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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.

A card sponsor must be a nongovernmental single legal entity doing business in the U.S. A Medicare Advantage (MA)organization (i.e., a Medicare managed care plan) may apply to become an exclusive card sponsor by limiting 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 are 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. 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.

Several issues have been raised since the program began operating June 1, 2004. All beneficiaries not enrolled in an MA plan have a choice of at least 34 national plans; in all but nine states, beneficiaries may also select from additional regional cards. CMS has placed on its website comparative information, by zip code, on plans available in the area and plan prices for drugs specified by a senior. Many observers have stated that beneficiaries are faced with too many confusing choices. While over 4 million persons have enrolled in the program, there is concern that many persons eligible for the $600 subsidy have not yet enrolled; special education efforts are being targeted toward this population group. Some observers have also suggested that discounts may not be that much when compared with other discounts available to seniors. Two recent studies suggest that these programs do provide savings when compared with retail prices and some other discount programs. 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] Sponsors began enrolling beneficiaries in May 2004 and began offering access to discounts and transitional assistance in June 2004. As of July 2004, over 4 million persons had enrolled in card programs; nearly 1 million of these persons received transitional assistance.

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 ineligible to enroll in a drug card program.[2] Conversely, an individual enrolled under

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[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.

[2] States are required to provide CMS with the necessary data to make this determination.
(continued...)

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 $600 in transitional assistance in both 2004 and 2005. 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 ($1,048 per month for a single, $1,406 for a couple). 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

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[2] (...continued)
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. (These figures include a $20 per month income disregard). 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. CMS has clarified that any assistance received under the transitional assistance program will not affect eligibility or amount of assistance under any other federal program.[4]

Transition assistance payments 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 drug obtained through the sponsor's endorsed program. The drug is covered whether or not it is on or off the formulary (if any) and regardless of whether or not 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.

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[4] Bolten, Joshua. *Medicare Modernization Act and Federal Programs*. Memorandum for the Heads of Executive Departments and Agencies, Executive Office of the President, Office of Management and Budget, July 18, 2004.

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 United States. 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;[5] (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

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

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); 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 website 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)[6] 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.[7] Similarly, an applicant for endorsement may submit an application to

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[6] 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.

[7] CMS estimates that about 1.3 million Medicare beneficiaries are residents of extended stay (continued...)

become a special endorsement sponsor to provide transitional assistance to American Indians/Alaskan Natives (AI/ANs) who use Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (ITU) pharmacies.[8] 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.[9] 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.

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[7] (...continued)
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.

[8] 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.

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

CMS Cost Projections

When CMS issued the interim final regulations on the card program in December 2003, it provided estimates of the number of persons expected to enroll in the program and the associated costs.

Beneficiaries

As noted earlier, not all persons eligible for the drug card program would elect to enroll.[10] 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. In December 2003, CMS estimated that 15.4 million beneficiaries (slightly over one-third of the total) would be both eligible for and could benefit from the discount card program. It estimated that 7.3 million persons would enroll in an endorsed card program in 2004 and 7.4 million would enroll in 2005; of these it estimated that 4.7 million persons each year will be eligible for transitional assistance.

Beneficiary savings attributable to lower negotiated prices were estimated to range from $1.4 to $1.8 billion in 2004 and $2.0 to $2.7 billion in 2005.[11] This estimate was based on two main assumptions. First, the program would result in average drug savings of 10%-15% over costs that would be incurred in the absence of the card program.[12] Second, the effects of beneficiary education would lead to a greater use of generic drugs and more effective management of expenses. Estimated beneficiary savings attributable to transitional assistance were $2.4 billion in 2004 and $2.6 billion in 2005.

The savings estimates did not reflect the annual enrollment fees which can range up to $30 per year. Factoring in the enrollment fees could reduce estimated 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 estimated that Medicare program spending would 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 were associated with transitional assistance

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[10] 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.

[11] 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.

[12] The CMS estimate is based on the 15% figure.

($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 would total an estimated $134 million.

Costs for Sponsors

Card sponsors 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 vary by sponsor, though all must have had experience in running large programs. CMS estimated that sponsors with low costs would be able to recover their costs through enrollment fees in both 2004 and 2005 and would have a sufficient revenue stream to carry them through the transition period. For those with the highest costs, enrollment revenues would not exceed such costs until 2005 (though they might be able to cover any losses through rebate revenues); they would however, have revenues greater than costs over the entire period.

Current Status

Approved card sponsors were able to begin enrolling beneficiaries in May 2004. They could begin offering enrollees access to discounts and transitional assistance on June 1, 2004.

Card Sponsors

The initial list of approved card sponsors was announced on March 25, 2004; additional sponsors were subsequently added to the list. As of June 2004, CMS had approved 39 national sponsors and 33 regional card sponsors. Regional card programs were offered to beneficiaries in all but nine states. CMS had approved an additional 84 exclusive card programs offered to enrollees of Medicare Advantage plans. Special approval was given to three programs to provide access to transitional assistance through long-term care pharmacies; four to provide discounts to residents in the territories, and three to serve federally recognized Indian tribe and tribal organization pharmacies.

A recent analysis by Health Policy Alternatives, Inc.(HPA) found that of the 72 general national and general regional card programs, 53% could be classified as pharmacy benefit managers (PBMs). Approximately 28% of the 72 sponsors were third-party administrators (TPAs) or pharmacy benefit administrators, commercial discount card companies, various medical and information technology companies, and an alliance of retail and chain pharmacies. The nine managed care organizations (13% of the total) that sponsored general card programs either operate their own

PBM or contract with a PBM or third-party administrator to run the card program. No information was available for the remaining 9%.[13]

The HPA study noted that five of the approved national plans never actually marketed their plans; this means that as of June 2004, 34 national plans were available. Further, it noted that the number of options was actually fewer than 34 when looked at in terms of actual variations in programs, drug prices, enrollment fees, and pharmacy access. This was attributed to the fact that many card programs are either offered by the same sponsor or work through the same PBM or TPA. However, the fact that a sponsor uses the same PBM or TPA does not necessarily result in common card features.

Beneficiary Education

Beneficiaries in fee-for-service Medicare can select from a large number of endorsed card programs. (Beneficiaries in managed care are required to enroll with the card program provided by the plan, if such a card program is offered.) CMS has taken a number of steps designed to make the selection and enrollment process easier. These efforts have been expanded over time as observers have stated the need for further improvements.

The key information source is the Prescription Drug Assistance Program (PDAP) tool put on the Medicare website at the end of April 2004. [http://www.medicare.gov]. Seniors (and their adult children or other persons assisting them) are able to obtain, by zip code, information on plans available in the area, plan prices for specific drugs specified by a senior, and pharmacies associated with available card programs. The site also directs low-income persons to state assistance programs, if any, which might be available to them.

CMS reports that it has recently made several improvements to the website. Beneficiaries can now obtain a listing of the "Top 5", that is, a list of the five plans offering the lowest aggregate prices for the selected drugs. In addition, beneficiaries will be able to enroll in card programs on the Internet.

Seniors may also call the Medicare toll-free number (1-800-MEDICARE). If they wish information on the drug card, they should have a list of the drugs they take frequently. After calling the phone line, they should receive a personalized booklet in the mail outlining their choices. This information is comparable to what is available on the website.

Since implementation of the card program, and the corresponding increase in the call volume, CMS has added additional call takers. In July, CMS reported that there were 3,000 operators answering an average of 50,000 calls a day. The average wait time was down to two minutes, considerably less than earlier reported.[14]

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[13] Health Policy Alternatives, Inc., *Medicare Drug Discount Cards: A Work in Progress*, report prepared for Henry J. Kaiser Family Foundation, July 2004 at [http://www.kff.org.]

[14] Testimony of CMS Administrator Mark McClellan, Senate Special Committee on Aging
(continued...)

CMS has taken a number of additional steps to assist beneficiaries in obtaining information. It is making money available to help community-based organizations to target persons who may be eligible for transitional assistance. This includes working with the Access to Benefits Coalition, a group of over 80 national non-profit organizations. CMS has also made available funds to State Health Insurance Assistance Programs (SHIPs) which provide assistance to beneficiaries through trained volunteer counselors. Additionally, the Administration on Aging and the Indian Health Service are working with their constituencies to encourage them to sign-up.

Enrollees

On July 29, 2004, CMS announced that enrollment in the card program had passed the 4 million mark on July 19, 2004. Of these persons, nearly 1 million were receiving the $600 in transitional assistance. Earlier data showed that 2.3 million persons were automatically signed up by their managed care organizations. Additional individuals have been automatically enrolled by their state pharmaceutical assistance program. The actual number of persons enrolling on their own is not available.

Manufacturer Assistance Programs

As of July 6, 2004, CMS reports that six drug companies are offering additional assistance toward the costs of certain specified drugs once a transition assistance beneficiary has exhausted his or her $600 subsidy. The companies offering this additional assistance are Abbott, AstraZeneca, Eli Lilly, Johnson and Johnson, Merck, Novartis, and Pfizer.[15]

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.

Beneficiary Enrollment and Selection of Plan

In General. As noted, beneficiaries are expected to make a selection from endorsed drug card programs available in their area. (An exception applies for MA plan enrollees who will get their card through the MA plan if the plan offers an exclusive card program.) Many persons have suggested that the enrollment figures are less than anticipated, while others contend that the numbers are good for a new

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[14] (...continued)
Helping Those Who Need It Most — Low-Income Seniors and the New Medicare Law, July 19, 2004.

[15] See [http://www.cms.hhs.gov/medicarereform/drugcard/mfragreements.asp], accessed Aug. 13, 2004.

program. Under the card program, beneficiaries are not penalized if they delay enrollment. However, there is concern that many low-income persons who should be taking advantage of the $600 subsidy have failed to sign up. As noted above, a special effort is currently being made to contact and enroll this population group.

Beneficiaries not enrolled with MA organizations can choose between a large number of card programs. Information on these programs is available on the Internet. Some people have suggested that beneficiaries have in fact had too many choices. Many, particularly older and frailer beneficiaries, are not comfortable using the Internet. Reportedly, both beneficiaries and persons assisting them have had trouble navigating the website and are confused by the large number of choices available to them. CMS has responded by making improvements to the website, including the listing of the best five for an individual in an area. However, some observers continue to suggest that the site is not user friendly.

Auto-Enrollment. Low-income populations are typically hard to reach. For example, enrollment in Medicare savings programs (i.e., (QMB, SLIMB, and QI-1) has traditionally been below desired levels. Some persons suggest that enrollment figures for the $600 subsidy could be increased through auto-enrollment of selected populations. While auto enrollment of these groups could potentially increase enrollment in the transitional assistance program, it would still fail to identify persons who have not established their potential eligibility through another program.

Medicare Savings Programs. Low-income persons enrolled in Medicare Savings Programs are potentially eligible for transitional assistance, since by definition they meet the income criteria. A number of persons have stated that CMS should automatically enroll them in the card program. CMS has been reluctant to do this for several reasons. It notes that some persons enrolled in Medicare Savings Programs may in fact have health insurance for drugs which would make them ineligible for transitional assistance. There are also questions about how beneficiaries could exercise a choice among the card programs. However, the biggest concern is that the law requires beneficiaries to submit an enrollment form certifying they do not have other drug coverage. Many states do not have representative authority to make the certification on behalf of Medicare Savings Programs enrollees.

The Access to Benefits Coalition recently commissioned a legal analysis on the auto-enrollment issue by Hogan and Hartson.[16] The analysis concluded that the law gives the Secretary authority to use alternatives to the standard enrollment form to enroll and certify persons for the $600 subsidy. This issue is expected to be of continuing interest as persons look for additional ways to increase the enrollment of low-income persons.[17]

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[16] Hogan and Hartson, *Transitional Assistance for Low-Income Beneficiaries in the Medicare Drug Discount Card Program*, memorandum from Sheree R. Kanner and Linda E. Fishman to the Access to Benefits Coalition, Aug. 3, 2004.

[17] CMS has indicated that it does not have authority to allow auto enrollment for the Medicare Savings population under the new drug benefit that will be implemented in 2006.

State Pharmacy Assistance Programs (SPAPs). A number of states operate state-funded pharmacy assistance programs for low-income individuals. Each state establishes its own eligibility criteria. It is estimated that approximately half of the enrollees would meet the eligibility criteria for transitional assistance. (The remaining enrollees generally have incomes above 135% of poverty, which is the cut-off for transitional assistance.)

As of June 2004, seven states provided for automatic enrollment for their SPAP enrollees who meet the eligibility criteria for transitional assistance. These states use authorized representative authority to auto enroll. Six of the states (Massachusetts, Maine, Minnesota, New Jersey, New York and Pennsylvania) automatically enrolled persons with a preferred card sponsor; Connecticut chose to implement the program with several cards. A review of auto enrollment found that it proved to be an effective strategy.[18]

Formularies

A key factor influencing a beneficiary's choice of card is presumably the drugs that are available on the plan's formulary. 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.

At this point it is difficult to assess the degree of variation in formularies that are offered by different programs. Beneficiaries using the website can tell which card programs in their area cover the drugs they use on a regular basis. However, available data and marketing materials do not provide a useful mechanism for extensive comparisons.

Beneficiaries who need costly drugs need to review available offerings carefully, since not all plans may cover all of their drugs. Some observers have noted that plans are permitted to change formularies throughout the year, even though beneficiaries are locked into their choice for the remainder of the calendar year. However, other observers have suggested that most plans are unlikely to make significant changes, in part because they do not wish to antagonize their enrollees.

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.

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[18] Kimberly Fox, *Testimony for Public Hearing of the State Pharmaceutical Assistance Transition Commission*, and Supplemental Tables, Rutgers Center for State Health Policy, July 7, 2004.

Price Negotiation

A related issue is the price that is negotiated for the drugs. 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. Some have suggested that plans will raise their prices. However, a preliminary review of selected drugs and selected card programs showed that overall prices remained relatively stable over the initial weeks of the program.

Another concern is the price information that is published. When CMS first posted price information on the website, there were reportedly a number of inaccuracies. This was attributed to the short turn around time to post the information and the submission of incomplete and/or incorrect information by sponsors. Many of the early problems have been corrected.

Measuring Negotiated Discounts

Virtually all observers agree that the $600 subsidy provides a meaningful benefit to enrollees with incomes under 135% of poverty. There has been less of a consensus with regard to the value of a card for other enrollees. Several observers have suggested that beneficiaries can obtain similar savings through other card programs.[19]

Comparative analysis is made difficult by the fact that PDAP price information is only accessible by plan and zip code. In the early weeks of the program, CMS was estimating savings in the range of 10-15%. More recently, two studies have attempted to further quantify the savings.

Health Policy Alternatives (HPA) Analysis. The HPA analysis, cited above, was issued July 2004. The study focused on prices available to persons not eligible for the subsidy. It tracked drug prices for a three-day supply for a set of 10 drugs commonly prescribed for Medicare beneficiaries and seven discount card programs. The programs picked were ones that offered discounts on all selected drugs at pharmacies in an urban and rural location in Maryland. The prices were compared to those reported by the Maryland Attorney General's (AG's) office which tracks retail prices paid by cash customers for selected drugs.

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[19] For example, an analysis prepared by the minority staff of the House Committee on Government Relations in Apr. 2004 (prior to the implementation of the program), found that prices expected to be available under the card program were higher than those that could be obtained in Canada or through the Veterans Administration and were no lower than prices that could be obtained without the card. Similarly, a Consumers Reports item in its Aug. 2004 issue, stated that its review of posted prices for five drugs in five cities in mid-May 2004, found that the prices under the card programs were higher than those available from Drugstore.com and Costco.com. It should be noted that some early pricing information on the website was inaccurate; additionally some plans lowered their initial price levels.

The HPA analysis showed that all seven card programs had prices that were significantly less than those reported by the Maryland Attorney General. For the basket of 10 drugs, it found that urban prices were 19% to 24% lower than the aggregate of the median AG reported prices, rural prices were 17%-22% lower than the AG prices, and mail order prices were 27%-32% lower than the AG prices for urban areas.

All six of the seven card programs offering mail order had prices for a 90-day supply for the basket of 10 drugs lower than COSTCO.com. Drugstore.com was competitive with the card mail order programs; the aggregate price on drugstore.com for the 10 drugs was 5% higher than the lowest priced card but 2% less than the highest priced card.

The HPA analysis also concluded that choice of card mattered, with considerable differences recorded between savings achieved from cards with the lowest and highest retail prices. Even greater differences were recorded when mail order prices were compared.

Lewin Group Analysis. On August 13, 2004, the Lewin Group issued its analysis of potential drug card savings. Its study, commissioned by the Healthcare Leadership Council, used three different approaches to measure savings available during June and July 2004. The first approach compared discount card prices to average retail prices in each state for the 150 most commonly prescribed drugs. This comparison would be most useful for persons using a small number of drugs. The second approach compared prices on a card-by-card basis for a market basket of the 25 drugs prescribed most frequently for beneficiaries. This analysis would be useful for persons taking a number of drugs. The third approach looked at typical drug regimens used to treat selected chronic conditions. In all cases comparisons were based on a 30-day supply of the most common form and strength of each drug. Only discounts available at retail pharmacies were used. They were compared to retail prices which would be paid by persons without other access to discounted prices. (Savings would be less for persons with access to other discount cards or enrolled in a state pharmaceutical assistance program). It should be noted that the savings estimates factor in the value of the $600 subsidy.[20] The following are some of the key findings form the survey:

- When looking at the top 150 drugs, the best available prices for brand name drugs represented average savings per prescription of $12.68 (18.6%); the best available prices for generic drugs represented average savings per prescription of $4.68 (67.5%).
- Available discounts vary by sponsor; therefore, the card a beneficiary picks has a significant effect on overall savings. All of the cards in the top quartile provided savings of at least 19.9% on the 25 drugs included in the market basket. Median card savings were 17.2% or $8.48 per prescription.

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[20] They do not however, factor in the savings attributable to manufacturer assistance programs offered to low-income beneficiaries who have exhausted their $600 subsidy during the year.

- Savings for beneficiaries using a typical drug regimen for diabetes ranged from 13% to 26% while those for a typical hypertension regimen average 28%.
- The best available price offered for a single drug under the card program seldom varied across markets. Thus while card sponsors offer uniform pricing nationwide, the savings from the cards vary geographically and by pharmacy due to variations in retail prices.
- The best available prices can generally be obtained at multiple pharmacies in an area.

The report also estimated national savings based on these findings. The savings estimates are based on several assumptions. First, it assumes that enrollment will reach the CMS estimate by January 1, 2005, namely that 7.3 million will enroll and 61% of enrollees (4.5 million) will be eligible for the subsidy. Second, the report assumes that beneficiaries will choose a discount card averaging savings of 19.9%, the 75th percentile of the market basket test. The savings for all beneficiaries over 18 months would average $1,247 (35.5% of median retail spending of $3,514); this estimate includes the $600 subsidy value. Savings for beneficiaries eligible for the subsidy would average $1,548 (47.3% of median retail spending of $3,270 for this group), while those for persons above 135% of poverty would average $775 (19.9% of median retail spending for this group of $3,895).[21]

Overall, the report estimated that savings would total $7.7 billion if enrollment reaches 7.3 million by January 1, 2005 and beneficiaries select cards in the 75th percentile with average savings of 19.9%. Of the $7.7 billion total savings, $4.3 billion (56%) is attributable to discounted prices and $3.4 billion to the subsidy (44%). Taking into account both discounted prices and the subsidy, $5.9 billion of the total $7.7 billion are estimated to accrue to low-income beneficiaries.

Price Changes Over Time. Both the HPA and Lewin analyses compared drug prices available through the cards with retail prices available on the same date to persons not covered under an endorsed discount card or eligible for discounts through another source (such as private insurance or non-endorsed discount card program). One question that has not been answered by the recent analyses is to what extent prices were raised prior to the start of the card program. If there were a sharp increase in prices prior to the program's introduction, the value of the discounts would be somewhat undercut. Pricing information in effect prior to implementation of the card program is proprietary so precise comparisons are not available.

However, some reviews suggest that recent increases may be considerable. An AARP report on the first quarter of 2004, showed that manufacturers' increases to wholesalers for widely used brand name drugs rose faster in the 12-month period ending March 2004, than in any of the previous four calendar years. The average annual percentage change for the period was 7.2% compared to the general increase

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[21] These estimates assume beneficiaries with higher drug costs are more likely to enroll as are those eligible for the credit.

in inflation of 2.0%.[22] A Families USA study of the top 30 drugs used by seniors found an average increase of 4.3 times the rate of inflation between January 2003 and January 2004. (In the three-year period from January 2001-January 2004, the average increase was 3.6 times the rate of inflation.)[23]

Pharmacy Access

As noted earlier, card sponsors are required to contract with a sufficient number of pharmacies (other than mail order) to ensure that beneficiaries have sufficient access to retail pharmacies. A number of card sponsors have made network pharmacy information available to potential enrollees through the PDAP website. Other sponsors will make pharmacy information available on request.

Questions have been raised regarding the accuracy of network pharmacy information. One review found that some card sponsors were using "passive acceptance agreements" to identify participating pharmacies. Unless a pharmacy specifically told a sponsor it would not be participating, the sponsor listed it as a participant. In certain cases pharmacies that had no intention of participating, or in certain cases were no longer in business at the stated address, were listed as participants on the PDAP.[24] It is not clear how widespread this problem may be.

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.[25]

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 subsides under the new Medicare drug benefit. 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 attest that their income falls below the threshold and CMS verifies the eligibility. Under the permanent program, states will make eligibility determinations using procedures currently in place for Medicaid.

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[22] David Gross, Stephen Schondelmeyer, and Susan Raetzman, *Trends in Manufacturer Price Changes for Most Widely Used Brand Name Prescription Drugs*, AARP Public Policy Institute, June 2004.

[23] Families USA, *Sticker Shock: Rising Prescription Drug Prices for Seniors*, July 2004.

[24] Henry A. Waxman, and Louise McIntosh Slaughter, letter to Hon. Tommy G. Thompson, Secretary of the Department of Health and Human Services, July 6, 2004.

[25] 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.

Another difference involves assets tests. There are no assets tests for the $600 subsidy under 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.

Plan Choices. 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

CMS received a large number of applications from entities wishing to become drug card sponsors. It unclear how many of these entities will actually submit applications to become PDP plans. Many may view participation in the card program 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.

However, some observers have suggested that many of the card programs may not apply to become PDP plans. Under the 2006 benefit, PDP plans are to provide a drug-only benefit and, unlike a discount card program, assume a portion of the financial risk of coverage. A drug-only product is largely untested; therefore, some entities may be reluctant to assume the unknown financial risk of the new benefit. This is less of an issue for MA-PDP plans since most of these entities have experience offering drug benefits and the drug benefit is offered as part of the overall benefits package.

Beneficiary Choices. It may be 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.

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.