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UNITED STATES SENATE
SPECIAL COMMITTEE ON AGING

The New Medicare Drug Discount Card: An Advance Prognosis

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I. INTRODUCTION

Good morning, Mr. Chairman and members of the Committee. I am Mark Merritt, President and Chief Executive Officer of the Pharmaceutical Care Management Association (PCMA). PCMA is the national association representing America's pharmaceutical benefit managers (PBMs). PCMA represents both independent, stand-alone PBMs and health plans' PBM subsidiaries. Together, PCMA member companies administer prescription drug plans that provide access to safe, effective, and affordable prescription drugs for more than 200 million Americans in private and public health care programs.

PCMA appreciates the opportunity to come before the Committee today to examine the issues associated with implementing the Medicare prescription drug discount card. The recent enactment of the bipartisan Medicare Modernization Act represents a paradigm shift in the financing and delivering of health care services, including a prescription drug benefit, to Medicare beneficiaries. Because of this law, beneficiaries will be paying less – in some cases, far less – in the coming years for their prescription drugs. By blending the very best that the private and public sectors have to offer beneficiaries, the Medicare Modernization Act has set the stage for moving forward with an historic private-public partnership in Medicare that expands the choices and health care benefits available to seniors and disabled beneficiaries and institutes much-needed reforms that will help ensure the long-term viability of the program.

With today's testimony, we would like to focus on four key areas:

- An overview of PBMs and how they provide value to the system;
- A review of independent, government data assessing PBMs' performance with drug discount cards;
- The value PBMs can bring to the Medicare program; and
- Key issues challenging the implementation of the Medicare prescription drug discount card and the permanent part D benefit.

II. OVERVIEW OF PBMs

PBMs are the one entity in the drug supply chain dedicated to lowering the price of prescription drugs. PCMA believes that "PBM" stands not just for pharmaceutical benefit manager, but for helping "People Buy Medicines." Each and every day across America, PBMs are making a difference and helping to expand consumers' access to safe, effective, and affordable medicines.

Prescription drugs are an essential component of an integrated and modernized health care program. The medical advances and improvements to individuals' quality-of-life that emanate from prescription drugs are now legendary. These advances afford individuals a level of independence and mobility that was simply unthinkable just one generation ago. Indeed, for millions of Americans, prescription drugs have transformed what were once acute medical conditions into manageable chronic illnesses.

The challenge, of course, is that while prescription drugs have brought forth impressive advances in medicine, they command a greater share of every dollar spent on health care. According to researchers at the Centers for Medicare & Medicaid Services (CMS), in 2002, prescription drugs accounted for 11 percent of health care spending, but represented 16 percent of the rate of increase in overall health spending. Overall, health spending rose by 9.3 percent in 2002, on the heels of an increase of 8.5 percent in 2001. [1]

While the drivers of increased health spending are varied, their impact on purchasers and consumers is clear. Private and public purchasers alike are wrestling with how best to maintain access to high-quality coverage and benefits – including prescription drugs – while reining in costs. Many purchasers – including health plans, self-insured employers, union-sponsored plans, federal and state employee benefit programs, and state Medicaid programs – rely upon PBMs to make prescription drugs more affordable and accessible to consumers.

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[1] "Health Spending Rebound Continues in 2002," Katie Levit, Cynthia Smith, Cathy Cowan, Art Sensenig, and Aaron Catlin, *Health Affairs,* Volume 23, Number 1. January/February 2004.

A positive trend emerging is that the rate of increase in prescription drug spending appears to be waning. For 2003, CMS projects that the rate of growth in private-sector prescription drug spending is projected to decelerate to 13.4 percent – the fifth consecutive year of decline in the growth rate. CMS projects the rate of growth in prescription drug spending to decline even further by 2005 to 12.4 percent. Taken together, CMS projects that the rate of growth in prescription drug spending will decline by 37 percent from 1999 to 2005. CMS attributes this decline to a variety of factors, including multi-tier formularies, therapeutic interchange, and increased competition in the marketplace – the very tools PBMs rely upon.

Origins of PBMs

PBMs emerged in the 1970s and 1980s largely to administer prescription drug insurance benefits and to offer mail-order pharmacy services. These early PBMs provided real-time electronic claims adjudication, which significantly reduced claims processing costs. Many also provided and managed networks of pharmacies willing to accept negotiated discounts on drug prices and dispensing fees. PBMs gradually expanded to include clinical services, such as preventing adverse drug interactions through drug utilization review. Mail-service pharmacy also became a prominent part of PBM operations, reducing costs and improving convenience for plan enrollees.

In the early 1990s, PBMs experienced significant growth, as an increasing number of HMOs and other managed care organizations and self-insured employers turned to PBMs to administer their entire prescription drug benefit programs. Combining managed drug benefits with formulary rebates from prescription drug manufacturers helped to improve the attractiveness of PBMs as drug plan managers.

Today's PBM Marketplace: Highly Competitive

The PBM marketplace today is highly competitive, with PBMs existing in a number of forms. PBMs may be independent entities, subsidiaries of health plans, or operated by large retail chain drug stores. Private and public purchasers negotiating drug benefits on behalf of consumers have a wide variety of choices among PBMs. Each PBM offers multiple variations of models,

including tiering, network access, a mail-order pharmacy option, and other similar tools and techniques. For its part, the Federal Trade Commission recently noted that national, independent PBMs see "significant" and "vigorous" competition from both health plans and retail pharmacy chains offering PBM services.[2]

PBMs' Tools & Techniques

PBMs provide purchasers with value through a variety of tools and techniques that promote quality, improve outcomes, and drive down the cost of prescription drugs. PBMs typically offer purchasers a set of core services designed to contain and improve the value of drug expenditures that include claims administration; pharmacy network management; negotiation and administration of product discounts, including manufacturer rebates; and mail-service pharmacy. PBMs also provide purchasers with clinically-based services designed to improve the appropriateness, safety, and quality of pharmacy benefits. These tools may also improve the cost-effectiveness of the drug benefit and include such activities as drug utilization review, clinical prior authorization, consumer and physician education, disease management, and consumer compliance programs.

- **Disease and Therapeutic Drug Management.** PBMs provide disease management functions that target those with the most serious and chronic medical conditions. PBMs work collaboratively with patients and their health care providers to ensure patients receive the necessary preventive medications, are aware of any potential adverse drug events, and help them to avoid hospitalization or further health problems. These strategies have been proven effective – in fact, according to a recent study in the Archives of Internal Medicine, therapeutic drug management served to increase the rate of achieving therapeutic goals for patients from 74 to 89 percent.[3]

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[2] Statement of the Federal Trade Commission, File No. 031 0239. February 11, 2004.

[3] Brian J. Isetts, PhD, BCPS; Lawrence M. Brown, PharmD; Stephen W. Schondelmeyer, PharmD, PhD; Lois A. Lenarz, MD. "Quality Assessment of a Collaborative Approach for Decreasing Drug-Related Morbidity and Achieving Therapeutic Goals." *Arch. Of Intern Med. 2003;163;1813-1820.*

PBMs are often the only source of information for a patient's total set of prescribed medications because all network pharmacy purchases of prescribed drugs for an individual are held – confidentially – in one centralized, electronic file. These data can be especially useful in preventing drug-to-drug interactions and adverse events when enrollees are prescribed medications by more than one physician or when enrollees use more than one retail pharmacy to purchase their prescriptions. PBMs also play an important role in helping to prevent fraud by monitoring for appropriate prescribing, including issues related to age, gender, and frequency of dispensing. Further, PBMs integrate a patient's prescription drug utilization with his or her overall medical history in order to facilitate targeted disease management activities. In a recent study, one large national PBM was able to demonstrate a 24 percent savings in per-member per-month costs for those patients with any number of chronic conditions who were part of a disease management program, compared to those patients with the same conditions who were not.

- **Formulary Development and Management.** Among the most important tools developed by PBMs to manage prescription drug benefits are formularies. Formularies create competition that benefits consumers by driving down the overall cost of prescription drugs. A formulary is a list of prescription drugs approved for reimbursement by the plan sponsor contracting with a PBM. PBMs develop formularies at the direction of the plan sponsor, who may require that it be customized to meet the particular needs of their benefit plans. Some may prefer broad unrestricted access to all medications and therefore are willing to accept higher costs to offset broader access. Other plan sponsors may be very concerned with containing drug costs and will opt for more restrictive formularies based upon their economic needs.

The Role of P&T Committees

In developing a formulary, the primary considerations are safety, efficacy and clinical appropriateness. PBMs use panels of experts, called Pharmacy and Therapeutics (P&T) committees, to develop their formularies and lists of preferred drugs. P&T Committees are comprised of physicians, pharmacists, and individuals with other appropriate clinical expertise. Often, individuals with special expertise are consulted when considering medications within particular therapeutic classes. Development and maintenance of formularies is an ongoing activity, as they must be continually updated to keep pace with new therapies, recent evidence from clinical research, changes in medical practice, and FDA guidance. Through their actions, P&T committees help drive discounts among competing brand-name prescriptions. P&T committee members are typically not employed by the PBM, a pharmaceutical manufacturer, or any other interested parties; do not have any other business or financial relationship with those organizations; and are not directly involved in rebate negotiations with manufacturers.

Once a drug is included on a formulary, it can be classified as preferred, non-preferred or generic. Such classification is known as tiering. Tiered formularies are developed based on the needs of the plan sponsor and what co-pay structure and cost sharing they wish to include in their prescription drug benefit. Often, generic drugs are assigned the lowest co-payment, followed by preferred, and finally non-preferred drugs.

- **Generic Substitution.** An important component of formulary development and management is access to generics. It has been well documented that generic substitution saves money and provides equally beneficial therapeutic value to equivalent brand names. A pharmacist cannot change a prescription but can serve to educate and encourage physicians and patients to consider other products. The ultimate authority for the medication prescribed for a patient rests with the physician or other appropriately licensed prescriber. PBMs help pharmacies recognize opportunities to dispense generic alternatives through real-time electronic messaging.

- **Drug Utilization Review (DUR).** PBMs also offer drug utilization review as part of formulary management activities. DUR is a broad function that encompasses quality, safety, and cost effectiveness. Concurrent DUR detects potential inappropriate utilization for a single prescription drug claim for a specific patient. This process will allow for real-time notification to a pharmacy when a drug is being dispensed that could cause an adverse reaction for that patient. Retrospective DUR is conducted to detect broad patterns of inappropriate prescribing and utilization. For example, a PBM may find as a result of retrospective DUR that a particular physician is prescribing a brand-name drug, while most others in the area are prescribing the more cost-effective generic therapeutic equivalent. Retrospective DUR also can be used to educate physicians about a particular drug when new clinical information becomes available (e.g., that a particular drug has been discovered to present serious risks for some patients with certain underlying conditions). The communications from PBMs to the physicians are typically via mail, fax transmissions, or phone calls.

- **Networks of Pharmacies**. Most PBMs establish a network of retail pharmacies with a broad geographic range. The larger PBMs have networks that include approximately 95 percent of the nation's retail pharmacies. Managing pharmacy networks entails recruiting and credentialing pharmacies, negotiating discounts from pharmacies for drug ingredients and dispensing services, monitoring pharmacies for quality and customer service, auditing pharmacy records, and providing technical support to pharmacies and pharmacists. The Medicare Modernization Act has specific requirements for ensuring beneficiaries have broad access to pharmacies.

- **Mail-Service Pharmacy Option**. Mail-service pharmacy allows for convenient access to prescription drugs at much more cost-effective prices. Mail-service pharmacies fill prescriptions for maintenance medications; i.e., prescriptions that are used on a continuing basis for individuals managing complex or chronic illnesses. Plan designs often allow consumers to obtain a 90-day supply of medication instead of the usual 30- or 60-day scripts that are filled by retail pharmacies. Consumers save money as well by paying only one co-payment for the 90-day supply of medication filled by a mail-service

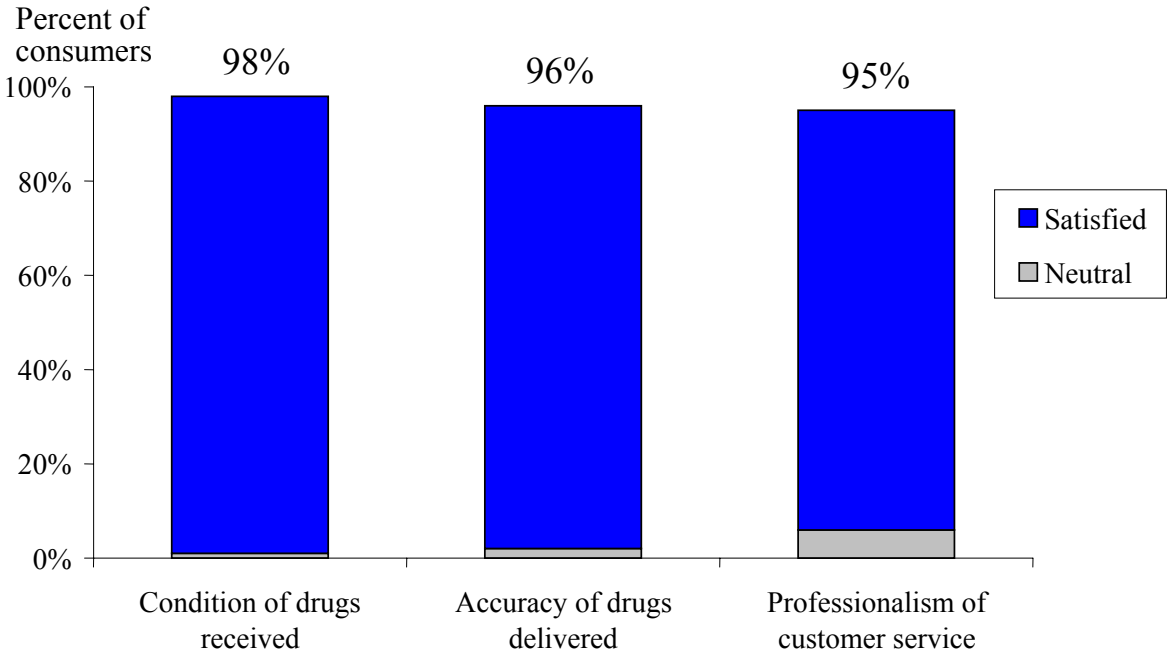
pharmacy, rather than the three separate co-payments required for 30-day supplies filled at a retail pharmacy.

Mail-service pharmacies also provide services comparable to those provided by retail pharmacies. Mail-serve pharmacies retain pharmacists on staff who are available to counsel consumers and consult with physicians on appropriate drug therapies. Counseling is done primarily through toll-free telephone communication. Most mail-service pharmacies have telephone counseling by pharmacists available 24 hours a day/seven days a week. The process offers convenience to consumers, particularly seniors and the disabled, who may have transportation or other constraints that make going to a retail pharmacy difficult. The mail-service pharmacy option is also particularly helpful in serving residents of rural areas who would otherwise have to travel long distances to the nearest retail pharmacy. In addition, some consumers may prefer telephone consultation in order to afford them more privacy than consultations available in public at retail pharmacies would.

Consumers Highly Satisfied with Mail-Service Pharmacy Option

Consumers are highly satisfied with mail-service pharmacies, according to a survey of nearly 14,000 mail-service pharmacy users nationwide (see Figure 1). From the professionalism in customer service to outstanding accuracy in the drugs received by consumers, mail-service pharmacies receive high marks. Older consumers as well as those who have used mail service for longer periods of time are most likely to cite convenience as an important factor as to why they choose mail service.

High Consumer Satisfaction With Mail-Service Pharmacies



Source: PCMA Patient Satisfaction Survey of Prescription Drug Benefit Programs, 2002.

(Figure 1)

Key findings on the satisfaction of mail-service pharmacy users:

- 98 percent were satisfied or neutral with the **condition of the drugs** they received;
- 96 percent were satisfied or neutral with the **accuracy of the drugs** that were delivered;
- 95 percent were satisfied or neutral with the **professionalism of customer service**;

Also, when mail service pharmacy users are asked to identify reasons they choose mail service:

- 95 percent cite cost savings;
- 82 percent cite convenience.

- **Rebates and Discounts**. One of the tools PBMs use to help lower the cost of prescription drugs for consumers is by negotiating rebates and discounts on prescription drugs with drug manufacturers. Independent data confirm that consumers see significant savings on prescription drugs in part because of PBMs' ability to negotiate discounts with drug manufacturers. Maintaining confidentiality is essential to preserving PBMs' ability to negotiate discounts for consumers and purchasers. Public disclosure of contract terms between PBMs, manufacturers, and retailers would dramatically alter the competitive landscape by giving competitors access to proprietary pricing strategies. For its part, the Congressional Budget Office has noted increased disclosure of proprietary pricing information would cost the Medicare program $40 billion over ten years as PBMs would have less ability to maximize savings for beneficiaries.[4]

- **Electronic Claims Processing.** A core activity of PBMs is the processing of pharmacy benefit claims. PBMs have electronic communications systems that link them to their network retail and mail service pharmacies. This allows them to adjudicate claims on a real-time basis quickly and efficiently.

  When a consumer presents a prescription to a pharmacy, the pharmacist is able to communicate immediately with the PBM to verify the individual's eligibility, whether the drug is covered, and determine, based on the benefit plan that is applicable to the individual, the amount the pharmacy will be paid for the drug, and the amount of coinsurance or copayment that is to be collected from the individual. This real-time electronic interchange also allows for the PBM to interact with the pharmacist for cost-management and quality interventions.

  About 98 percent of pharmacy benefit claims are processed electronically, thus eliminating most of the need for paper claims and retrospective adjudication. Enrollees may be required to file paper claims in certain circumstances, such as when a prescription

[4] Congressional Budget Office, "Cost Estimate of HR 1, Medicare Prescription Drug and Modernization Act, and S 1, Prescription Drug and Medicare Improvement Act of 2003," July 22, 2003

is dispensed by a pharmacy that is not within the PBM's network, or when the enrollee's eligibility cannot be verified at the time of purchase.

- **Consumer Information.** PBMs often provide general educational materials for consumers on appropriate prescription drug use as well as other health and wellness issues. PBMs will sometimes send educational information directly to plan enrollees about their specific disease or condition. Such information ranges from pamphlets to web-based interactive programs linked to the PBM's website. Enrollees with chronic conditions that benefit from self-management, such as asthma, congestive heart failure, and diabetes, are often targeted for such consumer education programs. Education regarding the importance of patient compliance is part of many PBMs' consumer education programs. Medication non-compliance can result in increased costs, particularly if the non-compliance leads to a relapse of the condition being treated and a hospitalization or other medical intervention results.

- **Consumer Compliance Programs.** Patients who unwillingly or unknowingly fail to comply with doctors' orders regarding prescribed medications can up end with poor medical outcomes and ineffective use of resources. For this reason, PBMs, with purchasers' and patients' consent, will often follow-up with patients to remind them to take medications and to get prescriptions refilled.

III. INDEPENDENT, GOVERNMENT DATA DOCUMENT SAVINGS, ACCESS PBM-ADMINISTERED DRUG DISCOUNT CARDS PROVIDE CONSUMERS

Numerous independent and government data have documented the quality, savings, and access that PBMs bring to the health care system, both for seniors with no prescription drug coverage and the under-65 population. With respect to drug discount cards, both the US General Accounting Office (GAO) and private researchers have assessed PBMs' record in the private sector – and with it, have provided a preview of what seniors and disabled beneficiaries should expect with Medicare-endorsed drug discount cards.

GAO Examines Savings, Access Provided by PBM-Administered Drug Discount Cards[5]

In September 2003, the GAO issued a report examining prescription drug discount cards available in the private market and sponsored by a number of entities, including PBMs and drug manufacturers. GAO examined the median retail drug-discount card price charged to consumers on nine prescriptions versus the median retail price charged to consumers with no drug card at pharmacies in the Washington, DC area, California, and North Dakota. Among the report's key findings:

- PBM-administered drug-discount cards can save consumers hundreds of dollars per year. According to the GAO, consumers using PBM-administered drug discount cards save as much as much as 44 percent off the median pharmacy price charged to consumers with no drug discount card. In Washington, DC, GAO found these savings for consumers average 18 percent for the nine drugs surveyed, translating to hundreds of dollars per year, even after deducting consumers' annual enrollment fee.

- Mail-order pharmacy provides consumers with significant savings over retail pharmacy prices paid without a drug discount card. For consumers who prefer the convenience and pricing advantages of the mail-service pharmacy option, drug discount cards also provide significant savings to consumers compared to what they would otherwise pay at the retail pharmacy counter without a drug discount card. GAO's comparative analysis of mail-service pharmacy prices and retail pharmacy pricing without a drug discount card found that consumers can save hundreds of dollars per year. In California, the savings provided to consumers from mail-service pharmacy options can potentially run into the thousands of dollars.

- PBM-administered drug discount cards provide much broader access to medications to working families and seniors than competing drug-manufacturer discount cards. GAO found that PBM-administered drug discount cards are available to all adults and can be

[5] "Prescription Drug Discount Cards: Savings Depend Upon Pharmacy & Type of Card Used," US General Accounting Office (GAO), September 2003

used to purchase most out-patient drugs. PBM-administered drug discount cards enroll more than 17 million Americans.

- Consumer savings with drug discount cards often depend upon the extent of the retail pharmacy mark-up. It is documented that prescription drug prices charged to consumers by retail pharmacies can vary widely, even among drug stores in the same chain in the same market. GAO found that "choice of pharmacy rather than choice of card had more effect on how much a person saved with a discount card." In short, GAO's analysis appears to suggest that consumers should shop around for lower drug prices, even when using a drug discount card.

PBM-Administered Drug Discount Cards Provide Savings for Uninsured Seniors[6]

In a survey published in March 2003, researchers at Brandeis University's Schneider Institute for Health Policy analyzed more than 3 million pharmacy claims from eight national drug discount card programs for individuals aged 65 and older. The data analyzed in this research represent savings provided by PBM-administered drug cards for 124 prescription drugs. Among the key findings:

- For seniors with no supplemental drug coverage, the total average savings for all prescriptions with a PBM-administered drug discount card was 15.3 percent.

- For seniors with no supplemental drug coverage, PBM-administered drug discount cards provide average savings for generic prescriptions of 26 percent ($7 per prescription) and average savings for brand-name prescriptions of 14 percent ($11 per prescription). These savings are over and above any discounts otherwise provided to individuals with no drug coverage at retail pharmacies.

[6] "PBM-Administered Prescription Drug Discount Cards: Savings for Uninsured Seniors," Brandeis University Schneider Institute for Health Policy," March 11, 2003

- For patients taking multiple prescription drugs concurrently, as many seniors do, savings for a month of medications were substantial, ranging between 12 percent and 21 percent overall. These savings could translate into hundreds of dollars per year. Savings depended on the mix of medications, location, and pharmacy.

- Card savings were similar for pharmacies located in rural states and those in urban states.

GAO Examines Savings Provided to Federal Employees' Health Benefits Program[7]

In January 2003, the General Accounting Office examined the cost savings provided to federal employees by PBMs participating in the Federal Employees' Health Benefits Program (FEHBP).

- For prescription drugs dispensed through mail-order pharmacies, the average mail-order price was about 27 percent below the average cash price paid by consumers for a brand-name drug at a retail pharmacy and 53 percent below the average cash price paid for generic drugs.

- For drugs dispensed at the retail pharmacy counter, PBMs negotiated discounts of 18 percent below what consumers would pay in cash at the retail pharmacy counter for 14 brand name drugs and 47 percent below what consumers would pay for 4 select generic drugs.

[7] "Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, & Pharmacies," GAO, January 2003

IV. MEDICARE SHOULD PRESERVE PBMs' PROVEN TOOLS & TECHNIQUES FOR BENEFICIARIES

The bipartisan Medicare Modernization Act represents an historic step forward for the nation's seniors and disabled beneficiaries. By preserving those very tools and techniques that PBMs have used to drive down the cost of prescription drugs in other parts of the system, Medicare stands poised to avail itself of this approach and reap the rewards for beneficiaries. Indeed, policymakers on both sides of the aisle have long recognized the value that PBMs can bring to the Medicare population. As some have noted, if PBMs did not exist, policymakers would have had to invent them.

The good news for millions of seniors and disabled beneficiaries is that the Medicare program has been modernized and that beneficiaries will have access to a wide range of medicines at a lower price. According to an estimate from the Congressional Budget Office, in 1999, 10 million Medicare beneficiaries had no prescription drug coverage. These beneficiaries have had no protection in the marketplace and typically paid the highest prices on prescription drugs at retail pharmacies. Moreover, these beneficiaries have tended to utilize fewer prescription drugs and pay higher out-of-pocket costs for their medicines.[8]

Beneficiary Savings

PCMA fully expects the interim Medicare drug discount card will provide important and meaningful savings to millions of beneficiaries when the program becomes operational in June 2004. While others groups in the past – most notably the retail pharmacy lobby – have sued the Administration (twice) to block a drug discount card program from taking effect, PCMA member companies have long thought that Medicare beneficiaries should benefit from the savings offered by Medicare-endorsed drug discount cards. While CMS estimates that seniors can expect savings on average of 10 to 25 percent, the experience of drug discount cards in the private sector indicates that in some instances seniors may well benefit from even steeper discounts – in some cases as much as 50 percent less than what they otherwise would have paid. While we

[8] "Medicare and Prescription Drug Spending," Kaiser Family Foundation, June 2003.

expect the savings provided to beneficiaries will be meaningful in all settings, in particular, we expect that mail-service pharmacies will offer beneficiaries the steepest discounts of all.

Pharmacy Access

Seniors can also expect to have access to a wide network of retail pharmacies through the interim Medicare drug discount card. Card sponsors seeking to offer a Medicare-endorsed discount card will have to meet pharmacy standards set forth in the TRICARE program (the Department of Defense's worldwide health care program). These standards are:

- For beneficiaries in urban areas, at least 90 percent of beneficiaries live within 2 miles of a participating pharmacy;

- For beneficiaries in suburban areas, at least 90 percent of beneficiaries live within 5 miles of a participating pharmacy; and

- For beneficiaries in rural areas, at least 70 percent of beneficiaries live within 15 miles of a participating pharmacy.

V. KEY CHALLENGES GOING FORWARD

PCMA believes strongly that the Medicare prescription drug discount card program will provide meaningful savings to beneficiaries. A key challenge before policymakers in implementing both the drug discount program and the full Part D benefit lies in preserving the ability of PBMs and other entities to negotiate maximum savings for beneficiaries.

Ensuring a Competitive Marketplace in Medicare

A competitive marketplace is key to making prescription drugs more affordable for consumers. PBMs represent the best alternative to direct government price controls on prescription drugs in Medicare. The Congressional Budget Office recently refuted the notion that price controls – or

"direct negotiation" by the federal government and manufacturers – would provide greater savings than would a competitive marketplace:

> "We estimate that striking that [non-interference] provision would have a negligible effect on federal spending because CBO estimates that substantial savings will be obtained by the private plans and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree. Because they will be at substantial risk, private plans will have strong incentives to negotiate price discounts, both to control their own costs in providing the drug benefit and to attract enrollees with low premiums and cost-sharing requirements."[9]

Maintaining Flexibility in Formulary Design

A key challenge before policymakers in implementing the Medicare Modernization Act lies in preserving the integrity and flexibility of formulary design. Clinically-based formularies are crucial to ensuring that beneficiaries have access to safe, effective, and proven prescription drugs. PBMs are well versed in devising formularies that achieve these goals and control costs. The goal of the card program is to create a competitive marketplace where Medicare beneficiaries will be able to select a card that best suits their needs in the selection and the cost of the covered drugs. We recognize that because of the limited time available to launch the new benefit and the need to ensure that plans provide coverage in key categories that the 209 class structure was used by CMS. We are concerned, however, that extending this level of mandate into the 2006 benefit may diminish the ability participating plans would have in negotiating discounts with manufacturers, which are vital for driving down drug prices for seniors. The outcome of the U.S. Pharmacopoeia (USP) process as described in the Part D portion of the statute for defining therapeutic categories will be critical to the success of the program. The legislation calls for substantial input into that process.[10] PCMA believes strongly that the category structure used in the discount card program should not be used as the starting point for the USP process.

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[9] January 23, 2004 Letter from Douglas Holtz-Eakin, Director, Congressional Budget Office to Honorable William H. Frist, Majority Leader, United States Senate.

[10] Social Security Act Section 1860D-4(b)(3)(C)(2), (Pub.L.No. 108-173, Sec. 101)

Card-sponsor requirements for pharmacy accountability and guarantees

The interim drug discount card regulation appears to require card sponsors to "guarantee" that network pharmacies notify enrollees of the cost differential between the price of a prescribed drug and the lowest-priced equivalent generic available at the pharmacy. In addition, sponsors are to guarantee that pharmacies charge the lower of the contract price or their usual and customary price (U+C), which is typically the amount a cash-paying customer with no drug coverage would pay at the retail pharmacy counter.[11] PCMA believes that the term "guarantee" could be misinterpreted as imposing liability on a sponsor if a pharmacy failed to comply with these requirements. PCMA believes that the regulation's intent would be satisfied by contractually requiring pharmacies to notify beneficiaries of lower-cost generic availability and the approximate cost differential. Such contracting requirements and routine network pharmacy auditing would also ensure compliance with the intent of the U&C pricing language. PCMA has requested that CMS clarify their intent with these provisions.

Standardized Industry Formats for Data Reporting

The interim regulation requires that sponsors submit certain data elements as part of claim and enrollment forms that are not a part of the current industry standard transaction set [National Council for Prescription Drug Programs (NCPDP)]. For example, CMS requests submission of the U+C price-without dispensing fee. The U+C price-without dispensing fee simply does not exist within current industry standards. The U+C price is the price pharmacies charge for cash paying customers in its totality and does not include a breakdown of the dispensing fee.

Another example is requesting the Drug Enforcement Agency (DEA) number for each prescriber. Not every prescriber has a DEA number, physicians may have more than one number, and in some cases institutions may have a DEA number under which house staff may prescribe (e.g., an emergency room or clinic). Therefore, the DEA is a less-than-ideal proxy for a unique physician identifier and would not provide the individual prescriber identification that CMS is seeking.

[11] 68 FR 69918

PCMA recommends following the industry standard for all data submissions, not only for the drug card program, but also in looking ahead to the Part D benefit. It is important that the agency model this program as much as possible on the existing private industry framework to ensure that the expected efficiencies will also mirror those obtained in the private sector.

State Payment of Transitional Assistance Coinsurance

The interim final rule allows for States to provide financial assistance to Transitional Assistance enrollees for paying the required 5 or 10 percent coinsurance (depending on income status) at the point of sale. Within the preamble and regulation it is not clear whether the State would make arrangements for payment of any coinsurance assistance to the card sponsor or the pharmacy. [12] Given the budgetary pressures under which states currently operate, PCMA believes CMS should defer to States the decision on how best to pass coinsurance payments made on behalf of a State's beneficiaries. CMS should ensure that its regulations provide as few obstacles as possible to encourage States to participate. If States use the plan sponsor to manage the coinsurance payment, they should only be required to demonstrate that pharmacies have actually received the amount covered. Since the card sponsor is responsible for managing all Transitional Assistance funding, this clarification would ease the tracking of such funds and assure the applicable coinsurance requirements have been met.

VI. CONCLUSION

The Medicare Modernization Act represents an historic opportunity to expand the benefits and choices available to seniors and disabled beneficiaries and to institute much-needed reforms that will put the Medicare program on a path to long-term viability. As a first step, the interim Medicare drug discount card will provide meaningful savings to beneficiaries. For low-income seniors and those without any drug coverage now, the savings provided by the drug card – as much as 50 percent in some cases off the retail price – represent a lifeline.

[12] 68 FR 69863 and 69883

PCMA and its member companies stand ready and willing to help implement the interim drug card and the permanent part D benefit. We are excited by the opportunity to bring the proven tools and techniques that have worked well in other parts of the system to the Medicare population and to helping expand beneficiaries' access to safe, effective, and affordable medicines. PBMs have worked well for 200 million Americans and we believe PBMs' participation in Medicare in the years ahead will only serve to strengthen the program.

Mr. Chairman and members of the Committee, thank you for the opportunity to testify today and we look forward to answering any questions you might have.