**LEGISLATIVE HEARING**

**H.R. 4489, the "FEHBP Prescription Drug Integrity, Transparency, and Cost Savings Act"**

**Tuesday, February 23, 2010**

**STATEMENT FOR THE RECORD**

## Introduction

The Pharmaceutical Care Management Association (PCMA) appreciates this opportunity to submit our statement for the record of the February 10, 2010 Subcommittee Hearing. 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).

When 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, employers, health plans, federal and state governments, and other payers. 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.

The Federal Employees Health Benefits Program (FEHBP) has long been the gold standard for employer-sponsored health benefits and is a model for health insurance reform efforts at the state and national levels. The hallmark of the FEHBP is consumer choice and competition. FEHBP offers a wide range of health insurance options for federal workers, retirees and their families and is extremely popular, with a recent OPM survey showing that enrollees are satisfied with their benefits by a 7 to 1 margin. Like any large employer, the Office of Personnel Management (OPM) structures benefits to attract and retain talented employees. Comprehensive prescription drug coverage, widely available at retail and mail pharmacies with

reasonable cost sharing, is a key component of benefit design in the FEHBP. Most plans that participate in the FEHBP competitively bid their drug benefit administration to PBMs.

OPM does not negotiate prescription drug prices or discounts directly with manufacturers or pharmacies, but instead uses its leverage with carriers to limit spending on prescription drugs for FEHBP enrollees. OPM through an annual call letter establishes parameters within which the health plans – and by extension, their subcontracted PBMs – must operate. OPM provides additional guidance on specific issues and practices it deems necessary to address. Through this process OPM encourages carriers to innovate and implement new initiatives to address rising costs and stimulate appropriate use of health care goods and services. In recent years, OPM has encouraged plans to explore greater use of therapeutic alternatives including generic drugs, tiered formularies, drug lists, and evidence-based health outcomes measures to control prescription drug expenditures.

This OPM-established model has allowed PBMs, working with health plan clients, to create broad access to prescription drugs while generating significant savings for health plans and enrollees. Just as they do for private-sector health plans and large employers, PBMs participating in FEHBP play a key role in negotiating price discounts from manufacturers and pharmacies in order to lower unit drug prices. Given that unit price is just one of many components of overall program costs, PBMs also help manage the amount and type of drugs used. PBMs encourage higher generic utilization, employ more affordable delivery options such as mail-service pharmacy, negotiate aggressively with retail pharmacies, and help doctors and patients understand when safer, more affordable options are available. Combined, these tools have a profound influence on overall drug costs for both FEHBP and its beneficiaries. To ensure added value of these services to payers, PBMs provide choice of formularies, broad access to medications, convenient pharmacy options, and other benefits for enrollees.

**Adverse Effects of H.R. 4489 on FEHBP Enrollees**

H.R. 4489 would impose drastic changes on the FEHBP program with no demonstrated value in either savings or improved quality of care for federal workers or retirees. The bill would rely on government price controls to fundamentally alter the FEHBP model and create the precedent for the program to look more like parts of Medicare and Medicaid — where price-controlled hospital and physician payments have left Medicaid with unusually high pharmacy dispensing fees and Medicare physicians threatening to pull out of the program due to below-market reimbursements. Part D – the one part of Medicare that most functions like FEHBP does now – has consistently come in under the CBO projections at the time of its enactment.

H.R. 4489 would set the precedent of federally controlling drug prices and dispensing fees within the FEHBP drug benefit, which could lead to similar fundamental shifts in how hospital and physician benefits are provided in FEHBP. This in turn could ultimately shift FEHBP to more closely resemble public programs such as Medicaid and Medicare than anything available through private sector employer and union plans. Such critical changes to health benefits would normally follow a major report or significant findings that benefits are substandard or services are overpriced compared to other employer payers. But that is not the case. Beneficiaries are overwhelmingly satisfied with FEHBP, and benefit levels and premiums are comparable to or better than those received by employees in the private sector.

H.R. 4489 would set in statute contract requirements for pharmacy benefit managers (PBMs) participating in FEHBP. PBMs would be required to disclose proprietary contract terms regarding drug acquisition costs and pharmacy dispensing fees to OPM, carriers, and enrollees, as well as similar information on private-sector contracts outside of FEHBP. The bill would establish drug price controls with reimbursement based on the average price a manufacturer receives from wholesalers for a given drug and require uniform maximum pharmacy dispensing fees determined by OPM. Further, the bill pre-empts state laws governing generic drug substitution and therapeutic interchange.

**Impact on Pharmacy Access.**

Eight million FEHBP enrollees – federal employees, retirees, and their families – currently benefit from convenient pharmacy access because virtually all of the nation's approximately 60,000 pharmacies participate in FEHBP through nationwide PBM-sponsored pharmacy networks. Changes in PBM and retail pharmacy reimbursement proposed by H.R. 4489 – e.g., carriers could not pay PBMs more than manufacturers, on average, charged wholesalers for the cost of a given drug – could result in payments to pharmacies and PBMs that are less than pharmacy acquisition costs, which could prompt many to reconsider participating in the program. As demonstrated by a retail pharmacy-contested provision of the Deficit Reduction Act (DRA) of 2005 regarding the use and disclosure of Average Manufacturer Price (AMP), such a policy should be carefully considered before disrupting federal workforce coverage.

**Impact on Drug Substitution and Patient Safety**

H.R. 4489 establishes several restrictions on drug substitution for FEHBP enrollees. Pharmacy and physician prescription practices are generally regulated by the States and developed by professional boards with clinical expertise. For example, the bill would not allow a drug substitution based on safety if the replacement drug were "higher in cost," even if concerns were raised about a generic company's manufacturing practices as has happened in the past. The drug substitution provisions of H.R. 4489 represent a substantial shift in existing law and could significantly compromise patient safety

The bill would also prevent pharmacies from substituting generic drugs without the approval of the prescribing doctor, despite state pharmacy laws requiring such substitution. Extensive patient and physician consultation and approval required by the bill would impose unnecessary obstacles that would substantially restrict dispensing of FDA-approved generic versions of brand equivalents. Generics have proven to be extremely effective at controlling costs and expanding access, which is why many states have implemented mandatory generic substitution laws.

Similarly, the bill would prevent collaboration on federally required post-approval drug market surveillance programs such as FDA drug sentinel programs and the Risk Evaluation and Mitigation Strategy (REMS) required by federal law.

**Impact on PBM Competition**

H.R. 4489 would prohibit any drug manufacturer or retail pharmacy from having a controlling interest, defined as 20 percent, in a PBM serving the FEHBP and would prohibit a carrier-controlled PBM from earning a profit, which would appear to include making an operating margin. By requiring plans to send enrollees, for every prescription, the prices paid to manufacturers for drugs and to pharmacies for dispensing them, the bill requires PBMs to publicly disclose their negotiated rates. The Federal Trade Commission has said such public disclosure, or "transparency," leads to higher – not lower – prices. These prohibitions and disclosure requirements, combined with an additional requirement that PBMs serving FEHBP disclose specific acquisition costs and other pricing information on their entire book of business, could severely limit the number of PBMs willing to participate in FEHBP.

PBMs may be unwilling to risk losing the pricing concessions negotiated with manufacturers and pharmacies for non-FEHBP accounts because of the disclosures to enrollees, carriers, and OPM required by the bill. Reduced competition among PBMs, with the possibility of only a single PBM administering all FEHBP drug benefits, would leave remaining PBMs with little or no incentive to lower costs.

**Impact of Cost-Plus Pricing Controls**

H.R. 4489 would require carriers to limit payments for drug charges to Average Manufacturer Price (AMP) minus enrollee cost sharing. AMP is the price manufacturers charge wholesalers. The bill also requires PBMs to pay carriers 99% of all compensation received from manufacturers. Given that 90% of all pharmaceuticals are purchased through drug wholesalers – which to stay in business must charge pharmacies more than the price at which they acquire a drug – requiring reimbursement at AMP would result in PBM reimbursements that are lower

than the pharmacy's acquisition cost. Without a dispensing fee that varied by drug and was high enough both to reimburse the pharmacy for its costs in preparing the prescription and the wholesaler's markup, the pharmacy would carry a loss on every prescription, whether the pharmacy served as the PBM's mail-service pharmacy or was a retail pharmacy. Retail pharmacies are currently contesting a provision of the Deficit Reduction Act of 2005 (DRA) that imposed requirements regarding use and disclosure of AMP, and provisions in both the House and Senate health care reform bills would have made substantially increased the DRA-mandated reimbursement to well above AMP to address pharmacy concerns.

Even assuming the AMP requirement is adjusted to a different benchmark rate, H.R. 4489 would lead to a cost-plus only pricing policy in FEHBP. Large employers, such as OPM, currently have the option to structure contracts using cost-plus pricing and many choose not to do so. Most prefer for the PBM to have an incentive to be aggressive negotiators by allowing PBMs to keep a portion of the savings they negotiate with manufacturers beyond the negotiated price.

**Impact of Data Use Controls**

H.R. 4489 would also restrict the sale of any FEHBP-related claims or utilization data. Such restrictions on the sale of data would establish road blocks for legitimate real-time use of data. For example, PBMs provide utilization data to pharmaceutical manufacturers for federally required post-market surveillance of drug safety. Specialty pharmacies also use claims data to conduct FDA-required risk-evaluation and mitigation strategies (REMS) for certain drugs. Undue restrictions on PBMs receiving reimbursement for sharing data for research and care management purposes could impede valuable research on the safety and efficacy of drugs and drug benefits.

**FEHBP Transparency and Disclosure Standards Already Exist**

OPM already has the authority to impose all of the bill's provisions without seeking any new authority from Congress. In fact, OPM routinely uses its existing authority to impose new PBM contract requirements – *when it deems them helpful to the program*. Indeed, OPM has already required FEHBP carriers to insist that their PBMs meet rigorous transparency and cost-savings standards – some quite similar to those in the bill. For example, in Appendix A of the 2010 Call Letter, OPM requires Experience-rated HMOs to meet an extensive set of standards, including disclosure, conflict-of-interest, and rebate pass-through requirements. These requirements are outlined in Attachment 1 to this testimony.

OPM already has the authority to require increased transparency and disclosures, and has exercised that authority as the many requirements in Attachment 1 demonstrate. FEHBP program management and oversight are best addressed through regulation and sub-regulatory guidance, not legislation. Carrier Call letters, FEHBP guidelines, and the FEHB Carrier Handbook are the appropriate vehicles for OPM to guide and monitor the practices of participating carriers and plans as well as their subcontractors.

**Conclusion**

FEHBP is successful because it relies on market forces and competition to deliver high quality benefits and services to its enrollees. We urge the Subcommittee to consider carefully the provisions in H.R. 4489 that would impose federal price controls on drug products and pharmacy services, pre-empt state laws that assure cost-savings from generic substitution, and require sweeping disclosures of pricing and proprietary business practices that could have the unintended effect of driving prices higher and stifling competition. The adverse impact of such changes on the federal workers, retirees, and dependents who rely on the FEHBP should not be taken lightly.

By using PBMs' management strategies proven in the commercial market, FEHBP carriers have achieved significant savings for their enrollees in their drug benefits and provide wide access to medications and pharmacies at affordable prices. Additional savings for the FEHBP could be obtained if OPM encouraged carriers to adopt even greater use of home delivery, formulary tiering, step therapy, prior authorization and other utilization management tools that facilitate cost-effective medication use.

PCMA looks forward to working with the Subcommittee and Congress to find additional ways to promote savings while continuing to deliver the highest quality prescription drug benefits for all payers.

**Attachment 1**

**Requirements for Experience-rated HMOs**

**From Appendix A of the 2010 FEHBP Call Letter**

(1) The PBM is not majority-owned or majority-controlled by a pharmaceutical manufacturing company.

(2) The PBM agrees to credit to the Health Plan either as a price reduction or by cash refund all Manufacturer Payments to the extent negotiated, if such an arrangement exists between the Carrier and the PBM. Manufacturer Payments are any and all compensation or remuneration the PBM receives from a pharmaceutical manufacturer, including but not limited to, discounts; credits; rebates, regardless of how categorized; market share incentives, commissions, and administrative or management fees. The term also includes any fees received for sales of utilization data to a pharmaceutical manufacturer.

(3) If the Carrier has negotiated with the PBM to receive all or a portion of Manufacturer Payments as described in (2) above, the PBM will provide the Carrier with quarterly and annual Manufacturer Payment Reports identifying the following information. This information shall be presented for both the total of all prescription drugs dispensed through the PBM, acting as a mail order pharmacy, and its retail network and in the aggregate for the 25 brand name drugs that represent the greatest cost to the Health Plan or such number of brand name drugs that together represent 75% of the total cost to the Health Plan, whichever is the greater number:

(i) the dollar amount of Total Product Revenue for the reporting period, with respect to the PBM's entire client base. Total Product Revenue is the PBM's net revenue which consists of sales of prescription drugs to clients, either through retail networks or PBM-owned or controlled mail order pharmacies. Net revenue is recognized at the prescription price negotiated with clients and associated administrative fees;

(ii) the dollar amount of total drug expenditures for the Health Plan;

(iii) the dollar amount of all Manufacturer Payments earned by the PBM for the reporting period;

(iv) the percentage of all Manufacturer Payments earned by the PBM for the reporting period that were Manufacturer Formulary Payments, which are payments the PBM receives from a manufacturer in return for formulary placement and/or access, or

payments that are characterized as “formulary” or “base” rebates or payments pursuant to the PBM’s agreements with pharmaceutical manufacturers;

(v) the percentage of all Manufacturer Payments received by the PBM during the reporting period that were Manufacturer Additional Payments, which are all Manufacturer Payments other than Manufacturer Formulary Payments.

(4) The PBM agrees to provide the Carrier, at least annually, with all financial and utilization information requested by the Carrier relating to the provision of benefits to eligible enrollees through the PBM and all financial and utilization information relating to services provided to Carrier.

(5) The Carrier shall provide any information it receives from the PBM, including a copy of its contract with the PBM to OPM. A PBM providing information to a Carrier under this subsection may designate that information as confidential commercial information. The Carrier, in its contract with the PBM shall effectuate the PBM’s consent to the disclosure of this information to OPM. OPM shall treat such designated information as confidential. However, this information may be subject to FOIA disclosure under 5 C.F.R. § 294.112.

(6) If the Health Plan’s PBM arrangement is with an Underwriter rather than with the Carrier, then all references to the Carrier appearing in this Section 1.28 shall be deemed to be references to the Underwriter.

(7) The carrier will require that its PBM contractors:

(i) Provide information to physicians, pharmacists, other health care professionals, consumers, and payers about the factors that affect formulary system decisions, including: cost containment measures; the procedures for obtaining non-formulary drugs; and the importance of formulary compliance to improving quality of care and restraining health care costs;

(ii) Provide consumer education that explains how formulary decisions are made and the roles and responsibilities of the consumer; and

(iii) Disclose the existence of formularies and have copies of the formulary readily available and accessible.