

CRS Report for Congress

Medicare Endorsed Prescription Drug Discount Card Program

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Summary

On December 8, 2003, the President signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA, P.L. 108-173). This legislation provides for the implementation of a Medicare prescription drug program, effective January 1, 2006. In the interim, MMA requires the Secretary of Health and Human Services (HHS) to establish a temporary program to endorse prescription drug discount card programs meeting certain requirements. The purpose is to provide access to prescription drug discounts to persons who voluntarily enroll with a private card plan. Each card sponsor is to provide each enrollee with access to negotiated prices. The program will also provide up to \$600 in transitional assistance in both 2004 and 2005 for low-income persons enrolled in endorsed card programs.

All Medicare beneficiaries, except those receiving Medicaid drug coverage, are eligible to enroll in a discount card program. Card enrollees with incomes below 135% of poverty are eligible for transitional assistance provided they do not have drug coverage under a group health plan. Not all persons eligible to enroll will actually enroll in the card program. Many persons who currently have access to discount prices through other sources will likely elect not to enroll in the temporary program. An individual can be enrolled in only one card program at a time. Sponsors may charge a uniform annual enrollment fee, not to exceed \$30; the Centers for Medicare and Medicaid Services (CMS, the agency administering Medicare) will pay the fee for those receiving transitional assistance.

An entity wishing to be a card sponsor must be a nongovernmental single legal entity doing business in the U.S. It must have three years private sector experience in pharmacy benefit management. At the time of application, it (or a subcontractor) must operate a pharmacy benefit program or similar program that serves at least 1 million covered lives. A Medicare managed care organization may apply to become an exclusive card sponsor by limiting drug card enrollment to persons enrolled in its managed care plan; certain requirements otherwise applicable to card programs are waived for this group.

At a minimum, card programs will be required to offer a negotiated price for at least one drug in each of the 209 therapeutic categories identified by CMS on a list of medications frequently used by Medicare beneficiaries. Further, sponsors must provide at least one generic drug for a negotiated price in at least 55% of the required categories. The sponsor must contract with a sufficient number of pharmacies (other than mail-order) in its service area to ensure that access requirements are met.

Implementation of the drug card raises a number of issues. Some are unique to the card program itself, while others have implications for the 2006 drug benefit. These include the ability of beneficiaries to make effective comparisons between card programs, the amount of change that will occur in formularies and prices during a beneficiary's enrollment in a card plan, how savings in prices will be measured, and the ease of transition to the 2006 drug benefit. The card program is slated to begin June 2004. This report will be updated as events warrant.

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Program Overview

On December 8, 2003, the President signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA, P.L. 108-173). This legislation provides for the implementation of a Medicare prescription drug program, effective January 1, 2006. In the interim, the legislation requires the Secretary of Health and Human Services (HHS) to establish a temporary program to endorse prescription drug discount card programs meeting certain requirements. The purpose of these programs is to provide access to prescription drug discounts to persons who voluntarily enroll with a private card plan. Each card sponsor is to provide each enrollee with access to negotiated prices. The program will also provide up to \$600 in transitional assistance in both 2004 and 2005 for low-income persons enrolled in endorsed card programs.

On December 15, 2003, the Centers for Medicare and Medicaid Services (CMS, the agency that administers Medicare) issued interim final regulations for the endorsed card program.¹ On February 5, 2004, CMS announced that it had received 106 applications for endorsement by the January 30, 2004 closing date. CMS is currently reviewing these applications. It is expected to announce those receiving endorsement this spring. Sponsors will begin enrolling beneficiaries in May 2004 and begin offering access to discounts and transitional assistance in June 2004.

This report provides an overview of the major features of the card program and highlights some of the major implementation issues raised to date.

Key Program Features

Program Eligibility

Basic Requirements. Persons enrolled in Medicare Part A and/or Part B are eligible to enroll in a discount card program. However, persons receiving any drug coverage through Medicaid (including under a Section 1115 waiver program) are

¹ U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Medicare Program; Medicare Prescription Drug Discount Card*, Interim final rule and notice; 68 *Federal Register* 69840, Dec. 15, 2003.

ineligible to enroll in a drug card program.² Conversely, an individual enrolled under a state pharmaceutical assistance program could be eligible provided he or she meets the other requirements.

It should be noted that not all persons eligible to enroll will actually enroll in the card program. Many persons who currently have access to discount prices through other sources will likely elect not to enroll in the temporary program.

Eligibility for Transitional Assistance. Certain low-income persons will be eligible for transitional assistance. Individuals will *not* be eligible for this assistance if they have drug coverage under a group health plan or other health insurance coverage, TRICARE coverage, or Federal Employees Health Benefits Program (FEHB) plan coverage. Persons qualifying for assistance are those with incomes below 135% of the poverty line. Persons who meet the definition of qualified Medicare beneficiary (QMB), specified low-income beneficiary (SLIMB), or qualifying individual-1 (QI-1) will be deemed to meet the income requirements.³ An individual deemed eligible will be considered eligible for the duration of the individual's enrollment in an endorsed card program. There are no assets tests for transitional assistance.

Transition Period to 2006 Prescription Drug Benefit. The new Medicare prescription drug benefit under Part D becomes effective January 1, 2006. Current Medicare beneficiaries will have a six-month open enrollment period, beginning November 15, 2005 to decide whether they wish to enroll for the new benefit. Beneficiaries who are enrolled in the endorsed drug card program can continue their enrollment in the card program until the effective date of their

² States are required to provide CMS with the necessary data to make this determination. On Dec. 15, 2003, CMS sent a letter to state Medicaid directors advising them of the information requirements; this requested information was designed with input from states and pilot tested. The law specifies that state costs of this activity are reimbursable as administrative expenses under Medicaid; the federal matching rate for these expenses is 50%.

³ QMBs are aged or disabled persons with incomes at or below the federal poverty level. In 2004, the monthly level is \$796 for an individual and \$1,061 for a couple. They must also have assets below \$4,000 for an individual and \$6,000 for a couple. Certain other assets such as the home are excluded from this limit. QMBs are entitled to have their Medicare cost-sharing charges, including the Part B premium, paid by the federal-state Medicaid program. Medicaid protection is limited to payment of Medicare cost-sharing charges (i.e., the Medicare beneficiary is *not* entitled to coverage of Medicaid plan services) unless the individual is otherwise entitled to Medicaid. SLIMBs are persons who meet the QMB criteria, except that their income is over the QMB limit. The SLIMB limit is 120% of the federal poverty level. In 2004, the monthly income limits are \$951 for an individual and \$1,269 for a couple. Medicaid protection is limited to payment of the Medicare Part B premium (i.e., the Medicare beneficiary is *not* entitled to coverage of Medicaid plan services) unless the individual is otherwise entitled to Medicaid. QI-1s are persons who meet the QMB criteria, except that their income is between 120% and 135% of poverty. Further, they are not otherwise eligible for Medicaid. In 2004, the monthly income level for QI-1 for an individual is \$1,068 and for a couple \$1,426. Medicaid protection for these persons is limited to payment of the monthly Medicare Part B premiums.

enrollment in Part D or May 14, 2006 (the end of the six-month Part D enrollment period), whichever occurs first. Any such time occurring on or after January 1, 2006, is considered as the individual's transition period. During this transition period no enrollment fee can be charged and any transitional assistance remaining on December 31, 2005 must be applied to the cost of covered discount card drugs purchased during the transition period. The endorsed card enrollment program terminates no later than May 14, 2006 for all enrollees.

Transitional Assistance

An individual determined eligible for transitional assistance in 2004 is entitled to \$600 in assistance in 2004 and \$600 in 2005. For individuals determined eligible in 2005, the amount available will be based on when the completed application is received. If such application is received during the first quarter of 2005, the full \$600 is available; the amount drops to \$450 for applications received in the second quarter; \$300 for those received in the third quarter, and \$150 for those received in the fourth quarter. The available amounts are to be applied only toward the costs of "covered discount card drugs" (i.e., all drugs that could be covered under a card program if there were no formulary limitations.) This includes *any drugs obtained through the 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.*

Transitional assistance individuals are required to pay coinsurance charges. Beneficiaries with incomes under 100% of poverty are liable for coinsurance charges of 5% of the drug's price; those with incomes between 100% and 135% of poverty are liable for coinsurance charges of 10% of the price. Pharmacies are permitted to waive these coinsurance charges; however they can not do so routinely, nor can they advertise the fact.

Any transitional assistance remaining at the end of 2004 can be rolled over into 2005; any amount remaining at the end of 2005 can be rolled over into the individual's transition period, if any, at the start of 2006. These rollover provisions only apply if the individual remains in the same endorsed card program, changes the program during the annual coordinated election period in 2004 (for 2005), or is eligible for a special election period and changes card enrollment during such period. (See enrollment, below.)

CMS will reimburse endorsed sponsors for any transitional assistance applied toward the cost of covered discount drugs obtained by transitional assistance enrollees. Sponsors will submit requests to CMS to debit the enrollees balance. CMS will only reimburse for those claims that are fully adjudicated for payment, not for pending claims.

Card Sponsor Qualifications and Endorsement

Experience. An entity wishing to be a card sponsor must demonstrate certain experience. It must be a nongovernmental single legal entity doing business in the U.S. It must have three years private sector experience in pharmacy benefit management including: (1) adjudicating and processing drug claims at the point of

sale; (2) negotiating with prescription drug manufacturers and others for discounts, rebates, and other price concessions on drugs; and (3) administering and tracking individual subsidies or benefits in real time. At the time of application, the applicant or subcontractor must operate a pharmacy benefit program, a prescription drug discount card program, a low-income drug assistance program or similar program that serves at least 1 million covered lives. In addition it (and any subcontractor the applicant relies on to meet the three years experience and 1 million covered lives requirements) must demonstrate a satisfactory record of financial stability and business integrity. CMS notes that the three years and 1 million lives requirements were included to ensure that the applicant (and subcontractors) are familiar with federal laws and will be able to quickly establish endorsed programs. Entities that could meet these requirements include pharmacy benefit management companies (PBMs), wholesale or retail pharmacy delivery systems, and insurers.

Service Area. Card programs are required to meet certain requirements with respect to service areas. Service areas must cover one or more states. The sponsor's program must be available to all eligible individuals residing in such state(s). It should be noted that the statewide requirement does not apply to Medicare managed care plans offering exclusive card programs (see discussion below).

Medicare Endorsement. CMS solicited applications from entities seeking to become endorsed sponsors. The law permits the agency to limit the number of endorsed sponsors in a state to two. However, the agency noted in the preamble to the interim final rule that it intended to endorse all applicants that (together with their subcontractors and other entities with which they have entered into a legal arrangement) meet or exceed the requirements for endorsement. Applicants meeting the requirements will enter into a contract with CMS. They will be able to use a Medicare-Endorsed Prescription Drug Card emblem.

Card sponsors will not be able to begin enrollment activities until they have completed certain activities including: finalizing pharmacy network contracts, negotiating manufacturer rebates or discounts, entering into all subcontracts necessary to assure full compliance with the conditions of endorsement, and obtaining CMS approval of information and outreach materials.

Enrollment in an Endorsed Plan

Enrollment Process. Enrollment in the card program is voluntary. Individuals must first select the card program they wish to enroll in. They will then complete a standard enrollment form and submit it to the selected sponsor. If they are applying for transitional assistance, they will need to certify, under penalty of perjury, that the income information they are providing is accurate. An endorsed sponsor cannot enroll a Medicare beneficiary in its program until CMS verifies the beneficiary's eligibility. If a beneficiary has applied for both the card program and transitional assistance and is determined eligible for the card program, but not transitional assistance, he/she has the option of deciding whether or not to enroll in the card program.

CMS will verify that the applicant meets the eligibility requirements, including income eligibility requirements in the case of transitional assistance. Every

beneficiary determined ineligible for the program and/or transitional assistance can request a reconsideration of the decision.

An individual can only be enrolled in one endorsed card program at a time. An individual enrolling in 2004 may change the election for 2005 during the annual coordinated election period (November 15, 2004-December 31, 2004). An individual may voluntarily disenroll at any time. In general, an individual who disenrolls in 2004 must wait until the annual coordinated election period to enroll in another plan for 2005. In general, an individual who disenrolls in 2005, will no longer be eligible. However, under certain circumstances, individuals who disenroll from a program will be entitled to a special enrollment period during which they can change their card enrollment. The special enrollment period will apply for persons who move out of the service area of the card sponsor, change residence to or from a long-term care facility, enroll in or disenroll from a Medicare managed care plan, or are in a plan which terminates or is terminated. A person eligible for transitional assistance, who disenrolls other than for one of these specified reasons, forfeits any remaining transitional assistance for the year.

CMS suggests that beneficiaries planning to change residence during the year should enroll in a national program.

It should be noted that while beneficiaries can only enroll in one endorsed program at a time, they may enroll in other card programs which are not Medicare-endorsed programs.

Enrollment Fees. Sponsors may charge a uniform annual enrollment fee, not to exceed \$30. Card sponsors must assure that enrollees are not charged any additional fees for products and services inside the scope of the endorsement. Products and services inside the scope of a sponsor's discount care program would include covered discount drugs as well as discounted nonprescription drugs.

Enrollees will pay the fee directly to the card sponsor. CMS will pay the fee for persons receiving transitional assistance. States may pay some or all of the enrollment fees for some or all persons not eligible for transitional assistance; payments are to be made directly to the sponsor. States may also pay some of the coinsurance amounts for transitional assistance enrollees. No federal matching payments would be available for these expenditures.

Program Design

Covered Discount Card Drugs. "Covered discount card drugs" are defined as virtually all recognized prescription drugs. However, an individual plan does not have to include all drugs on its formulary (see below) and not all formulary drugs have to be discounted. Individuals will select a card program based on which program will offer the discounted drugs they expect to use. Specifically, covered discount card drugs are defined in the law as prescription drugs and biologicals covered under Medicaid, vaccines licensed under Section 351 of the Public Health Service Act, and insulin. Necessary supplies associated with the injection of insulin are also included; syringes, needles, alcohol swabs, and gauze meet the definition while test strips or lancets do not.

The definition of covered discount drugs includes drugs when they are used for a medically accepted indication. In general this means the use is approved under the Federal Food Drug and Cosmetic Act or the use of which is supported by one or more recognized compendia.

Specifically excluded from the definition of covered discount card drugs are drugs excluded under Medicaid, except for smoking cessation. Thus, the following categories are specifically excluded: (1) agents when used for anorexia, weight loss, or weight gain; (2) agents when used to promote fertility; (3) agents when used for cosmetic purposes or hair growth; (4) agents when used for the symptomatic relief of coughs and colds; (5) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; (6) nonprescription drugs;⁴ (7) outpatient prescription 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; (8) barbiturates; and (9) benzodiazepines (central nervous system depressants).

Additionally, drugs which would otherwise be covered under the card program are not covered if they can be covered under Medicare Part A (in connection with covered inpatient services) or under Part B (which provides coverage for limited categories of outpatient prescription drugs including drugs which cannot be self-administered, immunosuppressive drugs under certain circumstances, and some oncology drugs).

Formularies. Endorsed card programs may use formularies. For purposes of the card program, a formulary is defined as 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 card program. CMS expects that allowing sponsors to use formularies will result in deeper discounts for card enrollees and enhanced use of generic drugs. In the interim final regulation, CMS stated that it wanted sponsors, when constructing their formularies, to include, at a minimum, the types of drugs commonly needed by beneficiaries (both aged and disabled). It developed a list of therapeutic classes and subclasses for medications frequently used by Medicare beneficiaries. At a minimum, card programs will be required to offer a negotiated price for at least one drug in each of the 209 categories identified in the list. A drug can be used only once to satisfy this requirement. Further, sponsors must provide at least one generic drug for a negotiated price in at least 55% of the required categories.

CMS indicated that there are several key issues applicants should consider in developing their formularies. These are: (1) evaluation of whether some drugs, not widely recommended for use in the elderly but appropriate in individual cases, should be included in the formulary; (2) importance of assuring discounted prices are available to special populations for the specific medication combinations they require (for example, for those persons who are HIV positive or those with mental illness);

⁴ However, MMA allows sponsors to offer discounts on nonprescription drugs through their discount card program.

and (3) ensuring that there are appropriate selections and dosage forms within each class or subclass (for example, long-acting versus short acting).

Pricing. Negotiated Prices; Price Concessions. Card sponsors are required to provide beneficiaries access to negotiated prices. As a condition of endorsement, sponsors must obtain discounts, rebates, subsidies, or other price concessions on at least some covered discount card drugs. Any such price concessions obtained by endorsed sponsors are to be taken into account in determining negotiated prices.

The interim final regulation requires that a *share* of such price concessions should be passed along in the form of lower prices; it does not specify what should constitute a share. The preamble to the regulation states that CMS would not set a minimum quantitative requirement either for the level of price concessions endorsed sponsors must obtain or the share of such concessions that must be passed along to card enrollees. Rather, CMS states that it 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.” CMS further notes that PBMs frequently obtain and pass through substantial rebates for their commercial populations.

CMS states that establishing a minimum level for price concessions could potentially undercut market competition, because manufacturers might tend to set their prices around the minimum level. It states that the CMS price comparison web site will enable beneficiaries to compare maximum negotiated prices for drugs under different endorsed programs. (See discussion below.)

Price Variation. It is expected that the level of discounts offered to card enrollees will vary across the spectrum of drugs offered. CMS is also allowing sponsors to vary prices and formularies by enrollee characteristics. For example, lower prices could be offered to transitional eligible enrollees or enrollees with a particular disease.

Updates. CMS will allow pricing changes to be made. (Its fact sheet on the program states that changes can be made on a weekly basis.) However, any increase in negotiated price is not allowed to exceed an amount proportionate to the change in the drug’s average wholesale price and/or an amount proportionate to the changes in the endorsed sponsor’s cost structure, including any change in price concessions received. An exception is provided for the week of November 15, 2004 (which coincides with the beginning of the annual enrollment period for 2005.)

Guarantees; Information. Card sponsors are required to guarantee that network and mail order pharmacies provide the lower of the customary price or the negotiated price.

They are also required to guarantee that a network pharmacy inform an enrollee at the point of sale of any difference between the price of a prescribed drug and the lowest price covered generic drug that is therapeutically equivalent and bioequivalent and available at the pharmacy. Mail order pharmacies are required to provide the information at the time of delivery of the drug.

Card sponsors are to synchronize changes in the list of and negotiated prices for drugs included in the formulary with those published on the CMS price comparison website.

Pharmacy Network Access. The sponsor must contract with a sufficient number of pharmacies (other than mail-order) in its service area to ensure that the following access requirements are met:

- On average, 90% of beneficiaries in urban areas are within two miles of a network pharmacy; urban areas are defined as zip codes with a population density over 3,000 persons per square mile.
- On average, 90% of beneficiaries in suburban areas are within five miles of a network pharmacy; suburban areas are defined as zip codes with a population density between 1,000 and 3,000 persons per square mile.
- On average, 70% of beneficiaries in rural areas are within 15 miles of a network pharmacy; rural areas are defined as zip codes with a population density less than 1,000 persons per square mile.

As required by law, these are the same standards established for use by the Department of Defense under the TRICARE Retail Pharmacy program.

The sponsor's network may be supplemented by mail order pharmacies.

Other Requirements

Information and Outreach Activities; Customer Service. Sponsors will be required to provide specified information (through the Internet and some other tangible medium, such as a mailing) to Medicare beneficiaries. The stated purpose is to promote informed choice among endorsed card programs. Information to be provided includes: the enrollment fee, negotiated prices for covered discount card drugs, discounts (if offered) on nonprescription drugs, and any other products or services offered under the endorsement program. The information and outreach materials may not describe services outside the scope of the endorsement. Sponsors must also provide information on a website (which is to include information on when the site was last updated and a disclaimer that the information may not be the most current). In general, CMS must approve outreach materials prior to distribution. The sponsor must also maintain a toll-free customer call center open during normal business hours.

Transitional Assistance. Card sponsors are required to administer transitional assistance funds received from CMS for transitional assistance enrollees. They are required to establish accounting procedures to manage the funds for each enrollee.

Medical Errors; Drug Interactions. An endorsed sponsor must provide a system to reduce the likelihood of medical errors and adverse drug interactions and to improve medication use. The preamble to the regulations states that sponsors have the flexibility to design their own individual systems. However, published scientific

and clinical literature (as well as the experience, if any, of the sponsor) should support the proposed approaches.

Grievance Procedures. Sponsors are required to establish and maintain a grievance process to handle a card enrollees's complaint or dispute regarding the manner in which he or she has received services under the endorsed program. The subject of a grievance may include such items as timeliness, appropriateness, access to and/or setting of services; failure to offer discounts on particular drugs; and incorrect administration of transitional assistance. The CMS application solicitation states that card sponsors must make enrollees aware of the process, accept grievances filed within 60 days of the event, respond within 30 days, and provide CMS, on a monthly basis, aggregate information on the number and disposition of grievances.

Reporting. Endorsed sponsors must report to CMS, on a periodic basis, information on key features of the endorsed card program including information on:

- Savings from pharmacies and manufacturers obtained through rebates, discounts, and other price concessions;
- Savings shared with enrollees by manufacturers, by all retail pharmacies, by all mail order pharmacies, and by all brand name and all generic covered discount card drugs;
- Dispensing fees;
- Certified financial records on transitional assistance used by transitional assistance enrollees;
- Utilization and spending for selected drugs;
- Performance on customer service measures;
- Grievance logs;
- Compliance with pharmacy network access standards.

Further, the sponsor must provide notice of and the rationale for negotiated price increases due to reasons other than changes in the average wholesale price. (This requirement does not apply during the week of November 15, 2004.)

Privacy. Sponsors are covered by the requirements of the Health Insurance Portability and Accountability Act (HIPAA) including the privacy requirements. A beneficiary's individually identifiable health information can only be used for health care operations and marketing of products and services covered under the endorsement. A sponsor may not request an enrollee to authorize the sponsor to use such information for purposes of marketing products and services not covered under the endorsement. Further, the sponsor is prohibited from using or disclosing any individually identifiable information for marketing purposes following termination of the sponsors's endorsement or termination of the drug discount card program.

Special Endorsements

Special Endorsement for Managed Care Plans. A Medicare managed care organization (i.e., Medicare Advantage organization)⁵ may apply to become an exclusive card sponsor by limiting drug card enrollment to eligible persons enrolled in any (but not necessarily all) of its managed care plans. Although many managed care plans already offer drug coverage, not all do so and most offer limited coverage. The discount card would be used in situations of no coverage or limited coverage under the plans.

Plans may limit their service area to the Medicare managed care plan's service area. If the plan uses a pharmacy network for its Medicare managed care plan, that network may be used for its endorsed program provided it is not limited to mail order pharmacies. If the managed care plan does not use a pharmacy network for its managed care plan, the Secretary must determine that the network for the card program provides sufficient access to covered discount card drugs at negotiated prices. Certain requirements otherwise applicable for drug card sponsors are deemed to be met or waived for Medicare Advantage plans.

Exclusive card sponsors are required to apply transitional assistance funds only to the cost to transitional enrollees of any discount card drugs obtained from a network or mail order pharmacy included in the sponsor's pharmacy network. The plan may wrap around the managed care plan's drug benefit (if any) by applying the \$600 toward the plan's copayments and deductibles as well as toward additional drugs not included under the plan's benefit or when the plan's benefit cap is reached.

Discount card eligible individuals enrolled in a Medicare managed care plan offering an exclusive card program may only enroll in that program. They are not permitted to enroll in another endorsed sponsor's program. The exclusive card sponsor may conduct group enrollment, i.e., enroll all or a subset of eligible persons. The sponsor must give all individuals it is enrolling in the group the opportunity to decline enrollment and the opportunity to apply for transitional assistance.

Special Endorsements. An applicant for endorsement may submit an application to become a special endorsement sponsor to provide transitional assistance to residents of long term care facilities through long-term care pharmacies.⁶ Similarly, an applicant for endorsement may submit an application to become a special endorsement sponsor to provide transitional assistance to American

⁵ MMA renamed Medicare+Choice plans as Medicare Advantage plans. Medicare Advantage plans receive monthly capitation payments for services provided to their Medicare enrollees. Certain other managed care plans continue to be reimbursed under cost contracts; they may also apply for special endorsement.

⁶ CMS estimates that about 1.3 million Medicare beneficiaries are residents of extended stay skilled nursing facilities and nursing facilities. An estimated 72% of these individuals are eligible for both Medicare and Medicaid and will be ineligible for the card program if they have Medicaid drug coverage. CMS estimates that up to 200,000 of the remaining population could be eligible for transitional assistance. Approximately 3,000 pharmacies serve the facilities' residents. Provision of drug benefits is generally coordinated through the facility and may be specially packaged.

Indians/Alaskan Natives (AI/ANs) who use Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies.⁷ The Secretary is to select at least two of the best qualified applicants for special endorsement for each category. Certain requirements otherwise applicable for drug card sponsors are deemed to be met or waived for these plans.

Territories. Residents of the territories (including those receiving drug coverage under Medicaid or Section 1115 waivers) are eligible for the endorsed drug card program.⁸ However, individuals in territories are not eligible for transitional assistance under the Medicare drug discount card program. Instead, territories choosing to provide low-income assistance are required to submit plans to the Secretary detailing how they intend to use their allotment (totaling \$35 million across the territories for the duration of the card program) to provide such assistance to some or all Medicare beneficiaries with incomes below 135% of poverty.

An applicant for endorsement may submit an application to become a special endorsement sponsor for all of the territories to provide access to negotiated prices. The Secretary will select at least one qualified applicant. The endorsed sponsor must provide access to negotiated prices.

CMS Activities

Beneficiary Education

CMS will disseminate basic information on the drug card to enrollees. In addition, it plans to disseminate specific comparison information to promote informed consumer choice among card programs including information on: enrollment fees; customer service hours; contact information; program website; and negotiated prices including dispensing fees. The law requires that the information should, to the extent practicable, be disseminated 30 days prior to the initial enrollment date. CMS states in the preamble to the regulations that the comparison information made available 30 days prior to the initial enrollment date will not include information on negotiated prices; this is because the required activities to validate such information can not be completed prior to that date. CMS does state that discount card eligible enrollees could contact endorsed sponsors to access

⁷ CMS estimates that there are approximately 87,000 AI/ANs over the age of 65 and 20,000 disabled enrollees using the services of the Indian Health Service (IHS). Of the total approximately 36,000 are covered by Medicaid. An estimated 18,000 may be eligible for transitional assistance. There are 201 I/T/U pharmacies in 27 states (with eight states having 11 or more, and three states having 20 or more). CMS reports that these pharmacies generally provide access to drugs off the Federal Supply Schedule (FSS) to AI/ANs. CMS states that the special endorsement provisions will provide an opportunity to provide prescriptions at the low FSS rate; coverage of costs would come in part from the IHS and in part from transitional assistance.

⁸ CMS reports that there are close to 600,000 Medicare beneficiaries in the territories with over 95% of those in Puerto Rico.

specific prices; CMS will provide the necessary contact information. The price information will appear at a later date on the website.

Both general and comparative information is to be made available on the web site, [www.medicare.gov] and through the toll-free Medicare number (1-800-MEDICARE). CMS also plans to use paid advertising to distribute information.

As noted, negotiated price information will be made available on the website. The site will include information on maximum (and possibly ranges of) negotiated prices, including dispensing fees, across card sponsors. Maximum prices will reflect estimates of the price charged at the point of sale. Sponsors can update their sites as often as weekly to reflect fluctuations in supply prices.

Oversight and Monitoring

CMS will develop an oversight system to assure compliance with program requirements, including those relating to marketing and enrollment policies and implementation of transitional assistance payments. It will develop a complaint tracking system to monitor and manage complaints not satisfactorily resolved through the sponsor's customer complaint process.

Sponsors who violate program requirements could be subject to sanctions, penalties or termination.

Impact

Beneficiaries

As noted earlier, not all persons eligible for the drug card program will elect to enroll.⁹ Some of these persons already have access to drug discounts either through their health insurance or through an existing card program. Further, transitional assistance is not available for persons who have other drug coverage. CMS estimates that 15.4 million beneficiaries (slightly over one-third of the total) will be both eligible for and could benefit from the discount card program. It estimates that 7.3 million persons will enroll in an endorsed card program in 2004 and 7.4 million will enroll in 2005; of these it estimates that 4.7 million persons each year will be eligible for transitional assistance.

⁹ CMS notes that because 2004 is the first year of the program, it does not have the benefit of prior experience. It also notes a number of limitations in the assumptions used in the impact analysis, for example, it is difficult to determine precisely how many persons will enroll in the program. Further, the estimate does not assume any increase in utilization stemming from the drug program.

Beneficiary savings attributable to lower negotiated prices will range from \$1.4 to \$1.8 billion in 2004 and \$2.0 to \$2.7 billion in 2005.¹⁰ This estimate is based on two main assumptions. First, the program will result in average drug savings of 10%-15% over costs that would be incurred in the absence of the card program.¹¹ Second, the effects of beneficiary education will lead to a greater use of generic drugs and more effective management of expenses. Estimated beneficiary savings attributable to transitional assistance are \$2.4 billion in 2004 and \$2.6 billion in 2005.

The savings estimates do not reflect the annual enrollment fees which can range up to \$30 per year. Factoring in the enrollment fees could reduce beneficiary savings by up to \$80 million each year.

Medicare

Program costs for persons eligible for transitional assistance are funded through general revenues which are credited to a separate account in the Medicare Part B trust fund; payments are made from this account. CMS estimates that Medicare program spending will increase by \$2.5 billion in CY2004, \$2.7 billion in CY2005, and \$0.1 billion in CY2006 (for those costs incurred during an individual's transition period). The vast majority of these costs is associated with transitional assistance (\$2.4 billion in 2004, \$2.6 billion in CY2005, and \$0.1 billion in 2006) with the remaining costs attributable to payment of enrollment fees for this population group. In addition, CMS administrative expenses will total an estimated \$134 million.

Costs for Sponsors

Card sponsors will incur a number of costs in setting up their programs. These include activities related to: program implementation, information and outreach, eligibility determination and enrollment processing, customer service operations, claims processing and claims adjudication, account maintenance, and logging and responding to grievances. Costs will vary by sponsor, though all will have had experience in running large programs. CMS estimates that sponsors with low costs would be able to recover their costs through enrollment fees in both 2004 and 2005 and will have a sufficient revenue stream to carry them through the transition period. For those with the highest costs, enrollment revenues will not exceed such costs until 2005 (though they may be able to cover any losses through rebate revenues); they will however, have revenues greater than costs over the entire period.

Issues

Implementation of the drug card raises a number of issues. Some are unique to the card program itself while others have implications for the Medicare drug benefit which will be put in place in 2006.

¹⁰ CMS estimates the 2004 (Apr.-Dec.) savings at 0.88-1.18% of total national aggregate drug spending in that period; 2005 savings are estimated at 0.89-1.18% of such spending.

¹¹ The CMS estimate is based on the 15% figure.

Eligibility

There are several differences between the eligibility requirements and determination procedures applicable for transitional assistance under the drug card program and the requirements and procedures applicable for low-income subsidies under the new Medicare drug benefit which begins in 2006. This could lead to potential confusion for beneficiaries.

CMS adopted streamlined procedures for the card program both because of the short lead time for the program and the fact that it is temporary. For the drug card, individuals will attest that their income falls below the threshold and CMS will verify the eligibility. Under the permanent program, states will make eligibility determinations using procedures currently in place for Medicaid.

Another difference involves assets tests. There are no assets tests for the drug card, while there are assets tests for low-income subsidies under the Medicare drug benefit. It is therefore possible that some persons will qualify for low-income assistance under the card program but not under the permanent drug benefit.

Formularies

As noted, each plan is required to offer a discount on at least one drug in each of 209 identified therapeutic categories; a single drug can not be used to satisfy the requirement for more than one category. CMS established these groupings in order to promote timely implementation of the temporary program and to provide access to discounts on drugs used most often by beneficiaries. Manufacturers have suggested that the minimum standard be expanded to include more than one drug in each class or a special endorsement for sponsors that follow this approach.¹² Other observers, have suggested that a more flexible framework, generally with fewer categories and/or allowing one drug to meet the requirement for more than one category, would be more appropriate. They are also concerned that the categorization may set a precedent for required coverage in 2006.¹³

Beneficiary Selection of Plan

As noted, beneficiaries are expected to make a selection from endorsed drug card programs available in their area. (An exception will be MA plan enrollees who will get their card through the MA plan if the plan offers an exclusive card program.) Questions have been raised about the ability of seniors, particularly those in frail condition, to make effective comparisons between card programs. As of this writing, it is difficult to determine how many choices the average beneficiary will have or how difficult it will be to make a comparison between the available options.

¹² PhRMA, *Comments on Medicare Prescription Drug Program; Medicare Prescription Drug Discount Program*, letter to CMS, Jan. 14, 2004.

¹³ AAHP-HIAA, letter to CMS, Jan. 14, 2004; and Academy of Managed Care Pharmacy, *Medicare Prescription Drug Discount Card*, letter to CMS, Jan. 14, 2004.

Presumably, two key factors in making these decisions will be differences in formularies and the amount of the discounts.

As noted, each plan is required to cover at least one drug in each of 209 identified therapeutic categories. At this point it is difficult to assess the degree of variation in formularies that will be offered by different programs. It is likely that potential enrollees will identify those drugs they use on a regular basis and determine which of the various programs cover these drugs. It is possible that some beneficiaries will be unable to find an endorsed program which covers all of the drugs they use. However, in all cases, there will be another drug, frequently a generic, that is covered in the same therapeutic class. While the drug may be on the formulary it may not necessarily have a discounted price.

Beneficiaries can elect to use a drug off the formulary, but they will not be able to take advantage of any negotiated price for the drug. However, if a beneficiary is entitled to transitional assistance, payment may be made for a drug, even if it is off the formulary.

Price Negotiation

A related issue is the price that will be negotiated for the drugs. While CMS will provide comparison information on its website, this information will not be available during the period immediately preceding implementation of the program in June 2004. Some observers are concerned that while card sponsors can change both formularies and negotiated prices after a beneficiary enrolls in a sponsor's program, beneficiaries are essentially locked into their choice for the remainder of the calendar year.

Another concern is the price information that is published. CMS states that the comparison site will show the maximum price that the beneficiary would face. The Pharmaceutical Research and Manufacturers Association (PhRMA) recommends that the comparison should show the actual price for a specific drug that an enrollee would face at each pharmacy under each card plan in their area.¹⁴ Conversely, other observers object to the publication of the information. The AAHP-HIAA (the national trade association representing health plans and private insurers) and the Blue-Cross Blue Shield Association (BCBSA) object to the publication of pricing information on the Web on the grounds that making drug-specific price information publically available is potentially confusing and has the potential to damage the ability of sponsors to negotiate effectively on behalf of beneficiaries. They recommend instead that CMS include on the site the range of reductions offered by sponsors, and provide that specific information be provided to beneficiaries on request through a toll-free hotline.¹⁵

¹⁴ PhRMA, *ibid.*

¹⁵ AAHP-HIAA, letter to CMS, Jan. 14, 2004; and Blue Cross Blue Shield Association, letter to CMS, Jan. 14, 2004.

Measuring Negotiated Discounts

CMS has estimated savings attributable to the discount program in the range of 10-15%, though savings will vary by sponsor and across the range of drugs offered. It is unclear how actual savings will be measured. Establishing a base for price comparisons may be difficult. The difficulties may be compounded since card sponsors are allowed to make pricing changes as frequently as once a week. Under the regulations, any increase in negotiated price can 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.

Pricing data are proprietary; therefore little information is available to determine prices among different payers. AWP has been used for paying for the limited number of drugs Medicare Part B currently covers. However, it is not a perfect measure. It is generally agreed that the AWP is only a published figure and bears relatively little relationship to actual prices. In fact, MMA includes a provision which specifies that Medicare Part B will no longer use AWP and will, instead, use the average sales price (ASP) to calculate payments. ASP information, to be calculated by the manufacturer, will only be provided for these drugs. No provision is made for obtaining this information across the board.

Transition to Permanent Drug Benefit

As noted, the Medicare endorsed drug card program is temporary and will be replaced by a permanent drug benefit under Medicare Part D in 2006. Under the Part D benefit, each Medicare beneficiary will be entitled to obtain qualified prescription drug coverage through enrollment in a prescription drug plan (PDP), or in the case of a MA enrollee, through enrollment in a MA-PDP plan.¹⁶

CMS has received a large number of applications from entities wishing to become drug card sponsors. It is likely that many of the applicants for endorsement are also intending to become PDPs. Many may view this as an opportunity to position themselves in the market and make themselves known to beneficiaries prior to the roll out of the new benefit in 2006. Presumably, the experience entities gain in administering the drug card, including dealing with the Medicare population, will prove useful when they take on the responsibilities for the new benefit. At the same time, CMS expects that information provided through the card program will assist it in further understanding the pharmaceutical industry.

It may be more difficult for some seniors to adjust to the changes between the card program and the new permanent benefit. As noted, there are differences between the two programs with respect to eligibility requirements and the process for determining eligibility.

¹⁶ For information on the new drug benefit, see: CRS Report RL31966, *Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, by Jennifer O'Sullivan, Hinda Chaikind, Sibyl Tilson, Jennifer Boulanger and Paulette Morgan.

There are also likely to be differences between the formularies and negotiated prices established under the endorsed card program and those made available by PDP plans, even if offered by the same entity. The consequences of individual choices between plans will become more important in 2006. As is the case with the drug card, negotiated prices will only be available for drugs on the plan's formulary. In addition, beginning in 2006, beneficiaries will receive federal subsidies for costs incurred with respect to drugs on a plan's formulary, but will not receive such subsidies (except in the case of successful appeals) for drugs not on a plan's formulary. Further, since beneficiaries will be paying premiums estimated at \$35 a month (rather than a maximum of \$30 a year for the card), they will want to select a program that best meets their needs.

These concerns highlight the necessity for beneficiary education on both the card program and the permanent drug benefit as well as the differences between them. CMS has begun this process. However, the material issued to date has proved controversial. CMS has stated that it is highlighting what new benefits will be available. However, some observers have charged that the material does not provide enough detail to give beneficiaries an understanding of the new choices.

Current Status

On February 5, 2004, CMS announced that it had received 106 applications for endorsement. Approximately half of the applications were from managed care plans. One quarter were from those proposing to offer coverage for any qualifying beneficiary living in the service area covered by the plan. The remaining quarter were from entities proposing to offer a national plan. CMS is currently reviewing the applications. It is expected to announce those receiving endorsement this spring. The program is slated to begin in June 2004.