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

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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 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 at a maximum enrollment rate of $25 per plan. Since the announcement of President Bush's proposal, several pharmaceutical companies announced that they would offer 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 25% 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, including formularies and the level of discounts, which are not yet available. Much depends on whether the card program would provide sufficient market leverage for card sponsors to negotiate lower drug prices from drug manufacturers and whether the card sponsors and pharmacies agree upon acceptable reimbursement rates for the pharmacies. 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.

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 filed a lawsuit against CMS on July 17, 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. In September 2001, a federal judge issued an injunction. The Administration proceeded with plans to modify the program and use a formal rulemaking process for a new proposal. On February 28, 2002, the Administration announced the revised proposal which would require card sponsors to share manufacturer rebates or discounts with Medicare beneficiaries. On March 6, 2002, CMS issued a proposed rule for the card program with a 60-day comment period. CMS and pharmacies are awaiting a ruling by the court on whether it will allow the rulemaking process to continue. This report will be updated as events warrant.

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Introduction

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.[1]

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. The plan was originally scheduled to be in effect in January 2002, but it has been put on hold because of a federal court order that prevented the program from being implemented (see section below on Pharmacists' Challenge to Medicare Discount Card Program). The Administration proceeded with plans to modify the program and use a formal rulemaking process for a new proposal. On February 28, 2002, the Administration announced the revised proposal which would require card sponsors to share manufacturer rebates or discounts with Medicare beneficiaries. 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 and pharmacies are awaiting a ruling by the court on whether it will allow the rulemaking process to continue.

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. One major difference is that the discount cards offered under the President's plan would be Medicare-endorsed and

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[1]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.

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 endorsed card plan.

This report will discuss 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, 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.[2] 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.[3] 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 (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.[4]

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

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[2]Poisal, John A. and Lauren Murray, "Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage," *Health Affairs*, March/April 2001.

[3]Ibid.

[4]Ibid, pp. 81-82.

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.[5] 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 announced that they would offer their own senior discount card plans beginning in early 2002. (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.[6] 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 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

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[5]*The New York Times*, "'Buyers' Clubs' for Medical Services Crop Up," by Milt Freudenheim, Aug. 25, 2000.

[6]For more information on formulary development see CRS Report RL30754, *Pharmacy Benefit Managers*, by Christopher J. Sroka.

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.[7]

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.

Recent Senior Discount Card Plans

A number of pharmaceutical companies recently announced the development of new discount card plans for low-income seniors. GlaxoSmithKline (GSK), Novartis, Pfizer, Eli Lilly, and a coalition of seven pharmaceutical companies have 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,

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[7] *Managed Care*, "Getting Serious About Formularies, " by Jean Lawrence, March 1998.

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.[8]

- 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.[9]

- 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.[10]

- 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 drug for $12. The company estimates that card users could save up to $850 per drug per year.[11]

- *Together Rx Card* from Abbott Laboratories, 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.[12]

- 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

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[8]GlaxoSmithKline Fact Sheet, *GlaxoSmithKline - Orange Card Key Facts*, undated.

[9]Novartis Fact Sheet, *Fast Facts: Novartis Care Card*[sm], undated. For more information, see [http://www.novargis.com/carecard/fast_facts.shtml].

[10]Pfizer Fact Sheet, *The Pfizer for Living Share Card*[TM] *Program*, undated. For more information, see [http://www.pfizer.com/pfizerinc/about/sharecard/factsheet.html].

[11]Eli Lilly Fact Sheets, *LillyAnswers*, undated. For more information, see [http://www.lillyanswers.com/questions_answers.html].

[12]Bureau of National Affairs, *Daily Report for Executives*, "Drug Companies to Unveil Joing Medicare Prescription Drug Card," April 10, 2002.

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.[13] 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.[14] 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.[15]

Description of the President's Drug Discount Card Proposal

The President's Medicare-endorsed prescription drug discount card program is currently on hold as a result of the injunction issued on September 6, 2001. The court allowed CMS to use a formal rulemaking process for a modified version of the original program. This section describes general features of the program as originally proposed, but that also apply to the revised version of the proposal, and key features of the revised proposal.

Original Discount Card Program

President Bush's proposal was a voluntary program that was, in many respects, modeled on existing plans offered by private companies, membership associations, and pharmacy benefit managers.[16] The primary objective of the President's program was to provide Medicare beneficiaries immediate prescription drug benefits at discounted prices. Under the program, Medicare beneficiaries would have the ability to obtain a discount card from one of a number of card sponsors. Each card would offer discounts from the retail prices of certain prescription drugs.

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[13]National Association of Chain Drug Stores news release, "Pharmacy Care Alliance Stacks Multiple Drug Savings Into One Senior Benefit Card," March 11, 2002.

[14]National Journal Group, Inc., *American Health Line*, "Rx Discount Cards: More Available, But Do They Help?," February 8, 2002.

[15]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.

[16] Centers for Medicare and Medicaid Services website, http://www.cms.gov.

The Medicare-endorsed card programs would be different from existing plans in that they would be required to provide cardholders 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.

The President's program would endorse and promote a number of qualified privately-administered prescription drug discount cards. It is unknown whether the program would have used existing discount cards or would have created new card programs that would have qualified for endorsement by Medicare.[17] The Medicare-endorsed card programs could charge no more than a maximum one-time enrollment rate of $25 per plan. Medicare beneficiaries would be given the option to choose one card from the card programs offered by competing private companies, but could change plans on a semi-annual basis. The Medicare card sponsors would be required to provide informational materials to beneficiaries, which would include information on drug prices, formularies, and pharmacy networks of all Medicare-endorsed prescription drug discount card programs. The intention was to help beneficiaries compare plans and choose the one most appropriate for their needs.

Program Administration. As proposed, President Bush's drug discount card program 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 annual certification of card providers based on criteria that included 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 would 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.

Endorsement of Card Sponsors. Each company endorsed by the Medicare discount card program would be responsible for administering the discount card plan it is offering and determining the discount amounts and formulary. Card sponsors would enter into the program on a voluntary basis and not charge any fees to CMS.

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[17] CMS received 28 applications from private entities for Medicare-endorsement of their proposed discount card plans. The names of the applicants were not released, but CMS stated that not all were pharmacy benefit managers.

They would be required to enroll all Medicare beneficiaries wishing to participate in their program and provide a discount on at least one brand and/or generic prescription drug in each therapeutic category. Card sponsors would have to guarantee that for drugs listed in the program formulary, beneficiaries would receive the lower of the program's discounted price or the price the pharmacy would pay a charge-paying customer. They would also be required to offer cardholders retail access to a national or regional pharmacy network. The company would be expected to use volume leverage and market-share agreements to secure discounts or rebates from drug manufacturers and pharmacy networks.

Endorsed card sponsors would be required to have at least five years of private sector direct experience in the United States in pharmacy benefit management or in providing a discount card program. They also would have to demonstrate experience in managing at least two million covered lives in an insured national pharmacy benefit or drug discount card program, and one million covered lives in a regional program.

Card sponsors could offer value-added information services such as advice on medications and prescription interactions. Card sponsors could offer discount mail order services for prescription drugs, but only as an optional service because, according to the Administration, the main objective of the program was to provide retail pharmacy discounts. Card sponsors could also market additional services to cardholders, but could not make participation in these services mandatory. Card sponsors could utilize cost-containment strategies that are common in private plans, such as formularies, preferred networks, and patient and physician education programs.

Consortium. Sponsors of the Medicare-endorsed card plans would be responsible for participating in and financing a consortium to handle all enrollment and eligibility functions and avoid duplicate card issuance. The consortium would manage a joint computer system to permit seniors to compare card programs using basic information on formulary content, networks, and discounts, as well as the mail order options offered by the various card programs. The system would be in place soon after the card program implementation. During the first year of the program, CMS would expect the system to have information on the anticipated discounts and prices, expressed as a percentage of the average wholesale price (AWP), as reported by FirstDatabank. By the second year, CMS would expect the consortium to publish the actual prices that beneficiaries would pay. Card sponsors would be required to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and related privacy rules and regulations.

Pharmacy Participation. Retail pharmacies participating in Medicare-endorsed card programs would agree to belong to a network of pharmacies arranged by the card sponsor. Most pharmacies already belong to one or more networks organized by PBMs. To obtain discounts, card holders would be required to use the pharmacies belonging to the card network. 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 note 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.[18] As proposed, the main stated objective of the President's discount card program was to offer discounts for seniors at retail pharmacies, although mail order services would also be an option.

Pharmacies have opposed the card program alleging the discounts will effectively lower the prices they charge for prescription drugs without reducing their costs for covered drugs, thus reducing or eliminating their profit margin. They also argue that the card programs' sponsors would encourage seniors to use more mail order services instead of retail pharmacies for their prescription drug purchases.

Expected Discounts: Diverse Estimates. The savings provided by the program were 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. The educational aspect, consisting of the informational material on drug prices, formulary content, and the pharmacy network offered by the card program, was intended to improve the ability of consumers to comparison shop and choose the plan that meets their needs at the lowest cost.

The Bush administration suggested that seniors would be able to obtain a 10% to 25% discount on prescription drug retail purchases through the Medicare-endorsed card program.[19] A fact sheet issued by the White House indicated that seniors could receive up to 24% reduction in costs per person, relative to 'usual and customary' (U&C) prices. The fact sheet mentioned two pharmacy benefit manager (PBM) reports that estimate the amount of savings beneficiaries would receive under their programs. One report states that seniors would save an average of 23% at a pharmacy or 32% through a mail-order program, relative to U&C prices for the top four brand name drugs used by seniors. Another report states that for the top seven brand drugs used by seniors, seniors would save 20% at a pharmacy or 26% through mail order. For generic equivalents, estimated savings on U&C prices may be even greater: 40% at a pharmacy and 50% through mail order.[20]

Some observers have commented that the Bush Administration's proposed discount program would probably provide seniors with some savings on their overall prescription drug bill. Questions have been raised about the actual size of the discounts that will be available. Specific information is not available on the discount amounts and formularies the proposed discount cards would have provided. The actual size of retail discounts may not be known until after the first year of program

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[18] 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.

[19]U.S. Department of Health and Human Service (HHS), *HHS News*, "Medicare will Endorse Discount Programs, Giving Purchasing Power to Beneficiaries for Drug Savings," July 12, 2001.

[20] White House Fact Sheet, "The President's Medicare Prescription Discount Program," undated.

operation. However, it is possible to compare prices available through existing discount card programs to those at retail pharmacies or Internet pharmacies. One of the constraining factors in conducting this kind of analysis, however, is the lack of widely available data on retail drug prices.

The U.S. General Accounting Office (GAO) recently completed a study on prescription drug prices for seniors offered by drug discount card programs, local pharmacies, or over the Internet.[21] 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 $7.62, or 13%, higher in rural Georgia than in Seattle, Washington.[22]

Critics of President Bush's program dispute the Administration's statements of potential discounts of up to 25%. Retail pharmacy groups, consumer groups, and some Members of Congress believe that the program is not likely to produce significant savings for seniors. Some Member 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.[23] Some Members of Congress have stated that the Bush proposal would provide only minimal savings for seniors and that the program would not offer additional 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

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[21]General Accounting Office, Report No. GAO-02-280R, *Prescription Drugs: Prices Available Through Discount Cards and From Other Sources*, December 5, 2001.

[22]Ibid, p. 4.

[23]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.

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.[24]

Proposed Regulations to Establish Card Program

The proposed regulations for the Medicare-Endorsed Prescription Drug Card and Drug Discount Card Assistance Initiative specify general rules for the Medicare-endorsed prescription drug card program. The proposed regulations would establish a revised version of the original discount card program proposed by President Bush in 2001. The revised program is similar to the original version, but with more detail on how the program would operate. A key difference in the revised version is that it would require card sponsors to pass discounts or rebates from drug manufacturers to pharmacies and beneficiaries. Card sponsors applying for endorsement would be required to submit an application and meet all the requirements outlined in the proposed regulations.[25]

In the revised program, Medicare endorsement would be effective for 15 months in the first year of the program. October 1, 2002 would be the first date that programs would begin marketing and enrollment. Endorsed programs would have to begin enrollment and discounts no later than January 1, 2003. Under the original proposal, CMS was to have announced endorsements of the 14-month agreements on September 14, 2001, with the first cycle beginning on November 1, 2001 and ending on December 31, 2002.[26]

Unlike the original proposal, in which card sponsors would not have been required to share drug manufacturer rebates with the pharmacies in the network, the revised version includes a requirement to pass manufacturer discounts to pharmacies and beneficiaries. Card sponsors seeking Medicare endorsement of their card program would have to ensure that a substantial share of the manufacturer rebates or discounts is provided to beneficiaries either directly or indirectly through pharmacies. The preamble to the regulations states 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.

The revised 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 and offering its own endorsement and having a distinct card. In a separate Notice issued on March 6, 2002, CMS outlined

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[24]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 [http://www.house.gov/reform/min/inves_prescrip/index.htm].

[25]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.

[26]CMS Notice of Application for Medicare-Endorsed Rx Discount Card Initiative.

additional steps it was considering to support state efforts to make affordable drugs more readily available and invited public comments on these efforts.

CMS solicited comments on a number of issues in the proposed regulation. 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 seek numerous changes before a final rule is 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".[27] Pharmacy groups issued a comment saying CMS should withdraw the proposed rule. Pharmacies maintain that the discount card program would hurt pharmacy profits and that CMS lacks the statutory authority to implement the plan. CMS and pharmacy groups are awaiting a ruling by the court on whether it will allow the rulemaking process to continue.

Administration Arguments in Support of Discount Card Program

President Bush 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.

The Bush administration highlighted four key elements that it believed would make the Medicare-endorsed cards different from existing discount cards.[28] The first was that the Medicare discount card programs would have a lower enrollment fee than most existing programs. Administration officials estimated that drug discount card programs usually had annual enrollment fees of $15 to $125, while the Bush plan would have a maximum one-time enrollment fee of $25 per plan. This would be comparable to that of several other popular discount card plans. Two existing discount card programs, AARP and YOURxPLAN, have enrollment costs of $10 and $25, respectively. Another card program recently announced by Citizens Health, which will be offering retail discounts on prescription drugs, has a membership cost of $12 for an individual and $28 for a family.[29] On the other hand, most other card programs charge a yearly fee, while the enrollment fee for a Medicare-endorsed program would be paid only once per plan.

The second difference mentioned by the Administration is that President Bush's plan was expected to offer larger discounts because the membership in the Medicare-endorsed programs would be better defined. The Administration believed this could

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[27]BNA, *Daily Report for Executives*, "SBA, Interest Groups Seek Changes in Medicare Discount Card Proposal," May 9, 2002.

[28]HHS Fact Sheet, p. 3.

[29]*The Green Sheet*, "Bristol, Glaxo Offering Rx Discounts Through Citizens Health Card Program," October 8, 2001.

help card sponsors negotiate bigger discounts for beneficiaries. 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. It is difficult to assess whether the President's proposed program would result in further discounts than the various options that are currently available in the marketplace.

Third, the Administration believed that the "one-stop-shopping" feature of the Medicare-endorsed card program would benefit seniors in that they could compare 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 enrollment fees of up to $25 per switch. 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.

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.

Another factor to consider is whether the card sponsor plans under the proposed Medicare program include drug utilization review 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. Drug utilization review may prevent the duplicative use of drugs that fall within the same therapeutic category, thereby enhancing patient safety while lowering prescription drug costs. Also, promoting lifestyle changes which may improve overall health could lessen the dependence on prescription drugs. Some observers have suggested that a Medicare-endorsed card plan should be careful in using the Medicare name for private discount card plans. They believe that a Medicare card program should have strict standards and controls in the structure of the individual plans and that these should be established by Medicare and not by the private card sponsors. Other observers have suggested that a Medicare card program be transparent and provide detailed information on prices and where the discounts are coming from.

The final point mentioned by the Administration was that because the discount card was 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 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. The consortium of card sponsors would be required to provide information on key characteristics of the various card programs and this could lead to an improvement of marketing materials and drug price information for seniors. However, for the many seniors who do not have access to a computer or the Internet, published information would continue to be the most important vehicle for ensuring that program participants realized 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 managed the consortium and provided customer service.

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 Secretary Tommy Thompson and the CMS Administrator Tom Scully to block the Administration's prescription discount card program. 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.[30] 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. The NACDS/NCPA opposed the motion for a stay on the grounds that HHS does not have the statutory authority to implement it. The Administration responded by submitting a memorandum to the court seeking permission to undertake rulemaking to develop a new card proposal. The Administration stated that it would take several months to finalize the new policy on the card program. 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."[31] On November 8, 2001, Judge Friedman issued a clarification of his order

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[30]*The Washington Post*, "Judge Blocks Prescription Discount Plan," by Amy Goldstein, September 7, 2001, p. A01.

[31]BNA *Health Care Daily*. "Court Allows HHS to Submit New Plan for Providing Medicare (continued...)

granting the defendant's motion for a stay of proceedings. The judge stated that he had not lifted the preliminary injunction, but that he had granted a stay of "court proceedings in reliance upon defendants' express representation that they will continue to comply with the injunction and will not take steps to implement the Medicare Prescription Discount Card Program...".[32] Judge Friedman also noted that HHS is not going forward with its original program, but instead will be proposing a new policy on the issue, which will be published for comment. In addition, he wrote that the stay of proceedings will continue only while HHS submits its proposed policy for notice and comment. The plaintiffs, he stated, may return to court at any time after such a policy has been published.

On November 19, 2001, CMS Administrator Thomas Scully announced that CMS intended to publish a proposed rule with comment period by December 2001. Scully acknowledged that the new prescription drug plan would need approval from a federal judge or be able to be implemented by a law passed by Congress that the President would have to sign. According to Scully, the November 5 decision to stay the lawsuit will require the judge to rule on the legality of the new proposal before a final rule could be issued.[33] On December 14, 2001, a federal judge stated that the legality of the new proposal will be decided when the pharmacies ask the court to review it, which is expected to happen as soon as the proposed rule is issued. Alternatively, Scully noted that Congress could grant the Administration the statutory authority to proceed.[34]

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.[35] The pharmacy associations argue 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

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[31](...continued)
Discount Drug Cards," November 7, 2001.

[32]U.S. District Court for the District of Columbia. Judge Paul L. Friedman. *Memorandum Opinion to Clarify Order Staying Proceedings.* November 8, 2001.

[33]*Daily Report for Executives.* "CMS Chief Says New Drug Card Proposal with 'More Meat on its Bones,' Coming Soon," November 20, 2001.

[34]Ibid.

[35]Eight organizations representing pharmacist owners, managers, and employees united to 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).

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 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.[36] 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 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.[37]

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 non-pharmaceutical 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*[38] 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.[39] 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

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[36]NCPA news release. *NCPA, Others Issue Letter to the President Opposing Discount Card Program.* July 12, 2001.

[37]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.

[38]Standard and Poor's. *Industry Surveys, Supermarkets and Drugstores.* August 2, 2001.

[39]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.

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.[40] 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.[41] 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.

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 106th Congress. However, there was no consensus on how the coverage should be structured. In the 107th Congress, numerous bills have been introduced to provide a Medicare prescription drug benefit. The House Ways and Means Committee and House Energy and Commerce Committee are considering a Medicare reform and prescription drug benefit bill (H.R. 4954) proposed by Republican Members. The bill includes a provision to provide authority to the Medicare Benefits Administrator to establish a Medicare prescription drug discount card endorsement program and would give the Administration legal authority to implement such a program.

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

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[40]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.

[41]Standard and Poor's, pp. 5-6.

approximately 65% of our country's seniors."[42] 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. ... [43]

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.

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.

Numerous approaches have been suggested for providing a Medicare drug benefit. Some policymakers have suggested that the Administration not focus on interim solutions and instead work toward providing a more significant benefit under a reformed Medicare program. Others have stated that alternative approaches for a Medicare card program could require drug companies to sell prescription drugs to seniors at certain price levels, such as those the companies offer to the federal

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[42]PriceWaterhouseCoopersLLP. Study of Pharmaceutical Benefit Management. HCFS Contract No. 500-97-0399/0097. June 2001. p. 14.

[43]Drug Topics' Redbook, 2001, p. 94.

government and other major purchasers.[44] Pharmaceutical manufacturers have asserted in the past that such requirements could remove market incentives for investing in research and development for advancements in the treatment of conditions such as strokes and asthma. Critics have disputed such claims.

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.[45]

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

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[44]Letter to HHS Secretary Tommy G. Thompson on January 3, 2002 from six Members of Congress. For more information, see [http://www.house.gov/reform/min/inves_prescrip/index.htm].

[45]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].