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President Bush's Proposed Medicare-Endorsed Drug Discount
Card Initiative: Status and Issues

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Updated February 7, 2003

**Abstract.** This report discusses prescription drug coverage gaps for seniors, private sector discount card programs, and the discount card program the President originally proposed in July. Implementation issues of the program, as well as asserted benefits and limitations, are also be explored.



### Report for Congress

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# President Bush's Proposed Medicare-Endorsed Drug Discount Card Initiative: Status and Issues

**Updated February 7, 2003** 

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#### President Bush's Proposed Medicare-Endorsed Drug Discount Card Initiative: Status and Issues

#### Summary

On July 12, 2001, President Bush announced a Medicare-endorsed prescription drug discount card program to help seniors lower their out-of-pocket drug costs. The President stated that the discount card program would be an interim measure until a broader Medicare prescription drug benefit for seniors can be created. Many seniors do not have adequate prescription drug coverage. In 1998, an estimated 10 million elderly people, or 27% of Medicare beneficiaries, did not have any form of prescription drug coverage.

The Administration planned to implement the card program in January 2002, but it was put on hold because of a federal court order. Pharmacy groups successfully filed a lawsuit against CMS in 2001, asking a federal court to issue an injunction that would halt the card program on the grounds that the Administration had no statutory authority to establish the program. The Administration proceeded with plans to modify the program and use a formal rulemaking process for a new proposal. On August 30, 2002, CMS issued the final rule. Pharmacies continued to claim that the Administration lacked the statutory authority to implement the initiative. On January 29, 2003, a federal district court ruled that the Administration did not have the statutory authority to offer the card program. CMS issued a statement saying that it would be evaluating its options and it would likely appeal. In the 108th Congress, Representative Mark Foley introduced a bill (H.R. 513) in the House on January 31, 2003 to authorize the Secretary of Health and Human Services to endorse prescription drug discount cards for use by Medicare beneficiaries.

The proposed card program would be similar to prescription drug discount card programs that are currently available from a number of sources. The Administration's card would endorse and promote a number of qualified privately-administered prescription drug discount card plans which would have a one-time maximum enrollment rate of \$25 per plan. Since the announcement of President Bush's proposal, several pharmaceutical companies have implemented their own senior discount card plans for low-income seniors beginning in early 2002.

The Administration has stated that the Medicare-endorsed card plans would offer discounts in the range of 10% to 13%, and up to 15%, on retail prescription drug prices. The net overall effects of President Bush's proposed program would depend on the details of the individual card plans, which are not yet available. Congressional critics of President Bush's proposal dispute the Administration's estimates of potential discounts. Some Members of Congress believe that the card program would not provide additional benefits for seniors. They cite a recent study by the U.S. General Accounting Office (GAO) on prescription drug discount prices available at retail pharmacies, Internet pharmacies, and existing drug discount card programs. The Members believe that the study indicates that seniors already have access to drug discount cards and that these programs offer little savings for seniors.

This report will be updated as events warrant.

### Contents

Background
Gaps in Senior Prescription Drug Coverage
Existing Commercial Prescription
Discount Card Programs
How Prescription Drug Discount Card Programs Work
Discount Card Plans for Low-Income Seniors
Description of the Medicare-Endorsed
Drug Card Initiative
General Features of Drug Card Initiative
Program Administration
Final Rule for Medicare Drug Card Initiative
General Rules for Endorsement
Eligibility Requirements for Endorsement
Beneficiary Enrollment
Public Comments
Key Differences between Proposed and Final Rule
Pharmacy Participation
Expected Discounts from Card Initiative:
Diverse Estimates
Administration Arguments in Support of Discount Card Program
Pharmacists' Challenge to Medicare Discount Card Program
Procedural Objections
Economic Objections
Observations 2

### President Bush's Proposed Medicare-Endorsed Drug Discount Card Initiative: Status and Issues

#### **Background**

On July 12, 2001, President Bush announced a Medicare-endorsed prescription drug discount card program to help Medicare beneficiaries reduce their out-of-pocket drug costs. The President stated that the discount card program was an interim measure that would precede broader Medicare reform measures, including a prescription drug benefit for seniors. Medicare does not cover most outpatient prescription drugs. Most seniors have some form of supplementary health insurance to cover expenses not met by Medicare; however, many of these plans do not offer drug coverage or offer limited protection for drug expenses.<sup>1</sup>

The President's card program is controversial and immediately prompted criticism from the retail pharmacy industry, from some Members of Congress, and from some consumer groups. Critics of the plan have argued that the plan would not bring additional benefits for seniors and that retail pharmacies would bear the burden of prescription drug cost reductions for seniors. Shortly after the card initiative was announced in 2001, pharmacy groups successfully filed a lawsuit against CMS, asking a federal court to issue an injunction that would halt the card program on the grounds that the Administration had no statutory authority to establish the program. The Administration proceeded with plans to modify the program and used a formal rulemaking process for a new proposal. On March 6, 2002, CMS issued a proposed rule for the card program with a 60-day comment period. On August 30, 2002, CMS Although pharmacies continued to assert that the issued the final rule. Administration lacked the authority to implement the initiative, CMS proceeded with the program. On January 8, 2003, CMS formally solicited applications from parties interested in offering Medicare prescription drug discount cards. Applications were due on March 7, 2003.

On January 29, 2003, a federal district court judge ruled against the Medicare discount card initiative, stating that the Administration did not have the statutory authority to implement the program. CMS withdrew its solicitation for applications and issued a statement saying that CMS is evaluating the court decision and the

<sup>&</sup>lt;sup>1</sup>For more information on prescription drug coverage for the Medicare population, see CRS Report RL30819, *Medicare Prescription Drug Coverage for Beneficiaries: Background and Issues*, by Jennifer O'Sullivan.

various options CMS has, including a likely appeal.<sup>2</sup> The Bush Administration has stated that it would include prescription drug coverage in its plan to revise Medicare, but it is unclear whether the prescription drug discount card would be included in the Administration's proposal. In the 108<sup>th</sup> Congress, legislation has been introduced (H.R. 513) to authorize the Secretary of Health and Human Services to endorse prescription drug discount cards for use by Medicare beneficiaries.

Currently, many private companies and membership organizations offer prescription discount cards for seniors. The Medicare discount card program would allow private companies to develop discount card plans for beneficiaries and apply for Medicare endorsement of their plans. The President's proposed program would, in most respects, be similar to these other plans. The major difference is that the discount cards offered under the President's plan would be Medicare-endorsed and would provide consumers with comparative information on the formularies and prices offered within the card program. Another key difference is that beneficiaries could have only one Medicare-endorsed card plan.

This report will discuss prescription drug coverage gaps for seniors, private sector discount card programs, the discount card program the President originally proposed in July, and the key differences in the final regulation issued in August 2002. Implementation issues of the program, as well as asserted benefits and limitations, will also be explored. This report will be updated as events warrant.

#### **Gaps in Senior Prescription Drug Coverage**

In 1998, an estimated 10 million elderly people, or 27% of Medicare beneficiaries, did not have any form of prescription drug coverage. The remaining 28 million Medicare beneficiaries had some form of drug coverage for at least part of the year. However, coverage is not always stable and access to drug benefits for seniors is declining.<sup>3</sup> Medicare beneficiaries are among the highest users of prescription drugs. They represent 14% of the total U.S. population, and account for 43% of the nation's total drug expenditures.<sup>4</sup> With national spending on prescription drugs rising, Medicare beneficiaries face increasing challenges in being able to pay for their prescription drug needs.

Although most Medicare beneficiaries have some form of prescription drug coverage, they still pay a portion of their total drug expenses out of pocket. In 1998, beneficiaries with coverage paid approximately 33% of their total drug expenses out of pocket. Average out-of-pocket drug expenditures for beneficiaries with coverage was \$325 in 1998, while expenditures for those without coverage was \$546. For those in poor health, the out-of-pocket expenditures for uncovered beneficiaries averaged \$820. According to the 1998 Medicare Current Beneficiary Survey

<sup>&</sup>lt;sup>2</sup>Centers for Medicare and Medicaid Services, Press Release from Public Affairs Office, "Statement by CMS Administrator Tom Scully," January 29, 2003.

<sup>&</sup>lt;sup>3</sup>Poisal, John A. and Lauren Murray, "Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage," *Health Affairs*, March/April 2001.

<sup>&</sup>lt;sup>4</sup>Ibid.

(MCBS), covered beneficiaries paid a larger percentage of their total drug costs out of pocket in 1998 than in 1997. Between 1997 and 1998, out-of-pocket expenditures for covered beneficiaries increased by almost 18 percent, while beneficiaries with no coverage had no change in expenses.<sup>5</sup>

# **Existing Commercial Prescription Discount Card Programs**

Prescription drug discount cards are widely available through some private companies and membership organizations, such as AARP (formerly the American Association of Retired Persons). These companies have set up buying clubs that offer savings on prescription drugs and other medical services to attract consumers looking for a better price on these items. The companies vary from Internet mail order service companies to pharmacy benefit managers (PBMs) that offer discount card services, such as Merck-Medco and the AARP Member Choice Program (provided through the United Health Group Incorporated, with mail order prescriptions filled by Express Scripts). Card plans usually require an annual membership fee that can range from \$15 to \$50 per year and offer discount cards that are accepted by a network of drugstores and/or doctors.<sup>6</sup> The plans offer a discount to card holders on their prescription drug purchases at retail pharmacies. Since the announcement of President Bush's proposal, several pharmaceutical companies formed their own senior discount card plans in early 2002. (Some of these plans are described in the section below titled Senior Discount Card Plans).

#### **How Prescription Drug Discount Card Programs Work**

Card sponsors arrange a network of retail pharmacies that will participate in the program and offer discounts to card holders. The retail pharmacies in the network agree to accept the card sponsor's reimbursement rate. This reimbursement rate is often lower than what retail pharmacies charge cash-paying customers who have no healthcare coverage. Pharmacies generally accept the lower price agreed to in the program because belonging to the program network results in a larger volume of business. However, the lower prices accepted by the pharmacies may result in lower prescription drug revenues for the store.

The operators of card programs typically control the costs of a prescription drug benefit by developing formularies. A formulary is a list of drugs that the card sponsor generates to provide the higher benefits to participating members at a reduced cost. In deciding which drugs to include in the formulary, the card sponsor determines which drugs are most cost-effective to include in the list. Discount card programs generally use restricted formularies. Patients may obtain discounts only on

<sup>&</sup>lt;sup>5</sup>Ibid, pp. 81-82.

<sup>&</sup>lt;sup>6</sup>The New York Times, "'Buyers' Clubs' for Medical Services Crop Up," by Milt Freudenheim, Aug. 25, 2000.

<sup>&</sup>lt;sup>7</sup>For more information on formulary development see CRS Report RL30754, *Pharmacy Benefit Managers*, by Christopher J. Sroka.

the drugs included in the formulary offered by the card program and must pay full price for the drugs not included in the card's formulary.

Private discount card programs are similar to other drug benefit programs, such as those offered by private health insurance plans, in that they generally develop formularies by consulting with an independent pharmacy and therapeutics (P&T) committee. A number of drugs may be used to treat a certain condition or disease. Such drugs are said to be therapeutically equivalent or belonging to the same therapeutic category. A formulary does not always include every drug in a given therapeutic category, but usually includes at least one brand-name drug per category. The P&T committee evaluates the safety, efficacy, substitutability and cost of therapeutically equivalent drugs. The members of the committees and the decision-making process vary by healthcare plan, but most often include physicians, pharmacists, medical directors, and/or health plan staff members. Some larger drug benefit sponsors, however, do not allow their staff to participate in P&T committees because of potential conflict of interest. Some health plans say that they emphasize outcomes in choosing formulary drugs, while others look more at clinical comparability, bioequivalency and cost.<sup>8</sup>

Formularies allow card providers to contain the cost of prescription drugs primarily through manufacturer rebates and retail pharmacy discounts. Drug manufacturers give rebates to the card providers to increase market share and/or utilization. If a manufacturer's products are included in the formulary, the manufacturer expects the use of its drugs to increase. The amount of the rebate offered by a manufacturer to a sponsor varies by plan. These rebates vary significantly across the industry, and there is no reliable data to suggest the size of such rebates. The rebates effectively lower the net prices that the benefit sponsor must pay for the prescription drugs its members use. Retail pharmacies provide discounts in order to gain access to card plan members.

In addition to retail pharmacy discounts, many card programs offer mail order services to their members. Mail order pharmacies operate at lower costs than traditional retail pharmacies and tend to be less expensive for the card sponsor. Some card sponsors encourage their members to use the mail order pharmacy by offering lower prices through the mail order service than are available at retail pharmacies.

Some card sponsors perform drug utilization review (DUR) to evaluate whether a patient was prescribed the proper dosage, whether the patient is getting the appropriate dosage, or if prescriptions are being refilled too frequently. DUR also screens prescriptions for drugs that may be inappropriate for the patient, for dangerous drug interactions, for duplicate prescriptions, for the overuse of controlled substances, and for fraud and abuse. Actions resulting from incidents uncovered through DUR may result in the card sponsor sending educational material to the physician or pharmacist, or in dropping coverage for the patient.

<sup>&</sup>lt;sup>8</sup>Managed Care, "Getting Serious About Formularies," by Jean Lawrence, March 1998.

#### **Discount Card Plans for Low-Income Seniors**

In 2002, a number of pharmaceutical companies started offering discount card plans for low-income seniors. GlaxoSmithKline (GSK), Novartis, Pfizer, Eli Lilly, and a coalition of seven pharmaceutical companies each formed senior discount card plans for medications they produce. The programs are intended for low-income seniors and are limited to those Medicare beneficiaries who meet the eligibility requirements defined by each company. In addition, a pharmacy group announced their own card program which is also intended to benefit the nation's elderly low-income population. Details of the plans include the following:

- GSK *Orange Card*: The card is available to Medicare beneficiaries who have annual incomes below 300% the federal poverty level, or \$26,000 for a single person and \$35,000 for a couple. The card, in effect since January 2002, offers discounts of 25% on the GSK list price for wholesalers, which is the Average Wholesale Price (AWP) reported by First Data Bank, for all GSK outpatient prescription products. The card does not have an enrollment fee. A cardholder would present the discount card at participating pharmacies and realize the savings at the point of sale.<sup>9</sup>
- Novartis *Care Card*. The card is available for Medicare beneficiaries who lack prescription drug coverage and whose annual income is below 300% the Federal Poverty Level (approximately \$26,000/single or \$35,000/couple). Eligible participants must be U.S. citizens. The card is free of charge and offers discounts of 25% off the AWP price for select Novartis outpatient prescription products at participating pharmacies. Seniors would realize their savings at the point of sale.<sup>10</sup>
- Pfizer *Share Card*. The card is available for low-income Medicare beneficiaries (\$18,000/single or \$24,000/couple annual income) who have no other prescription drug coverage. Plan participants would pay a \$15 fee for each 30-day Pfizer prescription drug supply and have no limits on the number of prescriptions. The plan also includes two co-promoted drugs. The program was in effect as of March 1, 2002.<sup>11</sup>
- Eli Lilly *Lilly Answers*. The card is available for Medicare-eligible seniors and the disabled with yearly individual incomes under \$18,000 of annual household incomes under \$24,000. The card is free for qualifying individuals. Card holders would be able to buy a 30-day supply of any Lilly prescription

<sup>&</sup>lt;sup>9</sup>GlaxoSmithKline Fact Sheet, *GlaxoSmithKline - Orange Card Key Facts*, undated.

<sup>&</sup>lt;sup>10</sup>Novartis Fact Sheet, *Fast Facts: Novartis Care Card*<sup>sm</sup>, undated. For more information, see [http://www.novartis.com/carecard/fast\_facts.shtml].

<sup>&</sup>lt;sup>11</sup>Pfizer Fact Sheet, *The Pfizer for Living Share Card<sup>TM</sup> Program*, undated. For more information, see [http://www.pfizer.com/pfizerinc/about/sharecard/factsheet.html].

drug for \$12. The company estimates that card users could save up to \$850 per drug per year. 12

- *Together Rx Card* from Abbott Laboratories, AstraZeneca, Aventis, Bristol-Myers Squibb Company, GlaxoSmithKline, Johnson & Johnson, and Novartis... The card is available for Medicare beneficiaries with yearly incomes up to \$28,000 for individuals and \$38,000 for couples. The companies announced that card holders would save 20-40% on retail prices on over 150 widely prescribed medicines through a variety of savings options.
- Pharmacy Care Alliance Pharmacy Care One Card. The Pharmacy Care Alliance was created by the National Association of Chain Drug Stores and created the card program to offer low-income seniors access to drug manufacturer programs through one card. The pharmacies announced that the card will allow seniors to access multiple manufacturer discount and subsidy programs using only one card at the pharmacy of their choice.<sup>14</sup> This card program is different from the others in that it is open to all drug manufacturers and community pharmacies for participation.

The pharmaceutical companies issuing the cards stated that they developed the cards to assist seniors who do not have prescription drug coverage while a prescription drug benefit is added to Medicare. Critics of these card discount programs argue that the pharmaceutical companies are trying to deflect public pressure away from the rising costs of prescription drugs and attempting to switch consumers to products manufactured by these companies. They claim the companies' efforts are only a marketing tool and would not lower prices. Retail pharmacies have been critical of discount card programs offered by drug manufacturers, arguing that discounts come entirely from reductions in the prices charged by pharmacies and not from the manufacturers.

<sup>&</sup>lt;sup>12</sup>Eli Lilly Fact Sheets, *LillyAnswers*, undated. For more information, see [http://www.lillyanswers.com/questions\_answers.html].

<sup>&</sup>lt;sup>13</sup>Bureau of National Affairs, *Daily Report for Executives*, "Drug Companies to Unveil Joint Medicare Prescription Drug Card," April 10, 2002.

<sup>&</sup>lt;sup>14</sup>National Association of Chain Drug Stores news release, "Pharmacy Care Alliance Stacks Multiple Drug Savings Into One Senior Benefit Card," March 11, 2002.

<sup>&</sup>lt;sup>15</sup>National Journal Group, Inc., *American Health Line*, "Rx Discount Cards: More Available, But Do They Help?," February 8, 2002.

<sup>&</sup>lt;sup>16</sup>Brown, Joseph, "Pharma Companies Take Lead for Drug Discounts: As the Government Works on Long-Term Prescription-Drug Coverage for Seniors, GlaxoSmithKline and Novartis are Issuing Discount Cards," Med Ad News, No. 1, Vol. 21, p. 32, January 1, 2002.

# Description of the Medicare-Endorsed Drug Card Initiative

The final regulation for the Medicare-endorsed prescription drug initiative was announced by the Centers for Medicare and Medicaid Services (CMS) on August 30, 2002 and published in the *Federal Register* on September 4, 2002.<sup>17</sup> It is not known when or if the program will be implemented because a federal district court ruled on January 29, 2003 that the Administration did not have the authority to implement the card initiative. The Administration has said it is likely to appeal the court's decision. If the Administration decides to appeal the case, the outcome of the appeal would determine whether or not the initiative will be implemented. The Administration may also move forward with the initiative if Congress grants legal authority to HHS to implement the program. On January 31, 2003, Representative Mark Foley introduced a bill (H.R. 513) in the House to authorize HHS to endorse prescription drug discount cards for use by Medicare beneficiaries. This section describes general features of the drug card initiative, a description of how the program would be administered, details of the final rule establishing the initiative, and pharmacy participation in the card programs.

#### General Features of Drug Card Initiative

The Medicare-endorsed card initiative would be a voluntary program that is, in many respects, modeled on existing plans offered by private companies, membership associations, and pharmacy benefit managers. The primary objective of the proposal is to provide Medicare beneficiaries immediate prescription drug benefits at discounted prices. In his original proposal, President Bush emphasized that the initiative would be an interim measure and that it was not intended to be a substitute for a broader Medicare prescription drug benefit.

The drug card initiative would authorize Medicare to endorse a number of qualified privately-administered prescription drug discount cards for Medicare beneficiaries. Each card would offer discounts from the retail prices of certain prescription drugs. The card program would be different from existing plans in that a consortium of card sponsors would be required to provide participants with comparative information on prices and formularies. This would provide Medicare beneficiaries with one central source of information to compare features of all Medicare-endorsed cards, including drug-specific discounted prices, pharmacy networks, enrollment fees, and other drug services. In addition, the card sponsors would be required to follow certain guidelines provided by the Centers for Medicare and Medicaid Services (CMS), the office responsible for administering the program.

Medicare beneficiaries would be allowed to participate in only one Medicareendorsed card program at a time, but could change plans on a semi-annual basis. CMS stated that multiple enrollments could weaken the negotiating leverage of each company offering card plans, which could lead to lower rebates from drug

<sup>&</sup>lt;sup>17</sup>Federal Register. 42 CFR Part 403. *Medicare Program: Medicare-Endorsed Prescription Drug Card Assistance Initiative*. Final Rule. Vol. 67. No. 171. September 4, 2002.

manufacturers, and, therefore, lower discounts to card holders. Medicare beneficiaries could enroll in other discount card plans that are not Medicare endorsed.

CMS expects to endorse 15 card sponsors if the drug card initiative is implemented. It is unknown whether the program would use existing discount cards or create new card programs that qualify for endorsement by Medicare.<sup>18</sup>

#### **Program Administration**

As outlined, President Bush's drug discount card initiative would be managed by CMS, but, in general, would entail limited government involvement. The government's role would mainly consist of providing Medicare beneficiaries with information on the card program and facilitating access to the private companies that offer Medicare-endorsed discount cards. CMS oversight would consist of certification of card providers based on criteria that would include membership thresholds, pharmacy network thresholds, and inclusion of all drug classes in the discount program. CMS has stated that it expects most of the funding for the program to come from the consortium of card providers, and that the federal administrative costs would be small. The federal administrative costs for the program would be funded through the CMS budget.

Upon implementation of the program, CMS would provide detailed information on each endorsed discount card program to Medicare beneficiaries. The information provided by CMS would include descriptive information on the endorsed discount cards through the Medicare website, and general information by telephone on the Medicare toll-free line. CMS would promote the cards to beneficiary and consumer groups, health care providers, states, and other interested groups.

#### **Final Rule for Medicare Drug Card Initiative**

The final rule for the Medicare-Endorsed Prescription Drug Card Assistance Initiative appeared in the Federal Register on September 4, 2002. The revised initiative was similar to President Bush's original proposal, but with more detail on how the program would operate and with changes to some key aspects of the program. The final regulations specify general rules for the Medicare-endorsed prescription drug card program. Card sponsors applying for endorsement would be required to submit an application and meet all the requirements outlined in the final regulations.<sup>19</sup>

The final federal proposal includes an effort to coordinate with state programs by proposing that states could partner with private drug card program sponsors by selecting a Medicare-endorsed card program, offering its own endorsement and

<sup>&</sup>lt;sup>18</sup> On the original proposal, CMS received 28 applications from private entities for Medicare-endorsement of their proposed discount card plans, but no details of the individual card programs were released.

<sup>&</sup>lt;sup>19</sup>For detailed information on requirements listed in the proposed rule, see CRS General Distribution Memorandum, "Medicare-Endorsed Prescription Drug Card Assistance Initiative-Summary of Proposed Regulations," by Jennifer O'Sullivan, March 13, 2002.

having a distinct card. In a separate Notice issued on March 6, 2002, CMS outlined additional steps it was considering to support state efforts to make affordable drugs more readily available and invited public comments on these efforts.<sup>20</sup>

**General Rules for Endorsement.** The regulations provided a number of requirements for entities seeking Medicare endorsement of their card programs. All candidates would be required to submit applications announced in the solicitations by CMS and meet all requirements for endorsement. Applicants may sponsor up to a maximum of two card programs, but may have operational responsibilities in multiple card programs. Endorsements would be effective for a period of 12 to 24 months in year one of the initiative, and 12 to 15 months in year two of the initiative. CMS could terminate endorsement of a card program at any time, while card sponsors could choose not to continue participation in the card initiative at any time. In the event of the termination of an endorsed card program, the card sponsor would be responsible for giving 90-day notice to beneficiaries that the card program will be ending.

**Eligibility Requirements for Endorsement.** The regulations list a set of requirements that applicants must meet in order to have their card programs endorsed by Medicare. Applicants must meet specific criteria related to experience, structure of their proposed card program(s), ability to manage a consortium and provide customer service. The following sections summarize the requirements listed in the final rule.

**Experience, structure, and participation in administrative consortium.** Applicants must demonstrate three years experience in pharmacy benefit management, in administering a prescription drug discount program, or in administering a low income drug assistance program. They must demonstrate experience in managing at least one million covered lives in an insured pharmacy benefit, prescription drug discount program, or a low income drug assistance program.

Applicants must demonstrate they have formed a pharmacy network serving all fifty states and the District of Columbia, or have a regional pharmacy network serving at least two contiguous states, with the exception of Hawaii and Alaska which can partner with two or more contiguous states.

Applicants must be financially solvent and have a satisfactory record of integrity and business ethics. They must agree to jointly administer, abide by the guidelines of, and fund a private administrative consortium with other Medicare-endorsed prescription drug card program sponsors in accordance with CMS requirements. They must also demonstrate the ability to manage such a consortium. Applicants must comply with all applicable federal and state laws.

**Customer Service.** Applicants' proposed card programs must follow certain guidelines in offering customer service. They must limit their one-time enrollment

<sup>&</sup>lt;sup>20</sup>Federal Register, Vol. 67, No. 171, Rules and Regulations, September 4, 2002, pp. 56683-56684.

fee to \$25 during first year of the program initiative. CMS may adjust the amount of the one-time fee after first year of the initiative. The proposed card programs are required to enroll only Medicare beneficiaries, and enroll all Medicare beneficiaries who apply for enrollment. Applicants must agree to provide information on their card program and outreach materials to all enrolled beneficiaries. They also must maintain a toll-free customer call center that is open during usual business hours and that provides customer telephone service, including to pharmacists, in accordance with standard business practices.

**Discounts, Rebates, and Access.** Applicants must offer a discount on at least one brand name or generic prescription drug in each therapeutic category of the prescription drugs most commonly needed by Medicare beneficiaries. They must obtain pharmaceutical manufacturer drug rebates or discounts on brand name and/or generic drugs and ensure that a substantial share is provided to beneficiaries either directly or indirectly through pharmacies. They must ensure that no changes would occur to drug formularies for periods of at least 60 days, and notify CMS, the consortium, and network pharmacies of any changes to the formulary 30 days before the change becomes effective. They must guarantee that Medicare beneficiaries would receive the lower of either the price offered by the discount card program or the price a pharmacy would charge a cash paying customer. Endorsed card sponsors would be required to provide the administrative consortium with information on drugs included in the applicant's formulary and the prices.

Applicants must have a proposed national or regional contracted pharmacy network sufficient to ensure that pharmacies are locally accessible to all beneficiaries. At least 90 percent of beneficiaries, on average, must live within five miles of a contracted pharmacy in all Metropolitan Statistical Areas (MSAs) served by the program and within ten miles of a contracted pharmacy in all non-MSAs (rural areas).

Administrative Consortium. Sponsors of Medicare-endorsed card plans would be responsible for forming and financing a joint consortium to handle all enrollment and eligibility functions and avoid duplicate card issuance. The consortium would be responsible for ensuring that beneficiaries are not enrolled in more than one Medicare-endorsed card program at the same time. It would facilitate the publication of comparative price information on discounted drugs available through the endorsed card programs, to assist beneficiaries select the most appropriate program for their needs. The consortium would be required to ensure the integrity of the information provided by card sponsors; develop and implement a written data security plan for protected health information; and abide by applicable federal and state laws including the Health Insurance Portability and Accountability Act of 1996 (HIPPA). CMS may assist in the start-up of the administrative consortium and perform some of these functions for a transitional period of time.

**Beneficiary Enrollment.** Medicare beneficiaries enrolling in a Medicare-endorsed prescription drug card program for the first time may enroll at any time. Beneficiaries may enroll in only one Medicare-endorsed card program at a time, but may change enrollment to a different program on the first day of the following January or July from after the request for the change is made. In the event the card

program is terminated by either the sponsor or CMS, enrolled beneficiaries may enroll in a different endorsed card program effective immediately.

**Public Comments.** CMS solicited comments on a number of issues in the proposed regulation which was issued in March 2002. According to press reports, CMS received 26 comments, including those from the Pharmaceutical Research and Manufacturers of America (PhRMA) and AARP. Both PhRMA and AARP expressed support for the initiative, but sought numerous changes before the final rule was issued. The Small Business Administration submitted a comment that stated that the proposed rule for the card could significantly reduce profit margins of many pharmacies, noting that the financial impact analysis conducted by CMS was "incomplete". Pharmacy groups issued a comment saying CMS should withdraw the proposed rule. Pharmacies asserted that the discount card program would hurt pharmacy profits and that CMS lacked the statutory authority to implement the plan.

**Key Differences between Proposed and Final Rule.** CMS announced that, in response to comments received during the public comment period, the final regulation differs from the proposed regulation published on March 6, 2002 in several respects. Some key differences include the following:<sup>22</sup>

- Enhanced information on drug prices, including information about generic alternatives, and other endorsed card program features that would be available through the consortium website and by telephone.
- Endorsed card sponsors would be required to secure manufacturer rebates or discounts on brand name and/or generic drugs.
- The experience requirements changed from five years to three years, and from managing two million lives in a national pharmacy benefit or drug discount card program to managing one million lives. Changes to the qualifying criteria would provide increased opportunities for pharmacy and other organizations to offer Medicare-endorsed card programs.
- Endorsed card sponsors would be allowed to offer two program designs, providing beneficiaries more choice.
- Endorsed card sponsors would have to ensure stable drug formularies and prices. They would not be able to increase drug prices or change drugs from their formulary for periods of at least 60 days, beginning on the first day of the program's operation.
- New privacy requirements for Medicare card sponsors would improve privacy
  protection for beneficiaries. Endorsed card sponsors would be required to
  align their privacy protections with privacy standards under HIPAA, including
  the final changes in the recently announced update of those privacy standards.

<sup>&</sup>lt;sup>21</sup>BNA, *Daily Report for Executives*, "SBA, Interest Groups Seek Changes in Medicare Discount Card Proposal," May 9, 2002.

<sup>&</sup>lt;sup>22</sup>CMS Media Release, *CMS News*, "HHS Issues Final Regulation on Medicare-Endorsed Prescription Drug Card Initiative," August 30, 2002.

#### **Pharmacy Participation**

Retail pharmacies participating in Medicare-endorsed card programs would agree to belong to a network of pharmacies arranged by the card sponsor on a volunteer basis. Most pharmacies already belong to one or more networks organized by PBMs. As part of the agreement with the card sponsor, retail pharmacies would accept a negotiated reimbursement rate from the card sponsor. The reimbursement rate could be lower than the usual price the pharmacy charges for a drug, and, possibly, result in lower profit margins for the pharmacy. However, the proposal's promoters have noted that pharmacies typically agree to join card networks because they gain access to the large number of members belonging to the card plan, which would be expected to increase their customer base and sales volume. Pharmacies not electing to join a network arranged by card sponsors risk losing customers.<sup>23</sup>

# **Expected Discounts from Card Initiative: Diverse Estimates**

The potential savings provided by the program are expected to come from the market leverage that card sponsors obtain from the formulary and pharmacy network, and also from the "education attributes" of the program.<sup>24</sup> The educational aspect, consisting of the informational material on drug prices, formulary content, and the pharmacy network offered by the card program, is intended to improve the ability of consumers to comparison shop and choose the plan that meets their needs at the lowest cost.

CMS has estimated that seniors would be able to obtain a 10% to 13%, and possibly up to a 15%, discount on prescription drug retail purchases through the Medicare-endorsed card program. A fact sheet issued by CMS states that it projects that the first year of the program would provide Medicare beneficiaries between \$1.2 and \$1.6 billion savings on their prescription drug purchases.

Some observers have commented that the Administration's proposed discount program would probably provide seniors with at least some savings on their overall prescription drug bill. Questions have been raised about the actual size of the discounts that would be available. Specific information is not available on the discount amounts and formularies the potential card sponsors would offer. The actual size of retail discounts may not be known until after the first year of program operation. While it is possible to compare prices available through existing discount card programs to those at individual retail pharmacies or Internet pharmacies, one of the constraining factors in conducting this kind of analysis is the lack of widely available data on retail drug prices.

<sup>&</sup>lt;sup>23</sup> PriceWaterhouseCoopersLLP. "Study of Pharmaceutical Benefit Management." HCFA Contract No. 500-97-0399/0097. June 2001. See pp. 57-58 for a discussion of how pharmacy networks are created by PBMs.

<sup>&</sup>lt;sup>24</sup>CMS Fact Sheet, "Medicare-Endorsed Prescription Drug Card Assistance Initiative," available on the CMS website [http://cms.hhs.gov].

The U.S. General Accounting Office (GAO) completed a study in 2002 on prescription drug prices for seniors offered by drug discount card programs, local pharmacies, or over the Internet.<sup>25</sup> The study included surveys on prices available from five companies that administer large drug discount card programs, five Internet pharmacies, and several retail pharmacies in four different geographic areas (Washington, D.C., Chicago, Seattle, and rural Georgia). Prices listed in the study show that the discounts on brand name drugs offered by the card programs ranged from 6% to 32% on the average retail pharmacy prices. The average size of the discount on all drugs was about 12%. The Internet pharmacy prices on the GAO survey varied. In some cases the Internet prices were up to 19% higher than those available by discount card programs, while for other drugs, the prices were up to 12% lower. The Internet pharmacy prices were consistently lower than retail pharmacy prices. The retail pharmacy prices obtained by GAO demonstrated that prices may vary considerably in different geographic regions. For example, the average price for a 30-day supply of 10-mg tablets of Lipitor was 13% higher in rural Georgia than in Seattle, Washington.<sup>26</sup>

Critics of President Bush's program have disputed past statements made by the Administration of potential discounts of up to 25%. More recent announcements by CMS have stated that discounts would probably be within the range of 10% to 13%, and possibly up to 15%.<sup>27</sup> Retail pharmacy groups, consumer groups, and some Members of Congress believe that the program is not likely to produce significant savings for seniors. Some Members of Congress argue that, based on their interpretation of data collected by GAO, existing discount card programs do not work and provide no more than 10% savings on retail prices.<sup>28</sup> They have stated that the Bush proposal would not offer greater discounts for seniors than those already available in the market. In a letter to the U.S. Department of Health and Human Services (HHS), six Members of Congress state that a Medicare discount card program is unlikely to provide significant discounts on brand name drugs for seniors. They cite the price study by GAO and say that the study indicates that seniors already have access to drug discount cards and that these programs offer little savings for seniors for commonly used brand name drugs. They believe that the findings of the GAO price study indicate that unless the proposed Medicare discount card program requires a significant discount from the drug manufacturers that is passed on to seniors, the program would not provide additional benefits for seniors.<sup>29</sup>

<sup>&</sup>lt;sup>25</sup>General Accounting Office, Report No. GAO-02-280R, *Prescription Drugs: Prices Available Through Discount Cards and From Other Sources*, December 5, 2001.

<sup>&</sup>lt;sup>26</sup>Ibid, p. 4.

<sup>&</sup>lt;sup>27</sup>CMS Factsheet, "Medicare-Endorsed Prescription Drug Card Assistance Initiative."

<sup>&</sup>lt;sup>28</sup>Bureau of National Affairs, *Health Care Daily*, "House Small Business Panel Asks CMS to Substantially Revise Drug Card Proposal," October 26, 2001; Goldstein, Amy. "GAO Tests Value of Discount Cards; Savings Less Than 10%, Study Shows," *Washington Post*, January 4, 2002.

<sup>&</sup>lt;sup>29</sup>Six Democratic congressmen sent a letter to HHS Secretary Tommy G. Thompson on January 3, 2002 in which the Members urge an alternative approach to President Bush's proposed Medicare-endorsed drug discount card program. For more information, see (continued...)

# Administration Arguments in Support of Discount Card Program

President Bush has emphasized that the discount card program would not be a substitute for a new prescription drug benefit provision under Medicare. The discount program was intended to be an interim solution that would provide some immediate cost relief for seniors while other options were under consideration.

CMS highlighted several key elements that the Administration believes would make the Medicare-endorsed cards better than the current discount cards currently available in the market. The first is that the exclusive enrollment feature, combined with the formulary, pharmacy network, and informational attributes of the programs, would provide the card sponsors and their members with the necessary "market clout" to obtain larger rebates from pharmaceutical manufacturers and pass the rebate to the consumer. The consumer of th

CMS has said that the market has shown that discount cards can obtain manufacturer rebates, but that these programs do not always pass the rebate back to the consumer. The Administration believes that because the Medicare-endorsed card initiative would require that card sponsors pass the rebate to the pharmacy and the consumer, Medicare beneficiaries could obtain larger discounts than those in currently available card programs. Because the membership in the Medicare-endorsed programs would consist entirely of seniors and some disabled persons, it seems likely that the Medicare card program could provide card sponsors with some market leverage in negotiating discounts with the drug manufacturers on the most commonly prescribed senior drugs. However, no information is publicly available on the amount of the proposed discounts or rebates, nor on the amount of the rebates that would be passed on to Medicare beneficiaries.

Second, the Administration believes that the comparative price information feature of the Medicare-endorsed card proposal would benefit seniors in that they would have access to comparative price, formulary, and pharmacy network information on the various card programs and choose the best plan for their needs. Discount program participants would be able to switch from one card program to another at 6-month intervals, although this could result in additional one-time per plan enrollment fees of up to \$25.

The informational feature is potentially one of the most valuable features of the President's discount program, because it would provide a single source of information on drug prices, formularies, and pharmacy networks of all Medicare-endorsed discount card programs. Some existing card programs individually provide information on prices and formularies, but information on competing programs is not available in one easily accessible location. For the many seniors who do not have

<sup>&</sup>lt;sup>29</sup>(...continued)

<sup>[</sup>http://www.house.gov/reform/min/inves\_prescrip/index.htm].

<sup>&</sup>lt;sup>30</sup>CMS Fact Sheet, pp. 3-4.

<sup>&</sup>lt;sup>31</sup>Ibid.

access to a computer or the Internet, however, published information would continue to be the most important vehicle for ensuring that program participants realize the informational benefits of the program. The success of this aspect of the program would depend on the final details of the individual card programs and how well the companies manage the consortium and provide customer service for easy access to price and pharmacy network information.

The publication of drug price information could eventually put pressure on pharmaceutical manufacturers, pharmacies and/or card sponsors to match lower prices offered by competitors. Although this could result in additional savings for seniors, the retail pharmacy industry believes that pharmacies would face reduced profit margins if they were pressured to reduce prices without a change in what they pay the wholesalers or drug manufacturers for the drugs, while the latter two groups would benefit at the pharmacists' expense. Although the final rule requires that a portion of the pharmaceutical rebates or discounts be provided to beneficiaries either directly or indirectly through pharmacies, the pharmacies argue that the rule does not specify the amount of the discount that should go to pharmacies.

Another factor to consider is whether the card sponsor plans under the proposed Medicare program include drug utilization review (DUR) to determine whether patients are using therapeutically equivalent drugs. Patients sometimes use drugs prescribed by different doctors to treat the same condition and are not aware of it. DUR may prevent the duplicative use of drugs that fall within the same therapeutic category, thereby enhancing patient safety while lowering prescription drug costs. DUR can also identify harmful drug interactions that may occur when a patient with more than one medical condition treats those conditions with drugs that, when taken together, are harmful.

The third item mentioned by CMS is that the Medicare drug card initiative would require card sponsors to offer broad access to retail pharmacies, and only offer mail-order services as an option. Some existing drug card programs offer only mail-order services, and do not include a retail pharmacy network in their plan. The Medicare initiative would not endorse these types of plans. Pharmacy associations assert that, while mail-order card programs may provide lower prescription drugs prices, these programs do not provide seniors with the personal help they may need from community pharmacists. Pharmacy associations have also argued that the Medicare drug card initiative could be an incentive for Medicare beneficiaries to shift their prescription drug purchases from retail pharmacies to mail-order services, and that this would come at a cost to retail pharmacies. CMS has stated that the network pharmacy requirement in the Medicare drug card proposal would ensure that Medicare beneficiaries continue to purchase their drugs from retail pharmacies.

The final point mentioned by CMS is that Medicare-endorsed card sponsors would be expected to provide clear and reliable educational information services to Medicare beneficiaries such as pharmacy counseling, generic substitution, and DUR programs to monitor and prevent drug-drug interactions. CMS believes that this feature would assist seniors and people with disabilities select a quality discount card

program.<sup>32</sup> As mentioned earlier, the informational aspects of the Medicare initiative could be valuable in helping seniors lower their drug costs by choosing the card program most appropriate for their needs. Much, however, would depend on the quality of service that card sponsors provide. Because the drug discount card initiative is intended only for Medicare beneficiaries, features of the program such as customer service, marketing material, and included drugs would be geared toward Medicare beneficiaries. The card program, it is argued, could result in more coordination among companies offering card discount programs and CMS, which could improve the service and information seniors receive when shopping for their prescription drugs. A consortium of card sponsors could lead to an improvement of marketing materials and drug price information for seniors. However, because details of the card programs that would be proposed are not known at this time, it is difficult to assess how much of an improvement there would be over existing drug card programs.

# Pharmacists' Challenge to Medicare Discount Card Program

#### **Procedural Objections**

On July 17, 2001, the National Association of Chain Drug Stores (NACDS) and the NCPA, as plaintiffs, filed a suit in the Federal District Court for the District of Columbia against Department of Health and Human Services (HHS) Secretary Tommy Thompson and the CMS Administrator Tom Scully to block the Administration's original prescription discount card initiative. On July 26, 2001, the NACDS/NCPA asked the court to issue an injunction preventing the Bush Administration from proceeding with the discount card initiative on the grounds that, among other arguments, the Administration exceeded the statutory authority granted to it by the Social Security Act and that the Administration failed to comply with the procedural requirements of the Administrative Procedure Act.

On September 6, 2001, U.S. District Court Judge Paul Friedman issued an injunction, stating that the pharmacy groups "had a substantial likelihood of success" in winning their case on two grounds: that the Administration did not have the legal authority to establish the program and that it had not followed the proper rulemaking process.<sup>33</sup> On October 9, 2001, the Administration asked the court for a stay of the proceedings to allow it to use the formal rulemaking process for a new Medicare discount card proposal that could be different from the original one announced in July. On November 5, 2001, Judge Friedman issued a stay of the proceedings to allow HHS to submit "its proposed policy for notice and comment pursuant to the Administrative Procedure Act."<sup>34</sup> At a later date the judge stated that the stay of

<sup>&</sup>lt;sup>32</sup>CMS Fact Sheet, p. 4.

<sup>&</sup>lt;sup>33</sup>The Washington Post, "Judge Blocks Prescription Discount Plan," by Amy Goldstein, September 7, 2001, p. A01.

<sup>&</sup>lt;sup>34</sup>BNA *Health Care Daily.* "Court Allows HHS to Submit New Plan for Providing Medicare (continued...)

proceedings would continue only while HHS submitted its proposed policy for notice and comment. The plaintiffs, he stated, could return to court at any time after such a policy has been published.

CMS proceeded with the rulemaking process in late 2001 although CMS Administrator Thomas Scully acknowledged that the new prescription drug plan would need approval from a federal judge or be approved by Congress. On March 6, 2002, CMS issued a proposed rule for a Medicare-Endorsed Prescription Drug Card and Drug Discount Card Assistance Initiative (42 CFR Part 403) with a 60-day comment period. CMS issued the final regulation on September 4, 2002.

On September 13, 2002, the Department of Justice (DOJ) filed a motion with the U.S. District Court for the District of Columbia to require pharmacy groups to tell the court by September 20 whether they plan to proceed with the case against CMS and the Department of Health and Human Services to halt the program. DOJ asked that all motions in the case be filed by October 28, 2002. On September 27, 2002, pharmacies responded to this motion by rejecting the federal government's schedule for filing motions in the case, and suggested their own schedule in which they would file a motion to enforce the existing injunction in the case.

On January 29, 2003, Judge Paul Friedman held that the NACD demonstrated it had standing to show pharmacies would suffer economic harm from the Medicare discount card initiative. Judge Friedman rejected the argument by HHS Secretary Thompson that the federal government had the authority to implement the card program under the Medicare Beneficiary Assistance Act of 1990.<sup>36</sup> On the day of the ruling, CMS Administrator Tom Scully announced that CMS would be evaluating its options and continue to work with Congress to help strengthen Medicare and push for a comprehensive prescription drug benefit. He also stated that the court's decision hastened the "course of a likely appeal."<sup>37</sup>

#### **Economic Objections**

In addition to the procedural issues that the pharmacy associations successfully raised, they also criticized President Bush's Medicare discount card program on economic grounds. The coalition of pharmacy organizations, which represents all segments of pharmacy practice, issued a letter on July 11, 2001 to President Bush opposing any form of prescription discount cards.<sup>38</sup> The pharmacy associations argue

Discount Drug Cards," November 7, 2001.

<sup>&</sup>lt;sup>34</sup>(...continued)

<sup>&</sup>lt;sup>35</sup>BNA, *Daily Report for Executives*, "Justice Asks for Motion Schedule in Medicare Prescription Drug Card Case," September 18, 2002.

<sup>&</sup>lt;sup>36</sup>BNA, *Daily Report for Executives*, "Court Rejects Drug Discount Card, Finds Administration Exceeded Authority," January 30, 2003.

<sup>&</sup>lt;sup>37</sup>CMS Public Affairs Office, "Statement by CMS Administrator Tom Scully," January 29, 2003.

<sup>&</sup>lt;sup>38</sup>Eight organizations representing pharmacist owners, managers, and employees united to (continued...)

that discount card programs put the burden of cost reductions for seniors on the retail pharmacies. They say that the card programs do not reduce the prices that pharmacies pay for medications and claim that providing discounts will disproportionately reduce net profits of pharmacies vis a vis card sponsors and drug manufactures.

The final regulation of the Medicare drug card initiative is different from the original proposal in that card sponsors would be required to have contractual arrangements with drug manufacturers for rebates or discounts and a contractual mechanism for passing on the bulk of the rebates or discounts that are not required to fund operating costs to beneficiaries or pharmacies either through lower prices or enhanced pharmacy services. However, pharmacies remain concerned that the revised initiative would harm their profits because, although the card initiative requires card sponsors to pass discounts to beneficiaries, it does not stipulate how much of those savings should be given to seniors.<sup>39</sup>

The associations estimate that the price a pharmacy pays for the medications represents about 78 percent of the average prescription price. The remaining 22 percent represents gross margins, and after accounting for operating expenses, results in a net profit of only 2 percent. The pharmacies also claim that the proposal could limit seniors' access to the pharmacy of their choice and that price incentives would encourage the use of mail order pharmacies, resulting in an underutilization of lower-cost generic drugs. They argue that the formularies used by the card plans would not always include generic equivalents of brand name drugs, and, therefore, promote the use of brand name drugs. It is difficult to assess the statements made by the pharmacy associations, because the effect on pharmacies would depend on specific formularies and prices offered by the proposed card programs, which is information that is not publicly available

The National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores filed a declaration with the Washington, D.C. federal court on July 25, 2001 in support of the lawsuit filed against the federal government. The declaration by Stephen Schondelmeyer, Ph.D., Director of the University of Minnesota's PRIME Institute states that pharmacies will lose almost \$2 billion in revenues as a result of the discount card program and that 2,500 to 10,000 community pharmacies will cease to operate within three years if the card

<sup>&</sup>lt;sup>38</sup>(...continued)

oppose President Bush's discount card program. The organizations include the National Community Pharmacists Association (NCPA), the American College of Clinical Pharmacy (ACCP), the American Pharmaceutical Association (AphA), the American Society of Consultant Pharmacists (ASCP), the American Society of Health-System Pharmacists (ASHP), the Food Marketing Institute (FMI), the National Association of Chain Drug Stores (NACDS), and the National Council of State Pharmaceutical Association Executives (NCSPAE).

<sup>&</sup>lt;sup>39</sup>BNA, *Daily Report for Executives*, "CMS Releases Final Rule Establishing Program for Medicare Discount Drug Card," September 3, 2002.

<sup>&</sup>lt;sup>40</sup>NCPA news release. NCPA, Others Issue Letter to the President Opposing Discount Card Program. July 12, 2001.

program is implemented. According to Schondelmeyer's declaration, the card program would encourage the use of mail order pharmacies which would steer card users away from retail pharmacies. Schondelmeyer also states that the card discounts would reduce profit margins for pharmacies.<sup>41</sup>

**CRS-19** 

Although drugstores' profit margins on prescription drug sales may decrease as a result of discount cards, some analysts believe that overall net profits may increase due to larger volumes of prescription drugs sold and higher sales in nonpharmaceutical items. While the profit margins of drug stores have fallen considerably since the 1970s, recent data suggests that this trend may change in coming years as prescription drug sales increase. A recent Standard and Poor's (S&P) *Industry Survey*<sup>42</sup> reported that drugstores' gross profit margins were expected to fall again in 2001, as they had in 2000 and 1999, due to increases in prescription drug sales to third-party plans. 43 For the drugstore industry as a whole, however, total sales increased 7.7%. The number of prescriptions dispensed by traditional drugstore chains increased 7.1% in 2000, while that of independent drugstores increased by 0.3%. The S&P report indicated that rising prescription volumes helps increase the sales of over-the-counter drugs and front-end merchandise (nonpharmacy-related goods) which accounts for the overall net profit increase of 6% for the drugstore industry in 2000.<sup>44</sup> In the larger chains, such as CVS and Walgreens, net income increased an average of 19.5%. Although gross margins have been falling in recent years, the S&P report indicated that these are expected to improve in the long term as drugstore chains negotiate better agreements with third-party payers, and decline to renew plans that are marginally profitable.<sup>45</sup> The S&P report did not evaluate the potential impact of the Administration proposal.

The lack of available information on the details of the President's discount card proposal for seniors makes it difficult to assess the potential economic impact on retail pharmacies. The Administration has issued general statements about the expected size of the discounts and has stated that the administrative cost of the program would primarily be borne by the card sponsors. However, very little information has been issued on potential card sponsors and their individual programs. Until the details on individual card programs are available, an analysis on the economic impact on pharmacies would be based on speculation of how the Administration plans to modify its original proposal and how card sponsors would determine their discounts.

<sup>&</sup>lt;sup>41</sup>Declaration of Stephen W. Schondelmeyer, Pharm.D., Ph.D., filed by the National Association of Chain Drug Stores and the National Community Pharmacists Association in the United States District Court for the District of Columbia, July 25, 2001.

<sup>&</sup>lt;sup>42</sup>Standard and Poor's. *Industry Surveys, Supermarkets and Drugstores*. August 2, 2001.

<sup>&</sup>lt;sup>43</sup>Gross profit margins are calculated as net sales minus the cost of goods sold, as a percentage of gross sales. Gross margins reflect a company's product mix and operational efficiency.

<sup>&</sup>lt;sup>44</sup>Net income is the difference between total sales and total expenses, commonly called the "bottom line". The net profit margin is net income as a percentage of net sales.

<sup>&</sup>lt;sup>45</sup>Standard and Poor's, pp. 5-6.

#### **Observations**

The proposal for a Medicare discount card program was presented as an interim attempt to meet an immediate need. On several occasions, the Congress has considered providing coverage for at least a portion of beneficiaries' drug costs. The issue received renewed attention in the  $106^{th}$  and  $107^{th}$  Congress. However, there was no consensus on how the coverage should be structured. In the  $108^{th}$  Congress, Representative Mark Foley introduced a bill (H.R. 513) in the House on January 31, 2003 to authorize the Secretary of HHS to endorse prescription drug discount cards for use by medicare beneficiaries. The bill would give the Administration legal authority to implement the Medicare drug discount card initiative.

While it may not be essential that a senior drug benefit be administered through a pharmacy benefit manager (PBM), it seems clear that PBMs now play a major role in U.S. healthcare delivery. According to a report prepared by PriceWaterhouseCoopers LLP for the Health Care Financing Administration, "PBMs manage the drug benefits of approximately 70% of the United States, including approximately 65% of our country's seniors." In the debate over the Administration's drug discount card plan, the central role of PBMs has clearly emerged as an issue, especially for the retail pharmacy sector. The issues that retail pharmacies have raised with PBMs go well beyond President Bush's Medicare discount card proposal. In fact, the 2001 Drug Topics' Redbook characterized the relationship as follows:

Pharmacy benefit managers - can't live with 'em, can't live without 'em. Most pharmacists would only agree with the first option, while insurers and payers might lean more toward the second description. Survey after survey points to the idea that pharmacists find third-party issues to be the toughest they deal with. ... <sup>47</sup>

For Congressional critics, discount cards are not seen as a solution to high costs of prescription drugs for uninsured or partially insured seniors. They point to the existence of numerous discount programs and argue that even with plans that possibly deliver a 10% to 25% discount, the problem of high drug prices remains a serious one. The prices of pharmaceutical products charged by pharmaceutical manufacturers have been identified by some Members of Congress as a special problem requiring congressional action. The complexity of drug pricing procedures makes it difficult to understand how the system operates, let alone devise policies that make it possible to deliver prescription drugs to seniors at prices comparable to those paid by clients of third-party purchasers (PBMs) and their sponsors (employers, insurers, HMOs, and drug discount card sponsors). If the President's revised discount program proposal manages to resolve the issues raised by the pharmacy industry, Members of Congress may still raise concerns about whether seniors will get prescription medications at affordable prices.

<sup>&</sup>lt;sup>46</sup>PriceWaterhouseCoopersLLP. Study of Pharmaceutical Benefit Management. HCFS Contract No. 500-97-0399/0097. June 2001. p. 14.

<sup>&</sup>lt;sup>47</sup>Drug Topics' Redbook, 2001, p. 94.

Discount drug programs may provide additional discounts to seniors, although it is possible that many of the covered drugs would still remain expensive for low-and middle-income seniors who do not have health insurance that covers prescription drugs. Nevertheless, there is anecdotal evidence that suggests that consumers who are willing to comparison shop on the Internet for prescription drugs can, in some cases, match or beat discount card prices. The difficulty that the Administration and Congress face in developing a senior drug benefit will be to develop a policy that delivers necessary medications to seniors, while providing pharmaceutical manufacturers, wholesalers, PBMs, and pharmacists with incentives to continue to participate in the marketplace.

In summary, a Medicare-endorsed discount card program might provide some savings on prescription drugs for seniors, although the net overall effects are not clear because of the lack of details on the individual card programs. The broad effect on the senior population would depend on the size of the discounts and the formularies that the plans offer. The size of the discounts would depend on whether the card program would provide sufficient market leverage for card sponsors to negotiate higher manufacturer rebates from drug manufacturers. Seniors could benefit from certain features of the discount card program, such as more access to information on drug prices and formularies offered by the different plans. This information could enhance seniors' abilities to comparison shop and save money by choosing the plan that would best fit their needs. President Bush's revised proposal could offer seniors some savings on medications, depending on the final details of the various card plans. As noted earlier in this report, critics of the Bush plan believe that the Medicare-endorsed discount cards would not bring additional benefits for seniors. They have argued that the benefit is very minimal and duplicates a service (discount cards) that the marketplace already provides.<sup>48</sup>

The two most important concerns for pharmacists are related to (1) who bears the burden of the cost for the Medicare-endorsed discount card proposal and (2) the fear that card sponsors would structure their programs in such a way that seniors are induced to switch from their local pharmacies to mail order pharmacies for their prescription drug purchases. The overall effect on pharmacies would likely depend on the potential agreements they reach with the card sponsors and whether the card sponsors pass a portion of the drug manufacturer rebates to the pharmacies.

Seniors are equally concerned that discounts are passed all the way through the system to the ultimate intended beneficiaries. The effect on pharmacies would also depend on the response of seniors to the card program and whether they would continue shopping at retail pharmacies for their prescription drug purchases or use more mail-order options to save money. While seniors and others who must get a prescription filled quickly will continue to patronize their local pharmacies, deeper discounting by PBM-owned or operated mail order pharmacies could lead to

<sup>&</sup>lt;sup>48</sup>See U.S. House of Representatives, Committee on Government Reform, "Problems with Prescription Drug Cards," prepared for Rep. Henry Waxman by the Minority Staff, July 12, 2001; The Seniors Coalition, "Medicare Prescription Discount Card Could Limit Seniors' Access to Medicines and Increase Drug Costs, Warns The Seniors Coalition," October 19, 2001, [http://www.seniors.org].

CRS-22

behavioral changes among those seniors who have an ongoing need for prescription drugs to treat chronic conditions.