account is created within the Federal Supplementary Medical Insurance Trust Fund and kept separate from all other funds within that fund.

(b) The Managing Trustee of the Transitional Assistance Account shall pay on a monthly basis from the Account the amounts certified by CMS as necessary to make payments for transitional assistance as allowed in § 403.808.

(c) Endorsed sponsors must routinely account to CMS for the transitional assistance provided to the transitional assistance enrollees for finalized (not pending, or denied) claims up to the allowed balance provided by CMS to the sponsor.

(d) Payment transactions will be audited by the Secretary or his agent.

(e) Federal funding in excess of the amount of the balance included in CMS's system is not permitted.

PART 408—PREMIUMS FOR SUPPLEMENTARY MEDICAL INSURANCE

■ 1. The authority citation for part 408 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Amend 408.20 to add new paragraphs (a)(5) and (b)(4) to read as follows:

§ 408.20 Monthly premiums.

(a) * * *

(5) The law was further amended in 2003 to ensure that amounts payable from the Transitional Assistance Account described in § 403.822 of this chapter shall not be taken into account in computing actuarial rates or premium amounts.

(b) * * *

(4) In no case shall payment made for transitional assistance costs under part 403, subpart H of this chapter be included in the formula used to calculate actuarial rates or standard monthly premiums.

* * * * *

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

Dated: December 8, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 8, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–30753 Filed 12–10–03; 1:00 pm]

BILLING CODE 4120–01–P