



Designing a Medicare Drug Discount Card: Implications of Policy Choices For Medicare Beneficiaries and Card Sponsors

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Executive Summary

This report analyzes the issues surrounding the design and implementation of a Medicare prescription drug discount card program. Prescription drug discount cards have figured prominently in the recent federal policy debate over how to help Medicare beneficiaries manage the rapid increases in their out-of-pocket expenditures for prescription drugs. Proponents of this policy argue that a drug discount card program could help lower prescription drug costs for millions of Medicare beneficiaries – particularly those who lack drug coverage—at relatively low cost to the federal government.

In July 2001, President Bush called for the Medicare program to endorse qualified private-sector drug discount cards and to promote beneficiary participation in these programs. The Department of Health and Human Services has tried to use its regulatory authority to implement a discount card program for Medicare beneficiaries, but that effort has been blocked by a federal court ruling that the Administration lacks statutory authority to implement its plan absent explicit congressional approval.

In the 108th Congress, the discount card issue has been joined with the larger discussion of a Medicare prescription drug benefit. In June 2003, both the Senate and the House of Representatives included a discount card program as a component of their respective proposals to create a Medicare prescription drug benefit. In both proposals, a Medicare discount card program would operate as an interim arrangement during 2004 and 2005, and it would sunset when the Medicare “Part D” drug insurance benefit became available in 2006. The congressional proposals have also added an important new element to the debate, with each bill proposing that the Medicare discount card issued to low-income beneficiaries also operate as a “debit card” that has a fixed initial dollar value, which beneficiaries would use to subsidize prescription drug purchases until the debit account is depleted.

The current debate has caused policymakers and others to focus on how well current discount card programs work and on how the Medicare program could be used to increase the opportunities for beneficiaries to benefit from discount card arrangements. The regulatory effort by the Department of Health and Human Services and the recent debate in Congress have identified a number of important issues around the design of a Medicare discount card program, which are discussed in this paper. Some of these issues would be important in any discussion of a Medicare discount card program, while others stem from the accelerated implementation and temporary nature of the discount card programs contained in the pending House and Senate Medicare bills.

The purpose of this report is to identify key policy design issues in a Medicare drug discount card, and to consider the implications of those issues from a beneficiary interest perspective. This report examines five key policy areas:

1. **Consumer Value:** How would Medicare discount cards achieve savings for beneficiaries? Would beneficiaries save money on their prescriptions as a result of the new Medicare discount card program, and how will they know it? Given that information about the real costs of prescription drugs is not publicly available, how should the value of discounts provided by discount card sponsors be presented to consumers? What would be the implications of requiring that a card sponsor assure a minimum level of savings as a condition of participating in the program, or of requiring that card sponsors disclose the value of their rebates from manufacturers and other price discounts? Should there be limits on the claims that card sponsors can make about their discounts?
2. **Product Design and Consumer Safeguards:** To what extent should a Medicare discount card program set standards around program features such as formularies and pharmacy networks? Should there be limits to how often a card program sponsor can change its preferred drug list or the prices of the drugs on the list, and if so, what are the implications of those limits for beneficiaries and sponsors? Should beneficiaries be locked-in to the card sponsor they choose for some minimum period of time, and if so, should there be exceptions if manufacturers make significant mid-year changes in the price of prescriptions? Should card sponsors be required to contract with any pharmacy that agrees to meet the sponsor's terms? How could standards be designed to protect Medicare beneficiaries' interests without disabling the economic incentives for card sponsors to participate and generate savings?
3. **Timeframe for Implementation and Termination of Program:** What are the challenges of implementing the discount card program within a short period after enactment, and of having the program expire by January 2006? How would the abbreviated implementation timeline and short program duration proposed in the House and Senate bills affect the ability of a discount card program to provide value to beneficiaries? Would card sponsors be willing to make changes to their current discount card programs in order to participate in a Medicare discount card program that is scheduled to last for less than two years? If the Medicare discount card program were to simply rely on endorsing existing discount card arrangements, what new value would it bring to beneficiaries? Could the subsidy provisions called for in the House and Senate bills be implemented effectively within the contemplated timeframe? Could a discount card program be extended beyond January 2006 if a significant number of Medicare beneficiaries perceive it to be preferable to the Medicare prescription drug benefit slated to replace it?

4. **Subsidies for Low-Income Beneficiaries:** What are the administrative implications of requiring card sponsors to administer subsidies for low-income Medicare beneficiaries who are not also eligible for Medicaid?
5. **Regulatory Oversight:** What type of regulatory oversight should be incorporated into the drug discount card program, particularly in light of the proposed Medicare endorsement? What systems should be in place to resolve beneficiary complaints? Given the history of marketing abuses involving products targeted to Medicare beneficiaries, and the likely confusion for beneficiaries that would result from the use of the word “Medicare” on privately-operated discount card programs, should CMS (or some other federal or state agency) establish standards for marketing activities and review marketing materials?

Conclusions—Using the framework of these five issues, we analyzed the Medicare drug discount card provisions in the House-passed and Senate-passed Medicare reform bills (H.R. 1 and S. 1), as well as the Bush Administration’s regulatory proposal from 2002. That analysis resulted in the following conclusions:

- A Medicare discount card program has the potential to provide modest but measurable consumer value, in the form of lower retail prescription drug prices that would be paid by Medicare beneficiaries who do not have any other form of prescription drug coverage. In theory, by requiring beneficiaries to enroll exclusively in one discount card for a year at a time, and by giving card sponsors the ability to implement a formulary, the new Medicare drug discount card program should give card sponsors new negotiating leverage with drug manufacturers and retail pharmacies to obtain price concessions on behalf of cardholders. The value that beneficiaries ultimately realize would depend on several factors, including how much price competition there would be among Medicare discount card sponsors, i.e. how drug price information would be made available to beneficiaries and how they respond to this information; the ability of card sponsors to structure product offerings that include formularies (which are used by health plans and pharmacy benefit managers to obtain manufacturer price concessions in prescription drug benefit programs but typically are not found in commercial discount card offerings); the adoption of price disclosure requirements that would not reduce card sponsors’ negotiating leverage with drug manufacturers; and the ability of card sponsors to limit the number of pharmacies in their networks in order to enhance the sponsors’ leverage in negotiations with pharmacies over dispensing fees.
- A discount card “exclusivity” requirement like that contained in both pending Medicare bills and in the Bush Administration’s 2002 regulatory proposal could reduce savings for some Medicare beneficiaries, even as it enables card sponsors

to negotiate price discounts from manufacturers on behalf of beneficiaries. Currently, beneficiaries who purchase multiple discount cards might use them to maximize their individual savings by using the combination of cards that gives them the highest return for their particular prescription drug needs. For these individuals, a policy that limited them to only one Medicare discount card might make it difficult for them to sustain their current level of savings. On the other hand, a policy requiring exclusive enrollment in one Medicare discount card, combined with the flexibility to implement a formulary, might give card sponsors sufficient negotiating leverage with drug manufacturers (which they generally do not have with current card programs) to obtain price concessions on behalf of cardholders.

- The incentive for card sponsors to participate could be dampened if federal policymakers require that the Medicare discount card program be implemented and then terminated in a relatively short timeframe. As a practical matter, any new program that uses Medicare's name and prestige to encourage purchase of a private product would contain minimum standards for appropriate conduct. The administrative complexity and new conditions of participation for card sponsors that necessarily would accompany such a new program, when combined with a sunset date less than two years following implementation, could significantly complicate decisions by private firms about whether to participate in the program. Card sponsors would need to calculate whether they could recoup the investments that they would need to make to adapt their current card programs to the new standards in the limited period of time that the program is intended to operate.
- Some Medicare beneficiaries who enroll in the new discount card program might resist giving it up to enroll in the new Medicare Part D prescription drug benefit scheduled to start in January 2006. Under either the House or Senate legislation, the new Part D benefit would require Medicare beneficiaries to bear significant cost-sharing liabilities. Most Part D enrollees would be required to make monthly premium payments estimated by the Congressional Budget Office to be an average of \$35 per month in 2006 (actual premium liabilities would vary based on the cost of Part D coverage in the particular region of the country in which a beneficiary resides), would pay from 20 to 50 percent of covered benefit costs, and have a large gap (the so-called "donut hole") in the amount of their drug spending covered by Medicare. These aspects of Part D could lead some beneficiaries to perceive, rightly or wrongly, that they would be worse off under the Part D benefit than they would be if they did not enroll in Part D but kept participating in the discount card program. If this group of beneficiaries is large or vocal, it could prove politically difficult to phase out the discount card program.

- The Centers for Medicare and Medicaid Services (CMS) would face extraordinary operational challenges in implementing a discount card program within the timeframes proposed in H.R. 1 and S. 1 (i.e., within 90 days of enactment or by January 1, 2004, respectively). To improve the chances of a smoother program launch, Congress could provide CMS with a longer implementation period so it can complete the final rule-making process, followed immediately by bidding and contracting with discount card sponsors. Exempting the discount card program from the standard regulatory process would expedite implementation, but could result in less effective implementation of the proposed beneficiary protections. CMS also will need more than 90 days to conduct an effective outreach and education campaign for the millions of Medicare beneficiaries who are potentially eligible for the discount card. An ineffective outreach and education effort would make it much more difficult for information about the program to reach eligible beneficiaries and for beneficiaries who elect to participate to benefit from the program by making a well-informed card selection.
- The proposed subsidies of up to \$600 per year for low-income beneficiaries would encourage the least well-off beneficiaries to enroll in the discount card program, and thereby enable them to take advantage of otherwise unavailable price discounts. Inclusion of low-income subsidies, however, increases the administrative complexity and costs of the discount card program in two ways. First, either the federal government or the card sponsors would have to bear the costs of performing new income-based eligibility determinations for potentially hundreds of thousands of Medicare beneficiaries with incomes too high to qualify for Medicaid but low enough to qualify for the discount card subsidy. Second, there would be administrative costs for issuing and maintaining the debit cards that have been proposed to track the subsidy account balances of low-income beneficiaries. The current use of debit cards in conjunction with individual flexible savings accounts for medical expenses is relatively limited even among private employers.¹ Application of this new program architecture to a Medicare drug discount card might also require additional implementation time.

¹ “Currently, less than 400,000 people have flexible spending accounts with debit cards. However, Consumer Driven Market Report, a newsletter covering health-care financing, predicts that number will jump to 1.5 million by next April.” Ron Lieber, “Employers Offer New Pretax Perk,” *Wall Street Journal Online*, 2 September 2003.

- The current regulatory environment for drug discount cards is vague. State regulatory activity is more prominent than federal activity, with state jurisdiction usually residing in agencies with general authority over trade and consumer protection. State and federal agency jurisdiction over discount cards would need to evolve if a Medicare discount card program were enacted. In addition, CMS would need to carefully oversee card sponsors' use of the "Medicare" name. Ongoing monitoring and auditing of discount card operations, and a clearly defined mechanism for beneficiary complaint resolution, would be critical.

Introduction

Prescription drug discount cards have figured prominently in the recent federal policy debate over how to help Medicare beneficiaries, particularly those with no prescription drug insurance coverage, manage the rapid increases in their out-of-pocket expenditures for prescription drugs. In July 2001, President Bush introduced a prescription drug discount card plan as a cornerstone of his Administration's Medicare reform proposal. The plan called for the Medicare program to endorse qualified private-sector drug discount cards and to promote beneficiary participation in these programs. The Administration's plan has not been implemented as of this writing, however, due to a federal court ruling issued in January 2003, which found that the Administration lacked the statutory authority to implement the plan.

Since then, policymakers have continued to contemplate adding a drug discount card to Medicare, either as an alternative to or as a transitional step toward a Medicare drug insurance benefit. The Medicare prescription drug benefit bills that passed the House and the Senate in June 2003 (H.R. 1 and S. 1, respectively) both contain a drug discount card program. In both bills, however, the drug discount card program would serve only as an interim device to reduce prescription drug prices paid by participating seniors in 2004 and 2005, and would be eliminated when a funded Medicare prescription drug benefit became available in January 2006.

Although drug discount cards are well established in the private sector and in certain public-sector environments, designing such a program for Medicare poses formidable challenges for several reasons:

- The size of the population that is likely to enroll in a Medicare card program. An estimated 9 to 10 million Medicare beneficiaries have no insurance coverage for prescription drug costs², and many of them might be able to benefit from the discounts that such a program could offer.

² The Centers for Medicare and Medicaid Services (CMS) stated in the final rule for the Medicare-Endorsed Prescription Drug Card Assistance Initiative (published September 4, 2002) that "over 9 million Medicare beneficiaries are without drug coverage." (67 FR 56619) Similarly, the Congressional Budget Office (CBO) reported that "in 1999, one-quarter of the Medicare population [10.1 million beneficiaries] had no prescription drug coverage." (CBO, *Issues in Designing a Prescription Drug Benefit for Medicare*, October 2002.) Another study published in early 2002 made a significantly higher estimate, finding that approximately 13 million Medicare beneficiaries had no prescription drug benefits in the fall of 1999. (Mary A. Laschober, et al., "Trends in Medicare Supplemental Insurance and Prescription Drug Coverage, 1996-1999," *Health Affairs*, <http://www.healthaffairs.org/Library/v21n2/s4.pdf> (27 September 2002). The authors attribute the difference to their use of a point-in-time estimate of Medicare beneficiaries' self-reported drug coverage status, as opposed to the other studies' counting as "uninsured" only those beneficiaries who did not have coverage for all or most of the year (1999) studied.

- The lack of familiarity among some Medicare beneficiaries with drug discount cards and with the tools (such as using Internet sites to make drug price comparisons) that might be used to support the Medicare drug discount card market.
- The complex relationships in drug discount card programs between card sponsors, drug manufacturers, and retail pharmacies. Policymakers would need to use care in regulating these relationships to achieve their goal of lowering prescription drug prices paid by Medicare beneficiaries.
- A new Medicare discount card program would bring with it new requirements for card sponsors that elect to participate, such as providing meaningful disclosure of drug prices and discounts, administering low-income subsidies through debit card technology, and applying pharmacy network access standards from other federal government programs to the discount card program. Some of these program requirements would be relatively easy for potential card sponsors to comply with (for example, card sponsors that already participate in other federal programs such as TRICARE would be familiar with their pharmacy network access standards), but others, such as administering debit cards, could require card sponsors to incur new costs. Any new costs would ultimately be borne by consumers because card sponsors would recoup their investment by increasing their enrollment fees or by retaining portions of manufacturer and retail pharmacy price concessions that otherwise would accrue to the consumer.

Background

This section of the report presents a brief background on the drug discount card concept, emphasizing the fundamental differences between prescription drug discount card products and prescription drug insurance products. This section also discusses examples of drug discount card programs that are currently active in the public sector and provides a summary of the role that they are playing in the current Medicare debate.

Drug Discount Cards Defined

Prescription drug discount cards are products that seek to lower the prices of prescription drugs that are purchased by consumers at retail, usually consumers who do not have health insurance coverage that includes prescription drugs. As described in more detail in the next section, discount cards might be sponsored by membership

organizations, state governments, pharmacy benefit management companies (PBMs),³ retail pharmacy chains, or other entities. Many of these sponsors will subcontract with a PBM to actually administer the discount card program, and in particular to negotiate on behalf of the program's enrolled members with the other entities in the prescription drug supply chain that determine a drug's retail price. The goal of each discount card program is to give its enrollees access to discounts from the full retail prices for drugs that an individual with no prescription drug insurance would pay.

It is important to recognize that the source of savings on prescription drugs in a discount card program differs from the source of savings in a prescription drug insurance benefit. In an insurance benefit, price discounts generally come from drug manufacturers (via reductions in the prices of their products) and from retail pharmacies (via reductions in retail price markup and in prescription dispensing fees). In both cases, the drug manufacturer or retail pharmacy agrees to the price reductions after concluding that the increases in their sales volume as a result of participating in the program will make them better off than if they did not participate and charged higher prices. By contrast, almost all of the savings that consumers realize in the current commercial discount card market come from negotiated reductions in the retail pharmacy charges.⁴ Unlike drug insurance programs, current discount card programs generally do not move market share from one drug to another, so manufacturers have little incentive to negotiate price discounts with discount card sponsors.

The proposed designs for the new Medicare discount card program have the potential to provide deeper discounts than current discount card arrangements. By requiring beneficiaries to enroll exclusively in one discount card for a year at a time, and by giving card sponsors the ability to implement a formulary, the new Medicare drug discount card program would give card sponsors significant influence over which therapeutically-equivalent products their enrollees use, which in turn would allow card sponsors to negotiate with drug manufacturers to obtain price concessions on behalf of cardholders. As is the case with prescription drug insurance benefits today, card sponsors could negotiate price discounts from manufacturers in return for agreements to move market share to the manufacturer's products. Card sponsors could also increase savings to enrollees by providing enrollees with an incentive to use the card sponsor's

³Pharmacy benefit management companies (PBMs) are firms that administer drug benefit programs for employers and health insurance carriers. PBMs contract with managed care organizations, self-insured employers, insurance companies, unions, Medicaid and Medicare managed care plans, the Federal Employees Health Benefits Program and other federal, state, and local government employers to provide managed prescription drug benefits. For more information, see The Health Strategies Consultancy, "Demystifying PBMs" (June 2003) at www.healthstrategies.net/conferences/demystifyingpbms.html.

⁴Health Strategies Consultancy interviews with discount card sponsors. See also Health Policy Alternatives, Inc., "Prescription Drug Discount Cards: Current Programs and Issues," prepared for The Kaiser Family Foundation (February 2002).

mail-order prescription program, which generally can provide prescriptions at a lower consumer price than a retail pharmacy. The exclusivity and enrollment lock-in policies also increase card sponsors' negotiating leverage with retail pharmacies (provided that sponsors have the ability to restrict participation in their pharmacy networks). Card sponsors might be able to negotiate additional reductions in their payments to retail pharmacies (e.g., dispensing fees) in return for encouraging more foot-traffic through contracted pharmacies by requiring their discount cardholders to use those pharmacies.

A Medicare discount card program also could benefit from the credibility associated with the Medicare name. Beneficiaries generally view Medicare quite positively, so discount card sponsors should be able to attract more customers if they are able to use Medicare's endorsement in their marketing materials. Card sponsors also might benefit from efforts by CMS to provide information about endorsed options to beneficiaries. Medicare in the last several years has significantly enhanced its ability to provide information on different plan options to beneficiaries, and a Medicare discount program could build on this capability.

Although a Medicare discount card program would be likely to provide greater savings than current discount card efforts, it is difficult to quantify how much in benefits that beneficiaries would be likely to receive under such a program. Just knowing at an aggregate level what the discounts cardholders receive today is difficult, because the results for each individual are dependent on the particular drugs they purchase, the variety of retail pharmacies to which they have access, and their willingness to purchase drugs through the mail rather than at a retail pharmacy. Marketing materials from commercial card sponsors claim that discounts will range from 15 to 35 percent for brand-name drugs and from 25 to 60 percent for generic drugs. In its regulations to implement a Medicare drug discount card program in 2001 and 2002, the Bush Administration characterized typical price discounts at around 10 to 15 percent. A 2001 study by the U.S. General Accounting Office (GAO) found that drug discount cardholders could obtain discounts on the retail purchase of selected drugs ranging from approximately 9 to 15 percent on selected brand-name drugs and from approximately 50 to 67 percent on selected generic drugs⁵. The drug prices reported in the 2001 GAO study also indicated that cardholders could receive even greater discounts when filling prescriptions through some discount card sponsors' mail-order pharmacy service.

The GAO published an updated report on prescription drug discount cards in September 2003, which concluded:

⁵ The GAO analyzed the retail prices of 17 drugs that it determined were the most frequently prescribed drugs for participants in the AARP drug discount card program, which restricts participation to persons age 50 and over. See U.S. General Accounting Office, "Prescription Drugs: Prices Available Through Discount Cards and From Other Sources" (GAO-02-280R), Letter to Congressional Requesters (5 December 2001).

Medicare beneficiaries can receive prices with prescription drug discount cards at retail pharmacies that are generally lower than those available to seniors without cards. Prices available for a particular drug tend to be similar across PBM-administered cards. Savings from PBM-administered cards, however, can differ because retail pharmacy prices vary widely. For example, in Washington, D.C., which had the highest median retail pharmacy prices of the three areas GAO surveyed, median savings using a PBM-administered card ranged from \$2.09 to \$20.95 for a 30-day supply of the nine drugs frequently prescribed for the elderly that GAO examined. ...Prices available with a pharmaceutical-manufacturer-sponsored card for a particular drug are typically lower than prices obtained using PBM-administered cards, and are often a flat price of \$10 or \$15.⁶

Many, but not all, discount card programs require payment of an annual or monthly enrollment fee for access to the discounted prices negotiated by the card sponsor. Enrollment fees range from \$12 to \$50 per year for individuals and from \$25 to \$100 per year for households, but they often are waived for qualified low-income enrollees.

A final and important point about how discount cards work is that the card sponsor *does not pay for drugs* – this responsibility remains with the card holder, who benefits from the reduced drug prices but still bears all financial risk for drug purchases. For this reason, discount cards are not drug insurance, which is particularly important in the context of state regulatory oversight of drug discount card products.⁷ Indeed, the difference between discount card products and insurance products is so fundamental that some states require discount cards to explicitly disclose that they are not insurance products in marketing materials and include the label “NOT AN INSURANCE PRODUCT” in bold type on the face of the card itself.

Drug Discount Cards in the Private and Public Sectors Today

In the private sector, drug discount cards have proliferated rapidly over the past few years. Discount card sponsors include nonprofit membership organizations (e.g., AARP), retail pharmacy chains (e.g., CVS), third-party administrators (TPAs, e.g., MagnaCare), insurance companies (e.g., Medical Mutual of Ohio), and private companies (e.g., Independent Lifestyle Association, Provider Financial Services). Many of these sponsoring entities subcontract with PBMs (e.g., AdvancePCS, Express Scripts, Medco Health Services) for administrative services. In addition to administering discount cards on behalf of third-party sponsors, most of the large PBMs also sponsor

⁶ U.S. General Accounting Office, “Prescription Drug Discount Cards: Savings Depend on Pharmacy and Type of Card Used” (GAO-03-912), Report to Congressional Requesters (3 September 2003).

⁷ In an effort to regulate discount card programs, California and Washington have enacted laws requiring drug discount card companies to register as insurance companies. Health Policy Alternatives, Inc., “Prescription Drug Discount Cards: Current Programs and Issues,” prepared for The Kaiser Family Foundation (February 2002).

and administer their own discount card products. Finally, most of the major pharmaceutical companies sponsor discount cards for their own products, but enrollment in manufacturer-sponsored cards usually is limited to Medicare beneficiaries with no prescription drug coverage and incomes below a specified threshold, e.g., 150 or 200 percent of the Federal poverty level.

Commercial discount cards operate on either a national or a regional basis. While some card programs are open to all applicants residing in the card's coverage area, the majority of discount cards are marketed preferentially toward seniors, and some programs restrict enrollment only to individuals over age 50 or only to individuals who already are eligible for Medicare.

Beginning in January 2000, a number of states began implementing their own drug discount programs. As of September 1, 2003 at least 38 states had established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most of these programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but others use discounts or bulk purchasing approaches. Twenty-eight state programs now are in operation; in addition, Arkansas, Hawaii, Louisiana, Montana, New Mexico, Ohio, South Dakota, Tennessee, Texas and Washington have enacted laws that are not yet in operation. Thirty states' laws provide for a direct subsidy using state funds, while twenty states have created or authorized programs that offer a discount only (no subsidy) for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.⁸ A 2002 study of selected state discount card programs found that enrollment fees ranged from zero to \$60 per year, and enrolled members received access to drug discounts that often were greatest if the product purchased was on a "preferred drug list". Most of these programs were administered by PBMs under contract to the state.⁹

Drug Discount Cards in the Medicare Prescription Drug Benefit Debate

Drug discount cards have figured prominently in the recent debate over prescription drugs in Medicare. In July 2001, President Bush introduced a prescription drug discount card program that he called the first step in his plan for larger Medicare reform. Under the Administration's plan, the Centers for Medicare and Medicaid Services (CMS) would have endorsed discount cards issued by qualified private sector sponsors, which

⁸ National Conference of State Legislatures, "State Pharmaceutical Assistance Programs," <http://www.ncsl.org/programs/health/drugaid.htm> (accessed 26 September 2003).

⁹ The Health Strategies Consultancy LLC and American Management Systems, Inc., "An Overview of State Prescription Drug Discount Programs," prepared for the Centers for Medicare and Medicaid Services, Contract No. GS-23F-9785H (August 2002).

would have charged beneficiaries a one-time enrollment fee of no more than \$25 and would have used beneficiaries' group purchasing power combined with preferred drug lists to offer discounts of 15 to 25 percent off drugs' retail prices.

The Administration's plan immediately encountered resistance; the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacist Association (NCPA) filed suit in federal court to block the program's implementation, claiming that the Bush administration lacked the authority to implement such a plan without Congressional approval and that the Administration violated federal rules by failing to hold open meetings or a public comment period prior to drafting the plan. In September 2001, a U.S. District Court issued an injunction temporarily delaying implementation of the program,¹⁰ and in November 2001, the Administration withdrew its original plan.

The Administration issued a more detailed version of the plan in a Notice of Proposed Rule-Making in March 2002, which was followed by a public comment period and issuance of a Final Rule in September 2002. CMS immediately began work on implementation, but the chain drug stores renewed their legal objections, and in January 2003, a U.S. district court permanently enjoined the Department of Health and Human Services (HHS) from proceeding with the program. The court ruled that HHS lacked statutory authority to proceed with implementation without Congressional approval. The court rejected the HHS's argument that an administrative clause authorizing CMS to educate Medicare beneficiaries allowed it to implement a budget-neutral program based on educating beneficiaries about existing private sector instruments. After the court's ruling halted the program's implementation, CMS Administrator Tom Scully said that the Administration would still seek to implement its Medicare discount card plan, either through Congressional authorization or further legal appeal.¹¹

Meanwhile, legislative momentum for a funded Medicare drug insurance benefit increased dramatically in the first half of 2003. In March, the Administration issued a new Medicare reform proposal that included \$400 billion for a Medicare drug benefit. At the end of June, the House of Representatives and the Senate separately passed legislation to establish a Medicare prescription drug benefit under new Part D. Both bills included a Medicare discount card program that would serve as an interim measure to lower drug prices for Medicare beneficiaries who chose to enroll in the program before the Medicare Part D benefit became available. In both bills, the discount card program would start on or about January 1, 2004 and be phased out in January 2006 when the Part D prescription drug insurance benefit began.

¹⁰ *National Association of Chain Drug Stores v. Thompson*, No. 01-1554 (D.D.C. 2001).

¹¹ Neely Tucker, "Judge Rejects Bush's Drug Discount Plan," *Washington Post* (30 January 2003).

Five Policy Issues in Designing a Medicare Drug Discount Card

1. Consumer Value

A Medicare discount card program has the potential to provide modest but measurable consumer value, in the form of lower retail prescription drug prices that would be paid by Medicare beneficiaries who do not have any other form of prescription drug coverage. As discussed above, the proposed designs for the new Medicare discount program have the potential to provide deeper discounts than current discount card arrangements. By requiring beneficiaries to enroll exclusively in one discount card for a year at a time, and by giving card sponsors the ability to implement a formulary, the new Medicare drug discount card program could give card sponsors enhanced negotiating leverage with both manufacturers and pharmacies. The Medicare imprimatur also could increase beneficiary awareness and participation, further enhancing the leverage of card sponsors and potentially increasing the discounts that card sponsors could negotiate.

A key issue for policymakers, therefore, is assuring that beneficiaries receive the benefit of discounts negotiated by card sponsors under the program. The current Medicare proposals would rely on competition among drug card sponsors; e.g., that beneficiaries would choose to enroll with card sponsors that provide the drugs that they need at low prices with good service. For this competition to be effective, beneficiaries would need good information about the relative value of different card sponsor offerings in order to make informed decisions about which offer the best value. Other approaches intended to assure that beneficiaries receive the value of negotiated discounts include requiring card sponsors to guarantee a minimum level of savings (included in the Senate proposal for cards provided to lower income beneficiaries) and requiring that card sponsors report the discounts that they receive to regulators or the public. Some of the key issues raised by these alternatives are discussed below.

Beneficiary access to comparative price information. Beneficiaries participating in a discount card program need access to timely and accurate information about prescription drug prices (1) before they enroll in a program, so that they can compare discount card programs and determine with ones provide them with the best value; and (2) after they enroll in a program, so that they (working with their physicians) can compare different prescription treatment alternatives to determine how to take advantage of the potential savings offered by the card program in which they have enrolled.

The seemingly straightforward task of communicating drug price information to beneficiaries must deal with the fact that there is dramatic variation in the pricing of pharmaceuticals. Drug pricing variation results from the complexity of the pharmaceutical supply chain, the freedom that drug manufacturers and retail

pharmacies have to set prices, and the presence of third-party negotiators such as PBMs.¹² Two recent reports by the General Accounting Office found wide variations in retail prices for the same drug, depending on the geographic location of the pharmacy where the drug was purchased or whether the purchase was made through a retail, mail order or Internet pharmacy.¹³ And the GAO studies present only part of the picture since they compared drug prices available at certain points in time, whereas Medicare discount cardholders would also encounter the fact that there are frequent, sometimes daily, changes in some drug prices, particularly among multi-source brand drugs and generic drugs. Price changes over relatively short periods of time could lead to instances of a Medicare beneficiary choosing to enroll in a particular discount card because of the price it offered for a specific drug that the beneficiary needs to manage a chronic illness, only to find that the price has gone up by the time he or she needs to actually purchase the drug in question.

To facilitate price comparisons by beneficiaries evaluating different programs prior to enrollment, policymakers might want to develop ways to assure that beneficiaries have access to consistent information in a standard format from each drug card sponsor. Options include developing a central web site (or requiring card sponsors to host web sites) disclosing price information and requiring card sponsors to develop booklets or brochures with price information that can be provided to beneficiaries prior to enrollment.

In the Administration's 2002 final rule for its Medicare prescription drug discount card program, CMS raised the prospect of an Internet website where beneficiaries could compare drug lists and prices for Medicare discount cards. This approach would give consumers improved access to information needed to compare programs and could be the most effective strategy for providing comprehensive and current prices. At the same time, web-based information is unlikely to be useful for a relatively large share of seniors who are not regular Internet users. Requiring card sponsors to distribute booklets or brochures containing price information to potential enrollees would make information available to beneficiaries who are uncomfortable using the Internet, but such a method would be costly and the price information would quickly become out of date.

Policymakers also must decide on the content of the price information that is disseminated to beneficiaries. This issue involves several related policy choices. First, policymakers would need to decide whether price information should be available for all available drugs or only for a subset, such as the most commonly prescribed drugs for Medicare beneficiaries. Routinely gathering and disseminating price information for the

¹² Richard G. Frank, "Prescription Drug Prices: Why Do Some Pay More Than Others Do?," *Health Affairs* (March/April 2001): 115-128.

¹³ *Ibid.*, footnote 4.

most commonly-used drugs would reduce administrative costs for CMS and for card sponsors, and would make comparing the consumer value of each card manageable and comprehensible for many beneficiaries. From the beneficiary's perspective, however, having access to a comprehensive and current price list would clearly be preferable.

Second, policymakers would need to determine the most straightforward manner to express price information. This involves making a choice about whether discounts should be expressed as a percentage or dollar reduction from a drug's Average Wholesale Price (AWP) or expressed as the actual prices that cardholders would pay at the retail pharmacy using each card. In its proposed regulation for a Medicare discount card program, CMS stated that publishing discounts relative to Average Wholesale Price (AWP) would not be meaningful to beneficiaries. Indeed, the meaning of AWP itself has come under increasing government scrutiny in recent years in connection with setting Medicare reimbursement rates for outpatient prescription drugs covered under Medicare Part B, and these well-documented criticisms of AWP as a measure of a drug's price would apply to a Medicare discount card program, as well. Requiring card sponsors to publish drug prices in dollar terms for the standard prescription amounts most often prescribed to Medicare beneficiaries would provide beneficiaries with the clearest and best means of comparing competing discount card programs.

Beneficiaries in a drug card program would also need access to price information after enrollment in order to effectively evaluate their drug options. Beneficiary prescription needs might change after enrollment, as might the price discounts offered by card sponsors. Methods of providing up-to-date price information include requiring that it be made available on the Internet, establishing a call center (or equipping the existing "1-800-MEDICARE" call center to provide price information), or requiring that comparative price information be made available at the pharmacy when a prescription is filled. Of the options, the Internet approach has the potential to provide the most information to beneficiaries in a cost effective manner, but, as noted above, there are concerns that many beneficiaries might not as yet be comfortable with the technology, so alternatives might be needed.

The retail pharmacy option has the potential to provide a more limited amount of price information to beneficiaries precisely at a time when they could put it to use. Virtually every pharmacy transaction is performed electronically, giving each retail pharmacy access to up-to-the-minute drug price comparison information. Both of the Medicare prescription drug bills under consideration in Congress would take advantage of this information technology by requiring Medicare discount card sponsors to use the medium of the retail pharmacy to inform enrollees at the point of sale if there is a difference between the price of the prescribed drug and the price of the lowest-cost generic version of the same drug (as long as the generic alternative is covered under the enrollee's discount card program and is therapeutically equivalent and bioequivalent). This approach could be expanded to require that information about lower-priced brand-

named drugs be disclosed to beneficiaries, although actually switching prescriptions would require physician consent. Beneficiaries also could be informed of less expensive mail-order dispensing options at this point.

The call center option might provide a reasonable fallback for beneficiaries that cannot find price information any other way. While an 800 number service could provide up-to-date price information to beneficiaries, providing complicated price information (e.g., describing and spelling the drug alternatives as well as listing prices for various dosages) orally might lead to substantial confusion and misunderstanding. This option also would require a significant investment of resources and infrastructure to handle the potential increase in call volume.

Requiring Minimum Discount Levels

Given the complexity of prescription drug pricing generally, and in particular the concern that discounts are not being passed on to consumers, some policymakers have suggested that competition alone might not ensure that card sponsors pass along most of the discounts that they receive to their enrollees. Some of these policymakers have proposed that the government should require card sponsors to guarantee to enrollees a minimum percentage reduction from AWP or some other price benchmark on the average price of all the drugs covered. For example, a provision in the Senate Medicare bill would require each card sponsor to provide low-income Medicare beneficiaries with access to retail purchase prices that reflect a minimum average discount of no less than 20 percent of AWP for all of the drugs covered under the discount card program. While such a provision would provide a minimum guarantee of value to enrollees, it also has the potential to reduce the range of drugs covered under discount programs, because card sponsors could include drugs only if they were able to negotiate longer-term price contracts with manufacturers. Most card sponsors are not insurers and would not be able to take the financial risk of promising a minimum level of price reductions without some assurances from manufacturers that they could provide the drugs at the reduced prices.

Disclosure requirements for manufacturer rebates and other discounts

Some policymakers also believe that, in the absence of transparent retail pricing practices for prescription drugs, the government should require some degree of “transparency” in the transactions between card sponsors and drug manufacturers in order to ensure that cardholders are receiving the maximum amount of consumer value possible from the discount card program. As discussed above, the fundamental issue here is that retail drug prices are determined by a complex supply chain, are subject to considerable local and temporal variation, and therefore are difficult to understand.

The House-passed Medicare bill would require Medicare discount card sponsors to disclose to the Secretary of HHS “the extent to which discounts or rebates or other remuneration or price concessions made available to the entity [i.e. card sponsor] by a manufacturer are passed through to enrollees....” The Senate bill would require disclosure of “information relating to program performance, use of prescription drugs by eligible beneficiaries enrolled in the program, financial information of the sponsor, and such other information as the Secretary may specify.” Both provisions would put legal restrictions on further disclosure of the information beyond HHS¹⁴ to ensure that disclosure of detailed transaction information would not dampen card sponsors’ leverage in negotiating rebates and other discounts with drug manufacturers.¹⁵ Aggregate disclosure of price discounts as a percentage of AWP is not subject to these issues.

2. Product Design and Consumer Safeguards

This section discusses the tools that card sponsors would use to obtain price discounts from drug manufacturers and their implications for consumers.

Use of formularies. One issue for policymakers is whether the government should set standards about the content of drug card program formularies. Resolving the issue requires policymakers to balance consumer access to a broad range of drugs against card sponsors’ ability to negotiate deeper discounts for a more limited range of drugs.

Permitting card sponsors to have substantial discretion in developing their formularies enhances their leverage with manufacturers because the sponsor would be relatively free to exclude drugs for which they could not get a good price. On the other hand, if, as proposed in both pending Medicare bills, beneficiaries would be limited to enrolling in only one discount card program at a time, policymakers might want to establish some minimum standards on formulary content to assure that beneficiaries could find drug programs that include the drugs that they need.

In the Administration’s final rule in 2002 for its Medicare discount card program, CMS proposed that card sponsors would have considerable latitude in designing proprietary formularies as long as each formulary would discount at least one drug in each group of medications. Groups of medications would have been defined in a drug classification scheme published by CMS. The issue of who defines the drug classifications is

¹⁴ For H.R. 1, see Sec.1807(i)(5) as added by Sec. 105; for S. 1, see Sec. 1807(h)(4) as added by Sec. 111. The Senate bill has disclosure language almost identical to the House language, but applies it only to the entities (prescription drug plans and health plans) that would provide the full Medicare prescription drug benefit (see Sec. 1860D-6(e)(3) as added by Sec. 101 of S. 1).

¹⁵ For a discussion of the economic analysis underlying this concern, see Joseph P. Kalt, et al., “Regulatory Reform and the Economics of Contract Confidentiality,” *Regulation*, vol. 19, no. 1 (1996).

important in such a scheme, because decisions about whether to separate similar drugs into different classes or lump them together into the same class can have important financial implications for consumers (the more a formulary is split into subclasses, the greater the number of drugs that must be discounted to satisfy a requirement of having at least one drug discounted in each group).¹⁶

The House and Senate Medicare bills handle the issue of who defines drug classes in quite differently. In both bills, card sponsors would be required to discount at least one drug in each group of medications, but in the House bill, card sponsors would be able to define the groups of medications, while in the Senate bill, the Secretary of HHS would define the groups of medications that all card sponsors would be required to use. This is an important difference because having a single drug classification scheme would change the market dynamic and the way in which discounts will be negotiated with manufacturers.

Enrollment exclusivity and enrollee lock-in. A controversial aspect of the Administration’s proposed discount card program was an “enrollment exclusivity” provision, which would limit beneficiaries to enrolling in no more than one Medicare-endorsed discount card over a defined period of time. The pending House and Senate Medicare bills also would require that beneficiaries choose only one discount card program and would lock them into their choice, in most cases for a year.

As discussed above, the argument in favor of requiring exclusivity for a defined period is that it enhances the ability of discount card sponsors to negotiate rebates from drug manufacturers. If Medicare beneficiaries can participate in more than one card, or can change often from one card to another, their drug utilization would not be confined to one formulary, and thus card sponsors would be deprived of their most important bargaining tool with drug manufacturers. For some beneficiaries, however, the exclusivity provision could result in a loss of benefits as compared with current drug card programs. For example, beneficiaries taking multiple drugs might be able to realize more savings by having multiple drug discount cards and using the drug discount card offering the highest price discount when filling any one particular prescription.

Requiring a “lock in” period for drug prices. The discussion above suggests that locking beneficiaries into one prescription drug card for defined periods is an important design element in a prescription drug card program if card sponsors are to have any leverage in negotiating with drug manufacturers. This feature, however, raises the issue

¹⁶ We should note that this issue has greater implications in the design of a drug insurance program than in the design of a drug discount card program. In an insurance program, the sponsor is financially responsible for paying some or all of the costs of the drugs, so requiring programs to expand the number of drug categories and to have a preferred drug in each category may have important financial implications for the sponsor. In the case of a discount card program, however, where the sponsor is an intermediary and is not responsible for the costs of the drugs on its formulary, the card sponsor can respond to formulary mandates by simply including a drug on its formulary at cost.

of whether it is fair to lock beneficiaries into a card program they choose even if the card sponsor substantially changes the terms of the arrangement (e.g., substantially increases prices or alters which drugs are on the formulary). In response to this concern, some policymakers have suggested locking-in the prices that card sponsors use for some period after enrollment, such as 60 days.

Some potential card sponsors have argued that a price lock-in policy could be problematic for them because they need the ability to adjust retail prices frequently in response to constant manufacturer and wholesaler price changes. In essence, a price lock-in would require card sponsors to assume financial risk for manufacturer and wholesaler price increases. Unless card sponsors could negotiate price guarantees from manufacturers (or some other suppliers) for the drugs on the sponsors' formularies, the card sponsors would be forced to take substantial financial risk for price changes that would be almost completely beyond their control. This could create an economic incentive for card sponsors to give smaller discounts to Medicare discount cardholders as a hedge against potential cost increases to the card sponsor. On the other hand, if there is no price lock-in, beneficiaries bear the financial risk of drug price increases, which would reduce the value of the discount card to them.

The behavior of drug prices supports both positions on this issue, and suggests options for a policy solution. Prices for sole-source brand drugs appear to be fairly stable over the course of a year¹⁷, while prices for highly competitive multi-source brand and generic drugs change almost every day. A price lock-in policy could be crafted that reflected this pricing behavior, i.e. require 60-day price stability for sole-source brand drugs, but allow card sponsors to change retail prices for multi-source brand and generic drugs as frequently as their manufacturer or wholesale prices change. Another option would be to have a price lock-in policy that guarantees a cardholder's price will go down if the card sponsor's acquisition price goes down. A third option would be to not require a price lock-in but permit cardholders to switch to another discount card program if the prices or the formulary in their program changes substantially.

Contracting requirements for retail pharmacy networks. A typical consumer protection in virtually all health plan contracts is to require a reasonable distance standard for access to a retail pharmacy, and it is likely that policymakers would want to include a similar kind of access standard for the Medicare drug discount card program. Requiring a more expansive network could affect a discount card's value, however, as retail pharmacies could take advantage of generous access standards to negotiate smaller discounts on their markups and fees as a condition of participating in a given card sponsor's network. This incentive could be compounded if card sponsors also are required to negotiate pharmacy contracts that are specific to the Medicare discount card

¹⁷A recent study by a large national PBM of its commercially-insured book of business reported that drug manufacturers made from one to four price changes during 2002 on the most frequently prescribed sole-source brand drugs. See Express Scripts, Inc., *2002 Express Scripts Drug Trend Report* (June 2003): 20.

program, rather than being able to use their existing pharmacy contracts, because card sponsors would be less able to combine their commercial and Medicare clout in negotiating dispensing fees with pharmacies.

The pending House and Senate Medicare bills take significantly different approaches to pharmacy network requirements for the discount card program. The House bill would apply the same pharmacy network standards on the discount card program that it would to the Medicare Part D prescription drug benefit. Those standards include an “any willing pharmacy provider” requirement for card sponsors, as well as retail pharmacy access standards that are at least as stringent as those used in the Defense Department’s TRICARE retail pharmacy (TRRx) program.¹⁸ The Senate bill simply states that the Secretary of HHS must “take into account reasonable distances to pharmacy services in urban and rural areas and access to pharmacy services of the Indian Health Service and Indian tribes and tribal organizations.” Minimum distance standards are normal business requirements for private-sector discount card programs, but policymakers might deter or delay participation by potential card sponsors if they impose additional requirements that exceed commercial standards.

Use of mail order pharmacies. Recent analyses of commercial discount card programs have found that mail order pharmacies can offer cardholders lower prices than retail pharmacies for some drugs.¹⁹ Mail order pharmacies can create additional consumer value because there is no “retail markup” in a mail order pharmacy and mail order dispensing fees are lower than retail pharmacy dispensing fees.

The retail pharmacy industry has argued that mail-order pharmacy threatens to undermine the consultative relationships between beneficiaries and their local pharmacy providers; however, others in the policy debate argue that these relationships are more important to some beneficiaries than others, and that the inclusion of mail order pharmacy in a Medicare discount card program would not prevent beneficiaries from seeking out local retail pharmacy providers if they chose to. Perhaps in response to both the consumer value and retail pharmacy arguments, the House and Senate Medicare bills would allow card sponsors to include mail order pharmacies as an option for

¹⁸ See TRICARE Retail Pharmacy (TRRx) Solicitation No. MDA906-03-R-0002 (13 March 2003), Section C, http://www.tricare.osd.mil/contracting/healthcare/solicitations/retail/0000/00_Section_C.pdf (accessed 16 October 2003). The TRRx pharmacy network access standards state that TRICARE contractors shall maintain a pharmacy network in which a pharmacy is available within two miles of 90 percent of the beneficiaries residing in an urban area, within five miles of 90 percent of the beneficiaries residing in a suburban area, and within 15 miles of 70 percent of the beneficiaries residing in a rural area.

¹⁹ U.S. General Accounting Office, “Prescription Drugs: Prices Available Through Discount Cards and From Other Sources” (GAO-02-280R), Letter to Congressional Requesters (5 December 5, 2001), and Health Policy Alternatives, Inc., “Prescription Drug Discount Cards: Current Programs and Issues,” prepared for The Kaiser Family Foundation (February 2002).

cardholders to obtain drugs at discounted prices, but also would prohibit card sponsors from offering only a mail order pharmacy with no retail pharmacy network.

3. Timeframe and Administrative Costs for Implementation

If policymakers decide to mandate implementing the Medicare discount card program within a very short time period following the enactment of authorizing legislation, while simultaneously requiring that the program expire in January 2006, they will impose significant policy and administrative challenges from the points of view of beneficiaries and card sponsors. The Administration's July 25, 2003 draft comments on the House and Senate discount card provisions recognized this, and instead the Administration requested a six-month implementation timeframe. More significantly, a compressed implementation timeframe would increase the probability that the discount card program will have difficulty attracting card sponsors willing to meet any new Medicare discount card requirements. If enough card sponsors do decide to participate quickly, it is not clear whether they would be able to offer Medicare beneficiaries additional value beyond what they can get in existing commercial discount card programs.

Policymakers also will need to understand that their commitment to the discount card program would need to extend beyond the initial authorizing legislation to include adequate administrative budget support for CMS to successfully implement the program. Medicare officials would face considerable challenges educating beneficiaries to understand the difference between the drug discount card program and the pending drug insurance benefit, disseminating understandable explanations of two very complex drug initiatives, and helping beneficiaries navigate the drug discount card enrollment process in 2004 and again in 2005. Congressional policymakers on the Medicare authorizing committees could work with the Administration to make a good faith estimate of the administrative costs CMS would incur to implement and manage the Medicare discount card program, and include that estimate in the authorizing legislation. The pending House Medicare bill includes a provision authorizing appropriation of funds "not otherwise appropriated" to cover the costs of the program²⁰, but this would simply place the discount card program in competition with all of the other activities supported by CMS' Medicare program management budget. Given that the discount card program could be used by up to 10 million Medicare beneficiaries, it is important for policymakers to consider the administrative costs associated with this undertaking²¹ and the consequences of insufficient administrative funding.

²⁰ Sec. 1807(a)(j)(6) as added by Sec. 105 of H.R. 1.

²¹ For a discussion of some of the administrative costs associated with a new Medicare discount card program, see The Health Strategies Consultancy LLC and American Management Systems, Inc., "Call Center Parameters and Regulatory Authority for Drug Discount Cards," prepared for the Centers for Medicare and Medicaid Services, Contract No. GS-23F-9785H (20 May 2003).

When the Medicare prescription drug benefit begins in 2006, policymakers could find it more difficult than expected to manage the transition between the discount card program and the drug insurance benefit. Correctly or not, some Medicare beneficiaries might perceive that the value to them of the new Medicare Part D drug benefit is less than the value of the discount card. This perception could arise, for example, if a particular drug that the beneficiary is using is not on the formulary of any of the prescription drug plan options available in their area. Since the discount card would be phased out over a period of months, there also might be questions about part-year eligibility issues, such as treatment of annual enrollment fee refunds if a beneficiary enrolls in a discount card program only six months before the program's termination. From card sponsors' perspective, clear rules governing the termination of the discount card programs will be important to their decisions about the financial feasibility of the discount card program.

Policymakers also should consider the possibility that there would be continued demand for a Medicare discount card program after the inception of a Medicare prescription drug benefit. When compared on an annual basis, the \$30 enrollment fee for the discount card program would be much lower than the estimated \$420 in monthly premiums for the new Medicare drug insurance benefit, and program rules will be much simpler. A discount card might be preferable for beneficiaries whose drug costs exceed the initial coverage limit specified in the Medicare prescription drug benefit (e.g., \$2,000 in H.R. 1 and \$4,500 in S. 1) but are not enough to qualify for catastrophic coverage.²² The discount card program also might be preferable to beneficiaries whose out-of-pocket payments would be reduced significantly—or at least would appear to be less than the deductibles and coinsurance required under the prescription drug benefit—if they stayed enrolled in the drug discount card program.

To the extent that a significant number of beneficiaries perceive that they are actually better off under the drug discount card program, or if beneficiaries simply do not want to pay the premiums associated with the new drug benefit, it could prove politically difficult, if not impossible, to phase out the discount card program. Perhaps recognizing this potential situation, the Administration recommended in its July 25, 2003 draft comments on the House and Senate discount card provisions that the Secretary be given the discretion to decide when the discount card program should be phased out.

4. Subsidies for Low-Income Beneficiaries

The Medicare bills that passed the House and Senate in June 2003 include provisions for limited subsidies for low-income Medicare beneficiaries. In effect, a certain amount of money would be credited to each enrollee's discount card and each time the enrollee purchases prescription drugs, the discounted purchase price would be debited from the

²² This so-called "donut hole" or gap in insurance coverage is a prominent feature of the Medicare drug insurance bills currently before the Senate and the House.

card's account. The following table summarizes the low-income subsidy provisions of the two bills ("FPL" means Federal Poverty Level, which in 2003 is \$12,120 for a two-person household):

House Bill (H.R. 1)	Senate Bill (S. 1)
Establishes prescription drug accounts for individuals who have no other source of drug coverage. Federal contributions to accounts vary with income on a sliding scale: Below 135% of FPL: \$800 From 135% to 150% of FPL: \$500 Over 150% of FPL: \$100	Provides an annual federal subsidy of \$600 loaded onto the drug discount card for beneficiaries with income below 160% of FPL who are not eligible for drug benefits through Medicaid.
Allows rollover of unused debit account funds from year to year.	Allows rollover of unused debit account funds from year to year.
Individuals, former employers, and states may contribute additional funds to an enrollee's prescription drug account. Contributions would be limited to \$5,000 per year.	No provision for additional contributions.

The proposed subsidies would encourage low-income Medicare beneficiaries to enroll in the discount card program and thereby enable them to take advantage of the price discounts available to cardholders.

From an implementation standpoint, however, the inclusion of low-income subsidies would greatly increase the administrative complexity of the discount card program because it would introduce the need for either the federal government or the card sponsors to perform an income-based eligibility determination. A sliding-scale subsidy as contemplated in the House bill would be even more complex to administer. Policymakers will need to consider the costs associated with administering a low-income subsidy as they make decisions about funding the discount card program's implementation.²³

5. Regulatory Oversight

An analysis of Federal Trade Commission (FTC) data in early 2003 indicated that consumers lodged very few complaints with the FTC against discount card sponsors in

²³ An alternative approach would be to administer the subsidy through a refundable tax credit, which could be calibrated to offer the same amount of subsidy to low-income Medicare beneficiaries. Implementation of this policy would be complicated by the fact that 50 percent of elderly households have no federal income tax liability and therefore do not file a federal income tax return, due to the exclusion of Social Security income from taxation. These households would need to file a return to obtain the refundable tax credit.

2001 and 2002.²⁴ Although we know of no systematic analysis of complaints to state agencies, a Medicare drug discount card program would expand industry volume significantly, and would increase the likelihood of problems ranging from poor customer service to outright fraud and abuse. While sponsor eligibility rules should discourage disreputable discount card operations from taking advantage of beneficiaries, policymakers likely would desire to implement formal safeguards to ensure beneficiary/consumer protections. Important steps would include identification of potential beneficiary protection issues, clarification of the processes for beneficiary complaints and grievances, and establishment of clear regulatory jurisdictions for federal and state enforcement agencies.

Potential beneficiary protection issues. There are several potential beneficiary protection issues, ranging from the more benign to the more serious. More benign issues would include prescription fill issues, such as incorrect pill counts, incorrect packaging or labeling, and delays in drug delivery. While such problems would usually occur at the level of the individual pharmacy, policymakers could use their endorsement powers to encourage drug discount card sponsors to exert pressures on pharmacies to improve customer service. Discount card sponsors with large mail order operations could be held more directly responsible for problems with drug order fulfillment.

More serious issues would include deceptive marketing and enrollment practices (e.g., misleading reporting of formularies and/or prices), unauthorized or fraudulent use of personal data (e.g., selling beneficiary information to other organizations), failure to sufficiently pass on manufacturer rebates to beneficiaries, credit or billing disputes, and repeated failures to resolve beneficiary complaints through the customer service process. Such problems could potentially warrant referral to state and federal regulatory agencies (see below).²⁵

Procedures for resolving beneficiary complaints. Most established drug discount card administrators maintain their own customer service call centers and have standard procedures for addressing beneficiary complaints and, if unresolved by a customer service representative, referring those complaints either to the discount card sponsor (if

²⁴ Analysis of Federal Trade Commission “Consumer Sentinel” data in The Health Strategies Consultancy LLC and American Management Systems, Inc., “Call Center Parameters and Regulatory Authority for Drug Discount Cards,” prepared for the Centers for Medicare and Medicaid Services, Contract No. GS-23F-9785H (20 May 2003). This analysis also found that complaints directed against discount card sponsors were much less common than complaints against sponsors and administrators of insured drug benefits. The most important complaint categories for discount cards were incorrect billing of enrollment fees, pharmacies overcharging for drugs, and delayed delivery of mail order drugs. This analysis did not systematically examine state-level consumer complaint activity concerning discount cards.

²⁵The Health Strategies Consultancy LLC and American Management Systems, Inc., “Call Center Parameters and Regulatory Authority for Drug Discount Cards,” prepared for the Centers for Medicare and Medicaid Services, Contract No. GS-23F-9785H (20 May 2003).

the complaint pertains to enrollment or benefit design) or to internal teams of investigators (if the complaint pertains to drug discount card operations). Affiliation with the Medicare program would introduce a new level of complexity, however, because many seniors might call the general 1-800-MEDICARE hotline to lodge complaints about discount cards.

While it may seem to be an administrative detail in the debate over the design of a Medicare drug discount card, perhaps the most important factor for policymakers to consider in designing a process to resolve beneficiary complaints is whether to encourage or require discount card sponsors to print the 1-800-MEDICARE number on the cards themselves, or whether to list only the card administrator's customer service number. Since some beneficiaries would still call 1-800-MEDICARE even if that number did not appear on the cards, Medicare officials would have to establish procedures for dealing with such calls.

Requests for information (e.g., comparative formularies and drug prices) could be handled by trained customer service representatives with access to a computer database or could be forwarded to the appropriate agency. Complaints about isolated pharmacy or discount card operational matters could be referred back to individual discount card administrators, perhaps with direct telephone links for efficient call routing. Medicare might consider establishing procedures for emergency referrals to on-call pharmacists for questions regarding allergic reactions to drugs, or other adverse events. Pervasive and serious operational complaints should be referred to the appropriate federal and/or state enforcement agencies for further investigation.

Regulatory oversight and enforcement jurisdiction. Medicare officials would want to establish the appropriate channels for referral of beneficiary complaints suggesting fraud or abuse. However, at the present time, the regulatory environment for discount cards is quite vague, owing to the relative small size and immaturity of the private sector discount card industry. State and federal agency jurisdiction over discount cards would need to evolve if a Medicare discount card program were enacted.

At present, state regulatory activity is more prominent than federal activity, with jurisdiction at the state level usually residing in agencies with general authority over trade and consumer protection. Because drug discount cards are not insurance products, state departments of consumer protection have generally assumed the primary regulatory role, with departments of insurance and pharmacy oversight boards playing smaller roles. Most states²⁶ lack specific laws regulating discount cards, and

²⁶ In an effort to regulate discount card programs, California and Washington have enacted laws requiring drug discount card companies to register as insurance companies. Health Policy Alternatives, Inc., "Prescription Drug Discount Cards: Current Programs and Issues," prepared for The Kaiser Family Foundation (February 2002).

those that do have laws tend to have only general labeling (e.g., “NOT AN INSURANCE PRODUCT” displayed in bold type on the face of the card), marketing and registration requirements.²⁷ If a Medicare discount card program is enacted, Medicare officials might encourage states to develop their regulatory frameworks and to assume more responsibility for handling complaints by proactively communicating expectations for state involvement (e.g., through workshops for state officials and publication of guideline materials on how to monitor and police discount card practices).

On the federal level, primary jurisdiction would probably lie with the Federal Trade Commission (FTC) and, to a lesser extent, the Department of Justice (DOJ), although neither agency is presently engaged in much activity related to drug discount cards. (The DOJ currently has strong interest in investigating PBMs for violating safe harbor provisions in their insured businesses.) Other federal agencies with possible oversight roles include the Food and Drug Administration (FDA) and the Department of Health and Human Services Office of Inspector General (OIG).

Lastly, Medicare endorsement is a concept that would have to be fleshed out more fully and enforced by CMS to ensure that beneficiaries are not misled about Medicare’s involvement in actual discount card program operations. Also, program integrity requirements would need to be strict in order to ensure that the “Medicare” name is used properly. Ongoing monitoring and audit rights for discount card operations, and a clearly defined mechanism for complaint resolution, would be critical in this regard.

Conclusion. A Medicare prescription drug discount card program has the potential to provide modest but measurable consumer value in the form of lower retail prescription drug prices to Medicare beneficiaries with no other source of drug coverage. This is the central reason to implement a Medicare discount card. In practice, the value of the discount card program to beneficiaries would depend critically on several factors.

The value of the program for enrollees would be enhanced—above and beyond the value they could receive from discount card programs today—by a high overall level of participation, because higher enrollment can be a factor in increasing card sponsors’ negotiating leverage with pharmaceutical manufacturers. To achieve that goal, CMS would need to make an immediate effort to conduct outreach to beneficiaries with no drug insurance to raise their awareness of, and facilitate their enrollment in, the card program. CMS would need to educate beneficiaries about comparing, choosing, and using a discount card. CMS would also need to ensure that all eligible discount card enrollees receive the low-income subsidies.

²⁷ As of October 2002, 16 states had passed laws regulating one or more aspects of prescription drug discount card programs. See U.S. General Accounting Office, “Prescription Drug Discount Cards: Savings Depend on Pharmacy and Type of Card Used” (GAO-03-912), Report to Congressional Requesters (3 September 2003): 12-14.

The extent to which a Medicare discount card program provides savings to beneficiaries would also depend up on its ability to use tools that could require some limitations for beneficiaries. For example, requiring beneficiaries to annually “lock in” to a particular card would limit beneficiaries’ choices relative to the current discount card market, but could provide card sponsors with additional leverage to obtain rebates and other price concessions from drug manufacturers.

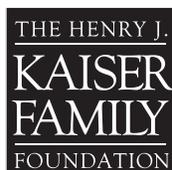
Finally, to give beneficiaries the information they need to make informed choices – with respect to choosing a program or selecting among comparable prescriptions on the program’s formulary, and helping beneficiaries understand that this new Medicare discount card program is *not* a subsidized Medicare drug *benefit*, CMS would require sufficient administrative funds to implement the discount card program. Sustained budget support from the Administration and congressional appropriations committees for CMS activities related to the discount card would be vital for its successful implementation and operation. CMS would need administrative funding in order to help beneficiaries get the maximum possible value out of the discount card program, for example, by increasing support for the 1-800-MEDICARE call center and for the units within CMS that would be responsible for overseeing the performance of card sponsors. Further, this fiscal support would need to be sustained consistently over time.

Appendix 1
Comparison of House (H.R. 1) and Senate (S. 1) Provisions for a Medicare Drug Discount Card Program

Policy	House Bill (H.R. 1)	Senate Bill (S. 1)
Types of entities that can be discount card sponsors	Pharmacy benefit management companies (PBMs), insurers, pharmacies, Medicare Advantage plans	Pharmacy benefit management companies (PBMs), insurers or pharmacies
Definition of beneficiaries eligible for discount card participation	Beneficiaries enrolled in Part A or B and who are not enrolled in a Medicare Advantage plan that offers drug coverage	Beneficiaries enrolled in Parts A and B who are not dual eligibles (i.e. also eligible for Medicaid)
Annual enrollment fee	\$30 Beneficiaries may only enroll in one plan at a time and must remain in the plan for one year	\$0 for low-income beneficiaries; \$25 for all others Beneficiaries may only enroll in one plan at a time
Requirements on access to negotiated prices	Card sponsors negotiate prices for drugs and must disclose the extent to which rebates are passed to enrollees; Negotiated prices must apply equally to mail order and retail pharmacy purchases; Medicaid best price provisions do not apply to negotiated prices; Pharmacists must inform beneficiaries at the point of sale of price difference between prescribed drug and a generic equivalent (if available)	Card sponsors negotiate prices for drugs; Negotiated prices can be no more than 80% of AWP for low-income enrollees; Medicaid best price provisions do not apply to negotiated prices; Beneficiary must pay at least 10% of the negotiated price for the drug; Low-income beneficiaries must have access to nursing home pharmacies as in-network pharmacies
Requirements on use of formulary/preferred drug list	Same provisions as new Medicare Part D drug insurance benefit apply “insofar as the Secretary determines that such requirements can be implemented on a timely basis.” Therapeutic classes must be defined by the card sponsor’s pharmacy and therapeutics (P&T) committee, taking into account US Pharmacopeia-	Same provisions as new Medicare Part D drug insurance benefit apply. Therapeutic classes will be defined by the CMS Administrator through regulation, using compendia and other recognized sources. Cards must cover drugs within each therapeutic

Policy	House Bill (H.R. 1)	Senate Bill (S. 1)
	<p>Drug Information standards.</p> <p>Cards must cover drugs within each therapeutic category and class of covered drugs, but not all drugs within such classes.</p> <p>Enrollees may appeal to receive coverage of non-formulary drugs if their physician determines that the formulary drug is not as effective or has adverse effects.</p>	<p>category and class of covered drugs, but not all drugs within such classes.</p> <p>Enrollees may appeal to receive coverage of non-formulary drugs if their physician determines that the formulary drug is not as effective or has adverse effects.</p>
Pharmacy network requirements	<p>Requirements of new Medicare Part D drug insurance benefit also apply to entities offering a discount card.</p> <p>Part D requires plans to permit the participation of any pharmacy that meets the terms and conditions of participation that the plan has established. However, the plan may offer reduced coinsurance or copayments for its enrolled beneficiaries who use the plan's selected in-network pharmacies.</p> <p>The card sponsor also must secure the participation in its network of enough pharmacies that dispense drugs directly to patients (other than by mail order) to ensure "convenient access", including adequate emergency access, as defined by the Secretary of HHS through regulation. The Secretary must establish convenient access rules that are no less favorable discount card enrollees than the rules for convenient access to pharmacies of the Secretary of Defense established as of June 1, 2003, for purposes of the TRICARE Retail Pharmacy (TRRx) program.</p>	<p>Each drug discount card sponsor must secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access.</p> <p>Standards for convenient access, including adequate emergency access, must be determined by the Secretary of HHS through regulation. The standards must take into account reasonable distances to pharmacy services in urban and rural areas and access to pharmacy services of the Indian Health Service and Indian tribes and tribal organizations.</p>

Policy	House Bill (H.R. 1)	Senate Bill (S. 1)
	The card sponsor must permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a community pharmacy, rather than through mail order, with any differential in charge paid by enrollees.	
Subsidies/debit accounts for low-income beneficiaries	Establishes prescription drug accounts for individuals who have no other source of drug coverage. Federal contributions to accounts vary with income on a sliding scale: Below 135% of FPL: \$800 From 135% to 150% of FPL: \$500 Over 150% of FPL: \$100	Provides an annual subsidy of \$600 loaded onto the drug discount card for beneficiaries with income below 160% of FPL who are not eligible for drug benefits through Medicaid.
Rollover of debit account funds from year to year	Balance can be carried forward from year to year	Balance can be carried forward from year to year.
Additional contributions to debit account funds allowed?	Individuals, former employers, and states could also contribute funds to the prescription drug account. Contributions would be limited to \$5,000 per year.	No provision for additional contributions.



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