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Before the

UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

The Medicare Drug Benefit:
Are Private Insurers Getting Good Discounts for the Taxpayer?

July 24, 2008

Introduction

Good Morning Chairman Waxman, Ranking Member Davis, and Members of the House Committee on Oversight and Government Reform.

I am Mark Merritt, President of the Pharmaceutical Care Management Association (PCMA). PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP).

Managing prescription drug benefits – in either the private or public sectors – PBMs utilize a number of tools and strategies to maximize value for their clients, the payors. A common thread connecting all programs administered by PBMs is that success depends on saving their clients money and offering the best overall value in terms of cost, quality, access, and convenience. To stay in business, PBMs must deliver high quality prescription drug benefits at highly competitive prices.

Today, PBMs manage most Medicare Part D drug benefits, either as stand-alone Prescription Drug Plans (PDPs) or as contractual service providers to PDPs and MA-PDPs. Within the competitive Part D framework established by Congress and implemented by CMS, PBMs have worked hard to meet the justifiably high expectations of seniors and policymakers alike and have successfully achieved savings comparable to union plans, State employee health plans, FEHBP, and other commercial payors.

In addition to drug rebates, there are several other key reference points for measuring Part D cost trends, including: pharmacy discounts, dispensing fees, generic substitution rates, formulary compliance rates, use of low-cost delivery channels, and the number and type of prescriptions used by beneficiaries.

While there is always room for improvement, PBMs are proud of their performance in Part D. PBMs and Part D sponsors have reduced overall program costs by 30 percent below original government projections, offered beneficiaries lower than expected premiums, generated high levels of generic utilization while providing broad choice of drugs and access to over 60,000 pharmacies, all while attaining a continually high rate of beneficiary satisfaction.

The Role of PBMs in Medicare Part D

In many respects, the role of a PBM in Medicare Part D is that of a federal contractor competing to provide services to the program. PBMs work with Part D plans to submit competitive bids which are either approved or rejected by CMS. Competition is further enhanced as each Medicare beneficiary then compares plans and chooses to enroll in the plan that best meets their needs. Finally, plans are subject to rigorous oversight by CMS and Congress.

Working within the competitive Part D framework, PBMs offer Medicare and its beneficiaries the best overall value by using proven tools and strategies that both control costs and provide the highest quality prescription drug benefits.

In addition to reviewing PBMs performance in Part D, I would like to discuss ways in which we believe additional savings are possible for the Medicare Program using common-sense measures that can be implemented by Congress. These include: establishing a clean pathway for biogenerics, reducing regulatory barriers to generics entering the market, implementing e-prescribing effectively, and enhancing mail service pharmacy options. PCMA and the PBM industry look forward to working with you on this and other measures that provide high levels of access, improve efficiency, and save money for the Medicare program and its beneficiaries.

PBMs Help Medicare Program and Seniors Save Money

PBMs have played a major role in creating broad access to prescriptions drugs while generating significant savings for Part D and its beneficiaries.

- **Part D Savings:** Part D expenditures over the 2008–2018 period are now projected to save more than $117 billion than estimated last July.

- **Premiums:** At about $25, the average monthly Part D plan premium paid by beneficiaries is far below the CBO estimate of $35 and CMS estimate of $37 for average premiums during the first year of Part D.

As a result of better-than-expected plan savings and lower-than-expected premiums, the Part D program will be 30 percent less expensive for the first 10 years than originally estimated.[1] According to analysis conducted by PricewaterhouseCoopers, overall savings of PDPs in Part D are also comparable to levels achieved by PBMs in the Federal Employees Health Benefits Program (FEHBP).

In addition, Part D has helped many beneficiaries obtain drug coverage and save money, as high satisfaction levels with the program attest:

- **Coverage:** The percent of seniors with prescription drug coverage has increased from 75 percent prior to Part D, to more than 90 percent in 2007. Surveys have shown that those few remaining seniors without drug coverage are those that don't want it because they take few or no prescriptions.[2]

- **Drug costs:** According to CMS, Medicare seniors today are saving an average of $1,200 a year versus those who previously had no drug coverage.

[1] According to the CMS actuaries, projected Part D spending over 2008-18 will be $117 billion lower than projected in OMB's Mid-Session Review released in last July.
[2] Swanbrow, Diane. "Most seniors now have drug coverage, study shows" *The University Record* University of Michigan News Service. August 13, 2007. Available at http://www.ur.umich.edu/0607/Aug13_07/18.shtml

- **Satisfaction:** A variety of surveys from sources such as AARP, J.D. Power and Associates, and the Kaiser Family Foundation show that more than three quarters of seniors are satisfied with their Part D drug benefit.

PBMs Encourage Generic Drug Use in Part D

One of the most important ways that PBMs help the Medicare program and its beneficiaries save money is by encouraging the use of generic drugs whenever clinically appropriate. Generic drugs cost on average, 71 percent less than brand drugs.[3] For each percentage point increase in the generic utilization rate, Part D drug spending falls by an estimated $12 billion.[4] In addition to substituting for their brand equivalents, generic drugs are also frequently effective therapeutic alternatives to similar branded products within the same class.

As they do in the private sector, PBMs encourage generics in Part D through lower or waived copayments and formulary compliance programs such as step therapy. To make sure that generic substitution occurs as soon as generics come to market, PBMs educate physicians and patients beforehand. In addition, Part D plans encourage generics by ensuring that pharmacies make the prices of both generics and brands available for comparison by beneficiaries. According to the MMA, each Part D plan should ensure that its network pharmacies inform beneficiaries of the cost differential between the price of the prescribed drug and the lowest cost generic drug equivalent.

Generic drug utilization in the Part D program averages 56 percent, as compared with 54 percent in Medicaid.[5] Among some Part D sponsors, utilization of generics exceeds 80 percent.[6] More recent evidence suggests that generics have reached 63 percent of Part D prescriptions in

[3] Office of the Inspector General, Department of Health and Human Services. "Generic Drug Utilization in the Part D Program" November, 2007. OEI–05-07-005130 Available at http://www.oig.hhs.gov/oei/reports/oei-05-07-00130.pdf
[4] PriceWaterhouseCoopers. "Medicare Part D: An Assessment of Plan Performance and Potential Savings" A Report Prepared for the Pharmaceutical Care Management Association. January 2007
[5] OIG. "Generic Drug Utilization in the Part D Program"
[6] Ibid

2008, up dramatically from just 50 percent when the program began in 2006.[7] We believe this substantial increase in generic drug use among Medicare seniors attests to the effectiveness of Part D plans.

By encouraging generics, PBMs help many seniors avoid the statutorily created coverage gap or "doughnut hole." According to a PCMA analysis, beneficiaries can avoid their entry into the doughnut hole by an average of 74 days by utilizing of generic drugs and mail-service pharmacies.

Some Part D plans also cover generics in the coverage gap, and while we believe it would be preferable for Congress to eliminate the doughnut hole entirely, a recent study suggests that it does encourage seniors to switch to generics. For those beneficiaries that do switch to generics to save money in the gap, just 6 percent return to using brands after coverage resumes.[8]

Getting more generic drugs to market sooner would also further reduce Part D costs. PCMA is pleased that steps were taken in this year's Food and Drug Administration Authorization Act to reduce frivolous citizens petitions that delay market entry for generic drugs. We support removing loopholes that prevent generics from entering the market, and fully support establishing a regulatory pathway for approval of generic biologic drugs.

With spending on biologics expected to double from $54 billion to $99 billion by 2010, creating an effective regulatory pathway to approve generic biologics would save Medicare billions of dollars. PCMA looks forward to working with you to help pass the Access to Life Saving Medicines Act. This legislation meets what we believe to be the most important criteria for any biologics legislation Congress considers by:

- Empowering the FDA to use its expertise to determine on a case-by-case basis what scientific data they need to approve comparable and interchangeable products;

[7] Wolters Kluwer Health. "New Study Says Generic Drugs Now Own 63% of Medicare Part D Market — Up from 50% Less Than Three Years Ago" Press Release. June 23, 2008. Available at http://www.wolterskluwer.com/WK/Press/Product+Press+Releases/2008/Jun/pr_23Jun08b.htm

[8] Ibid

- Being free of administrative barriers that impede the FDA's ability to approve safe and effective biogenerics; and

- Providing a clear and timely resolution to patent disputes and prohibits frivolous suits that restrict access and delay competition.

Thank you for your leadership on this important initiative.

Unit Price Discounts Just One Component of Total Value

Just as they do in the private sector, PBMs play a key role in negotiating price discounts from manufacturers and pharmacies in order to lower unit drug prices in Medicare Part D. Unit price is one of many components of overall program costs, with the amount and type of drugs used being of at least equal importance. Encouraging higher generic utilization, employing more affordable delivery vehicles such as mail-service pharmacy, negotiating aggressively with retail pharmacies, and helping doctors and patients understand when safer, more affordable options are available all have a profound influence on overall costs to the program and its beneficiaries. The added value of these services to the Medicare program includes choice of formularies, broad access to medications, convenient pharmacy options, effective medication therapy management, and other benefits for Part D enrollees.

PBMs Negotiate Price Discounts in Part D Comparable to FEHBP

Lower-than-expected program costs and high beneficiary satisfaction indicate that PBMs have provided the Part D program and its beneficiaries strong overall value. According to PricewaterhouseCoopers, PBMs are achieving overall savings in Part D of about 29 percent relative to unmanaged drug expenditures, taking into account both prices and utilization. This is a figure comparable to FEHBP.

Manufacturer rebates negotiated by PBMs in Part D are similar to those attained under FEHBP. According to this Committee's October 2007 report, rebates reduced Part D plans expenses by 8.1 percent.[9] According GAO, in FEHBP, manufacturer rebates negotiated by PBMs reduce total annual drug spending by 3 to 9 percent.[10]

How Coverage Mandates Help Manufacturers and Hurt Part D

While Part D savings to date have been comparable to FEHBP, we remained concerned with successive regulatory and statutory measures that erode the ability of PDPs to develop formularies consistent with best practices in the commercial sector. Of particular concern is the recent codification of CMS regulations requiring that "all or substantially all" drugs be covered in certain drug classes of clinical concern.[11] While there is little evidence that this requirement improves access to appropriate medications, it does reduce the ability of Part D plans to negotiate discounts with drug manufacturers. The upward cost implications of such measures are clear. As CBO explained in its original cost estimates for Part D:

> "How effectively PDPs could control Medicare drug costs would also depend on whether and to what extent they were allowed to use the various tools at their disposal, such as enforceable limits on the number and types of drugs included in their 'formulary,' or list of covered drugs."[12]

Alternatively, PCMA supports using an evidence-based approach to Part D formularies. Allowing for more clinical input through refining the two-drugs-per-class rule and the set of

[9] U.S. House of Representatives, Committee on Oversight and Government Reform, Majority Staff. "Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage," October, 2007.
[10] Government Accountability Office. "Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies," GAO-03-196, January 2003.
[11] Public Law 110-275, as enacted by Congress, includes a section (176) on formulary requirements with respect to certain categories or classes of drugs
[12] Congressional Budget Office, "A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit," July 2004.

protected classes would better help to ensure that formularies are able to accommodate for differences across drug classes.[13]

Use of PBM Tools in Part D Guided by Congress, CMS, and Beneficiary Choice

Unlike the way PBMs manage benefits in the commercial market, under Part D they must work with plan sponsors to provide PDP offerings that both comply with Medicare's unique program requirements and also attract individual beneficiaries to enroll. While the tools and strategies available to PDPs are similar to those used by PBMs in the commercial sector, their use in Medicare is guided by statute, regulation, and beneficiary plan choice. This framework, as established by Congress, relies on a delicate balance between ensuring beneficiary access and utilizing tools (such as those of PBMs) to control costs. Moving further in one direction or the other would result in either decreased quality and access or increased costs.

For example, the pharmacy contracting and formulary requirements of Part D ensure access and a higher quality benefit for enrollees, but the Program's unique features (stand-alone nature of its drug plans, insurance risk, and extensive regulatory reporting and compliance costs) mean that its administrative costs are often higher than in commercial sector or government fee-for-service plans. The trade-off is that beneficiaries can keep traditional Medicare A and B and add drug coverage by selecting from a wide range of drug plans based on their individual needs and preferences. It is the competition among Part D plans that ensures plans strive to keep administrative costs as low as possible by achieving ever-greater efficiencies.

Regardless of the size of its enrolled population, the ability of any plan to negotiate substantial rebates with drug manufacturers depends on the extent to which it can implement an effective formulary and management strategies to encourage compliance with that formulary. PBMs negotiate the highest rebates from manufacturers of brand medicines that face competition from several similar brand products within the same therapeutic class. If competing brand drugs

[13] This idea has been outlined by Jack Hoadley of the Commonwealth fund. Hoadley, J., "Medicare Part D: Simplifying the Program and Improving the Value of Information for Beneficiaries," Commonwealth Fund, May 2008.

are judged to be close therapeutic substitutes, as determined by third party experts,[14] the PBM will then negotiate price concessions from a manufacturer in return for a preferred formulary tier position. Typically, the actual manufacturer rebate amount will be calculated at the end of the benefit year when sales figures are available to show how successful these strategies were in increasing the market share of the preferred brand product relative to its competitors. PBMs will also utilize other strategies, such as educating both prescribing physicians and patients about more affordable alternatives. High formulary compliance results in increased market share for the preferred product and higher rebate savings.

How PDPs Use Rebates to Lower Costs for Medicare and Beneficiaries

Questions have been raised as to how much of the manufacturer rebate is "retained" by the PDP, particularly in the context of beneficiary spending in the coverage gap. PDPs are required to pass "some or all" of these rebates back to the program and the beneficiaries it serves. Rebates may be used to expand coverage or to reduce any combination of premiums, negotiated prices, deductibles, copays, or other cost sharing. Rebates lead to lower bids, result in lower premiums and lower plan costs while allowing PDPs to better attract enrollees. Likewise lower premiums reduce costs for *all* of a plan's enrollees rather than only those beneficiaries with high utilization. Although PDPs are allowed to retain a portion of rebates to cover administrative costs, competition forces each PDP to allocate rebates efficiently in order to assure their bids are approved by CMS and to attract and retain enrollees.

Comparing Manufacturer Rebates in Part D to Medicaid and VA

When comparing unit price discounts achieved by PBMs in Part D to the discounts of other government administered programs such as Medicaid and the VA, it is important to remember that drug manufacturers are required by law to provide these programs with discounts equal to the best price concessions they offer to large buyers in the commercial sector:

[14] PBMs rely on panels of third-party experts known as Pharmacy and Therapeutics (P&T) Committees. P&T Committees are made up of physicians, pharmacists, and individuals with specialized clinical expertise. Typically, to avoid conflict of interest, P&T Committee members are not employed by drug manufacturers or PBMs and are not involved in rebate negotiations with manufacturers.

- The Medicaid program receives a legally required unit price discount from drug manufacturers that is tied to the best prices manufacturers provide to their commercial sector clients or a statutory minimum discount.

- The VA program receives unit price discounts based on Federal Supply Schedule (FSS) drug prices which, like Medicaid, are statutorily tied to the best discounts manufacturers provide large private-sector clients. In addition, the VA is a closed system that purchases, takes possession of, and dispenses drugs itself.

The linkage of manufacturer price discounts in federal programs to the best discounts received in the commercial sector has had the effect of shifting costs from government to private purchasers. Research suggests that Medicaid rules substantially increase prices for non-Medicaid consumers:

- When Federal Supply Schedule (FSS) prices were included in the calculation of the Medicaid best price in the early 1990s, the VA experienced related price increases on brand name drugs.[15] Congress subsequently passed legislation to exempt FSS from the Medicaid best price formula.

- CBO estimates that a Medicaid-style "best price" system in Part D "would put upward pressure on prices paid by the VA, Medicaid, and private purchasers" and "would encourage drug manufacturers to reduce private-sector discounts."[16]

- One study found that a ten percentage-point increase in the market share of the Medicaid program was associated with a 10 percent increase in the average price of a prescription.[17]

[15] Congressional Budget Office. "Pricing for Brand-Name Drugs Under Selected Federal Programs," June 2005.
[16] Congressional Budget Office. Letter to the Honorable Debbie Stabenow, April 16, 2007.
[17] Duggan, Mark G. and Scott Morton, Fiona M., "The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing" (November 2004). NBER Working Paper No. W10930. Available at SSRN: http://ssrn.com/abstract=622874

Based on this experience, Congress exempted Medicare Part D from the calculation of Medicaid best price. CBO estimated that this exemption reduced spending in the Part D program by 1.6 percent.[18]

According to CBO, "For HHS to use the greater market share of the entire Medicare population as a source of leverage to secure deeper price discounts and greater cost savings, it would probably have to threaten similar exclusions and limitations on coverage for that entire population,"[19] or, in other words, institute a national formulary for Medicare beneficiaries. Likewise, CBO notes that "under current law… PDPs have both the incentives and the tools to negotiate drug prices that the government [does not currently have].[20]"

Unique Features of Part D Determine Administrative Costs

In addition to processing claims, PDPs actively manage prescription drug benefits, using tools and strategies to encourage greater utilization of generics, preferred brands, and low cost pharmacy options. They also implement medication therapy management, physician and consumer education, and e-prescribing programs that enhance the safety, quality, and affordability of Medicare's prescription drug benefit.

These PBM administered programs add up to significant savings for the Part D program. For example, an analysis of costs in commercial plans sponsored by large employers finds that PBMs accounted for 3 cents of each prescription dollar.[21] In return for that investment, PBMs

[18] Avalere Health. "Follow the Dollar: Understanding Drug Prices and Beneficiary Choices Under Medicare Part D," April 2006.
[19] Congressional Budget Office. "A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit," July 2004.
[20] Congressional Budget Office. Letter to the Honorable John D. Dingell, Chairman of the House Energy and Commerce Committee, January 10, 2007.
[21] Bain and Company. "Pharmaceutical Benefit Channel: Economics, Fulfillment Models," presented at the PCMA Annual Meeting, October 2005.

reduce overall costs by 29 percent relative to an unmanaged benefit.[22] While administrative costs may be higher in Part D due to its unique features, the overall cost reductions are comparable.

Mail-Service Pharmacies Provide Additional Savings Opportunity

Mail-service pharmacies provide the Medicare program and its beneficiaries with another opportunity to achieve greater overall savings. While seniors with short-term acute needs must obtain their prescriptions from local pharmacies, those with chronic conditions such as high-blood pressure can be more affordably served by mail-service pharmacies.

As a result of high levels of automation and efficiency, prescriptions filled through a mail-service facility cost approximately 10 percent less than equivalent retail pharmacy prescriptions.[23] Today, about 20 percent of prescription volume flows through mail-service pharmacies. If this were to increase to 50 percent, the Medicare program and its beneficiaries could save more than $40 billion over the next ten years.[24]

We commend CMS for enabling Medicare beneficiaries to compare their drug costs through local vs. mail-service pharmacies on the Plan Finder website. We also look forward to exploring with Congress how the use of mail-service pharmacies can be encouraged in Medicare.

E-Prescribing Implementation

Another way to not only increase savings in the prescription drug market, but also increase safety, is to continue to increase adoption of electronic prescribing (E-Prescribing). E-prescribing allows doctors to access formulary information and patient drug history, ensuring the most affordable drug treatment and protecting against harmful drug-drug interactions.

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[22] PriceWaterhouseCoopers. "Medicare Part D: An Assessment of Plan Performance and Potential Savings" A Report Prepared for the Pharmaceutical Care Management Association, January 2007.
[23] The Lewin Group. "Mail-Service Pharmacy Savings: A Ten Year Outlook for Public and Private Purchasers", report prepared for the Pharmaceutical Care Management Association, August 2005.
[24] Ibid.

Earlier this month, Congress enacted critical legislation that will for the first time require physicians to e-prescribe under Medicare. We thank you for your support of this important initiative. The inclusion of an e-prescribing requirement in Medicare is a major victory for America's seniors. From a patient's perspective, e-prescribing is the most important issue in the Medicare bill because it saves lives and saves money. This is a historic step forward for e-prescribing as the new requirement in Medicare will now lead to broader adoption of overall health care information technology.

Conclusion

By using PBMs' proven strategies within the competitive Part D framework, the Medicare Program has achieved better-than-expected savings and a majority of beneficiaries are extremely satisfied with their plans, which provide wide access to medications and pharmacies at affordable monthly premiums.

As the Part D program continues to grow and succeed, PCMA looks forward to working with this Committee and Congress to find additional ways to promote savings while continuing to deliver the highest quality prescription drug benefits for America's seniors and Medicare's beneficiaries.

Mr. Chairman, this concludes my testimony. Once again I appreciate the opportunity to appear before this panel today. I am happy to answer any questions that you may have. Thank you.