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Mr. Lynch and members of the Subcommittee on the Federal Workforce, Postal Service and District of Columbia of the Committee on Oversight and Government Reform, thank you for inviting me to testify this morning. I am Jack Needleman, Associate Professor of Health Services at the University of California, Los Angeles School of Public Health. I am also director of the Department of Health Services PhD and MSHS Programs. Prior to coming to UCLA in 2003, I was on the faculty at the Harvard School of Public Health. Before going to Harvard, I was Vice President and Co-Director of the Public Policy Practice at Lewin-ICF, now the Lewin Group. I am testifying as an individual, and the views I express are my own and not those of UCLA or the University of California.

In your invitation to me, you asked me to address four questions:

- What impact does the lack of transparency in the pricing of prescription drugs have on the United States Office of Personnel Management's (OPM) ability to evaluate the overall value of these PBM provided benefits;

- How are prescription drug benefits priced, delivered, and analyzed in other government agencies, such as Department of Defense, Veteran Affairs, and Health and Human Services;

- How are prescription drug benefits priced and delivered in the private sector; and

- Should OPM consider alternative pricing and contracting methods for the FEHBP's prescription drug benefit?

FEHBP plans operate much as private sector insurance or managed care plans. For this reason I address the third bullet first.

1. How are prescription drug benefits priced and delivered in the private sector?

Overwhelmingly, in the private sector, health insurers or self-insured groups contract with Pharmacy Benefit Management Firms (PBMs) to manage and administer drug benefits. It has been estimated that 95 percent of patients with drug coverage receive benefits through a PBM, and that 70 percent of prescriptions and 80 percent of spending on prescription drugs are processed by PBMs.

There is substantial concentration in the PBM industry. In the first quarter of 2009, according to data from AIS which is a principal source of information on PBMs, The top five PBMS had 49% of market share, and the top 10 had 70% market share. [1] Since that survey was completed, the fifth largest PBM, Express Scripts bought the number seven PBM, WellPoint's NextRx.

FEHBP plans, like other insurers, overwhelmingly contract with PBMs. Plans may contract separately for retail pharmacy services and mail-order services. (Mail order services are most likely to be used for long term prescriptions associated with chronic illnesses.) In2006, the five largest fee-for-service plans – Blue Cross Blue Shield, Mail Handlers Benefit Plan, Government Employees Hospital Association (GEHA), National Association of Letter Carriers (NALC), and the American Postal Workers Union (APWU) -- all contracted either with CareMark or Medco (the number 1 and number 4 plans respectively in 2009 prior to the Express Scripts acquisition of WellPoint NextRx) for mail order pharmacy services and either CareMark, Medco or FirstHealth (the 19th largest plan) for retail pharmacy services management. (Table 1) Few of the plans self-administered their pharmacy benefits or had a captive PBM.

Over time PBMs have evolved in the market from passive payers of claims to active managers of pharmacy benefits. Among the key roles they have taken on are:

- Negotiation of prices with pharmacies and drug companies (Discussed further below)
- Development and construction of drug formularies with health plans.
- Utilization review, administration of tiered cost-sharing, and disease management and patient education programs with respect to pharmaceuticals and drugs
- Implementation of generic drug substitution and therapeutic interchange programs (Generic drug substitution is substitution of generic equivalents for branded subscriptions; therapeutic interchange is substitution of other drugs that are not therapeutically equivalent but are within the same drug class. Therapeutic interchange must be coordinated with the prescribing physician.)

In discussing drug prices and PBMs, one needs to distinguish the price PBMs pay for drugs, and the price that the insurer is charged by the PBM. One also needs to distinguish prices for multi-source drugs, typically drugs no longer protected by patent and available in generic form, and prices for branded single-source drugs still under patent and available from only one manufacturer.

Historically, the **average wholesale price**, the list price published by the manufacturer, has served as a benchmark for drug pricing. Created in the 1960s, it was considered at that time an accurate estimate of acquisition costs of pharmacies of the drugs they dispensed. Since then, because of widespread discounting, it is no longer an accurate benchmark. One suggested alternative is the **wholesale acquisition cost**, the manufacturers' reported prices to wholesalers, but this figure often overstates actual payments because it does not include additional discounts for such factors as high volume purchases or prompt payment. Increasingly, attention has

focused on measures such as **average sales price** or **average manufacturer price**, both based on actual sales data. [2]

In addition to these measures derived from the manufacturers' prices or actual prices in the marketplace, for multi-source drugs PBMs or health plans may establish **maximum allowable costs**, their reimbursement limit, based on their assessment of the market and prevailing prices. For branded single-source drugs, PBMs will negotiate with the individual drug manufacturers for discounts. The extent of the discount will depend in part on the number of alternatives in the drug class (which establishes the relative bargaining position of the manufacturer and the PBM) and the expected volume of sales through the PBM, which will be influenced by the PBM's size and its decision (in coordination with its contracted plans) to include the drug in its formulary, which tier of copayment will apply to the drug, and whether to include other drugs in the same therapeutic class in the formulary as well. This formulary decisions are also entwined with pricing.

For multisource, generic drugs, PBMs typically pay pharmacies the maximum allowable cost and a dispensing fee. Additional fees may be paid to pharmacies for implementing therapeutic interchange activities. For single-source branded drugs, PBMs will typically pay the pharmacy an amount reflecting the costs the pharmacy paid for the drugs plus dispensing and other fees. The pharmaceutical manufacturer will then rebate to the PBM the difference between the price it paid and the negotiated price.

Historically, the actual prices paid by the PBMs for the drugs they purchase are usually not made available to the health plans. Instead, plans are often charged a discounted amount from the average wholesale price, typically in the range of 15% to 18% for a branded single-source drug and 60% for generic drugs. [3] Plans may or may not pay additional administrative fees to the PBMs. Data from financial reports and other sources indicate that PBMs earn a significant portion of their profits from the difference between what they pay for drugs after rebates and what they are reimbursed by health plans. [4, 5] This lack of transparency has been the subject of unsuccessful lawsuits, and general concern has been expressed that the PBMs manipulate choices among drugs and between generic and branded drugs to maximize their profits. [6]

2. **What impact does the lack of transparency in the pricing of prescription drugs have on the United States Office of Personnel Management's (OPM) ability to evaluate the overall value of these PBM provided benefits?**

As previously noted, the lack of transparency in health plan-PBM relationships has been a major source of tension between these organizations. It has been possible to develop a general sense of the savings from PBM administration of pharmacy benefits compared to retail purchase at full retail price. Estimates of savings by PBMs for FEHBP, other private health plans, and Medicare Part D plans vary but are in the 15-30 percent range. In 2003, GAO estimated savings for FEHP compared to retail of approximately 18 percent. [7] A 2007 report by PriceWaterhouseCoopers prepared for the Pharmaceutical Care Management Association using a proprietary methodology estimated that PBMs saved FEHBP 28 percent and Medicare Part D plans 29 percent compared to unmanaged drug benefits. [8]

A general sense of savings, however, does not allow an assessment of whether the full potential benefits are being received by the health plans.

3. **How are prescription drug benefits priced, delivered, and analyzed in other government agencies, such as Department of Defense, Veteran Affairs, and Health and Human Services?**

The Federal government purchases prescription drugs through a wide range of programs. In 2005, the Congressional Budget Office compared and contrasted purchasing for brand-name single-source drugs without generic substitutes under:

- The Federal Supply Schedule (FSS) for pharmaceuticals, which is available to all direct federal purchasers
- The federal ceiling price (FCP) program, which is available to the Department of Veterans Affairs (VA),
- the Department of Defense (DoD), the Public Health Service (PHS), and the Coast Guard
- The Department of Veterans Affairs' pharmaceutical prime vendor program
- The Department of Defense's TRICARE pharmaceutical program
- The Medicaid rebate program
- The Public Health Service's 340B drug pricing program.

CBO did not look at purchasing under Medicare Part D, but as discussed above, it is similar to the purchasing of drug benefits through PBMs used by FEHBP and private sector health plans.

CBO found substantial variations in the prices paid in these programs, ranging from the Best Price, the obligation of companies to give the Federal Government the best price offered any private sector purchaser, at 63 percent of the average wholesale price, to 42 percent for the VA and 41 percent for DoD Military Treatment Facilities, the latter two the result of additional negotiations with the drug manufacturers around VA and DoD formulary decisions. Each of these discounts is substantially greater than the 15-18 percent discount cited as the typical PBM branded drug discount. Discounts at these levels are achieved through either direct negotiation or through transparency, requiring drug companies to disclose their best prices and make them available to the Federal government.

In comparing these discounts to those realized by PBMs, two points should be kept in mind. First, these prices do not include costs associated with the other services provided by PBMs and for which they are reimbursed – enrollment and beneficiary servicing and education, claims processing and payment, monitoring for drug-drug interactions, generic substitution, and therapeutic interchange.

Second, as has been documented in several GAO reports, while the discounts available to state Medicaid agencies and PHS-funded clinics and disproportionate share hospitals under Section 340B are substantial, they have often not been realized because of the complexity of the schedules, and inadequate sharing of pricing information between DHHS and the states and eligible providers. In response to these findings, DHHS has taken steps to address these challenges, but they underscore how difficult administering a complex price regime can be.

4. Should OPM consider alternative pricing and contracting methods for the FEHBP's prescription drug benefit?

The short answer to this question is yes. At a bare minimum, OPM should be taking advantage of the recent efforts to demand greater transparency in pricing and charging by PBMs, and be a leader in these efforts. Currently, the HR Policy Association, comprised of chief human resource officers of more than 260 of the largest corporations in the United States, has developed a set of Standards for Transparency in Pharmaceutical Purchasing Solutions (TIPPS^{SM}) and is certifying PBMs that comply with these standards. [9] They include:

> Acquisition Cost for Retail Payments
> Charging coalition members no more than the amount the PBM pays the pharmacies in its retail network for brand and generic drugs.
>
> Acquisition-Based Pricing for Mail Service Claims
> Charging coalition members the acquisition cost of drugs at mail order pharmacies, plus a dispensing fee, based on actual inventory cost (AAC) or wholesale acquisition cost (WAC).
>
> Pass Through of Pharmaceutical Revenue
> Passing through any and all pharmaceutical manufacturer revenue that the Coalition member's utilization enables the PBM to earn.
>
> Specialty Pharmacy
> Providing all transparency standards as described above for specialty pharmacy products.
>
> Plan Management and Consumer Engagement
> Providing decision support tools, including online formulary tools, price comparison functionality, and agree to apply all credits including rebates at the point of sale.
>
> Right to Audit
> Granting coalition members full rights to audit their claims, the PBM's pharmacy contracts, utilization management clinical criteria, and any and all pharmaceutical manufacturer contracts and mail service purchasing invoices related to the Coalition member's contract to ensure compliance.

These are minimum standards for transparency and all PBMs contracting with FEHBP health plans should be in full compliance with them. Many of the largest PBMs have been certified by

this program, but implementing these standards in contract and assuring compliance will remain a challenge. [10] It is a challenge OPM and FEHBP should embrace, however.

Beyond improving its purchasing consistent with the best practices of private sector HR programs, the Federal government should give serious consideration to require FEHBP plans to contract under transparent pricing of the Federal Supply Schedule or Best Price, or perhaps the VA or DoD schedule of prices. Under such a regime, the drug pricing would be clear and the PBMs would compete for FEHBP plan business on their costs and value-added services they offer. There are many issues that would have to be resolved for such pricing to be effectively implemented, but given the potential cost savings, and the significant proportion of FEHBP expenditures going for pharmaceuticals, there are strong reasons for considering such steps.

Thank you for the opportunity to testify this morning and I would be happy to answer any questions.

Table 1: PBMs for selected FEHBP Plans, 2006

Plan	PBM Mail Order	PBM Retail
	Fee for Service Plans	
APWU (47)	Medco Health Solutions	Medco Health Solutions
Association (42)	Express Scripts	Express Scripts
BXBS Service Benefit (10, 11)	Medco Health Solutions	Caremark
	Caremark	Caremark
	Medco Health Solutions	AdvancePCS/Caremark
Foreign Service (40)	Medco Health Solutions	Medco Health Solutions
GEHA (31)	Medco Health Solutions	Medco Health Solutions
Mailhandlers (45)	Caremark	First Health
NALC (32)	Caremark	Caremark
Panama Canal (43)	None	None
Rural Carriers (38)	Caremark	Caremark
SAMBA (44)	Medco Health Solutions	Medco Health Solutions
Secret Service (Y7)	AdvancedPCS	AdvancePCS
	Experience-Rated HMO PBM's	
Altius (9K)	Caremark	Caremark
Avera Health (AV)	Express Scripts	Express Scripts
Blue Cross of Calif. (M5)	Wellpoint Pharmacy	Wellpoint Pharmacy
Blue HMO (R5)	Anthem Pharmacy	Anthem Pharmacy
Blue Shield of Calif. (SJ)	Blue Shield Pharmacy Services	Blue Shield Pharmacy Services
BlueChoice of MO (9G)	Wellpoint Pharmacy	Wellpoint Pharmacy
CareFirst BlueChoice (2G)	AdvancePCS	AdvancePCS
Coventry of Iowa (SV)	Caremark	Caremark
GHI (80)	Express Scripts	Express Scripts
HMO Blue of TX (YM)	Advance Paradigm	Advance Paradigm
HMSA (87)	self-administered*	self-administered*
Health Alliance (FX)	Med Impact	Med Impact
Health Partners (53 and HQ)	self-administered	none
KPS (VT)	MedImpact	MedImpact
Mercy Health (7M, HM)	Walgreen's	Caremark
Optima Health (9R)	Walgreen's	Walgreen's
Triple S (89)	MC-21	MC-21
Unicare of IL (17)	Wellpoint Pharmacy	Wellpoint Pharmacy

Source: Staff of Committee on Oversight and Government Reform, Personal communication, June 6, 2009

Table 2: Description and Estimates of Prices Paid to Manufacturers, Relative to List Price, for Brand-Name Drugs Under Selected Federal Programs, 2003

Price	Description of Price and Associated Federal Program	Average Price as a Percent of List Price
Average Wholesale Price (AWP)	The AWP is a publicly available, suggested list price for sales of a drug by a wholesaler to a pharmacy or other provider. It is not the actual price that wholesalers charge but serves more like a sticker price in the automobile industry. It was chosen as the reference price for this analysis because it is commonly used in pharmaceutical transactions.	100
Average Manufacturer Price (AMP)	The AMP is used to calculate the rebates that manufacturers are required to give to federal and state governments for sales to Medicaid beneficiaries. The AMP is the average price paid to a manufacturer for drugs distributed through retail and mail-order pharmacies. The AMP does not include rebates paid by the manufacturer to third-party payers. Both the AMP and the nonfederal average manufacturer price exclude sales to direct federal purchasers.	79
Nonfederal Average Manufacturer Price	The non-FAMP is used to calculate the maximum price that manufacturers can charge the "Big Four"---the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Public Health Service (PHS), and the Coast Guard---for brand-name drugs. The non-FAMP is the average price paid to the manufacturer by wholesalers (or others who purchase directly from the manufacturer) for drugs distributed to nonfederal purchasers, taking into account any cash discounts or similar price reductions given to those purchasers but not taking into account any prices paid by the federal government. The non-FAMP does not reflect rebates paid by the manufacturer to third-party payers.	79
Best Price	The best price is used to calculate the rebates that manufacturers are required to give to federal and state governments for sales to Medicaid beneficiaries. The best price is the lowest price paid by any private-sector purchaser for the drug product, and it includes discounts, rebates, chargebacks, and other pricing adjustments.	63

Federal Supply Schedule Price	All direct federal purchasers of pharmaceuticals can purchase drugs at prices listed in the Federal Supply Schedule for pharmaceuticals (FSS prices). The VA negotiates FSS prices with manufacturers on the basis of the prices that manufacturers charge their most-favored commercial customers under comparable terms and conditions. Furthermore, during a multiyear contract period, those FSS prices may not increase faster than inflation.	53
Medicaid Net Manufacturer Price	The Omnibus Budget Reconciliation Act of 1990 requires manufacturers to pay a rebate to the Medicaid program. For brand-name drugs, the basic rebate is equal to the greater of 15.1 percent of the AMP or the difference between the AMP and the best price. There is an additional rebate if the AMP rises faster than inflation. The Medicaid net manufacturer price is the AMP minus all rebates.	51
340B Ceiling Price	Section 340B of the Public Health Service Act of 1992 extends the Medicaid drug rebate program to PHS-funded clinics and disproportionate share hospitals. Eligible entities are free to negotiate steeper discounts than the Medicaid rebate amount. Not all eligible entities choose to participate in the program, however.	51
Federal Ceiling Price	The FCP is the maximum price that manufacturers can charge the Big Four for brand-name drugs. It is calculated annually. In the first year of an FSS contract, the FCP equals 76 percent of the previous fiscal year's non-FAMP minus an additional discount if the non-FAMP rises faster than inflation. In subsequent years of a multiyear contract, the FCP also cannot exceed the previous year's FSS price, increased by inflation.	50
Price Available to the "Big Four"	Under the federal ceiling price program, the Big Four purchase brand-name drugs at a price that cannot exceed the FCP. About two-thirds of the brand-name drug products on the FSS have one FSS price (which cannot exceed the FCP). The remaining one-third of the brand name drug products have both an FSS price, offered to all non-Big Four purchasers, and an FSS Big 4 price, offered to the Big Four. The price available to the Big Four is the FSS Big 4 price when it exists and is the FSS price offered to all federal purchasers otherwise.	49
VA Average Price	The VA average price for a drug may be lower than the price available to the Big Four because VA negotiates further price reductions using its preferred formulary. The VA average price takes into account all the various pricing schedules and contracts under which VA purchases drugs, and it includes discounts from the prime vendor that averaged about 3 percent of the contract price in 2003, or about 1.4 percent of the AWP.	42

DoD's Military Treatment Facility Average Price	The DoD military treatment facility average price for a drug may be lower than the price available to the Big Four because DoD negotiates further price reductions using its preferred formularies. The MTF average price takes into account all the various pricing schedules and contracts under which DoD purchases drugs.	41

Source: Congressional Budget Office

Notes: In this analysis, the list price is the average wholesale price.

The study sample includes 130 single-source brand-name prescription drugs that accounted for about 50 percent of U.S. sales through retail pharmacies and about 70 percent of U.S. sales of brand-name drugs through retail pharmacies in 2003. The estimates of average price are based on the quantities of those drugs sold in the United States and, with the exception of the FCP, are for the third quarter of 2003. (The FCP is calculated annually, so the estimate of average price is for calendar year 2003.) Results for other quarters in 2003 are similar. Prices exclude dispensing costs.

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