

FEHBP'S PRESCRIPTION DRUG BENEFITS: DEAL OR NO DEAL?

HEARING

BEFORE THE
SUBCOMMITTEE ON FEDERAL WORKFORCE,
POSTAL SERVICE, AND THE DISTRICT
OF COLUMBIA

OF THE
COMMITTEE ON OVERSIGHT
AND GOVERNMENT REFORM
HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

JUNE 24, 2009

Serial No. 111-11

Printed for the use of the Committee on Oversight and Government Reform



Available via the World Wide Web: <http://www.gpoaccess.gov/congress/index.html>
<http://www.house.gov/reform>

U.S. GOVERNMENT PRINTING OFFICE

51-394 PDF

WASHINGTON : 2009

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FEHBP'S PRESCRIPTION DRUG BENEFITS: DEAL OR NO DEAL?

WEDNESDAY, JUNE 24, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON FEDERAL WORKFORCE, POSTAL
SERVICE, AND THE DISTRICT OF COLUMBIA,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 3:03 p.m., in room 2154, Rayburn House Office Building, Hon. Steven Lynch (chairman of the subcommittee) presiding.

Present: Representatives Lynch, Cummings, Connolly, and Norton.

Staff present: William Miles, staff director; Aisha Elkhessin, clerk; Jill Crissman, professional staff member; Jill Henderson, detailee; Daniel Zeidman, intern; Jennifer Safavian, minority chief counsel for oversight and investigations; Dan Blankenburg, minority director of outreach and senior advisor; Adam Fromm, minority chief clerk and Member liaison; Ashley Callen, minority counsel; and Molly Boyd, minority professional staff member.

Mr. LYNCH. First of all, I'd like to apologize for the lateness of our hearing. There are some strategic maneuvers being undertaken in the House for other reasons than the flow of legislative business, so we are expecting that there may be some interruptions in the hearing.

What I would like to do is to not have that affect your appearance here, or the value of your testimony. So if there are any disruptions, we will try to ask Members to go and vote and come back while we continue the hearing. That is the theory, anyway. But let me first call this subcommittee hearing to order.

The Subcommittee on the Federal Workforce, Postal Service, and the District of Columbia will now come to order. Welcome Ranking Member Chaffetz and members of the subcommittee hearing, and all witnesses and those who are in attendance.

Today's hearing will examine the Federal Employees Health Benefits Program, Drug Benefit, and the impact that the lack of pricing transparency has on the Office of Personnel Management's ability to evaluate the overall value of those benefits. The hearing will also discuss alternative pricing and contracting methods for the FEHBP's prescription drug benefit. The Chair, the ranking member and subcommittee members will each have 5 minutes to make opening statements, and all Members will have 3 days to submit statements for the record.

At this time, I would like to ask unanimous consent that the testimonies from Change to Win, and the National Community Pharmacies Association, be submitted for the record. Hearing no objection, it is so ordered.

[The prepared statement of Change to Win follows:]



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June 24, 2009

Committee on Oversight and Government Reform
U.S. House of Representatives
Subcommittee on Federal Workforce, Postal Service, and the District of Columbia
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Lynch and Members of the Subcommittee on Federal Workforce, Postal Service, and the District of Columbia:

Change to Win is a partnership of seven unions, including the Service Employees International Union (SEIU), Laborers' International Union of North America (LIUNA), and United Food and Commercial Workers International Union (UFCW), and our affiliates represent over six million workers, including 150,000 workers in the Federal Employees Health Benefits Program (FEHBP). We strongly urge the Committee to move to adopt a more transparent pricing approach in the purchase of prescription drug services, and to take a hard look in particular at CVS Caremark, which is the largest provider of prescription drug benefits to the FEHBP.¹

A lack of transparency is one of the key problems in the pharmacy benefit management (PBM) industry. For example, PBMs often charge the health plans they serve significantly more for drugs than they pay the pharmacies that distribute those drugs to patients.² PBMs also may switch patients to a drug other than the one their doctor prescribed, sometimes a drug more expensive for the health plan and patient, to take advantage of rebates the PBM receives from drug manufacturers, which are often hidden from the PBM's customers.³ More transparent contracting would shed light on these practices and help the Office of Personnel Management (OPM) find efficiencies and save the government money; many other large government plans have achieved savings through greater transparency and direct government participation, including TRICARE and Medicaid.⁴

While a lack of transparency and poor oversight are problems throughout the PBM industry, these problems appear to be particularly acute in the FEHBP's prescription drug contracts. Estimates suggest that prescription drug costs make up close to 30 percent of the FEHBP's premiums, while the industry norm is between 15 and 20 percent. For example, Regence Blue Cross Blue Shield, with three million covered lives, spent only 12.2 percent of total healthcare expenditures on prescription drugs in 2005.⁵ And TRICARE's directly-contracted pharmacy program represented 19.7 percent of total healthcare spending in 2008 for the military's 5.3 million enrolled beneficiaries.⁶

Part of the problem may be that CVS Caremark is the largest provider of prescription drug benefits to the FEHBP. CVS Caremark manages retail pharmacy and clinical services for the Federal Employees Program (FEP), administered by the Blue Cross Blue Shield Association. Change to Win represents workers in CVS Caremark prescription drug plans that provide benefits to more than 10 million people, so we, like the federal government, have a stake in how the Company does business. For that reason, we recently completed a long-term investigation

into CVS Caremark's history and practices, and the information we found raises many concerns. We have provided the Committee with copies of our full report, and our key findings are summarized below; these findings underscore the urgent need for this Committee and OPM to look closely at whether the government is getting the best deal possible by using CVS Caremark in the FEHBP.

Key Report Findings

1. CVS Caremark Has Repeatedly Been Accused of Fraud and Poor Service

Numerous CVS Caremark clients have accused the Company of withholding money that the plans themselves were entitled to or engaging in deceptive or fraudulent practices that ended up costing clients more. Evidence of this includes OPM's own audits of the FEHBP program. In 2006 OPM identified over \$13 million in administrative fees collected from the FEHBP's Retail Pharmacy Drug program between 2000 and 2005 by AdvancePCS—which Caremark acquired in early 2004—that should have been considered drug rebates and returned to the FEHBP as the contract specified. The Blue Cross Blue Shield Association, the health plan that contracted with the government and AdvancePCS, agreed with these government findings.⁷ The most recent audit by OPM for the FEHBP was finalized in September 2008 and covers the contract years 2000 through 2002. This audit found that CVS Caremark potentially overcharged the FEHBP by as much as \$4.5 million for claims by patients not enrolled in the contract.⁸

This 2008 audit report also demonstrates the need for greater oversight and transparency by showing how far behind OPM is in its tracking of this major contract. There are no audit reports available after the 2005 contract year, and the audit conducted lacked the precision necessary to effectively audit a PBM contract. For example, in one area the audit reviewed a statistical sample of 415 claims out of 228,738.⁹ This is all the more troubling since effective auditing can expose costly errors—or fraud—by PBMs, and reap big benefits for plans.

Indeed, in March 2009, Maryland state auditors found that Caremark cost the state government \$10.8 million in 2005 and 2006 when it failed to pass through rebates and discounts that the contract required.¹⁰ A 2008 lawsuit filed by Kindred Healthcare against CVS Caremark alleged that Caremark overcharged it by providing service to employees who were no longer eligible.¹¹ In January 2009, First Medical Health Plan, the largest insurer of government employees in Puerto Rico, sued CVS Caremark for breach of contract. An audit conducted for First Medical Health Plan discovered CVS Caremark overcharged the plan and withheld rebates. The plan is seeking to recover approximately \$34 million.¹²

Many health plans have also had alarming experiences with misconduct by CVS Caremark. Some have experienced problems so serious they felt compelled to sue CVS Caremark to enforce their rights and protect their members. In these lawsuits, many of which the Company settled, plans alleged that the Company: put patient health at risk by improperly reselling returned medications and deceiving plans about these practices; engaged in fraud under its contracts or government programs; and provided service so deficient that plans switched to other PBMs mid-contract. Caremark paid \$137 million in 2005 to settle a false claims suit brought by the United States government alleging, among other things, that the Company engaged in fraudulent pricing schemes: "Defendant devised elaborate schemes which paid pharmacies at a much lower rate

than it in turn billed its customers, including Government Programs. In order to carry out these schemes, Defendant created false claims records to deliberately conceal the spread between its pharmacy reimbursement and what it billed its customers."¹³

2. CVS Caremark's Conflicts of Interest and Access to and Use of Private Patient Data

CVS Caremark has unprecedented access to patients' private information: it is estimated to have access to data on approximately 30% of all prescriptions in the country. Yet the Company has repeatedly been accused of disregarding patient privacy by selling or sharing patient data and improperly handling patients' medical and other private information, often in ways that suggest a serious conflict of interest.

The efforts of large drug companies, such as Merck, Eli Lilly, and Pfizer, to market their prescription drugs, including expensive television advertising campaigns and extravagant gifts for doctors, have been well-documented. What is less visible is the integral role PBMs play in this process. In fact, drug companies sometimes pay PBMs to promote their products through activities that may appear to be the provision of unbiased educational materials or client services.¹⁴ However, the true aim of these activities can be to influence doctor and patient behavior and thereby increase the sales of the drug manufacturers that fund these programs.¹⁵

For example, CVS Caremark sends letters to doctors promoting particular drugs as part of its *RxReview* program. These letters are paid for by pharmaceutical manufacturers and are not necessarily geared to saving money for health plans or consumers. In 2008 CVS Caremark sent letters to physicians recommending the diabetes drug Januvia. The letter was accompanied by "chart inserts" that identified the doctor's diabetes patients by name, patient identification number, and date of birth, and suggested that they might be candidates for a Januvia prescription.¹⁶ CVS Caremark does not receive the consent of the patient or the doctor to market to them in this way. According to some doctors, the letters identified all of their diabetes patients and suggested switching them to Januvia, regardless of whether those patients had other characteristics that made them inappropriate candidates for Januvia.

While CVS Caremark claims to save health plans money, pharmaceutical manufacturers such as Merck are paying it to promote expensive drugs like Januvia. Januvia is as much as eight times more expensive than other diabetes treatments according to a recent study in the *Archives of Internal Medicine*.¹⁷ Consumer Reports recommends other, lower-cost generic drugs over Januvia and says that Januvia is less effective than most other diabetes medications.¹⁸ Nonetheless, CVS Caremark's promotional activity helps Merck maximize its revenues—recently Merck announced that sales for Januvia jumped 64% to \$413 million in the last quarter, even as other marquee drugs saw big sales declines.¹⁹

Newly released legal documents show CVS Caremark also offered to send 120,000 letters to doctors promoting Eli Lilly's antipsychotic drug Zyprexa at \$5 per letter. Several large insurers are suing Lilly for \$6.8 billion, alleging the drug manufacturer downplayed Zyprexa's health risks and marketed it for uses not approved by the FDA to increase profits.²⁰

Many sources have also accused CVS Caremark of improperly switching patients to drugs different from the one their doctor prescribed in ways that cost patients and their health plans

more money, of switching patients to less effective drugs without adequate regard for patient health, and of switching patients' drugs without their doctors' approval. In just the first six months of 2008, the Company paid over \$75 million to settle lawsuits that included drug-switching claims.

3. CVS Caremark's Secrecy in its Business Practices Hinders Accountability

CVS Caremark is enormously resistant to transparency, and has demonstrated greater resistance than other PBMs in some specific instances. It has taken extraordinary measures to prevent greater disclosure of its practices, including interfering with audits by its clients, opting out of contract opportunities to avoid greater disclosure, and vigorously opposing legislative and other measures to increase transparency in the PBM industry. CVS Caremark has even lost several major clients in part because of its resistance to transparency.

One of the key ways in which CVS Caremark resists transparency is by limiting plans' ability to conduct meaningful audits to ensure that CVS Caremark is abiding by the terms of its contracts. While the Company says in its Corporate Social Responsibility Report released in May 2008 that it guarantees "rigorous audit rights" for clients,²¹ the contracts that CVS Caremark writes often limit plans' ability to audit its practices in myriad ways. These may include limiting the nature of the audit, requiring the plan to pay for the audit, restricting which documents can be audited, giving CVS Caremark veto power over who can conduct the audit, and requiring such strict confidentiality between the auditor and CVS Caremark that the auditor may not share information gathered in the audit even with the plan that hired it. These restrictions allow CVS Caremark to keep important information from plans, including information about drug pricing and the amount and source of fees and other revenues it receives from drug manufacturers and other companies.²² Further, in some instances when plans have attempted to audit CVS Caremark's practices, CVS Caremark has simply stonewalled. For example, the Southeast Pennsylvania Transportation Authority (SEPTA) sued Caremark in 2007 after it attempted, unsuccessfully, to conduct an audit of its plan. SEPTA claimed in its lawsuit that "Caremark has wrongfully blocked SEPTA's efforts to conduct an audit of Caremark's performance as SEPTA's pharmacy benefit manager" and "repeatedly interfered with or otherwise restricted SEPTA's attempt to audit Caremark."²³

CVS Caremark's resistance to transparency has prompted some plans to abandon the Company. In 2005 the University of Michigan stopped doing business with Caremark, expressing concerns about lack of transparency in pricing and the rebates Caremark received from drug manufacturers.²⁴ Similarly, after being a Caremark customer for over ten years, in 2007 the State of Maryland selected Catalyst Rx over CVS Caremark for a \$1.1 billion, five-year PBM contract to cover more than 200,000 state employees and their families. CVS Caremark appealed the state's decision and the Maryland State Board of Contract Appeals reviewed the contract award. After extensive review, the Maryland Board upheld the contract with Catalyst Rx over Caremark, even though CVS Caremark had made the lower bid. Transparency was a major factor for the state, and in rejecting Caremark, the state noted that Caremark's "commitment [to transparency] seemed vague—[our evaluation] team [was] not comfortable that they will be able to audit."²⁵

Battles with Caremark over public disclosure have also spread to state courts. In Texas CVS Caremark has brought at least eleven separate suits seeking to block the release of its contracts covering public employees in Texas, even after the Texas Attorney General issued legal opinions in each instance stating that the Caremark contract at issue should be released as a public document under well-established Texas law.²⁶ A similar lawsuit is also pending in Michigan. Thus, bringing greater transparency and oversight to the FEHBP, one of the largest PBM contracts in the country, could have far reaching impacts on the PBM industry.

Conclusion

CVS Caremark earns significantly more profits from its clients on each prescription it fills than do its biggest competitors—in the fourth quarter of 2007, CVS Caremark made an average of \$4.48 on each prescription it filled, while Medco made \$2.53, and Express Scripts made \$2.35²⁷—and many employers and health plans have saved millions of dollars by dropping CVS Caremark. With the completion of the merger between CVS and Caremark in 2007—the country's largest chain of retail pharmacies and second largest PBM—the Company became the largest provider of prescriptions in the United States, filling or managing more than 1.2 billion prescriptions annually. CVS Caremark's mammoth size and scope give it an unmatched ability to influence consumers, health plans, doctors, and drug manufacturers, and to compile unprecedented levels of personal information about its customers, exacerbating many of the problems outlined above.

We have a strong interest in how the FEHBP contracts for prescription drug benefits not only on behalf of plan participants, but also because we represent millions of workers across the country who receive prescription drug benefits through public plans whose benefit plans and methods of selection may be influenced by the FEHBP. In these difficult budgetary times at both the Federal and State level, the FEHBP can serve as a model to private and public plans alike seeking to provide high quality prescription drug benefits to their members in the most efficient way. However, the evidence suggests that today the FEHBP must strengthen its oversight to control costs and exercise greater control over its pharmacy benefit plans.

We hope that the Committee will push for FEHBP drug contracts that mandate full transparency in drug pricing, strong audit rights, disclosure of all rebates, and a prohibition on using private patient data for marketing purposes. We also urge the Committee to press OPM to conduct more thorough and frequent audits of FEHBP contracts, particularly the contract with CVS Caremark. Finally, we ask the Committee to take a hard look at whether CVS Caremark should remain the largest provider of prescription drug benefits to the FEHBP.

Please feel free to contact me with any questions you may have.

Sincerely,



Jasmin Weaver
Healthcare Initiatives Legislative Director
Change to Win

¹ CVS Caremark annually earns \$4 billion in revenue alone from the retail pharmacy and clinical services contract of the Blue Cross and Blue Shield Federal Employee Program (FEP) portion of the FEHBP. CVS Caremark. *Press Release*, "CVS Caremark Wins 3-Year Blue Cross and Blue Shield Federal Employee Program (FEP) Contract Renewal for Retail Pharmacy and Clinical Services." 6 Jun. 2007, available at <<http://www.cvscaremark.com/newsroom/press-releases/cvs-caremark-wins-3-year-blue-cross-and-blue-shield-federal-employee-program>>.

² Garis, Robert I. and Bartholomew E. Clark. *The Spread*; Prime Therapeutics. "Prime Therapeutics Supports CMS Proposal to Limit Spread Pricing in Medicare Part D Administration"; Sipkoff, Martin. "PBMs Raise the Curtain." See also, Sipkoff, Martin. "PBMs Raise the Curtain"; *United States ex rel. Brown*, SAC: at pp. 18-19; *SEPTA v. CaremarkPCS Health L.P.*, Amended Complaint: at p. 4.

³ U.S. Government Accountability Office. *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*. Report to the Honorable Byron L. Dorgan, U.S. Senate. GAO-03-196. Jan. 2003: at pp. 25-28, available at <<http://www.gao.gov/new.items/d03196.pdf>>; Martin, Steven S. "PBM Industry Today: Who's Managing Drug Costs?"; see also: *State of Ohio v. Caremark Rx, L.L.C.*, Complaint: at p. 5; *United States ex rel. Brown*, SAC: at p. 11; Drury, Susan. "Drug Pushing."

⁴ A 2007 U.S. House of Representatives Report reported that drug manufacturer rebates negotiated by the government reduce Medicaid drug spending by 26%, and that the Department of Veterans Affairs (VA) negotiates average manufacturer drug discounts of 50%. In addition, a 2008 GAO report on TRICARE's prescription drug benefit program found that the program not only benefits from Federal Supply Schedule pricing to get the best price for drugs, but has also achieved significant savings since 2005 by leveraging its uniform formulary; avoiding about \$450 million in drug costs in 2006 and \$916 million in 2007. See: U.S. House of Representatives, *Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage*. Majority Staff, Committee on Oversight and Government Reform. Oct. 2007: at pp. 9-11, available at <<http://oversight.house.gov/documents/20071015093754.pdf>>; U.S. Government Accountability Office, *DOD Pharmacy Benefits Program*. Report to Congressional Committees. GAO-08-327. Apr. 2008: at p. 4, available at <<http://www.gao.gov/products/GAO-08-327>>.

⁵ State of Oregon Department of Consumer and Business Services, Insurance Division, "Report of Financial Examination of Regence Blue Cross Blue Shield of Oregon as of December 31, 2005." Available at: <http://www.cbs.state.or.us/ins/company_exams/financial/bcbs05f.pdf>

⁶ Department of Defense, "Evaluation of the TRICARE Program: Fiscal Year 2009 Report to Congress," p33. Available at: <http://www.tricare.mil/hpae/docs/TRICARE09_4-7-09.pdf>.

⁷ The Blue Cross Blue Shield Association subcontracted with AdvancePCS to provide retail pharmacy benefits and process pharmacy claims, and to make payments to retail pharmacy providers on its behalf. See: United States Office of Personnel Management, Office of the Inspector General. *Final Audit Report: Report on the Audit of AdvancePCS*. Office of Audits. Report No. 1H-01-00-04-100. Washington. 30 Mar. 2006: at p. 4; United States Office of Personnel Management, Office of the Inspector General. *Final Audit Report: Report on the Audit of AdvancePCS*. Office of Audits. Report No. 1H-01-00-06-063. Washington. 7 Sep. 2006: at Executive Summary and p. 4.

⁸ United States Office of Personnel Management, Office of the Inspector General. *Final Audit Report: Audit of Blue Cross Blue Shield Retail Pharmacy Drug Program Operations at AdvancePCS Contract Years 2000-2002*, *Scottsdale, Arizona*, Report No. 1H-01-00-04-102. 29 Sept 2008: at p.6.

⁹ *Id.*

¹⁰ Office of Legislative Audits, Department of Legislative Services, Maryland General Assembly. *Audit Report: Department of Budget and Management, Office of Personnel Services and Benefits*. Feb. 2009: at Executive Summary and p. 9-12.

¹¹ Kindred Healthcare Inc., Complaint: at pp. 5-6, ¶¶ 11, 19.

¹² *First Medical Health Plan v. CaremarkPCS Caribbean*, Amended Complaint. Case No. 3:09-cv-01009-GAG

¹³ *United States ex rel. Brown*, SAC: at ¶ 51.

¹⁴ For a description of drug company payments for PBM educational services, see: *Proposal for PBM Services for Genesee County, MI from Automated Benefit Services and Caremark*. 7 Feb. 2008: at p. 78. For an example of PBM educational materials sent to prescribing physicians and paid for by a pharmaceutical company, see: CVS Caremark. *RxReview: New Trends in Prescription Therapies, Benefits & Costs*. Letter mailed by CVS Caremark to Arizona physician. For a description of the services PBMs provide to drug companies, see: U.S. Government Accountability Office. *Federal Employees' Health Benefits*: at pp. 27-28.

¹⁵ See, e.g., *United States ex rel. Brown*, SAC: pp. 6-14; *State of Ohio v. Caremark Rx, L.L.C.*, Complaint: at pp. 5-6.

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- ²¹ CVS Caremark. *2007 Corporate Social Responsibility Report*. May 2008: at p. 31, available at <http://media.corporateir.net/media_files/irol/99/99533/ CVS_Caremark_CSR.pdf>; see also: CVS Caremark. "CVS Caremark Releases Company's First Corporate Social Responsibility Report." *Press Release*. 6 May 2008: available at <<http://phx.corporateir.net/phoenix.zhtml?c=99533&p=irolnewsArticle&ID=1139962&highlight>>.
- ²² See, e.g., Golden Gate Bridge Highway and Transportation District, California. *Amended and Restated Prescription Benefit Services Agreement with Caremark*. 1 July 2006: at p. 9; Health Action Council of Northeast Ohio, Ohio. *Prescription Benefit Services Agreement with Caremark*. 1 Jan. 2006: at p. 10; Local Government Center HealthTrust, New Hampshire. *Prescription Benefit Services Agreement with Caremark*. 16 Feb. 2007: at p. 14; Michigan State University, Michigan. *Managed Prescription Drug Program –Participating Group Agreement with Caremark*. 1 Feb. 2007: at p. 29; Montgomery County Public Schools, Maryland. *Prescription Benefit Services Agreement with Caremark*. 1 Jan. 2005: at p. 8.
- ²³ *SEPTA v. CaremarkPCS Health L.P.*, Amended Complaint: at pp. 5, 8.
- ²⁴ Wessel, David, Bernard Wysocki Jr., and Barbara Martinez. "As Health Middlemen Thrive, Employers Try to Tame Them."
- ²⁵ Maryland State Board of Contract Appeals. *Opinion by Chairman Burns in the Appeals of Caremark Under DBM Solicitation No. F10R6200071*. Mar. 2007: at p. 21, available at <<http://www.msba.state.md.us/decisions/2007/pdf/caremarkpcs.pdf>>.
- ²⁶ The only exception to this is the AG opinion issued with respect to a request for the Caremark contract with the Texas Teachers' Retirement System, in which the Attorney General stated that because the availability of certain Caremark materials, including some contract materials, was already the subject of ongoing litigation, the Attorney General would refrain from ruling on the availability of those specific materials. Texas Attorney General, *OR2007-16246*. 10 Dec 2007: at p. 2. The eleven Texas Attorney General Open Records Decisions are OR2007-14751 (9 Nov 2007); OR2007-15005 (14 Nov 2007); OR2007-15122 (16 Nov 2007); OR2007-15814 (30 Nov 2007); OR2007-16246 (10 Dec 2007); OR2008-08944 (02 Jul 2008), OR2008-11771 (26 Aug. 2008); OR2006-10313 (Sept. 5, 2006); OR2006-05573 (26 May 2006); OR2006-04561 (4 May 2006); OR2006-04017 (20 Apr. 2006).
- ²⁷ Adler, Meredith. Lehman Brothers, Food & Drug Retailing Analyst Report. *CVS Corporation: Change of Earnings Forecast*. 1 Aug. 2008: at p. 3.

[The prepared statement of the National Community Pharmacists Association follows:]


WWW.NCPANET.ORG

June 23, 2009

Chairman Stephen Lynch
 Committee on Oversight and Government Reform
 U.S. House of Representatives
 2157 Rayburn House Office Building
 Washington, D.C. 20515

Re: Committee Hearing: FEHBP Prescription Drug Plan: Deal or No Deal?

Dear Chairman Lynch:

The National Community Pharmacists Association ("NCPA") applauds the fact that your committee is holding hearings on the Federal Employee Health benefit Plans and the delivery of drug benefits. We hope this is a first step by the Committee to examine the drug benefit plan and in particular the role of Pharmacy Benefit Managers ("PBMs"), in the delivery of those benefits. As we have testified before several state legislatures the PBM market is plagued with deceptive practices and a lack of transparency and this Committee's attention to those practices is critical to making sure that the federal government is able to deliver drug benefits in the most cost effective fashion.

NCPA is the leading association for Main Street community pharmacists throughout the United States, representing over 23,000 independent pharmacies and tens of thousands of community pharmacists. Our pharmacists serve millions of consumers every week, dispensing drugs, providing advice on drug utilization and helping consumers deal with the complex systems of drug reimbursement. Consumers value the personalized service and guidance provided by community pharmacists in advising on drug utilization and therapeutic usage. Moreover, community pharmacists enhance the quality of care by developing close patient-provider relationships, often providing crucial services rarely offered by chain pharmacies, such as home delivery, custom packaging, and round-the-clock emergency access. Community pharmacies often serve underserved rural and inner city markets, where there are few if any chain pharmacies.

We want to bring two issues to your attention. First, there is clearly a significant lack of transparency in PBM markets that makes it extraordinary difficult for plan sponsors such as the FEHBP to assess the overall benefits of the drug benefit program. Because of a lack of transparency OPM may not be able to detect the amount of rebates or other benefits a PBM receives and therefore may end up paying substantially more than it should. To give just one example, the state of Texas found that it could save several hundred million dollars if there was increased transparency in PBM contracting.

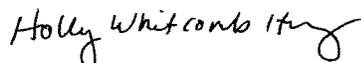
THE VOICE OF THE COMMUNITY PHARMACIST

100 Dangerfield Road
 Alexandria, VA 22314-2888
 (703) 683-8200 PHONE
 (703) 683-3619 FAX

Second, we ask you to examine the contracting practices of CVS/Caremark. CVS/Caremark's contract with the FEHBP generates over \$12 billion in revenue and deserves careful scrutiny because of the substantial costs of the FEHBP program. Moreover, for the past five months NCPA has been soliciting information from both consumers and community pharmacies about CVS/Caremark's conduct. To date, we have heard from over 250 consumers and pharmacies in 43 states, including numerous retired federal employees. The interviews we have conducted document a clear pattern of anticompetitive conduct that increases costs to consumers and reduces their choices, as well as apparent violations of consumer privacy. We have brought these issues to the attention of the Federal Trade Commission (see the attached letter to FTC Chairman Leibowitz). We believe this conduct may harm both current and retired federal employees and inflate the federal government's expenditures for drugs.

Again, we applaud your efforts in holding this hearing and look forward to working with you in the future.

Sincerely yours,

A handwritten signature in cursive script that reads "Holly Whitcomb Henry".

Holly W. Henry
NCPA President

Attachment (1)



May 12, 2009

The Honorable Jon Leibowitz
 Chairman
 Federal Trade Commission
 600 Pennsylvania Avenue N.W.
 Washington, DC 20580

Re: The Need for an FTC Investigation of CVS/Caremark

Dear Chairman Leibowitz:

I write on behalf of the National Community Pharmacists Association ("NCPA"). We appreciate the opportunity for numerous community pharmacists to meet with you and your staff on May 13 about anticompetitive conduct by CVS/Caremark and how that conduct both harms consumers and community pharmacies. We believe CVS' recent conduct calls for an extensive investigation of both antitrust and consumer protection concerns, before that conduct results in irreparable harm. This letter sets out some of the facts that will be the basis for our discussions.

NCPA is the leading association for Main Street community pharmacists throughout the United States, representing over 23,000 independent pharmacies and tens of thousands of community pharmacists. Our pharmacists serve millions of consumers every week, dispensing drugs, providing advice on drug utilization and helping consumers deal with the complex systems of drug reimbursement. Consumers value the personalized service and guidance provided by community pharmacists in advising on drug utilization and therapeutic usage. Moreover, community pharmacists enhance the quality of care by developing close patient-provider relationships, often providing crucial services rarely offered by chain pharmacies, such as home delivery, custom packaging, and round-the-clock emergency access. Community pharmacies often serve underserved rural and inner city markets, where there are few if any chain pharmacies.¹

As you know in December 2008, NCPA wrote to former Chairman Kovacic about our concerns over CVS' conduct. Since that time NCPA has been soliciting information from both consumers and community pharmacies about CVS' conduct. To date, we have heard from over 200 consumers and pharmacies in 43 states. The interviews we have conducted document a clear pattern of anticompetitive conduct that increases costs to consumers and reduces their choices, as well as apparent violations of consumer privacy.

Background

¹ See Appendix A: "Value of the Community Pharmacist"

In March 2007, CVS, the nation's largest retail pharmacy, merged with Caremark, the nation's largest Pharmacy Benefits Manager. The resulting prescription giant operates more than 6,800 pharmacies, with the number one or two market share in each of the country's top ten markets, with a market share as high as 47%. Caremark is the largest PBM and covers 134 million lives (more than twice as many as any other PBM). **The combined company dominates the pharmaceutical services industry, filling or managing more than 1.2 billion prescriptions annually and servicing an estimated 1 out of 2 Americans.**

By controlling Caremark, CVS has access to the most competitively sensitive information of rival pharmacies including the identity of their customers and prescribers, the drugs prescribed, the cost of the drugs, the amount of drugs acquired, the drug acquisition cost, and the reimbursement amount. By owning Caremark, CVS controls reimbursement for a substantial segment of reimbursement for its rivals. As far as we know, in no other industry does a rival have this type of control or access to this type of information of its rivals.

CVS is using Caremark to eliminate consumer choice and drive consumers from rival pharmacies. In recent months, CVS has embarked on a strategy of using the Caremark's PBM business to drive customers from independent and small chain drugstores to CVS stores. The conduct used to drive customers to CVS includes:

- Implementing a so-called "Maintenance Choice" program which forces consumers who use rival pharmacies to move their prescriptions to CVS stores or mail order or pay an increased co-pay. In some cases the so-called Maintenance Choice program has raised the costs to consumers by 900%;
- Cobranding "CVS Caremark" benefits cards in a confusion fashion, which makes customers (especially vulnerable elderly patients) believe they can only use their benefits card and fill prescriptions at CVS stores;
- Sharing Caremark confidential patient information with CVS to enable CVS pharmacists to call non-CVS customers at home and direct them to fill their prescriptions at CVS stores; and
- Creating obstacles for consumers trying to fill prescriptions at non-CVS pharmacies.

This conduct is anticompetitive and, we believe, violates Section 5 of the FTC Act, Section 7 of the Clayton Act, and Section 2 of the Sherman Act.

- Section 5 of the FTC Act prevents "unfair methods of competition" which may harm competition, including conduct that excludes competitors on a basis other than efficiency that harms consumers. As detailed below, CVS Caremark's conduct violates the FTC Act by restricting consumer choice and forcing consumers to pay higher prices.
- Section 7 of the Clayton Act prohibits acquisitions where "the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." CVS' acquisition of Caremark violates Section 7 because it

diminishes competition among pharmacies, by allowing CVS to engage in exclusionary conduct that drives consumers to CVS stores and mail order. This raises the costs of rival pharmacies, diminishing their ability to compete, ultimately leading to higher prices and reduced choice. The acquisition also gives CVS Caremark access to information of its PBM and pharmacy rivals, which may facilitate collusion.

- Section 2 of the Sherman Act prevents unlawful monopolization or attempts to monopolize. CVS' conduct threatens to monopolize several pharmacy distribution markets, by raising the costs of its rivals and other exclusionary tools.

CVS' conduct is inconsistent with its commitments when it acquired Caremark. The FTC cleared CVS' acquisition of Caremark in November 2006 without issuing a Second Request. We do not know what basis the Commission had for closing the investigation or what representations CVS made about the impact of the merger on consumers or other pharmacies. Nor do we know if CVS agreed to implement a firewall to prevent sharing of confidential information or what the terms of any firewall might have been. In any case, CVS has violated the public commitments the company made at the time of the merger:

- When the companies announced their merger, they promised consumers "unparalleled access" and "greater convenience and choice," pledging that "Caremark customers could continue to use any pharmacy they choose within their networks" and that consumers would have "more control over choice, access and how they spend their healthcare dollars." **CVS Caremark specifically promised, "we're going to be agnostic to where the consumer fills their prescription."**
- By forcing consumers to move their prescriptions, CVS Caremark has violated those commitments. By designing confusing benefits cards and misusing customer claims information to steal customers of rival pharmacies, CVS Caremark has shown that it is not "agnostic" about its patients' choice of pharmacy. And by implementing restrictive plans, CVS Caremark has reduced consumers' choice and raised prices. **CVS Caremark's strategy harms consumers by diminishing access to lower cost and higher quality pharmacy services.**

Moreover, CVS' conduct is often inconsistent with their commitments to their PBM customers. Some of the efforts by CVS to switch consumers to CVS stores are done without the permission or request of the plan sponsors.

We have received several hundred complaints from consumers and pharmacists for the past few months and have attached a document that summarizes those complaints. The document includes direct quotes from consumers and pharmacies harmed by this

conduct.² Briefly, CVS' conduct harms consumers directly and indirectly and causes significant anticompetitive effects, including:

- consumers pay higher co-pays if they want to use the pharmacy they traditionally use;
- diversion of prescription business from non-CVS retail pharmacies to CVS pharmacies or CVS mail order, even if customers may have otherwise chosen a rival pharmacy based on lower prices, better service, a more convenient location, or other factors;
- competing retailers are foreclosed from filling prescriptions for members of plans serviced by Caremark, raising their costs to service other PBMs;
- consumers steered to CVS retail pharmacies may pay more for front end products, on which CVS secures even higher profits than on pharmacy products;
- CVS uses its control of Caremark to force rival pharmacies to accept reimbursements for prescriptions so low that they cannot afford to dispense certain drugs to Caremark-covered patients; and
- CVS Caremark's actions severely curtail patients' access to drugs, especially specialty pharmaceuticals that require special handling. Moreover, many pharmacists predict that they will become financially inoperable if they continue to lose "Maintenance Choice" prescriptions to CVS, leaving many rural and inner city communities underserved.

This is only the beginning of potentially even more harmful conduct. The Maintenance Choice program was implemented only in December and CVS plans to continue to expand the program. Moreover, if not investigated CVS may design new means to use the CVS Caremark relationship to harm competition and consumers. Consumer advocacy groups as well as state legislators have recently weighed in on the need to investigate CVS Caremark for potential anticompetitive conduct, citing similar concerns.³

An investigation and enforcement actions is consistent with past Commission enforcement actions. During the 1990s, PBMs were acquired by pharmaceutical manufacturers – another form of vertical integration. The FTC brought enforcement actions against Lilly's acquisition of PCS and Merck's acquisition of Medco. As you know, the Medco acquisition was consummated in 1993 and the FTC reopened its investigation in 1995, ultimately bringing an enforcement action in 1998. Both the Lilly/PCS and Merck/Medco enforcement actions alleged that through vertical integration there were competitive concerns of (1) foreclosure – that rival drug manufacturers might find access to the market limited, and (2) collusion – that the integration might facilitate collusion between manufacturers or PBMs. Moreover, the enforcement actions raised the concern that through these vertical acquisitions, Medco or

² See Appendix B, "CVS Caremark: Raising Costs, Limiting Access, and Choking Competition." Reports from pharmacies and consumers collected between January 1, 2009 and May 8, 2009. Patient and pharmacist names are changed to protect privacy.

³ See Appendix C, "Consumer Groups' Letter to Chairman Jon Leibowitz on CVS Caremark" and Appendix D, "NLARx Letter to Chairman Jon Leibowitz on CVS Caremark."

PCS would be eliminated as an independent negotiator of pharmaceutical prices and this could potentially lead to higher drug prices.

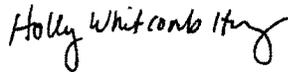
We believe CVS' acquisition of Caremark presents the same concerns. Through its acquisition, CVS can raise the costs of rival pharmacies, by decreasing reimbursement, shifting consumers through Maintenance Choice and other cost raising strategies, and engaging in egregious auditing activities. CVS can raise the costs of rival PBMs by making their access to non-CVS pharmacies more costly. CVS' access to the most sensitive business information of its rivals offers a fertile medium for potential collusion. Finally, CVS' ownership of Caremark eliminates its ability and incentive to be an independent negotiator of drug prices – despite its commitment to be “agnostic,” – CVS clearly uses Caremark to drive transactions away from rival stores.

Consistent with Merck/Medco and other enforcement actions, we urge the FTC to:

- Use both its competition and consumer protection resources to investigate CVS Caremark to attack both anticompetitive and deceptive conduct.
- Consider whether CVS' consummated acquisition of Caremark has reduced competition in the pharmacy and PBM markets, and seek appropriate relief, including imposition of enforceable firewalls and non-discrimination obligations, or divestiture, if necessary.
- Require Caremark to treat all pharmacies in a nondiscriminatory fashion.
- Prohibit CVS from creating programs that disadvantage rivals by imposing higher costs on them.
- Compel CVS to create an ironclad barrier between CVS and Caremark so that competitively sensitive Caremark information cannot be used by CVS.
- Prevent Caremark from sharing personally sensitive information with CVS.

Again, on behalf of the NCPA and the scores of pharmacists who will be visiting you on Wednesday, we are grateful for your time and attention. We look forward to working with the Commission on this important matter.

Sincerely yours,



Holly W. Henry
NCPA President

Mr. LYNCH. Again, because of the irregularities on the floor, we are going to proceed with as many Members as we have available. First of all, I would like to welcome all of our witnesses, and the fellow Members who will attend, eventually, as we examine this prescription drug benefit in the Federal Employees Health Benefits Program.

I would also like to thank all of today's witnesses for sharing their insight and expertise on this complex issue. I understand that several of you have come from quite a distance to be here with us today, and I deeply appreciate your willingness to help the subcommittee gain a better understanding of how the Federal Employees Health Benefits Program prescription drug benefit is structured and priced.

The Federal Government is currently facing one of its largest policy issues to date, health care reform. This issue affects everyone and many challenges must be addressed in the upcoming months to find the right solutions. Many policymakers look to the Federal Employees Health Benefits Program as a model for providing health care. That is why it is important to ensure that the program is providing the best quality in benefits at the best price.

Entitled, "Federal Employees Health Benefits Program Prescription Drug Benefits: Deal or No Deal," we have called for this afternoon's hearing to examine the contracting method used to deliver prescription drugs to the 8 million Federal employees, their dependents and annuitants and the Members of Congress, and their families that are covered under this program. Considering that prescription drug costs make up close to 30 percent of our program premiums, we need to do all we can to ensure that Federal employees, and the taxpayers, are getting the best value for their dollar.

Astonishingly, limited reviews or analyses have been performed on this increasingly expensive benefit, but that will change, starting today. For the most part, the Federal Employees Health Benefits Program Health Plans, contract with pharmacy benefit managers to price and provide the pharmacy benefit to Federal Employees Health Benefits Plan members.

In contrast with other Federal health programs, the Federal Employees Health Benefits Plan does not regulate or negotiate drug pricing for its members. Instead, it relies on the competition among various carriers and pharmacy benefit managers to keep prices low.

However, as we will hear today, prices are not low. In fact, when comparing the Federal Employees Health Benefits Program drug prices to that of other Federal programs such as the VA and the Department of Defense, Medicare, Medicaid and the Public Health Service 340(b) Program, we will hear that along with the Medicare Part D, FEHBP is paying substantially more for its drugs than the other Federal programs.

Now some research even shows that COSTCO and Drug-Store.com offer better prices for drugs than the Federal Employees Health Benefits Program. That is in spite of the fact that the Federal Employees Health Benefits Program has the buying power of 8 million members. That is especially troubling. In these economically challenging times, we shouldn't be asking Federal employees and the American taxpayer to accept this. If the Federal Employees Health Benefits Plan wants to remain a model for providing health

benefits, legislative changes that allow for alternative prescription drug benefit contracting and pricing are in order.

The key question we hope to explore today is, why is the Federal Government, and therefore the taxpayers, paying such different amounts for the same drug. And I am not an expert on pharmaceutical pricing, but I have a hunch that the pharmaceutical industry charges what they can to make the largest profits.

For the first 6 months of 2006, the 10 largest drug manufacturers enjoyed profits of close to \$40 billion. So, do I think that the pharmaceutical industry could afford to charge lower prices for our Federal employees? I certainly do. As chairman of this subcommittee, I am committed to providing the best benefits to our Federal employees at the best price. And we in Congress have asked a lot of taxpayers in the last few months to help us out with that very function.

We have a responsibility to make sure every dollar that is spent is necessary and is providing the greatest benefit. Again, I thank all of those in attendance, and I look forward to hearing from today's witnesses.

Normally I would yield to Mr. Chaffetz. I will, of course, afford every courtesy to Members as they arrive. So even though we may have to skip forward in the proceedings, I will certainly recognize the ranking member, and my other colleagues as they do arrive.

It is this committee's policy that all witnesses submitting testimony to this subcommittee are to be sworn. May I please ask you to rise and raise your right hands?

[Witnesses sworn.]

Mr. LYNCH. Let the record indicate that the witnesses have answered in the affirmative. Your entire written statement will be entered into the record. You don't have to worry about that. However, during your oral testimony the green light before you in that little box indicates you have 5 minutes to summarize your statement. The yellow light means that you have 1 minute remaining to complete your statement, and the red light indicates your time for remarks has ended. So we will proceed with the testimony.

Let me first offer brief introductions of our first panel of witnesses, who again, I appreciate your attendance. Mr. Patrick McFarland was nominated Inspector General of the Office of Personnel Management in 1990. As Inspector General, Mr. McFarland is responsible for providing leadership, that is independent, non-partisan and objective, and is dedicated to identifying fraud and mismanagement in programs administered by the Office of Personnel Management. Mr. McFarland is also a member of the Counsel of Inspectors General On Integrity and Efficiency.

Ms. Susan Hayes is the founder of Pharmacy Outcome Specialists [POS], with 28 years of experience in the health consulting and management industry. Before founding Pharmacy Outcome Specialists, she was a vice president of marketing for Systemed Pharmacy, Inc., and vice president of marketing for Walgreens Healthcare Plus. Ms. Hayes was the national practice leader for William M. Mercer, Inc., specializing in prescription drug auditing and bid procurement, amounting to over \$1 million annually in revenue.

Our next witness, Mr. James Sheehan, has served as New York State Medicaid inspector general. He has been the associate U.S. attorney for civil programs in the Eastern District of Pennsylvania. Mr. Sheehan has focused on health care fraud since 1987, having personally handled, or directly supervised, over 500 health care fraud matters from 1999 to 2006. Mr. Sheehan led the Federal Government's investigation in a case against Medco Health Solutions, which resulted in the recovery of over \$155 million, as well as substantial business changes to protect patients and pharmacists.

[The prepared statement of Hon. Stephen F. Lynch follows:]

STATEMENT OF CHAIRMAN STEPHEN F. LYNCH
SUBCOMMITTEE ON FEDERAL WORKFORCE, POSTAL SERVICE, AND
THE DISTRICT OF COLUMBIA

FEHBP's Prescription Benefits Hearing

Wednesday, June 24, 2009

Again, I'd like to welcome Ranking Member Chaffetz and my fellow members of the Subcommittee as we examine the prescription drugs benefits in the Federal Employees Health Benefits Program (FEHBP). I'd also like to thank today's witnesses for sharing their insight and expertise on this complex issue. I understand that several of you have come quite a ways to be here with us today and I deeply appreciate your willingness to help the Subcommittee gain a better understanding of how the FEHBP Prescription Drug benefit is structured and priced.

The Federal Government is currently facing one of its largest policy issues to date – Health Care Reform. This issue affects everyone and many challenges must be addressed in the upcoming months to find the right solutions. Many policy makers look to the FEHBP as a model for providing health care. That's why it's important to ensure the Program is providing the best benefits and at the best price. Entitled "FEHBP's Prescription Drug Benefits: Deal or No Deal?", I've called for this afternoon's hearing to examine the contracting methods used to deliver prescription drugs to the 8 million federal employees, their dependents, annuitants and Members of Congress that are covered under this program. Considering that prescription drug cost make up close to 30% of the FEHBP's premiums, we need to do all we can to ensure that federal employees and the taxpayer are getting the best value for their dollar. Astonishingly, limited reviews or analysis have been performed on this increasingly expensive benefit. But that will change starting today, I assure you.

For the most part, the FEHBP health plans contract with Pharmacy Benefit Managers (PBMs) to price and provide the pharmacy benefit to FEHBP members.

In contrast with other federal health programs, the FEHBP does not regulate or negotiate drug pricing for its members. Instead it relies on competition among the various carriers and PBMs to keep prices low. However, as we will hear today, prices are not low. In fact, when comparing FEHBP drug prices to that of other federal programs, such as the Veteran's Administration, the Department of Defense, Medicare, Medicaid and the Public Health Service's 340B Program, we will hear that along with Medicare Part D, the FEHBP is paying substantially more for its drugs than the other federal programs. Some research even shows that Costco and drugstore.com offer better prices for drugs than the FEHBP. In these economically challenging times, we shouldn't be asking federal employees and the American taxpayer to accept this. If the FEHBP wants to remain a model for providing health benefits, legislative changes that allow for alternative prescription drug benefit contracting and pricing may be in order.

The key question we hope to explore today is, "Why are the federal government, and therefore the taxpayer, paying such different amounts for the same drug?" I'm not an expert on pharmaceutical pricing, but I have a hunch that the pharmaceutical industry charges what they can to make the largest profits. For the first 6 months of 2006, the 10 largest drug manufacturers enjoyed profits of close to \$40 Billion. So, do I think that the pharmaceutical industry could afford to charge lower prices for our federal employees?? - - You bet I do.

As Chairman of this Subcommittee, I am committed to providing the best benefits to our federal employees at the best price. We in Congress have asked a lot of taxpayers in the last few months. With that, we have a responsibility to make sure every dollar spent is necessary and is providing the greatest benefit.

Again thanks and I look forward to hearing from today's witnesses.

Mr. LYNCH. Already, I am being asked to vote. Having no other Members here that might be able to do this while I vote, I am going to have to ask you to just hang in there, relax. I will be back momentarily. Thank you. We are in a brief recess.

[Recess.]

Mr. LYNCH. This hearing of the subcommittee is now reconvened. We will hear from each of our witnesses. Mr. McFarland, you are now recognized for 5 minutes for your opening statement.

STATEMENTS OF PATRICK E. McFARLAND, INSPECTOR GENERAL, U.S. OFFICE OF PERSONNEL MANAGEMENT; SUSAN A. HAYES, FOUNDER OF PHARMACY OUTCOME SPECIALISTS; AND JAMES G. SHEEHAN, MEDICAID INSPECTOR GENERAL, NEW YORK STATE OFFICE OF THE MEDICAID INSPECTOR GENERAL

STATEMENT OF PATRICK E. McFARLAND

Mr. McFARLAND. Mr. Lynch, Ranking Member Chaffetz and members of the subcommittee, good afternoon. My name is Patrick McFarland. I am the Inspector General of the U.S. Office of Personnel Management. I want to thank you for inviting me to testify at today's hearing, and especially for recognizing the significance of pharmacy manager contracts and their lack of price transparency in the context of the Federal Employees Health Benefits Program.

I am pleased to be appearing with my fellow panelists. Mr. Sheehan is particularly well-known to my office, as we had the privilege of participating in a number of health benefit fraud cases, some of which addressed instances of wrongdoing by PBMs, that he conducted during his tenure as the associate U.S. attorney in the Eastern District of Pennsylvania.

We found both his expertise on these matters and his leadership in complex, high-value cases to be unparalleled. Similarly, key members of my staff, who are responsible for auditing the Federal Employees Health Benefits Plans, and their PBMs, have attended training programs conducted by Ms. Hayes' firm. They speak very highly of the training.

The FEHBP is the largest employer-sponsored health insurance program in the United States. During calendar year 2008, the 266 insurance plans under contract to the FEHBP provided health insurance coverage to approximately 7.7 million persons, representing Federal employees, annuitants, and dependents. The Federal Employees Health Benefits Program paid a total of \$35.9 billion in premiums to these carriers. As reported to OPM, by FEHBP carriers, pharmacy costs reflected more than 25 percent of health care costs paid by the fee-for-service plans.

According to data furnished by OPM's contracting office, 12 different PBMs provided services to one or more FEHBP plans during 2008. My office has been addressing PBM issues from both an audit and investigative perspective since 2003. We were initially concerned that the health and safety of persons covered by the FEHBP may have been placed at risk by certain practices of PBMs.

As a result of our timely law enforcement efforts, we addressed and resolved these concerns without direct harm to FEHBP-covered persons. At this time, we have no information which suggests that

PBMs under contract with the FEHBP are operating in a manner that would compromise the well-being of covered persons. However, the prior violations are a strong reminder that the potential for safety risks to subscribers exists through poorly written contracts, lack of adequate industry oversight and the need for additional internal controls.

Currently in my office's estimation, the single-most important issue involving the PBMs, is that their contracts with the FEHBP carriers are not transparent, and do not reflect the actual costs of drugs to the PBM. My office is committed to providing the oversight needed to protect the integrity of FEHBP and the integrity of its enrollees.

Thank you again for inviting me here today. I will be happy to answer any questions.

[The prepared statement of Mr. McFarland follows:]

Statement of the Honorable
Patrick E. McFarland
Inspector General
U.S. Office of Personnel Management

before the

Subcommittee on Federal Workforce, Postal Service,
and the District of Columbia

on

“FEHBP’s Pharmacy Benefits: Deal or No Deal?”

June 24, 2009

Chairman Lynch, Ranking Member Chaffetz, and Members of the Subcommittee:

Good morning. My name is Patrick E. McFarland. I am the Inspector General of the United States Office of Personnel Management (OPM).

I want to thank you for inviting me to testify at today’s hearing, and for recognizing the significance of pharmacy benefits manager (PBM) contracts and their lack of price transparency in the context of the Federal Employees Health Benefits Program (FEHBP).

I am pleased to be appearing with my fellow panelists. Mr. Sheehan is particularly well-known to my office, as we had the privilege of participating in a number of health benefit fraud cases—some of which addressed instances of wrongdoing by PBMs—that he conducted during his tenure as an Associate United States Attorney in the Eastern District of Pennsylvania. We found both his expertise on these matters and his leadership in complex, high-value cases to be unparalleled. Similarly, key members of my office who are responsible for auditing the FEHBP plans and their PBMs have attended training programs conducted by Ms. Hayes’ firm.

As a means of emphasizing the significance of PBM matters within the FEHBP, I would like to point out that the FEHBP is the largest employer-sponsored health insurance program in the United States. During calendar year 2008, the 266 insurance plans under contract to the FEHBP provided health insurance coverage to approximately 7.7 million persons, representing Federal employees, annuitants, and eligible dependents. The FEHBP paid a total of \$35.9 billion in premiums to these carriers, of which \$29.1 billion went to the fee-for-service plans and \$6.8 billion to health maintenance organizations. As reported to OPM in the financial statements of FEHBP carriers, pharmacy costs reflected more than 25 percent of health care costs paid by the fee-for-service plans. Further, according to data furnished by OPM’s contracting office, 12 different PBMs provided services to one or more FEHBP plans during 2008.

FEHBP carriers have been using PBMs since 1990, initially for mail order pharmacy programs, but ultimately progressing into coverage of all pharmaceutical benefits. These PBMs directly provide some pharmacy benefits, process pharmacy claims, and pay retail pharmacy providers on behalf of the FEHBP carriers. My office began addressing PBM issues in 2003, initially in response to concerns that the health and safety of persons covered by the FEHBP may have been placed at risk by certain practices of PBMs. These included:

- Unauthorized switching of medications prescribed by physicians in favor of products for which the PBM had received a financial incentive from pharmaceutical manufacturers;
- Manipulation of receipt dates of prescriptions in order to provide the appearance that they were filled within contractual timeframes;
- Use of lower paid, non-pharmacist personnel to perform functions that state law required to be performed by or under the direct supervision of a licensed pharmacist; and,
- Dispensing prescriptions without performing drug utilization reviews to assure appropriate use of medications or to avoid dangerous drug interactions.

As the result of timely law enforcement efforts, these sorts of abuses were addressed and resolved without direct harm to FEHBP covered persons. The PBMs in question agreed to:

- Disclose to physicians and patients its financial incentives for certain drug switches;
- Disclose to physicians and patients the minimum or actual cost savings for health plans and the difference in co-payments made by patients;
- Disclose to physicians material differences in side effects between prescribed drugs and proposed drugs;
- Reimburse patients for their out-of-pocket health care costs related to drug switches, and notify patients and physicians that such reimbursement is available;
- Obtain express, verifiable authorization from the physicians for all drug switches; and,
- Inform patients that they may decline the drug switch and receive the initially prescribed drug.

The PBMs also agreed to observe acceptable ethical standards of practice and to provide training for their employees on these standards. Currently, my office, together with the Office of Inspector General (OIG) of the Department of Health and Human Services, is monitoring a PBM's execution of a corporate integrity agreement designed to assure adherence to the commitments it made in response to the Federal enforcement action.

At this time, we have no information which suggests that PBMs under contract with the FEHBP are operating in a manner that would compromise the well-being of covered persons. However, I do believe that the prior violations are a strong reminder that the potential for safety risks to subscribers exists through poorly written contracts, lack of

adequate industry oversight, and the need for additional internal controls. My office is committed to providing the oversight needed to protect the safety of FEHBP enrollees.

Similarly, our early initiatives to audit PBM activities within the FEHBP, using data from the 2000 – 2003 period, revealed a number of errors and shortcomings in the PBMs' administration of their FEHBP contracts, including:

- Billing FEHBP carriers for larger amounts of pharmaceutical products than were actually dispensed to patients; and,
- Dispensing drugs to persons who did not have a current enrollment in the FEHBP.

In these situations, we recommended that OPM recover the costs of improper claims submitted to the FEHBP carriers by PBMs.

The initial purpose of contracting with PBMs was to control drug costs and improve the efficiency of the FEHBP pharmacy program. However, in the years since the PBMs began servicing Federal enrollees, health care costs have continued to rise, including prescription drug costs. The Blue Cross and Blue Shield Service Benefit Plan, which covers approximately 50 percent of the FEHBP's beneficiaries, has incurred a steady increase in its prescription drug costs per FEHBP member since 1999. In 1999, the claims cost per member was \$591. Eight years later, the claims cost per member increased to \$1,161; almost twice the amount paid in 1999. Drug cost increases averaged 13.5 percent over the 8-year time period. These steadily rising costs call into question the effectiveness of the large PBMs which the BlueCross Blue Shield Association has contracted with in controlling prescription drug costs.

As we have continued our efforts to learn about and audit PBMs, we have concluded that the most significant issues with which OPM should be concerned do not involve the PBMs' compliance with or performance of their contracts with the FEHBP carriers, but rather the nature of the PBM contracts themselves.

In our estimation, the single most important issue which OPM must resolve is the fact that it is dealing with PBMs—which handle claims representing over 25 percent of fee-for-service health benefits costs—from a perspective in which the cost structures of the PBMs are utterly nontransparent. This means that there is no objective basis to determine whether the terms being offered to an FEHBP carrier by a PBM represent an advantageous arrangement, or if equivalent services can be obtained at a lower cost from another PBM or through use of a different means of providing pharmacy benefits. From our perspective as the agency's audit component, we find the absence of transparency to be deeply troubling, and we are planning an analytical study that should provide at least a limited basis for making *bona fide* comparisons regarding the costs of pharmacy benefits from various sources. To our knowledge, this type of review has not previously been conducted in the Federal sector, and thus we cannot reliably project a completion date at this time.

There are several elements of the present FEHBP contracting system that contribute to the absence of cost transparency.

- PBMs contract directly with the FEHBP insurance carriers and not with OPM. Therefore, OPM has limited control over the terms of these contracts, especially related to pricing and fees.
- Each FEHBP carrier individually negotiates the terms (pricing method, rebates, administrative fees, etc.) of its contract with a PBM. Therefore, there is no consistency among these contracts. OPM is also not provided an opportunity to approve the contracts before they are finalized.

My office believes that this lack of transparency invites bad pricing and contracting practices, because of such factors as:

- FEHBP carriers have little incentive to negotiate the “best price” for pharmacy services, because OPM reimburses them for all costs charged by the PBM in any event.
- No FEHBP carrier’s contract with a PBM is based on the actual cost of pharmaceutical products. Most if not all PBMs participating in the FEHBP use an “average wholesale price” (AWP) or similar methodology on which to base the price of their services to the carriers. The AWP was originally determined by comparing the average price that pharmacists paid for the drugs from several drug wholesalers and was assumed to be the “actual acquisition cost” (AAC) of the retail pharmacies that purchased from wholesalers. However, today the AWP is more comparable to a new car sticker price. It has little relationship to the true costs of drugs, which may include wholesaler rebates, chargebacks and incentive and volume discounts.
- Many PBM contracts do not require that the FEHBP receive the benefit of the pharmacy rebates associated with its claims. The carriers claim that they are able to negotiate a lower drug price for the FEHBP in lieu of the rebates. However, this has been difficult to verify because:
 - PBMs’ contracts with pharmaceutical manufacturers fluctuate and are modified regularly.
 - Manufacturers will offer lower rates/prices to PBMs with larger membership. In most cases, the FEHBP carriers add greatly to PBM enrollment. However, because of a current lack of transparency in the PBM contracts, it has been difficult if not impossible to determine whether the Federal group has received the benefit of these lower rates/prices.
 - Rebates are not related to the drug price from the manufacturer and there is no feasible means under the current PBM contracts to determine whether the FEHBP is saving or losing money as a result of foregoing rebates.

The result of these practices may in fact be a higher cost for the FEHBP but this in turn cannot be verified in the absence of cost transparency. For example, we are aware that

pharmaceutical manufacturers provide rebates to PBMs that steer members by use of preferred drug lists and other methods to use a given company's products. It has been the practice of major FEHBP carriers to allow the PBMs to retain all manufacturer rebates in exchange for what are claimed to be discounted drug prices. However, because the FEHBP carriers' contracts with PBMs do not require that they make their cost data available for audit, PBMs have refused to allow us to determine the actual rebate amounts paid to the PBM. This prevents us from determining whether the FEHBP has actually benefited more by the lower drug prices than it would have by demanding that the rebates be credited to it.

As stated above, FEHBP carriers have no incentive to negotiate the best price. A recent audit revealed a perfect example of the consequences that may flow from this situation. An FEHBP carrier's multiyear contract with a PBM limited increases in the monthly service fee unless membership increased by a certain minimum amount. The actual membership increase did not meet the minimum, but the carrier allowed the PBM to renegotiate the contract to increase the service fee (and thus the cost to the FEHBP) as if membership had increased.

Because of concerns about increasing prescription drug costs, numerous fraud and abuse allegations against pharmacy benefits managers, and the concerns of my office mentioned above, a working group comprised of representatives from OPM's Strategic Human Resources Policy (SHRP) Division, Human Resources Products and Services (HRPS) Division, and my office has been formed to consider short-term and long-term initiatives to strengthen the controls and oversight of FEHBP pharmacy programs. We hope that the working group will assist OPM in reviewing, rethinking, and redesigning the management of the FEHBP pharmacy benefits.

As part of this process, we have suggested that OPM consider the following contract and regulatory changes:

- Require the PBM contract's administrative costs to be paid based on actual costs not fixed fees.
- Require carriers using self owned PBM's for the FEHBP contract to pass-through the actual drug costs to the FEHBP and its subscribers (i.e., eliminating profit automatically built into their internal systems).
- Require that FEHBP carriers' contracts with PBMs allow OPM/OIG auditors to access the PBMs' pricing data (AWP/Wholesale Acquisition Cost/Maximum Allowable Cost and similar defined terms).
- Require consistency among the carriers' contracts with PBMs. Currently, each carrier negotiates the terms of the contract (i.e., pricing, rebates, administrative fees, etc.) with its PBM. Standard terms would facilitate oversight of the contracts, allow the implementation of "best pricing" practices across all FEHBP plans, and afford the carriers/PBMs less opportunity to overcharge the FEHBP.
- Change the language in the Federal Employees Health Benefits Acquisition Regulations to designate PBMs as Federal subcontractors. This would allow

OPM to impose stricter requirements on the PBMs. Also, Federal procurement rules would apply, which is another means to standardize PBM contracts.

- Require the PBMs to disclose the actual amounts paid for drugs and then reimburse them based on the actual costs of the drugs dispensed.
- Require the FEHBP carriers to provide Explanation of Benefits forms to FEHBP enrollees when drug benefits are utilized. This will allow enrollees to determine whether someone else is using their benefits and is a good tool in helping to prevent health care fraud and medical identity theft.

My office also believes that structural changes to the FEHBP itself may create transparency and lower the cost of pharmacy benefits. The following are examples of potentially advantageous changes:

- The pharmacy benefit could be carved out of the existing FEHBP benefit structure and be offered as a separate stand alone benefit open to all FEHBP enrollees. The PBM contract to administer this program would be negotiated directly by OPM. Because it would be a Federal procurement, the Truth in Negotiations Act would apply and require full disclosure of cost data by the PBM. The contract could be a cost plus fixed fee contract, based on the actual net cost of the drug to the PBM plus a fixed dispensing fee. Since market share is key in negotiating lower drug prices, the large size of a benefit covering all FEHBP enrollees should generate better contract terms (i.e., pricing) than could be negotiated by the individual carriers negotiating separately. This would be similar to the approach just taken by TRICARE in negotiating its new pharmacy benefit.
- As above, the pharmacy benefit could be carved out of the existing FEHBP benefit structure and be offered as a separate stand alone benefit open to all FEHBP enrollees. However, rather than contracting with a PBM, OPM could enter into an Economy Act (i.e., reimbursable) arrangement with TRICARE to administer the benefit for FEHBP enrollees.
- The Federal Supply Schedule (FSS) could be made available to the FEHBP PBMs. The Department of Veterans Affairs' (VA) National Acquisition Center negotiates Federal Supply Schedule (FSS) prices with drug manufacturers. These prices are available to Federal agencies but not to FEHBP carriers. FSS prices are intended to be no more than the prices manufacturers charge their most-favored nonfederal customers under comparable terms and conditions. Under Federal law, drug manufacturers must list their brand drugs on the FSS to receive reimbursement for drugs covered by Medicaid. All FSS prices include a fee of 0.5 percent of the price to fund VA's National Acquisition Center.

Thank you again for inviting me here today. I would be happy to respond to any questions you may have.

Mr. LYNCH. Thank you, Mr. McFarland.
Ms. Hayes, you are now recognized for 5 minutes.

STATEMENT OF SUSAN A. HAYES

Ms. HAYES. Good afternoon, Chairman Lynch and members of the Subcommittee on Federal Workforce. I want to thank you for the opportunity to testify in front of you and answer your questions this afternoon.

My name is Susan Hayes and I am a principal with Pharmacy Outcomes Specialists. In preparing my testimony today, I examined the problems encountered by Federal and State governments when contracting for pharmacy benefits. I see three major issues. Let us take these issues one at a time.

The pricing of prescription drugs is overly complex and hidden to purchasers, designed to confuse plan sponsors, and in turn, disadvantage plan sponsors in the negotiation process. Prices of prescription brand drugs, are based on discounts off Average Wholesale Price or AWP. The source of AWP pricing is primarily two pricing guides, which may charge as much \$25,000 per year to subscribe to obtain AWP prices.

AWP prices may change on a daily basis and are complicated by the fact that a single drug may have over 50 prices due to different strengths, package sizes and manufacturers. As a result, plan sponsors, such as OPM, have to pay exorbitant amounts, or hire auditors such as POS, to determine if they have been charged correctly and in accordance with the discount arrangements with their PBMs.

Prices for generic drugs are even more secretive. Each PBM sets a MAC list, Maximum Allowable Cost, which is closely guarded, which is not routinely given to clients and for which auditors must sign stringent non-disclosure agreements to obtain. MAC prices may vary by the day, the pharmacy or between clients of the same PBM. In fact, each PBM may have over 50 different MAC lists. Auditing these prices are complicated, even for the most experienced auditors, and impossible for plan sponsors.

Contracts between PBMs and plan sponsors, even the largest plan sponsors such as OPM, do not adequately disclose when PBMs realize revenue, and as a result, disadvantage plan sponsors in the negotiation process. In a recent decision, the First Circuit Court of Appeals observed: "The health benefit provider often has no idea that a PBM may not be working in its interests. This lack of awareness is the result of the fact that there is little transparency in a PBM's dealings with manufacturers and pharmacies."

Essentially, these contracts do not disclose the following: one, there are additional moneys or margins, perhaps as much as 5 percent of the drug spend, that are retained by PBMs; two, often as much as 50 percent of drug manufacturer rebate payments are never passed back to plan sponsors, but are retained by the PBM. PBMs come up with different names for these rebates, such as cost effectiveness rebates, formulary rebates and market share rebates, and then the PBM determines how to divide up the pie of rebate and retain what they want and pass back to plan sponsors what the PBM thinks that the client expects, without the client knowing that there is more; three, patient drug histories and physician pre-

scribing patterns are routinely sold to drug companies for profits by PBMs without physicians, patients or plan sponsors' knowledge or approval and without compensation by the plan sponsor or patient.

The lack of transparencies in PBM contracting is exacerbated by PBM's resistance to disclose this information, disclosure of public information, even when the disclosure is required by State sunshine laws. For example, one PBM has brought at least 11 separate lawsuits seeking to block the release of its contract covering public employees in Texas, even after the Texas attorney general issued legal opinions in each instance, stating that the PBM contract at issue should be released as a public document.

Contracts between PBMs and plan sponsors, limit plan sponsors' ability to audit these contracts and disadvantage plan sponsors from verifying if contract terms are met. Among the most insidious of these terms is mutually acceptable auditor. For Caremark, Medco and ExpressScripts, who together control a majority of the market, a mutually acceptable auditor, may be one that is not experienced with rebate contracts, AWP sources or PBM policies and procedures, or ones that are too expensive for most plans to afford.

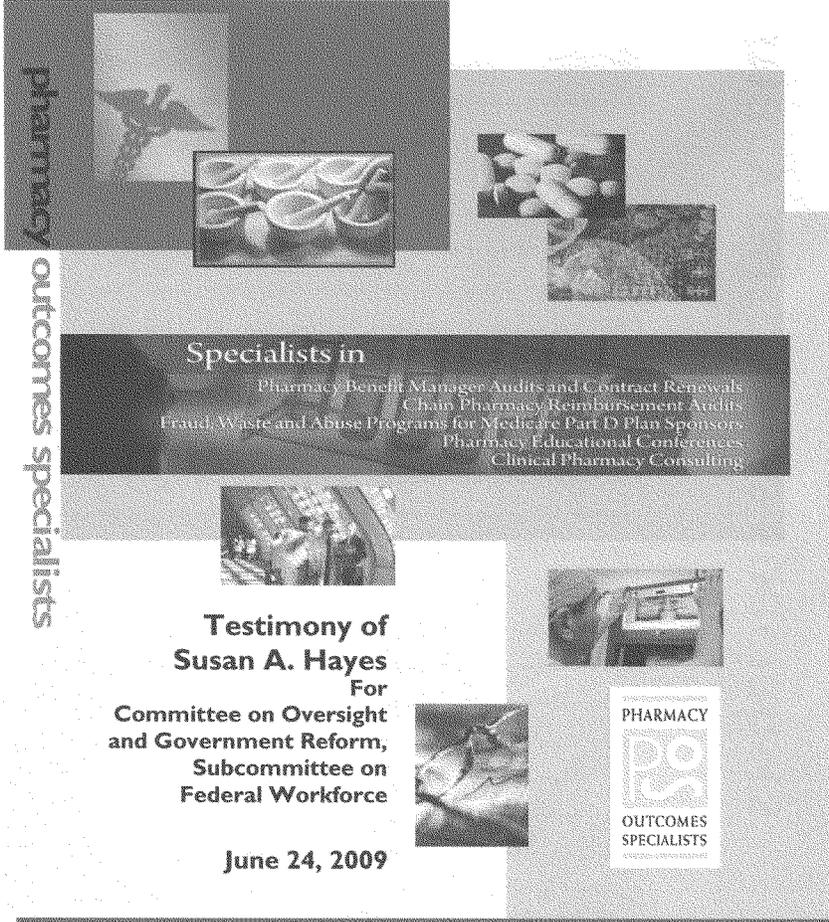
Chairman Lynch, I was surprised to see that your invitation letter to me stated that Federal costs for pharmacy benefits are 30 percent of total health care spending. Normally, I would see pharmacy costs as 20 percent of total health care, and I would conclude that your program is really, no deal.

I am hopeful that the Government will reform its contracting processes in the upcoming rebidding of several FEHBP plans, and I'm asking for the following measures: full transparent contracting for PBM services; pricing terms that are clear; AWP brand pricing information becoming readily available to plan sponsors; and PBM forced to publish MAC pricing for generics; rebate payment sources and types of rebate payments received by PBM fully disclosed; data selling of any kind associated with health care product spending or pharmacy data, should require the explicit approval of plan sponsors, physicians and patients; and that the plan sponsor selection of a qualified auditor should not be routinely thwarted by PBMs; and all plan sponsors should have the ability to fully audit all aspects of the PBM contract.

One again, I thank you for the opportunity and will entertain any questions you have.

[The prepared statement of Ms. Hayes follows:]

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**Testimony of
 Susan A. Hayes
 For
 Committee on Oversight
 and Government Reform,
 Subcommittee on
 Federal Workforce**

June 24, 2009



Good morning, Representative Lynch and members of the Subcommittee on the Federal Workforce, I want to thank you for the opportunity to testify in front of you and answer your questions this morning. My name is Susan Hayes and I am a Principal with Pharmacy Outcomes Specialists. I have been in health care consulting since 1980 and have been involved in pharmacy benefits consulting since 1985. I was responsible for pharmacy benefits consulting for William M. Mercer from 1985 to 1991, consulting to large employers such as Mobil, Sara Lee Corporation and Marmon Group. I was Vice President of Marketing for Walgreens' Health Plus from 1991 to 1994, and for Systemed, now a division of Medco Health from 1994 to 1996. In 1996, with my partner, Kevin Johnson, I founded Pharmacy Outcomes Specialists. I am a graduate from Northeastern Illinois University with a Bachelor's in Criminal Justice and am a registered pharmacy technician in the State of Illinois. We have been in business for 13 years and have consulted to large employers such as Intel and Northwest Airlines, large unions such as Sheet Metal Workers International, the Communication Workers of America Local 1180 and AFSCME Local 37, Coalitions such as the Connecticut Coalition of Taft Hartley Health Plans, the Midwest Business Group on Health and government entities such as the Office of Personnel Management, TriCare Management Activity and the Defense Contractors Auditing Agency.

Pharmacy Outcomes Specialists has conducted over 600 audits, dozens of procurement projects, audited almost a billion prescription drug claims and reviewed hundreds of client contracts with pharmacy benefit managers. Specifically for Office of Personnel Management, POS conducted a review of the contracts for OPM of the Government Employees Hospital Association (GEHA)

and BCBSA in 2000, both of whom contracted with Medco Health for pharmacy benefit administration. POS also conducted a second project for OPM. POS was selected as an expert to testify on rebate administration when the United States of America sued Merck-Medco Managed Care. As part of that litigation I was asked to assist in educating the jury on the industry practices pertaining to contracting and the payment of rebates and incentives by drug manufacturers to PBMs, and payments of rebates by PBMs to their clients. I was also asked to review contractual arrangements that were subjects of that litigation.

In preparing my testimony today, I examined the problems encountered by federal and state governments when contracting for pharmacy benefits. I see three major issues: 1) PBM contracts, especially in their pricing provisions, are needlessly complex; 2) PBM contracts do not disclose hidden revenue sources, including drug rebates and pharmacy margins, and plan sponsors are often not aware of these monies, disadvantaging them in the negotiation process; and 3) and, even when the federal government does negotiate a fair contract with a PBM, PBMs paralyze the ability of the Federal Government to audit and make sure contracted provisions are truly met. All of these problems result in the government and private health plans paying more and more for prescription drugs while PBM profits soar.

Let's take these issues one at a time.

1. The pricing of prescription drugs is overly complex and hidden to purchasers, designed to confuse plan sponsors, and in turn disadvantages plan sponsors in the negotiation process. Prices of prescription brand drugs are based on discounts off Average Wholesale Price or AWP. The source of AWP pricing is primarily two pricing guides which are

published by two pharmaceutical cost data collection companies which each may charge as much as \$25,000 a year to subscribe to obtain AWP prices. AWP prices may change on a daily basis and are complicated by the fact that a single drug may have over 50 prices due to different strengths, package sizes and manufacturers. As a result, plan sponsors, such as the OPM, have to pay exorbitant amounts, or hire auditors such as POS, to determine if they have been charged correctly and in accordance with the discount arrangements with their PBMs. Further, these prices are obtained from the actual manufacturer who sets the price of their drugs without the payor – plan sponsors – being aware of pricing changes or having the ability to negotiate these prices.

Prices for generic drugs are even more secretive. Each PBM sets a MAC list (Maximum Allowable Cost) which is closely guarded, which is not routinely given to clients and for which auditors must sign stringent non-disclosure agreements to obtain. MAC prices may vary by the day, the pharmacy or between clients of the same PBM. In fact, each PBM may have over 50 different MAC lists. Auditing these prices is complicated, even for the most experienced auditors and impossible for plan sponsors. Lastly, rebates are based on yet another anachronism, WAC (Wholesale Acquisition Cost) prices, which may loosely tie to AWP prices but have a life of their own, and may increase or decrease based on wholesaler backroom deals. Therefore, rebate amounts - more on this later – also cannot be easily verified by plan sponsors. Overall, the lack of transparency in how prescription drugs are priced and delivered makes these programs impossible to analyze by government agencies, which is no different than the private sector.

2. Contracts between PBMs and Plan Sponsors, even the largest plan sponsors such as OPM, do not adequately disclose where PBMs realize revenue and as a result disadvantage plan sponsors in the negotiation process. In a recent decision, the First Circuit Court of Appeals observed: "The health benefit provider often has no idea that a PBM may not be working in its interest. This lack of awareness is the result of the fact that there is little transparency in a PBM's dealing with manufacturers and pharmacies."¹

Essentially, these contracts do not adequately disclose the following:

i. There are additional monies or margin, perhaps as much as 5% of drug spend, that are retained by PBMs. This is done by charging a plan a higher amount for a prescription drug transaction than is reimbursed to a pharmacy for the same claim transaction, especially for generic drugs, since MAC lists are proprietary. This is known in the industry as "spread."

ii. Often as much as 50% of drug manufacturer rebate payments are never passed back to the plan sponsor but retained by the PBM. PBMs come up with different names for these rebates, such as cost effectiveness rebates, formulary rebates and market share rebates and then the PBM determines how to divide the "pie" of rebate and retain what they want and pass back to plan sponsors what the PBM thinks the client expects, without the client knowing that there is more.

iii. Patient drug histories and physician prescribing patterns are routinely sold to drug companies for profit by PBMs without physicians, patients or plan sponsor's knowledge or approval and without compensation by the plan sponsor or patient. Drug store chains who own PBMs also sell consumer

¹ *Change to Win, CVS/Caremark: An Alarming Prescription*, www.changetowin.org

spending information to insurance companies and others without compensation or the knowledge of patients, to the detriment of patients and these records of spending patterns are not considered "protected health information" under HIPAA.

The lack of transparency in PBM contracting is exacerbated by some PBM's resistance to disclosure of public contract information, even when this disclosure is required by state sunshine laws. For example, one PBM has brought at least eleven separate lawsuits seeking to block the release of its contracts covering public employees in Texas, even after the Texas Attorney General issued legal opinions in each instance stating that the PBM contract at issue should be released as a public document under well-established Texas law. A similar legal battle is underway in Michigan.

3. Contracts between PBMs and Plan Sponsors limit plan sponsors' ability to audit these contracts and disadvantage plan sponsors from verifying if contract terms are met. PBM contracts often contain certain "code words" that seem reasonable on the surface, but often stall audits for years or eliminate the audit altogether. Among the most insidious of these terms is "mutually acceptable auditor." For Caremark, Medco and Express Scripts, who together control a majority of the market, a "mutually acceptable auditor" may be one that is not experienced with rebate contracts, AWP sources or PBM policies and procedures, ones that are too expensive for most plans to afford, or ones that the PBMs coerces into fee arrangements to become "an acceptable" auditor. Most plan sponsors end up never finding an auditor that is acceptable to some PBMs. The Southeastern Pennsylvania Transportation Authority (SEPTA) sued its PBM in 2007 after it attempted, unsuccessfully, to conduct an audit of its plan.

SEPTA claimed in its lawsuit that Caremark, "has wrongfully blocked SEPTA's efforts to conduct an audit of Caremark's performance as SEPTA's PBM." Specifically the PBM engaged in tactics to delay and block the audit, first agreeing to provide certain claims data to SEPTA that was necessary to the audit, and then failing to produce that data and refusing to sign a tolling agreement to preserve SEPTA's claims while the audit was pending. In its lawsuit, SEPTA expressed the frustration of plan sponsors and auditors alike: "Having exhausted all efforts to conduct a thorough audit and to resolve amicably any and all problems with Caremark's practices, SEPTA was forced to bring this action to protect its public assets and interest of its members and beneficiaries in controlling the cost of prescription drugs."²

Another practice of PBMs to limit the auditing of contracts is to require the auditor to submit the audit report to the PBM first for approval before the audit report is delivered to the plan sponsor, after which the PBM holds its approval. This tactic often stalls an audit in progress for one to two years while the PBM continues to perpetrate errors.

Some impartial auditors are eventually approved. However, for some PBMs, "approved auditors" fall into one of three categories: one, the PBM has paid the auditor to place business with the PBM, two, the auditors testify for the PBM or three, the auditor and PBM have some "side deal arrangement." In the situation where the audit firm is paid to place business with the PBM, the audit firm is paid a per claim fee for the life of the three year contract to monitor the contract. No wonder these audits often find that the PBM is performing perfectly. Other auditors testify on behalf of a PBM in court cases in order to gain favor with

² *Change to Win, CVS/Caremark: An Alarming Prescription*, www.changetowin.org

the PBM. These auditors are then the only ones "tagged" as acceptable, but auditors that testify on behalf of the client are considered objectionable. Still other auditors have other mutual back-pay schemes with the PBM industry like a large consulting firm's arrangement with a PBM to pass this consulting firm additional consulting services to "review" the PBM Coalition formed by the auto industry, the consulting firm and the PBM; or other arrangements where the consulting firm is compensated by the PBM for placement of clients.

Why are some auditors so easily "approved"? Because objective third party audits expose costly errors by PBMs. Audits completed by the United States Office of Personnel Management in 2006 identified over \$13 million in administrative fees collected from the Federal Employees Health Benefits Program (FEHBP) Retail Pharmacy Drug Program between 2000 and 2005 by its PBM AdvancePCS – which should have been considered drug rebates and returned to FEHBP as the contract specified. These audits also found that AdvancePCS was not in compliance with all provisions of the contract and federal procurement regulations.

In my experience in over 600 audits, not one audit has yield a perfect report card. Some errors have been found in all 600 audits. Some were minor misunderstanding about plan design terms or eligibility "snafu's." Honest mistakes given that there are 12,000 drug code identifiers, 55,000 pharmacies, millions of patients, physicians and other providers and a host of system logic and rules applied to 3 second claims transactions. However, many findings related to ignoring PBM contractual obligation to plan sponsors to reduce costs and improve patient health.

Representative Lynch, I was surprised to see in your invitation letter to me that Federal Costs for pharmacy benefits are 30% of total health care spending. Normally, I would see pharmacy costs as 20% of total health care and I would conclude that your program is "no deal." All of the problems with the PBM industry that I discussed above are causing the government to spend more than it should on prescription drug benefits for the FEHBP. So that FEHBP can be a model for public and private plans, I am hopeful that the government will reform its contracting processes in the upcoming re-bidding of several of FEHBP plans, including PBM services that are subcontracted through Blue Cross and Blue Shield, and that regulations can be passed that require, particularly for Federal Employees, the following measures:

- Fully transparent contracting for PBM services, so that the government and the public can ensure that tax dollars are being wisely spent,
- Pricing terms are clear in PBM contracts and that pricing is "passed through" from the pharmacy to the plan sponsor with no margin,
- AWP brand pricing information becomes readily available to plan sponsors and PBM forced to publish MAC pricing for generics,
- Rebate payment sources and types of rebates received by the PBMs are fully disclosed and 100% of the rebates are passed on to the plan,
- Data selling of any kind, associated with health care product spending or pharmacy data should require the explicit approval of plan sponsors, physicians and patients,

- The plan sponsor's selection of a qualified auditor should not be routinely thwarted by PBMs and all plan sponsors should have the ability to fully audit all aspects of the PBM contract
- Auditors that accept payments of any kind from PBMs or drug companies should be required to fully disclose the information to prospective plan sponsors.

I once again thank you for the opportunity and will now entertain any questions that you have of me.

Mr. LYNCH. Thank you, Ms. Hayes.
Mr. Sheehan, you now have 5 minutes.

STATEMENT OF JAMES G. SHEEHAN

Mr. SHEEHAN. Thank you, Chairman Lynch, and members of the subcommittee for the opportunity to speak to you here today.

I also want to join, and I also really appreciate the opportunity to speak with Inspector General McFarland, who I have dealt with over a number of years, and is a leader in the Inspector General community, both on professional standards on these prescription drug issues.

What I would like to talk to you about today is my two experiences. One is in doing health care fraud cases with the Inspector General of OPM, where we were looking historically at what had happened within the OPM program and ended up recovering close to \$300 million from the companies and requiring major changes in their business practices.

And the second set of experiences in New York State, working with the Unitary System, where we would have one payer for prescription drugs and one data base that allows us to look at what is going on with the patients across the board. And I guess, like a lot of your witnesses, I have a five-point plan which I am going to do in 4 minutes.

The first part is, it seems to me OPM needs access to and a plan for use of integrated patient claims data, which includes drug data. We are going to talk today about costs and pricing, but the most important information about prescription drugs in addition to their costs, is what happens to the patients who take them. Do they experience better outcomes? Do they suffer adverse events? What is the cost to the patient? And assist them with those adverse events.

If you have these things parceled out through your, whatever number of plans that it is, over 100 plans, you are not going to have that data available to do the kind of analysis to see what the benefit is to the patient, and what the potential harms are, and kind of costs you are incurring for the drugs themselves and for the adverse events.

In New York State, we are a national leader in Medicaid data management, and in fact, most of the State Attorneys General who have worked on the drug cases, have used New York's data as their gold standard, to see what is actually happening. The same opportunity exists with OPM, it could be the gold standard in terms of data. OPM is a lot more experienced with drugs and drug payments than any other agency in the Federal Government, with the possible exception of the DOD.

The second issue is to take a look at identified drug risks, and there is data available to do that. That is laid out in my written comments. The third issue is focusing on drug pricing. Drug pricing within OPM's Health Plans was based, during the time I was working on reviewing it, upon percentage discounts off of average wholesale price, known in the trade as, ain't what is paid, and negotiated by the experience-rated plans with relatively little OPM oversight.

The net prices that we saw OPM paying, significantly exceed the net prices paid by State Medicaid programs, by DOD, and in certain cases, the programs which are run by private companies, like

HMOs, that didn't appear to be a reason for that. The Federal supply schedule, as you will hear later, works very well with DOD, and could be used in the OPM context as well.

The fourth issue that I would like to focus on is coordination of benefits between OPM plans and Medicare Part D plans. At the moment, one of the issues that we have seen in New York is you have to go very carefully to look at what, since Medicaid is the payer of last resort, and in certain circumstances OPM may be. Who has first responsibility for these charges and what kind of prices should they be charged?

And we have begun in the last year to obtain access to billing and payment information from those PBMs. I know the DOD is doing the same thing. I know OPM has the same potential. We have seen it is a significant dollar potential to recover. And also what happens to the patients is they may end up missing out on the doughnut hole if it is properly treated.

The fifth issue that I would focus on, is one Ms. Hayes raised, which is the choice of auditor and access to subcontractor PBMs. When you have a 100 plus plans, it is very hard to audit all of them. And when I was working with OPM on the contract side, it was very hard to figure out who the specific plans were, what specific subcontractor was used in each case. And each contract was different. So you needed a different auditor with a different set of information, and they were very aggressive at attempting to block certain auditors who were knowledgeable from looking at the program.

When I look at these programs with OPM, I believe there is significant opportunities for cost savings on prescription drugs through improvements in OPM operations, and a consolidation of the PBM contracts that exist. And as important, there are opportunities for better patient outcomes, more appropriate prescribing and reduced adverse events through integration and medical claim and diagnostic data, with pharmacy data maintained by the PBM subcontractors.

Thank you very much, Mr. Chairman, for the opportunity to speak today.

[The prepared statement of Mr. Sheehan follows:]

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Statement of

JAMES G. SHEEHAN
MEDICAID INSPECTOR GENERAL
NEW YORK STATE
OFFICE OF THE MEDICAID INSPECTOR GENERAL

before

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
SUBCOMMITTEE ON FEDERAL WORKFORCE,
POSTAL SERVICE,
AND THE DISTRICT OF COLUMBIA

on

FEHBP's Prescription Drug Benefits: Deal or No Deal?

June 24, 2009

Office of the Medicaid Inspector General

Chairman Lynch, Ranking member Chaffetz, members of the Subcommittee:

I appreciate the opportunity to join my good friend, OPM Inspector General Pat McFarland, in testifying before the Subcommittee today. Inspector General McFarland has long been a leader in the Inspector General community on professional IG standards and on prescription drug issues. I have worked closely with OPM and OPM-IG staff for ten years. I believe that the unique structure of the OPM health plans and members offer a significant opportunity to achieve higher quality health care outcomes for members and lower costs, and that the OPM plans can be a national model for effective, cost-conscious health care. New York's Medicaid experience can provide some helpful advice on how to achieve that result.

Before becoming New York's Medicaid Inspector General in 2007, I was the Associate U.S. Attorney in Eastern Pennsylvania. In that position, I worked with investigative and prosecutive teams for seven years, looking at the business practices of two major pharmacy benefit management (PBM) firms who did business with OPM plans. Medco Health, which handled the mail order contract for OPM's largest contractor, the Blue Cross and Blue Shield Association, and AdvancePCS (now part of Caremark) which handled the Blues' retail contract. These investigations involved allegations of false claims, improper payments from drug companies, and kickbacks to health plans by PBMs to steer business. At the conclusion of those investigations, these two companies paid over \$290 million to the United States, and agreed to make significant changes to their business practices. The Eastern Pennsylvania office was also a national leader in investigation of off-label drug promotion, most recently obtaining a \$1.4 billion settlement from Eli Lilly for promotion of its antipsychotic drug Zyprexa (olanzapine), and over \$400 million from Cephalon for promotion of its drugs.

In the Medco and AdvancePCS cases, federal investigators had the opportunity to interview witnesses and review documents from many companies over a long period of time, and to become educated in how the PBM business works. We also learned the business strategies used by pharmaceutical manufacturers in their relationships with PBMs and health plans.

In my new role as New York's Medicaid Inspector General, the staff in my organization and in New York's Department of Health, which manages the Medicaid program, have educated me on the opportunities for a payor for both cost savings and improved patient outcomes through direct access to integrated patient care information which includes prescription data.

As a federal employee, and now as a federal retiree, participating in the Blue Cross plan for 29 years, I have been exposed to the operation of the OPM drug benefit program as a consumer and parent.

Based upon this experience, I offer the following suggestions for the operation of OPM's prescription drug program:

1) OPM NEEDS ACCESS TO AND A PLAN FOR USE OF INTEGRATED PATIENT CLAIMS DATA

The most important information about prescription drugs is not how much they cost, but what happens to the patients who take them. Do they experience better outcomes? Do they suffer adverse events? What is the cost to the patient and the system of adverse events? Neither community rated plans nor experience rated plans have incentives within the OPM program to address these questions. To be fair, they are not addressed by CMS or the FDA either. But federal employees, and recent federal retirees like me are an ideal population to study for quality improvement, cost saving opportunities, and risks. OPM has access to six-plus years of data for every patient-and we are not leaving the program.

For hospital in-patients, the research from the 1990's suggests that adverse drug reactions leading to death in hospitals are about 106,000 per year in the US, and are between the fourth and sixth leading cause of death.¹ For ambulatory patients (that is, patients not in a hospital or nursing home) the research is also sobering. A 2003 Brigham and Women's study found that "of 661 patients who responded to the survey (response rate, 55 percent), 162 had adverse drug events (25 percent; 95 percent confidence interval, 20 to 29 percent), with a total of 181 events (27 per 100 patients).² Twenty-four of the events (13 percent) were serious, 51 (28 percent) were ameliorable, and 20 (11 percent) were preventable. Of the 51 ameliorable events, 32 (63 percent) were attributed to the physician's failure to respond to medication-related symptoms and 19 (37 percent) to the patient's failure to inform the physician of the symptoms."

New York's Medicaid program is a national leader in its data management. The New York state data allows us to determine every reported diagnosis and every Medicaid health care encounter for every Medicaid patient-which allows the state to identify risky, expensive, or inappropriate prescribing, and also allows New York to run an effective supplemental rebate program resulting (for some products) in prices lower than the Medicaid best price. New York's rich and accessible data systems have allowed the Department of Justice and National Association of Attorneys General to investigate and prosecute off-label drug promotion and marketing. The data available to New York as a payor are significantly more comprehensive, and far easier to use, than data available to

¹ Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies *JAMA*. 1998;279:1200-1205, Jason Laxarou et al.

² *Adverse Drug Events in Ambulatory Care* 348:1556-64 New England Journal of Medicine 4/17/03, Gandhi et al. The medication classes most frequently involved in adverse drug events were ssris (10 percent), beta-blockers (9 percent), ACE inhibitors (8 percent), and nonsteroidal anti-inflammatory agents NSAIDs (8 percent). Only the number of medications taken was significantly associated with adverse events.

OPM or Medicare for their programs-because of New York's contractual relationship with its carrier/fiscal agent.

This data has the potential to transform health care over the next ten years, because of the power of data-driven disease management and adverse event identification tools-which are especially significant for FEHBP's older population who are more likely to have chronic conditions. In New York Medicaid, electronic prescribing incentives will provide us with data about every prescription written for our Medicaid patients, at the time it is written. OPM could do the same.

2) A FOCUS ON IDENTIFIED DRUG RISKS-OPM HAS THE OPPORTUNITY TO REVIEW SIGNALS FROM MEDWATCH AND DETERMINE IF THEY ARE VALID AND PATIENTS ARE AT RISK

The FDA's Medwatch program is getting better, but is still not being used to its potential.³ The Institute for Safe Medication Practices (ISMP) has been reviewing Medwatch data for the past two years. The results of those reviews raise significant concerns:

Chantix (varenicline), a drug to help people stop smoking. Medwatch in one quarter had 227 domestic reports of suicidal acts, thoughts or behaviors, 397 cases of possible psychosis and 525 reports of hostility or aggression. These totals included 28 cases of suicide and 41 mentions of homicidal ideation, 60 cases of paranoia and 55 cases of hallucination.

Digoxin a drug used for heart disease and arrhythmia, Medwatch received more than 1000 patient deaths reported in connection with the recall of 800 million digoxin tablets manufactured in New Jersey by the Actavis Group. The tablets were recalled because of the possibility that the strength of tablets was greater than labeled and might provide a potentially lethal overdose to patients taking the drug to aid failing hearts.

3) FOCUS ON DRUG PRICING

Drug pricing within OPM's health plans was based, during the time period I was involved in reviewing it, upon percentage discounts off Average Wholesale Price negotiated by OPM experience-rated plans with little or no financial interest in the outcome of the negotiations, since the costs were passed through to OPM. The net prices paid by OPM significantly exceed the net prices paid by state Medicaid programs, like New York, who obtain the benefit of the Medicaid best price or better. OPM prices also exceed the prices paid by the Department of Defense under the Federal Supply Schedule. In the mail order pharmacy context, pharmacy benefit managers were able to provide prescriptions based upon the Federal Supply Schedule costs to DoD enrollees in the CHAMPUS program. There is no reason they could not provide the same service to OPM health plans.

³ A Medwatch report is based upon association, not causation. It is not proof, but suggests that further review is needed.

At retail, federal employees and OPM need to know what savings can be accomplished by purchasing generics. I found as a consumer that the retail pharmacies were often unwilling to discuss the price charged to the Plan, and when I obtained the price, much of the savings were retained by the PBM—due to the practice of passing through inflated generic prices.

4) COORDINATION OF BENEFITS BETWEEN OPM PLANS AND MEDICARE PART D PLANS

In the past year, New York finally began obtaining access to billing and payment information from PBMs including PBMs that operate private and Medicare Part D plans. The results were troubling—some pharmacies billing and being paid twice for the same prescription, payment for some dual eligible patients being denied by the plans for no apparent good reason and the prescription being billed to Medicaid, some pharmacies not submitting claims to the Part D payor because the Medicaid billing was easier and payment more reliable.

It is important to recognize that many OPM plan entities also manage a Medicare Part D plan. Many federal employees over 65 are enrolled in both plans. Experience-rated plans are not at risk on the OPM side, but are at risk on the Part D side. Audit and oversight are essential to assure that each plan fulfills its responsibilities to beneficiaries and to OPM.

5) CHOICE OF AUDITOR AND ACCESS TO SUBCONTRACTOR PBMs

Auditing PBMs requires experience and sophistication, and avoidance of conflicts of interest. PBMs limit audit access in their contracts with plans to auditors approved by the PBM. OPM and the plans should have the ability to retain auditors who are able to perform these duties effectively.

There are significant opportunities for cost savings on prescription drugs through improvements in OPM operations. As important, there are opportunities for better patient outcomes, more appropriate prescribing, and reduced adverse events through integration of medical claim and diagnostic data with pharmacy data maintained by PBM subcontractors.

Thank you for the opportunity to speak with you today. I am happy to take any questions.

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Thank you for the opportunity to speak with you today. I am happy to take any questions.

For additional information, please check our website www.omig.state.ny.us, and I can be reached at 518-473-3782 or my email address, jgs05@omig.state.ny.us.

Mr. LYNCH. Thank you, Mr. Sheehan. I now yield to myself 5 minutes.

Let me ask, we handle the purchase of our acquisitions through DOD and other entities, much differently than we do the purchase of pharmaceuticals. Maybe this is naive of me, but why wouldn't we just make the purchase of pharmaceuticals subject to the normal regulated acquisitions process?

Mr. MCFARLAND. That is, as a matter of fact, one of our suggestions that we are able to do that. We have certain proposals that we offer. One would be to have the Federal regulation changed in the FEHBP Act by Congress, of course, so that the PBMs would be considered subcontractors, rather than providers.

Because right now, they are really in concert with a doctor or a small pharmacy as a provider. And, in fact, they, multibillion dollar corporations, that are operating in a manner that we think would be certainly reasonable to have them considered a subcontractor. And by virtue of doing that, we would have the transparency that we need, and we would have the detail. We would get as close as possible to the actual cost. But short of that, that is the situation.

Mr. LYNCH. OK. Ms. Hayes, do you have any thoughts on that, about following this payment system and acquisition system through the Federal Acquisition Regulations?

Ms. HAYES. Well, I agree with Mr. McFarland and his position that these prices should be available to OPM and the Federal employees. Again, I think that even if AWP, Average Wholesale Prices, is used as the basis, pricing should be available to the public so that AWP information can be monitored routinely, rather than having it so secretive, and having it be bought, and really not have this information available. So I agree that Federal employees should get the same pricing as DOD and other Government agencies. But even if that isn't taken, I think that AWP and certainly MAC pricing under generic, should be available to the public to understand what those costs are.

Mr. LYNCH. Mr. Sheehan.

Mr. SHEEHAN. The difficulty that we encountered was the requirement for statutory change, and that did not appear to be likely to happen in the near future.

Mr. LYNCH. OK. Let's see, I still have a minute and a half left. In trying to dig down and understand this whole process. It is unbelievable the needless complexity of this whole system. It is built to thwart oversight. It is built to introduce as much complexity into the system as it possibly can. It is a scam of major proportions.

There is no reason that this health plan should have to operate like this. It is a disgrace. And in this day and age, when we are trying to save billions of dollars to fund this health care reform, this is an area that absolutely has to be cleaned up. This is a mess. It is shameful what is going on. And it is going to take a while, but we are going to get to the bottom of this. We are going to change this system. I promise you. So that is about all I have for time on this pass, but I will gladly recognize the gentle lady from the District of Columbia, Ms. Eleanor Holmes Norton, for 5 minutes.

Ms. NORTON. Thank you, Mr. Chairman, and what a find you have before us here. I am trying to understand just as you are, how

we could have taken this route. Let me try to cut to the chase, Mr. McFarland. If you were looking at this system, wouldn't you have to conclude that OPM simply patterned its own drug program for Federal employees on what the Federal Government was doing in the private sector. Isn't this simply the attempt to recreate what that program, and how that program was structured?

Mr. MCFARLAND. To recreate the private sector?

Ms. NORTON. The program for non-Federal employees, I am asking whether this is not simply an imitation of that program?

Mr. MCFARLAND. Well, my feeling about that, Ms. Norton, is that in 1959 when the Federal Employees Health Benefits Act was passed, it was very clear, very concise as to what was expected of OPM. Basically, OPM has stuck very close to that and not tried to go outside of any reasonable bounds, inasmuch as—

Ms. NORTON. Well, let me challenge you on that. Let me ask you, whether or not this program is modeled on similar programs already in the Federal sector? Like the program established for decades now for veterans. Wasn't there a clear precedent as to how to go about doing this?

Mr. MCFARLAND. What the Veterans Administration is doing, seems to be a very expeditious way of doing it, and that is one of our suggestions, that we might want to look at operating from the—

Ms. NORTON. Well, I am challenging you Mr. McFarland, when you said, all they did was try to follow what they have been doing. It seems to me, what the Veterans Administration is doing is more closely related to what one would have expected of the Federal Government. Here we had a brand new humongous program, the first thing you look for is, do I have something to guide me. Here you have a Federal agency, that has been doing it forever, you put that aside and proceed. I don't understand why that precedent was not relevant.

Mr. Sheehan.

Mr. SHEEHAN. Yes, ma'am.

Ms. NORTON. Do you believe that precedent should have anything to do with what was happening here, or was there no analogy between the Veterans Program and this program?

Mr. SHEEHAN. We explored the Veterans Program and the Medicare Part D Program, and the OPM Program. I think that Inspector General McFarland is correct, that what has happened is that the model that was used was the private sector model. But, many major companies are doing a better job now in identifying these costs and controlling them and dealing with them than we are in the Federal Government.

Ms. NORTON. I recognize this. If you look at our FEHBP, it deals with individual plans, and they do the negotiation. I don't remember people coming back saying they weren't getting a good deal. Is the reason that they don't come back and say they are not getting a good deal, because of oversight by OPM, Mr. McFarland? We have not had this complaint, so far as I know, among the FEHBP health programs, that you say is the model for this program.

Mr. MCFARLAND. We, in our office, exercise our audit and our criminal investigative efforts in this regard all of the time. This is what we do the most of in the health care that services the Federal

Government. So, I am not quite sure the best way to answer your question, because all of our efforts are going toward resolving these conditions. And we have our options and suggestions that we are providing to OPM for consideration.

Ms. NORTON. Well, we appreciate your work, and if the chairman will bear with me for just one more question. Understand we are trying to see what is appropriate for oversight here for the agency to do. I don't recall hearing of complaints about people who were pressured to move from one insurer to another.

But yet in this situation, there have been complaints of quite unusual, at least in the Federal sector, actions such as pressure to move one's prescription from a pharmacy to the larger pharmacy. I don't recall that in FEHBP we have had that kind of situation occur, and I wonder if you have seen that, and what you think of that and what can be done about it?

Mr. MCFARLAND. Well, certainly when the health carriers negotiate their contracts with the PBMs what they are attempting to do is get the best price for the prescription drugs. And they are—

Ms. NORTON. But the reports are that, in some cases, the cost to consumers has risen significantly. There wouldn't be any complaints, sir, if the same kind of economies of scale you get from mega stores were available here. But there have been complaints, and I am trying to find out what went awry here and what we can do about it. Because it is new in that system as far as I can tell.

Mr. MCFARLAND. Well, first of all, what it would take would be Congress to amend the FEHP Act so that certain things, such as you are suggesting can happen, and there can be more economies of scale.

Ms. NORTON. So you would recommend that?

Mr. MCFARLAND. Yes.

Ms. NORTON. Yes, sir.

Mr. MCFARLAND. That is one of our considerations. Yes.

Ms. HAYES. I would recommend that. One of the things that you asked was, is this patterned after private industry? And a lot of my clients are private industry. One of the things that private industry would never do, is divide up their negotiation power over 100 different contracts. OPM divides up their negotiation power over 100's of different contracts through health insurers, to the PBMs. And private industry would never do that. Private industry would use whatever leverage it had with its number of employees with one given PBM.

Ms. NORTON. Why don't they do that, Mr. McFarland? Isn't that really economies of scale? You are the biggest player in the market, that is what you have going for you. Why aren't you using that strength? Why aren't we using that strength the way the Veterans Department uses that strength?

Mr. MCFARLAND. Ms. Norton, the situation, as I see it, is somewhat simplified. And that is that from the beginning, in 1959, the FEHBP has operated by not going outside of bounds. They have a certain clarity that they are trying to stay within those bounds, as far as dealing with providers. They basically don't do that. They have contracts, OPM has contracts with 266 health carriers at the present time. And the health carriers then devote their time nego-

tiating contracts with PBMs. PRMs, in turn, negotiate their time with—

Ms. NORTON. Mr. Chairman, I won't take up more time, but I do want to say, your testimony then is you do not believe they had the power to do that? Are you saying—

Mr. MCFARLAND. Well, they do not have the power without Congress—

Ms. NORTON [continuing]. That they did not have the power to do what the Veterans Administration does, use the leverage of the Federal Government to reduce the costs to Federal employees, and that if we want that to happen, we should change the law? Is that your testimony?

Mr. MCFARLAND. If you change the law, or OPM can do the Federal regulation change—

Ms. NORTON. That is a very important "or." That is a very important "or," Mr. Chairman. Or if OPM was interested in looking at the system, a brand-new system for us, in terms of getting the best deal, they do have the regulatory power to do so?

Mr. MCFARLAND. Yes.

Ms. NORTON. Thank you, Mr. Chairman.

Mr. LYNCH. Thank you.

Let me ask, sort of following up on Ms. Holmes Norton's question, we have a plan that represents 7.7 million people, a lot of buying power there. In your own experience, do you feel like we are using that leverage to demand the best deal. Sort of the title of this hearing, Deal or No Deal. Are we getting a good deal, Mr. McFarland? Do you feel, based on the leverage, that we should have with 7.7 million participants and the position that we have?

Mr. MCFARLAND. We are concerned, Mr. Chairman, that we probably are not getting a good deal. There is a good chance that we are not getting a good deal, because of the lack of transparency. And when I say lack of transparency, I want to be more specific. We can't find out information such as the incentive pay, the rebate pay, volume discount pay, administrative fees. We can't find that information out because we can't audit that. It is not available to us now.

Mr. LYNCH. Right.

Mr. MCFARLAND. We can carve out something from the FEHBP, specifically the prescription drugs. We can carve that out and go after that. And then we have a tremendous amount of enrollees to make a difference. You are correct.

Mr. LYNCH. Do you want to comment on that? It is very difficult to conduct an audit on this system. I am talking about professional auditors going in there, because all of this stuff is so opaque, and it has been made so complex. There has been a deliberate attempt to build a system that is not auditable, and they have basically created that. It is a very frustrating situation here.

In this hearing process, what I am trying to do is to figure out whether we can introduce transparency on the existing system, or simply blow it up. Blow up the system, put them under the Federal acquisition regulations. Whole new ball game, because I am tired of this going on, where our auditors can't go in there. I can't even figure out the costs of manufacturing it, what their markup is, where the rebates are going.

You would think that the entity that actually generates the usage and the volume of these pharmaceuticals would earn the rebates themselves. I think, based on the evidence that we have had in so far, about 50 percent of the rebates go somewhere else. Maybe they go to the PBMs or some other groups, but they are not coming back to these Federal employees. And that is totally unacceptable.

So I am trying to figure out whether it is better to try to fix this system, and I am not so sure it is. Because the complexity is there and it may take too long to do some of these things. It may be better to just simplify things, get it into an existing system, and let it all shake out there. And that system requires transparency. Your own thoughts, Mr. McFarland?

Mr. MCFARLAND. Yes, when I answered before, this is exactly what I was getting at when I said it will take a change by the Congress. And we can carve out something that could be done, but it would take an amendment from the Congress. What we also can do, is the FAR regulation could be done by OPM, and they could do that and allow us to get in and take advantage of it like DOD does and Veterans Administration, Public Health Service and the Coast Guard.

Mr. LYNCH. Right. One of the other frustrating parts of this is the Average Wholesale Price or the MAC, the Maximum Allowable Cost. It is tough to dig down and figure out what the hard numbers are in terms of what we are being charged for 7.7 million beneficiaries. But I do have the ability to compare system to system, and when I look at the VA system that I am involved with, it looks like they are getting a discount from the Average Wholesale Price of somewhere between 55 and 65 percent. That is the discount I am seeing at the VA.

Now I have 7.7 million Federal employees, and I would say the average discount they are getting maybe 12 to 15 percent, somewhere in that range. Now I could understand if there were comparable discounts here, if one was at 45, the other one is at 55. But going from 60 percent to 12 percent, it just amplifies the sense that the Federal employees are getting a raw deal on this plan.

I have exhausted my time. If I could allow you to answer though, there are only a few Members here so I am sure everybody will be given ample time. Ms. Hayes do you have anything, in terms of comparing system to system? You have a lot of experience in this. I thought your written testimony was very powerful, and I thought you spoke very plainly, and the little bit of testimony from the professional side, that I could actually understand, and I appreciate that. Your sense of whether or not there is a way to drill down here and get this system into one of fairness on behalf of the Federal employees?

Ms. HAYES. Well, again, with what Mr. McFarland said, you have over 200 different health insurers subcontracting under 200 different PBM contracts. They all have different contracts. And, again, that creates chaos.

Mr. LYNCH. Yes.

Ms. HAYES. And you may have one contract that has one different list for generic drugs and another contract with the same PBM that may have another list for generic drugs, and they are all on different pricing. I agree that if OPM got Federal pricing, it

would give a level playing field. I think the other issue is transparency and disclosure. You have to understand pharmaceutical money that passes between drug companies to PBMs to plan sponsors. And that whole process needs to be 100 percent transparent. That has to be 100 percent transparent.

Mr. LYNCH. I agree.

Ms. HAYES. Money is being kept by the PBMs on your behalf, that should be going back and making those prices close to the Federal pricing. That is why you have a difference between a 12 percent discount and a 50 to 60 percent discount with the VA. That difference is, in part, rebate money that is not being passed back.

Mr. LYNCH. OK. Mr. Sheehan, same question.

Mr. SHEEHAN. I look at the system and I compare it with New York's system, and first, there is the breaking down into the 200 separate plans. But the second piece is, between the PBMs and the Federal system, there is yet another set of players, and that is the health plans.

And in the absence of OPM saying, this is what we expect, this is what we want, this is how we are going to pay, they have their own interests as an organization. So when we did our investigation of Medco, we found there were significant dollars changing hands from the drug companies to the health plans, and from the PBMs to the health plans, in ways that didn't show up in the reporting to OPM.

So there is a financial interest in these plans, which is separate from running an experience-rated plan, where you just pass the cost through. And so, it seems to me, that they should take control of the process, whether it is going to be a Federal supply schedule process or contracting across the board, that is an issue for the Congress to decide and not for us, but I think by letting it just happen, you are missing out on the opportunities at two separate levels.

Mr. LYNCH. Well, there might have been a day when we could afford that; that day has long since passed, and we have to try to maximize our savings here. At this point, I will yield. Mr. Cummings, would you like 5 minutes?

Mr. CUMMINGS. I don't have any questions, thank you, Mr. Chairman.

Mr. LYNCH. OK. Ms. Holmes Norton for 5 minutes.

Ms. NORTON. No, thank you, Mr. Chairman.

Mr. LYNCH. OK. Well, I have a lot more questions in my own mind. The problem at the pharmacy benefit manager level is so complex with the markup on the drugs themselves, the handling of rebates, whether they keep them, whether they give them to the end user, the employees, it seems to be a very mixed bag. And, again, the level of complexity goes not only to the drug manufacturer, but also very much to the PBM, or Pharmacy Benefit Manager.

Now, I haven't tried to really grapple with those entities on a one-to-one sort of basis, but what do you think about a PBM accountability act or some type of Pharmaceutical Benefit Manager Accountability Act, where you require transparency, you require those entities to operate in an open and understandable manner

with their clients, and open themselves up to an auditing process so that we can understand what the heck is going on at that level?

Mr. SHEEHAN. Chairman Lynch, if I could take a crack at that?

Mr. LYNCH. Sure.

Mr. SHEEHAN. I have investigated, I think, all the major PBMs over the last 10 years, and to some degree, the problem is that PBMs are like Larry the Cable Guy. That you may get a great offer today, but by the time they get the box in your house and you have to sit and wait for them, switching is very difficult, and there aren't that many places to switch to. So the question is, how do you make sure that the PBMs do what you need them to do, after the contractual relationship exists.

And it seems to me, that is a classic situation for regulation by Congress and by outside entities. You are not going to be able to negotiate anything in the contractual process, because your clout, once the contract starts and you have x-million patients or x-hundred thousand patients in the system, is very little.

Mr. LYNCH. You are saying, let us use the rebate situation. If we mandated that PBMs pass on the rebates to the end user, or 80 percent or 90 percent, when you say you have to tell them how to operate.

Mr. SHEEHAN. It gets more complicated than that, and there are contracts like that. The difficulty was, about 10 years ago, the companies started to do that, and what happened was everything that used to be a rebate got called something else. It was a data fee.

Mr. LYNCH. Yes. Right.

Mr. SHEEHAN. It was a thank you very much for visiting our facility fee. So part of it is making sure that in the contractual process there is a regulation that says, here is what the expectations are, and here is the minimum floor you have to meet. Otherwise, if you are a PBM, the trick is to, like Larry the Cable Guy, offer stuff on the front end. Then you are in the relationship. It is very hard to find out whether you got it, which is why the regulatory process is important.

Mr. LYNCH. OK. Ms. Hayes, did you have something to add on that?

Ms. HAYES. I do. As Mr. Sheehan said, once you get into the relationship, the auditors come in, and auditors have been thwarted by the PBM industry in every effort possible, to make sure that the contractual obligation that the PBM has to its plan sponsor is actually being upheld.

For example, when we go in and do rebate audits, that do not involve litigation, we have to go there and copy down every single line of every single contract, between the pharmacy benefit administrator, the PBM, and the drug manufacturer, because—I'm not sure why. Even though we are under very strict confidentiality rules, we have to copy down every single line of these very complex contracts. Some of the contracts are 5, 6 inches deep.

Mr. LYNCH. Yes.

Ms. HAYES. And so for us to copy down contracts that they have with drug manufacturers, not being able to take those to our offices and audit them in a normal manner that one would expect an auditor under confidentiality agreements to do, is very burdensome. And because of that, plan sponsors neither have the human re-

source ability or the financial ability to actually conduct these audits.

So PBMs go into this contracting mode, and they will contract, like Larry the Cable Guy. I love that analogy. They will go in and contract what they think the clients will expect, knowing full well, that the plan sponsor will never have the ability to actually audit these agreements properly.

Mr. LYNCH. Yes. I agree. I have only had limited experience with a couple of the health benefit plans that I had worked with as an attorney, but it seems as though many of the contracts are structured in a way that, by virtue of their density and length, defends against the risk of being read by anyone.

Ms. HAYES. Or understood.

Mr. LYNCH. Let alone an auditor. I think that the auditing piece here is problematic as well. In just reviewing what has gone on, there has also been a very, I think, concerted effort to either compromise the auditors or mystify them and bring in folks who really aren't equipped or able to conduct a valuable audit. And so they are often frustrated in their own efforts, and they end up giving a rather favorable review, probably with the hope of getting more auditing work.

So it is almost as if we need to clean that system up as well, and have certain parameters to make sure we are getting lucid and thorough audits on these audits that we do request. And I know there has been a game played with the contractual language of mutually agreed upon auditor, which has frustrated many of these plans in getting an auditor in. Sometimes these delays can go on for a couple of years, where the parties can't agree on an auditor because the drug companies, or the PBMs, are taking advantage of that language. But I don't want to monopolize the time.

Mr. Connolly, from northern Virginia, you are recognized for 5 minutes.

Mr. CONNOLLY. I thank the chairman and forgive me for coming late, I have been on the floor for a series of fascinating votes. Mr. Chairman, I would ask, without objection, that my opening statement be entered into the record at this point.

Mr. LYNCH. Without objection.

[The prepared statement of Hon. Gerald E. Connolly follows:]

Opening Statement of Congressman Gerald E. Connolly

Subcommittee on Federal Workforce, Post Office, and District of Columbia

June 24th, 2009

Thank you, Chairman Lynch for convening this hearing, which addresses the intersection of rising health care costs and the capacity of the federal workforce. As many of us have noted at prior meetings, we are confronting a brain drain at the federal level that requires enhanced recruitment and retention of federal employees. Benefits are central to this effort. Rising costs of benefits, including for prescription drugs, represents a serious obstacle to long term efforts to recruit and retain federal employees. This hearing also is important because it highlights some of the unsustainable aspects of our present system for health care delivery, including a reliance on private sector providers who have little to no incentive to control costs and all too frequent conflicts of interest in delivery of care.

The GAO reports that increases in prescription drug costs have accounted for 3-5% annual premium increases in overall Federal Employee Health Benefit Program (FEHBP) premiums between 2002 and 2007, and the Office of Personnel Management (OPM) predicts that rising prescription drug costs will continue to drive premium increases in the near future. OPM notes that prescription drugs account for 30% of overall FEHBP costs, compared to 15% for private sector benefit plans, largely because FEHBP participants are older than the average beneficiary nationally. Finally, OPM's Inspector General found that Pharmacy Benefit Managers (PBMs) who had contracts under FEHBP had switched medications upon receiving 'financial incentives from pharmaceutical manufacturers.' Our challenge is multifaceted.

First, we must tackle the dramatically and disproportionately rising costs of prescription drugs. As part of that effort, we must crack down on poor performance of PBMs, principally through increased transparency of the procurement process and implementation of reforms recommended by the OPM Inspector General's working group. We also need to identify cost control measures that deal with the structural challenge of providing care for a relatively old beneficiary pool.

Mr. Chairman, we face a daunting challenge in corraling the power of PBMs to control costs without creating so much flexibility that they are able to exploit conflicts of interest that end up hurting taxpayers and federal employees. We face a challenge in containing costs that result from an aging population. These challenges are directly connected to our need to enhance benefits in a manner that will help recruit and retain federal employees. These challenges are a microcosm of the broader need to reform our health care system, so I hope that this hearing may shed light on both steps that can enhance Federal provision of prescription drug benefits as well as lessons that can be applied more broadly.

Mr. CONNOLLY. I thank the Chair. And let me ask our panelists, do you agree with the OPM Inspector General's suggestion that the lack of transparency is a fundamental problem with PBMs acquisition of prescription drugs? And did you encounter similar problems with PBMs changing prescription drugs at pharmaceutical companies' behest or PBMs over-billing FEHBP carriers? Are those fair criticisms in your view?

Mr. SHEEHAN. Let me take one of those that I think we have addressed, which is the issue of switching prescriptions. Both Medco and CareMark, through advanced PCS subsidiary, signed agreements in 2004 and again in 2005, agreeing to limit the switching activity that they would engage in. And I would defer to my colleagues at the OPM as to the compliance with that, but it has been pretty good. That is not universal throughout the industry. So that piece, has been at least addressed in the short term through litigation.

The second piece though, which is the transparency on pricing, is still a huge problem and Ms. Hayes has talked about the audit side of that, but it is a problem just across the board, because it is very hard to figure out whether it is the retailer or the mail order pharmacy, or the PBM that is responsible for making sure the transparency occurs.

Mr. CONNOLLY. Ms. Hayes.

Ms. HAYES. Well, I would agree that transparency is a huge issue.

Mr. CONNOLLY. Ms. Hayes, I can't hear you.

Ms. HAYES. I am sorry. I would agree that transparency, or lack thereof, in this industry, is a huge issue as to why costs are increasing. We have talked about the fact that rebates from pharmaceutical manufactures, through the PBM, to the plan sponsor are not fully disclosed. And as a result, plan sponsors probably aren't getting as much as 50 percent of the rebates entitled to them, which would indeed, lower costs. So that is a large issue. I think the other large issue—

Mr. CONNOLLY. I am still having trouble hearing you, Ms. Hayes.

Ms. HAYES. I am sorry.

Mr. CONNOLLY. And I know that is an important point that you are trying to make there. We are not realizing 50 percent of the savings because of why?

Ms. HAYES. Because rebates between drug pharmaceutical companies, to the PBMs, to the plan sponsors, are not being passed back 100 percent I would agree that transparency is a large issue. I would also say that drug pricing and the complexity of drug pricing are large issues. As I said in my opening testimony, a single drug, a single brand drug, may have over 50 different prices depending on the manufacturer's strength and package size of that drug. Generics are even more mysterious, as far as pricing.

The actual PBM itself, so in OPM's situation, you have 200 different PBM relationships, are setting those prices. So the PBM has the ultimate control in plan assets by setting the generic pricing under these Maximum Allowable Costs. And those MAC lists, they consider proprietary. Not only are plan sponsors never given those lists, even auditors under non-disclosure and confidentiality agreements, have a hard time getting those to audit against those lists.

Those lists change daily. The pricing changes daily. And so it is very hard to hold anybody accountable for drug pricing. A transparency and lack thereof, I think, is a big issue of why prescription drugs are increasing in costs.

Mr. CONNOLLY. Right. Mr. McFarland.

Mr. MCFARLAND. Well, I think the best way to describe it is to let me give you this scenario that I have in front of me. And it is very simplistic, but it goes to the heart of the problem of where is the money, and who has it.

The drug manufacturer, the pharmaceutical company, sells a drug to a wholesaler for \$1, just using that as an example. This sets the wholesale price at \$1. The wholesaler sells the drug to a dispenser, either a PBM or a pharmacy, but in this case let us say it is the PBM for 70 cents, and charges back to the drug manufacturer the pharmaceutical company, 30 cents. So now they are made whole. The pricing in the PBM contract with the carrier is the wholesale price, minus the 15 percent discount. FEHBP pays 85 cents for the drug, but the PBM cost was only 70 cents, and apparently it is all legal, but it stinks.

Mr. CONNOLLY. I see my time is up, Mr. Chairman. I thank you.

Mr. LYNCH. Thank you. I have a couple of questions. If we were to, in fact, classify PBMs and/or pharmacies as subcontractors subject to the Federal acquisition regulations, I am trying to think that through. Would that, in your opinion, solve the transparency and cost issue in itself? Or would there be other downstream problems that I need to deal with? I am just trying to think this through.

Mr. MCFARLAND. It would be very beneficial if that were the case, that it could become a subcontractor. That would simply be that the Federal acquisition regulations would impose strict oversight by virtue of being there. But also the Truth in Negotiations Act, the law which protects the Federal Government and the taxpayer from unscrupulous contractors, that would be in play also. So that would be very helpful, and no law change would be needed. This would be something that OPM could do by changing the regulation.

Mr. LYNCH. Very good. Very good. All right.

Mr. MCFARLAND. Excuse me. Can I add something?

Mr. LYNCH. Sure. Absolutely.

Mr. MCFARLAND. What I forgot to mention was that would not necessarily guarantee a cost type contract. We would have to work with that aspect of it, but in the Federal acquisition regulations, it gives you that possibility of approaching that as a means of conducting your business. So that is what would be needed.

Mr. LYNCH. OK. That is very good. That is very helpful. I appreciate that. Let me ask, I guess I was assuming in my mind that in a simplistic way, that the people who actually are the end-users of these programs are the ones that are entitled to the rebates. That was an assumption I made, and I am not sure that is the case. Does the Federal Employees Health Benefits Plan have a right to the rebates?

Mr. MCFARLAND. Yes. They do have a right to the rebates, if it is written into the contract—

Mr. LYNCH. I see.

Mr. MCFARLAND [continuing]. Between the PBM and the health carrier.

Mr. LYNCH. OK.

Mr. MCFARLAND. But even in that situation, the great majority of rebates, we believe, are maintained by the PBM.

Mr. LYNCH. Please, Ms. Hayes?

Ms. HAYES. If I can add to that, it is like the definition of what "is" is. It is the definition of what a rebate is, and PBMs have been very careful in saying, OK, you get 100 percent of the rebates, but then there is other money that they receive from pharmaceutical manufacturers that aren't called rebates.

Mr. LYNCH. OK.

Ms. HAYES. They are called cost effectiveness rebates. They are called formulary rebates. And I think the most egregious is data selling fees. PBMs sell data to pharmaceutical manufacturers and get lots of money back for selling data. That money is typically never passed back to the plan sponsors. Those aren't considered rebates. So, again, you need to have a broader definition of rebates. In contracts that we write, we call them financial benefits. All financial benefits that a PBM receives from drug manufacturers need to be passed back.

Mr. LYNCH. OK. I appreciate that.

Mr. SHEEHAN. If I could?

Mr. LYNCH. Mr. Sheehan.

Mr. SHEEHAN. The one other piece of this to focus on though are the two kinds of plans. There is the experienced-rated plans where the money does in theory comes back to the Federal Governments and the program if it is paid by the PBM. But in community-rated plans, my understanding is community-rated plans that the rebates don't come back. They are negotiated by the plan and that entity gets to keep the benefit of that population.

Mr. LYNCH. OK.

Mr. Connolly, would you like to get 5 minutes?

Mr. CONNOLLY. I thank the Chair, and I would like to return to the previous dialog we were having. Is the PBM system more trouble than it is worth? Is the use of PBMs more trouble than it is worth?

Ms. HAYES. Are you asking me?

Mr. CONNOLLY. I don't care. Anyone who wants to answer. Who feels like pulling that mic real close to them and answering my question?

Ms. HAYES. OK. I feel that PBMs provide a very valuable service. And they do provide a very valuable service by going out and contracting with 55,000 pharmacies across the United States, by operating mail order pharmacies and providing plans a needed mechanism to process and pay prescription drug claims in a very efficient manner.

But they have been allowed to run rampant. They have been allowed to take that very good initial idea that was formed back in the 1970's and 1980's, and they have been allowed to kind of run without control. And I think that is why you get at the issues of AWP prices going out of control. MAC prices being their own invention for generic drugs. Rebates not being passed back. Auditors routinely not being able to audit contracts. So initially, they were

a great idea, and they have just been allowed to kind of run on their own.

Mr. CONNOLLY. And if I understood your previous answer, Ms. Hayes, from the previous round of questioning, they are actually withholding some of the savings from the prescription negotiations, the negotiated price of prescriptions for Federal employees. Is that correct?

Ms. HAYES. That is correct.

Mr. CONNOLLY. And then second, they are not only doing that, they are cloaking themselves in secrecy with non-disclosure agreements?

Ms. HAYES. That is correct.

Mr. CONNOLLY. Even requiring, if I understood you correctly, Government auditors not being able to sort of penetrate that shield of secrecy by making them also agree to such non-disclosure agreements. Is that correct?

Ms. HAYES. I am not sure about Government auditors, but I know private auditors are routinely not allowed to audit these contracts.

Mr. CONNOLLY. And I would just say to the chairman, and I thank him so much for having this hearing, I think this is a very significant point. If one of the most important things this Congress has to do, in the context of Government health care reform, is to get our arms around the cost of health care. It is one of the fastest growing costs for the American consumer and family, for small business, for large businesses, for the Federal Government itself.

Our deficits, our quality of life, our GDP, we are spending 18 percent on health care today of GDP. If we do nothing, by 2025 it is going to be 34 percent, unsustainable. And yet, we have mechanisms in place that, frankly, significantly impede our ability to get at those costs, if we can't penetrate that secrecy shield, and ensure that we have access to the savings we are effectuating, through the system that we created a number of years ago. So I really take your point. It was an efficient mechanism of delivering certain services, but it has gotten out of control. Mr. McFarland or Mr. Sheehan, would you care to comment on that?

Mr. SHEEHAN. I think that this is an issue that Pat and I have worked on for the last 10 years, and we think you are exactly right. I would agree with Ms. Hayes that the system of processing pharmacy claims is a major advance, and the PBMs have done it very well for a number of years. And you think about going to a pharmacy and getting your prescription filled and billed within 3 seconds, that is a pretty amazing system.

But the issue is, how much secrecy exists and what kind of disclosure takes place. It is when you got that box in your house and you are stuck with it, what can you find out about what you are being charged for, and why it is and how you could do it less expensively.

Mr. CONNOLLY. And before we hear from Mr. McFarland, if I could followup Mr. Sheehan, is that an area where you believe this Congress, legislatively, could perhaps help?

Mr. SHEEHAN. Absolutely, because it is regulation of a relationship after the relationship exists.

Mr. CONNOLLY. Since we are looking at comprehensive health care reform, what the heck, maybe we could look at this too.

Mr. SHEEHAN. And especially with OPM and a Government program.

Mr. CONNOLLY. Yes. Mr. McFarland.

Mr. MCFARLAND. The PBM concept, I think, is terrific. I think if done correctly and honestly, it would be a tremendous program. So it is not going to take a whole lot, other than making everybody honest. That is a big deal, of course. And we are certainly working toward that end.

We are in the process in our office of doing a new study, we believe it is going to be new in the Federal sector. We think we will be able, by virtue of this analytical review, we will be able to come awfully close to understanding, maybe not the exact cost of the prescription, but we will be able to make comparisons with DOD, Veterans, Public Health Service, Coast Guard. We will be able to find out what the comparisons are there. So that will be a start for us.

But I am in total concert with both what Ms. Hayes and Mr. Sheehan have said. And that is that it is very good, but we have some real groundwork to do.

Mr. CONNOLLY. It is hard for me, the Federal Government, to know whether I am saving money or not, if I don't have access to the information.

Mr. MCFARLAND. Well, that is exactly correct. And just going in and doing an average audit, by our auditors in our office, is a very difficult task. But it is almost insurmountable to go in and try and do an audit of a PBM, insurmountable. I think another example would be that a health carrier a while back was negotiating a multi-year contract with one of the PBMs. And part of the deal was that the PBM would get some additional money if the enrollment increased.

Well, guess what? The time came, enrollment did not increase, so what did they do? The health carrier and the PBM sat down and renegotiated the contract, got the money, turned to OPM, and OPM paid it.

Mr. CONNOLLY. Mr. Chairman, I just want to end with this. To hear the Inspector General of the Office of Personnel Management say, to this committee, that it is almost insurmountable for his auditors, to be able to access this information in doing an audit of PBMs, is an astounding statement, and one I would hope this committee and this Congress would find, not a reflection of you, an unacceptable situation that needs to be addressed. I thank the Chair for his indulgence.

Mr. LYNCH. Thank you, Mr. Connolly. At this point we have covered the landscape, I think. However, beginning with Mr. Sheehan, I am just going to ask you, is there some area of this that we have not thoroughly mined? If we haven't really dug into this, I would like to give you at least 2 minutes; if you think we have covered it all, then that is fine, but if you think there is an area where you could amplify or just single out as being very important to this process.

Mr. SHEEHAN. OK. Thank you, Mr. Chairman. The focus that I would leave you with, in addition to the very good points that have been raised so far, is to be conscious, not just of the price of drugs,

but what the effects are of the drugs that are given to patients. And OPM really does not have the ability to do that now, because these contracts are so broken up into small pieces.

So, it seems to me, one of the issues that OPM should be looking at is, what is the effect on patients of the drugs that we are buying, and how can we integrate that with other data that we have. So what we are doing is being a prudent purchaser across the board. And when you are talking about close to 30 percent of your total spend on health care is used on drugs, that really becomes a critical area. Thank you, Mr. Chairman.

Mr. LYNCH. A great point. Thank you, Mr. Sheehan. Ms. Hayes.

Ms. HAYES. Well, if I could summarize some of the things that we have talked about today. Certainly a single contract for OPM would benefit rather than this splintering of over 200 different contracts. Simple terms. Simple terms that the lay person can understand, and that the auditor can audit, would be very beneficial. And not needless complexity. Disclosure of where the money is going. We have talked about rebates. We have talked about AWP pricing. The ability to have any auditor that is experienced being able to audit these contracts, I think is something that is needed.

And I would also say that while it may benefit OPM to get Federal pricing in the Federal Employees program, I worry that may increase for private industry the cost of prescription drugs.

Mr. LYNCH. When you say Federal pricing are referring to the Federal supply schedule?

Ms. HAYES. Yes. The Federal supply schedule.

Mr. LYNCH. OK.

Ms. HAYES. The Federal schedule being applicable to OPM. I hope that does not increase for private industry the cost of prescription drugs. I hope that is not made up. And again, I feel that would be accomplished if AWP and MAC pricing could be published, so that plan sponsors do have an idea of what pricing is out there. So, again, that would be my recommendations.

Mr. LYNCH. Thank you. Mr. McFarland.

Mr. MCFARLAND. Well, just to wrap up, I think the important thing to concentrate on for us, other than getting to the bottom line price, is realizing sometimes that what we have to do from a criminal investigative prospective and audits, looking at some of the corporations that have gone astray, such as what has happened in the past with some of the PBMs. When there has to be a caution given to the corporation that they have to agree to ethical standards, and that they have to provide their employees with appropriate training, I think that leaves you with a very clear impression of how easy and how fast a company can go astray. And that is exactly what happened in a couple of the cases that Jim Sheehan and our office has worked together.

It is just mind-boggling, the things that have taken place. When you consider that the PBMs would actually switch drugs, and not really care about the patient. Or when a patient sends in a prescription and that prescription goes in the waste can, or gets shredded, because they have a certain accountability for how many they are going to do that day or that week. That kind of stuff is unbelievable, but it is here. It is in front of us. We have to deal with it. It is just dispensing prescriptions without talking to the doctor

and getting permission. And the cost to these people. So there is an awful lot to the overview and the oversight of this concern. And I know this isn't that unusual from maybe other corporations, but it is a big problem. Just the ethics alone.

Mr. CONNOLLY. Thank you, Mr. McFarland. I want to thank you, and just for the record, I know that we have several hearings going on right now, plus we have issues on the floor. I am going to allow any member of the committee to ask you questions in writing. And I would just ask you to respond to them, as well as inform the committee of your answers.

But with that, I want to thank you for coming before the committee today. I want to thank you for your willingness to help us work on this problem. It is an ongoing process, so we hope that you will continue to work with our offices as we try to devise some legislative and regulatory solutions to the problems that we have described here today. Thank you very much. Have a good day.

Mr. SHEEHAN. Thank you, Mr. Chairman.

Ms. HAYES. Thank you.

Mr. LYNCH. Welcome. It is the custom of this committee to swear all witnesses who are to provide testimony. May I please ask you to rise and raise your right hands?

[Witnesses sworn.]

Mr. LYNCH. Let the record indicate that all of the witnesses have answered in the affirmative. I will offer brief introductions of our next panel and we will have 5 minutes of testimony from each of the witnesses.

Ms. Nancy Kichak is the Associate Director for the Human Resources Policy Division for the Office of Personnel Management. In this position, Ms. Kichak leads the design, development and implementation of innovative flexible merit based human resource policies. Previously, Ms. Kichak served as the Director of the Office of Actuaries at the Office of Personnel Management.

Rear Admiral Thomas McGinnis, currently serves as chief pharmaceutical operations directorate, responsible for pharmacy operations of the TRICARE Management Activity. He is a member of the Board of Advisory Associates of Rutgers College of Pharmacy. Navy Mutual Aide Association, nonresident director, and the American Society on Health Systems Pharmacists.

Mr. John Dicken is a Director for Health Care Issues at the U.S. Government Accountability Office, where he directs GAO's evaluations of private health insurance, long term care quality, and financing and prescription drug pricing issues. He previously held Analyst and Assistant Director positions with GAO's Health Care Team. Welcome to you all. Ms. Kichak, you now have 5 minutes for an opening statement.

STATEMENTS OF NANCY H. KICHAK, ASSOCIATE DIRECTOR FOR STRATEGIC HUMAN RESOURCES POLICY DIVISION, U.S. OFFICE OF PERSONNEL MANAGEMENT; REAR ADMIRAL THOMAS J. MCGINNIS, CHIEF, PHARMACEUTICAL OPERATIONS DIRECTORATE, TRICARE MANAGEMENT ACTIVITY, OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS; AND JOHN E. DICKEN, DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE

STATEMENT OF NANCY H. KICHAK

Ms. KICHAK. Thank you, Chairman Lynch. Thank you for holding the hearing to discuss the oversight of prescription drug benefits within the Federal Employees Health Benefits Program. The FEHB law provides OPM with authority to contract with private sector health plans that cover specified areas of health care, including prescription drugs. We currently contract with 111 health plans, which provide 269 plan options nationwide, from which retirees and employees may select the option that best meets their needs. The program is a \$35 billion program and drugs present about 29 percent of claims.

Like many private sector employers, the FEHB plans use pharmacy benefit management arrangements. To improve the administration of the drug benefits, OPM issued regulations in August 2003, that allowed the OPM Office of Inspector General to have full access to experience-rated carriers' agreements with their pharmacy benefit managers. In 2005, OPM issued new contract requirements that included standards for FEHB carriers to use in contracts with vendors for retail and mail order pharmacy.

The carriers required to use these standards, which provide for PBM transparency, integrity and performance. Each year we negotiate with individual carriers to design a prescription drug package that provides access to FDA approved drugs placed in tiers, based on clinical effectiveness and cost. Carriers also use preauthorization to determine medical necessity for certain drugs, and drug utilization reviews to check for excessive use, duplication and frequency. Many carriers promote generic drug awareness and dispense generic equivalents, if available.

Next I would like to address the specific questions raised in your invitation to this hearing. You inquired about lack of transparency in the pricing of prescription drugs. First and foremost to OPM is providing information so that enrollees understand the benefits they are purchasing and the options they have. Therefore, many carriers provide drug transparency tools on their secure member Web sites. Through our regulations, our Office of the Inspection General has full access to the agreements our carriers have with PBMs. Whether increasing transparency alone will lead to lower pharmacy costs is unclear. In June 2008, the Congressional Budget Office found that more transparency did not necessarily lead to lower health care spending.

You asked how prescription drug benefits provided in other Government agencies, such as Defense, VA and HHS. Each of these Federal agencies operates under its own statutory framework. TRICARE and VA directly deliver health care as a significant part

of their service to their constituencies, and have access to drug prices based on statutory authorities.

You asked how prescription drug benefits are priced and delivered in the private sector. Private sector employers operate in competitive environments, and many directly contract with PBMs to manage their drug programs and to process and pay prescription drug claims. PBMs also develop drug formularies, contract with pharmacies and negotiate discounts and rebates with drug manufacturers. FEHB carriers rely on PBMs to manage drug cost and utilization for their enrolled population. OPM, in turn, negotiates with carriers on benefit design and program administration to encourage the efficient use of prescription drugs.

You asked if OPM should consider alternative pricing and contracting methods for the FEHB Program's drug benefits. The cost of drugs is of great concern to OPM, as it is to private companies and other Government purchasers. OPM is committed to studying all options that may improve the delivery of these benefits. We want the best and most affordable product and are looking for procedures that could be of assistance.

We are exploring a broad range of options, from improving our current contractual procedures, to completely redesigning how drug services can be delivered if our legislative framework is modified. I appreciate the opportunity to testify today, and I would be happy to answer any questions.

[The prepared statement of Ms. Kichak follows:]

STATEMENT OF
NANCY H. KICHAK
ASSOCIATE DIRECTOR FOR
STRATEGIC HUMAN RESOURCES POLICY
U.S. OFFICE OF PERSONNEL MANAGEMENT

before the

SUBCOMMITTEE ON FEDERAL WORKFORCE, POSTAL SERVICE
AND THE DISTRICT OF COLUMBIA
UNITED STATES HOUSE OF REPRESENTATIVES

on

FEHBP'S PRESCRIPTION DRUG BENEFITS

June 24, 2009

Chairman Lynch, Ranking Member Chaffetz, and Members of the Subcommittee:

I am here today on behalf of John Berry, Director of the Office of Personnel Management (OPM), to discuss the oversight of prescription drug benefits within the Federal Employees Health Benefits (FEHB) Program.

The FEHB law provides OPM with authority to offer competitive health benefits products for Federal workers by contracting with private sector health plans, much like other large employers. OPM currently contracts with 111 health plans which provide 269 health plan options nationwide from which employees and retirees may select the option which meets their needs. Approximately 8 million Federal employees, retirees, and their dependents are covered under this program.

The FEHB is an almost \$35 billion dollar program and drugs represent about 29 percent of claims expenditures in the program. Many large private sector employers use Pharmacy Benefit Management (PBM) arrangements in their health benefit programs and many FEHB plans also use PBMs. In 2003, the U.S. Government Accountability Office (GAO)¹ found that FEHB plans' private sector PBM partners helped them to provide affordable drug benefits that meet our enrollees' needs and help keep costs down.

The FEHB negotiates annually with its plans to provide benefits, rates, and administrative actions that are beneficial to our enrollees. To improve the administration of the drug benefits, OPM issued regulations in August 2003 that established requirements for FEHB experience-rated carriers' large provider agreements, including agreements with pharmacy benefit managers. The regulations became final July 1, 2005, and provide the OPM's Office of Inspector General (OIG) all the authority needed to conduct complete reviews of carriers' PBM arrangements. Also in 2005, OPM issued new contract

¹ Then General Accounting Office

requirements that included standards for FEHB carriers to use in contracts with vendors for retail and mail order pharmacy. The carriers are required to use these standards which provide for PBM transparency, integrity and performance.

We negotiate with individual carriers to deliver a package of health insurance benefits to plan members. Within the FEHB, carriers compete for enrollment by offering the benefits and providing services they believe Federal employees, retirees, and their families want to purchase. This competition requires controlling for the cost of enrollee benefits. Many carriers use formularies which are periodically updated to include all FDA-approved drugs placed in tiers based on clinical effectiveness and cost. Carriers also use pre-authorization to determine medical necessity for certain drugs and drug utilization reviews to check for excessive use, duplication and frequency. Many carriers promote generic drug awareness and dispense generic equivalents, if available, unless a physician requires a brand name be dispensed. FEHB benefit plans also have monetary incentives, such as lower copays for generic drugs.

Next, I would like to address the specific questions raised in your invitation to this hearing.

1. You inquired about lack of transparency in the pricing of prescription drugs and OPM's ability to evaluate the overall value of these PBM-provided benefits. First and foremost to OPM is providing information so that enrollees understand the benefits they are purchasing and the options they have. Therefore, many carriers provide drug transparency tools on their secure member websites. These tools allow enrollees to compare costs of generic vs. brand name drugs for prescriptions filled at retail and mail order pharmacies. Users can input the name of the drug and the dosage and the tool provides the actual cost of the drug and coverage information, such as whether preauthorization is required. Users can also access the entire formulary list or search for certain medications. And, the formulary provides information on what tier the drug falls under (e.g. generic, brand, or brand non-formulary) as well as information regarding drug alternatives. FEHB consumers are price sensitive, so health plans make every effort to offer their total benefit packages at affordable prices.

It is also true that the relationships between drug manufacturers, PBMs, health plans, and pharmacies (mail order and retail) are quite complex. As a result, the determination of actual prices and costs after the various discounts and rebates are applied is difficult. OPM expects contracting health plans to obtain the best possible products and prices using their provider contracting experts and other resources. Whether increasing transparency alone will lead to lower pharmacy costs is unclear. In June 2008, the Congressional Budget Office (CBO) addressed the potential effect of more transparency on the price of healthcare goods and services, total health care spending, and the Federal budget and found the answer ambiguous. Factors such as consumer behavior, market concentration of providers and variation in prices would make it difficult to determine which forces would outweigh the others.

2. You asked how prescription drug benefits are priced, delivered, and analyzed in other Government agencies, such as Department of Defense, Veterans Affairs (VA), and

Health and Human Services. We would point out that each of these Federal agencies operates under its own statutory framework. In addition, the methods for delivery of service may be different with Federal employees relying on the private market place while both TRICARE and VA undertake direct delivery of health care as a significant part of their service to their constituencies.

We have met with TRICARE representatives and continue to be committed to learning lessons from our sister organizations to improve the management of the FEHB Program.

3. You asked how prescription drug benefits are priced and delivered in the private sector. Private sector employers operate in competitive environments and many directly contract with PBMs to manage their drug programs and to process and pay prescription drug claims. PBMs are also used to develop drug formularies, contract with pharmacies, and negotiate discounts and rebates with drug manufacturers. This can be done either through direct contracting or through the health plan. Since there are over 200 pharmaceutical companies, PBMs can provide significant administrative support for employer companies and health plans. FEHB carriers rely on PBMs to manage drug cost and utilization for their enrolled population. OPM, in turn, negotiates with carriers on benefit design and program administration to encourage the efficient use of prescription drugs.

4. You asked if OPM should consider alternative pricing and contracting methods for the FEHB Program's prescription drug benefits. OPM is committed to studying all options that may improve the delivery of benefits. We want the best and most affordable product and are looking for procedures that could be of assistance. We also understand that optimal solutions for the delivery of health care services, including dispensing prescription drugs, can be different for different populations and plan types within the FEHB structure.

The cost of drugs is of great concern to OPM as it is to private companies and other Government purchasers. At present, drug costs account for almost 30 percent of FEHB costs, compared to about 15 percent in the private sector. Much of that difference is due to the large share of retirees in the FEHB system and the different pattern of drug usage among these individuals. Given the share that drug costs make up of pharmacy benefits, there is concern that the cost of drugs could crowd out other needed benefits.

To address these concerns, we are exploring a broad range of options from improving our current contractual procedures to completely redesigning how prescription drug services can be delivered if our legislative framework is modified.

Mr. Chairman, I appreciate this opportunity to testify before the Subcommittee on this very important issue. I will be glad to answer any questions you or other Members may have.

Mr. LYNCH. Thank you, Ms. Kichak.
Rear Admiral McGinnis, you are recognized for 5 minutes.

STATEMENT OF REAR ADMIRAL THOMAS J. McGINNIS

Admiral MCGINNIS. Mr. Chairman and distinguished members of the committee, thank you for the opportunity to discuss the evolution of the Department of Defense TRICARE Pharmacy Program.

Over the last 10 years, DOD has learned many lessons in the area of pharmacy benefit management. Prior to 2004, DOD's purchase care pharmacy benefit, that is the retail and mail order portion benefit, was carved into the five regional TRICARE Managed Care Support Contracts, which provided the TRICARE medical benefit. DOD determined that this type of carving, decentralized pharmacy benefit management structure, created significant challenges to the department. And it was clear that DOD needed to make some major changes for a number of reasons.

First a fragmented market share gave DOD less leverage with pharmaceutical manufacturers to negotiate favorable pricing, in exchange for formulary placement. Second the pharmacy benefit lacked portability across the regions, and the lack of standardization led to a non-uniformity of the benefit. And most importantly, actual expenditures and rebates received by its contractors for pharmaceuticals, were not transparent to TRICARE. This structure also led to duplicative administrative services and fees, along with the inability to effectively plan and develop cost-saving measures.

Moreover, Federal discounts in the retail pharmacy venue were inaccessible because management of the benefit was not under direct DOD control. DOD, like many large U.S. employers, took action to carve out the pharmacy benefit from the managed care contracts and placed it under DOD management using a single PBM.

DOD now had the leverage it needed for very favorable pricing with the pharmaceutical industry for formulary management. DOD has implemented formulary decisions in 38 drug classes since 2005, representing over 50 percent of the fiscal year 2008 total DOD drug expenditures. Mr. Dicken, of the GAO, reported last year in April 2008, that DOD avoided over \$447 million in drug costs in fiscal year 2006 due to the formulary process. And \$916 million in fiscal year 2007. TRICARE also received an additional \$60 million in rebates from the pharmaceutical industry in fiscal year 2007, making the savings to the U.S. taxpayer nearly \$1 billion.

The fiscal year 2007 drug costs of \$6.5 billion, accounted for 18 percent of DOD's total health care costs. Legislation passed in 2008 authorized DOD access to Federal discounts for all covered drugs dispensed in its retail pharmacy network, bringing prices in the retail network more in line with what DOD pays for pharmaceuticals dispensed in its military treatment facilities and in the TRICARE Mail Order Pharmacy Program, which are some of the lowest prices available in the country.

Today TRICARE has virtually every community pharmacy in the country as a member of its retail network, and experiences outstanding customer service based on a DOD quarterly survey of its beneficiaries.

I want to thank the committee for giving me the opportunity to speak today about the TRICARE Pharmacy Program, and how we

continue to provide a world-class pharmacy benefit to active duty uniform service members, retirees and dependents around the world.

[The prepared statement of Admiral McGinnis follows:]

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STATEMENT BY

RADM Thomas J. McGinnis
Chief, Pharmaceutical Operations Directorate
TRICARE Management Activity
Office of the Assistant Secretary
of Defense (Health Affairs)

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
Subcommittee on the Federal Workforce, Postal Service, and District of Columbia

HEARING ON FEHBP's Prescription Drug Benefits: Deal or No Deal?

June 24, 2009

NOT FOR PUBLIC RELEASE UNTIL RELEASED BY COMMITTEE

Mr. Chairman and distinguished members of the committee, thank you for the opportunity to discuss the evolution of the Department of Defense (DoD) TRICARE Pharmacy Program.

Overview of the DoD Pharmacy Benefit

DoD, through TRICARE, provides a pharmacy benefit to all eligible Uniformed Services members, their family members, and all retirees and their family members, including beneficiaries ages 65 and over. The benefit covers over 9 million individuals through three outpatient venues of distribution: 1) military treatment facility (MTF) pharmacies; 2) Retail Pharmacies including a 60,800 TRICARE Retail Pharmacy (TRRx) network as well as other non-network retail pharmacies; and 3) a TRICARE Mail Order Pharmacy (TMOP) program. In Fiscal Year (FY) 2008, 71% of eligible beneficiaries (6.9 million) used the pharmacy benefit. In that year, more than 122 million prescriptions were filled at an expense of \$6.9 billion in the context of a \$31.5 billion Defense Health Program Operation & Maintenance budget.

Legislative Framework

The National Defense Authorization Act (NDAA) for FY 2000 established the parameters for the DoD Pharmacy Benefits program. This federal law required the Secretary of Defense to establish an effective, efficient, and integrated pharmacy benefits program. Under this program, the Secretary must ensure the availability of pharmaceutical agents for all therapeutic classes, establish a uniform formulary based on clinical effectiveness and cost-effectiveness, and assure the availability of clinically appropriate pharmaceutical agents to members and retired members of the Uniformed Services and their family members. By law, the Uniform Formulary may not exclude access to any medication used in the ambulatory care setting and must make all Food and Drug Administration (FDA) approved prescription medications available to beneficiaries

, even those medications designated as “nonformulary,” a key difference from civilian pharmacy benefit plans. These drugs are all available at a nominal copayment. The Secretary of Defense implemented the current TRICARE Pharmacy Benefit regulations, a key component of the TRICARE program, effective May 3, 2004.

Benefit Structure

The law stipulated a three-tier cost-sharing structure and limited the amount of the highest copayment category—the nonformulary or third tier category—to 20% for active duty family members and 25% for retirees and their family members of the costs of drugs in the third tier. The first tier is comprised of generic drugs for the most part and the second tier is comprised of preferred brand name drugs. Although the law allows established copayments to be adjusted periodically based on experience with the uniform formulary, changes in economic circumstances, and other appropriate factors, the copayment structure has not changed since 2001. Legislation in FY 2007, FY 2008, and renewed in FY 2009 froze all TRICARE copayments in the retail pharmacy network.

Expenditures

DoD’s pharmacy program expenditures grew significantly from \$1.6 billion in 2000 to \$6.9 billion in 2008 but have begun to plateau. The primary driver for DoD’s increase in pharmacy expenditures was the implementation of the TRICARE Senior Pharmacy Program as promulgated in the NDAA for FY 2001. This legislation expanded pharmacy coverage for beneficiaries ages 65 and over, providing them access to the retail pharmacies and TMOP. Prior to the enactment of this legislation, this beneficiary category had only limited access to MTF pharmacies. With the maturation of the TRICARE Senior Pharmacy Program for DoD’s 1.5 million Medicare-eligible population, retail costs rose dramatically. This escalation in pharmacy expenditures was further compounded by other cost drivers such as drug price inflation, increased

utilization, and an increased number of beneficiaries. Many commercial health plans have seen their pharmacy spending increased by some of these same drivers.

Before the NDAA for FY 2008 DoD had very limited discounts available for medications dispensed through the retail venue. Although military pharmacies and the TMOP both had access to significant federal pricing discounts under the Veterans Health Care Act, the retail venue did not. With the passage of the NDAA for FY 2008 legislation, the TRICARE network retail venue is now also covered by federal pricing discounts. DoD is in the process of implementing procedures to collect refunds from manufacturers. The total amount of refunds expected in Fiscal Year 2010 is more than one billion dollars (counting both appropriated funds and accrual funding for DoD beneficiaries).

Pharmacy Benefit Management Tools

Pharmacy benefit management in the commercial arena uses a number of tools to control costs. Among them are the use of formulary management—which provides the ability to drive utilization to formulary medications by restricting access to more expensive medications that are not proven to be more clinically effective; the implementation of timely adjustments to cost-shares; and mandating the use of less expensive venues, such as mail order, by restricting access to more expensive venues. In addition, commercial pharmacy benefit managers' ability to restrict access to nonformulary medications or render some medications unavailable to beneficiaries is a powerful leveraging tool with the pharmaceutical industry. Although DoD has a longstanding mandatory generic substitution policy, this policy does not mitigate the use of brand name products that have no generic equivalent. Additionally, since medications are available at low cost-share differentials (\$3 for generics versus \$9 for brand names), there is little incentive for the patient or provider to choose a less expensive brand drug over a clinically equivalent higher costing drug.

Management of the DoD pharmacy benefit has unique challenges for benefit delivery. Under the Act, DoD may not, for example, mandate the use of the less expensive mail order venue, but instead must focus its efforts on educating beneficiaries about the convenience and cost savings of mail order to encourage beneficiaries to use it. These efforts have had unprecedented success, and TMOP use has continued to increase over the years. Further increases in TMOP use however, could be realized.

Carved In Pharmacy Benefit

Prior to 2004, the DoD purchased care pharmacy benefit, i.e., the retail and mail order pharmacy programs, were part of the five regional TRICARE Managed Care Support Contracts (MCSCs). This type of pharmacy benefit management structure created significant challenges:

- Federal discounts in the retail pharmacy venue were not accessible because management of the retail benefit was not under direct government control.
- With a fragmented “book of business” and market share, DoD had less leverage with pharmaceutical manufacturers for favorable pricing.
- Lack of portability of the benefit, i.e., access to the pharmacy benefit could not cross the five regional contract lines.
- Lack of visibility to beneficiaries of the five separate formularies managed by the MCSCs as to what was included and lack of standardization, led to an unequal benefit across the five regions.
- Absence of standard policy application across the regions; i.e., in some regions, the mandatory generic policy was strictly followed, in other regions, it was not.
- Lack of visibility of pharmacy expenditures in the purchased care portion of the pharmacy benefit made it difficult for TRICARE to track and analyze these costs.
- Duplicative administrative services and fees by five MCSCs added to the costs and complexity of administering the program.

Carved Out Pharmacy Benefit

From 2001 to 2002, overall DoD pharmacy expenditures rose 48%, primarily due to the addition of the age 65 and over population to the benefit. The MCSCs reported an 88% increase in DoD retail pharmacy costs alone. Under the carved in structure, the MCSCs could not access DoD's federal discounts in the retail or mail order venues. The result of this decentralized management structure was a disparate, non-transparent, non-portable and increasingly costly benefit.

A significant factor in DoD's consideration in redesigning the pharmacy benefit management structure, was the subject of access to federal discounts in the network retail pharmacy venue used by DoD beneficiaries. Promulgated through the Veteran's Health Care Act, federal discounts could be obtained only if DoD carved the pharmacy benefit out of the MCSCs and placed it directly under the control of a DoD Pharmacy Benefit Management (PBM) office. DoD's goal was to consolidate the pharmacy benefit under one structure to maximize leverage with the pharmaceutical industry and to streamline the management structure and practices.

The decision to carve out the retail pharmacy benefit from the MCSCs was made in 2002 and in 2004 TRICARE implemented its Retail Pharmacy contract. TRICARE had implemented its Mail Order Pharmacy contract in 2003. Even without broad access to federal discounts initially, overall cost increases slowed from an annual rate of 48% in 2002 to 22% in 2004 and in retail slowed from 88% in 2002 to 31% in 2004. Upon carve out, \$50 million in savings (year one alone) were immediately recognized based on consistent, uniform and appropriate management of the mandatory generic policy. Between March 2004 and June 2007, the generic dispensing rate for TRRx increased from 43.6% to 58.6%. Placing the benefit under centralized management with a Uniform Formulary afforded DoD the leverage it needed for favorable negotiations with the

pharmaceutical industry. Through April 2008, Uniform Formulary decisions had been implemented in 32 drug classes representing 53% of FY 2007 total DoD drug expenditures. The 32 drug classes representing 343 drugs were reviewed at 12 quarterly meetings of the DoD Pharmacy and Therapeutics Committee and the Beneficiary Advisory Panel, resulting in the classification of 85 drugs (24.8%) in tier 3, 92 drugs (26.8%) in tier 2, and 166 drugs (48.4%) in tier 1. The Government Accountability Office reported in April 2008 that DoD avoided over \$447 million in drug costs for FY 2006 and \$916 million in FY 2007 due to the Uniform formulary process. An additional \$60 million in rebates from drug companies was obtained in FY 2007 through the Voluntary Agreements for TRICARE Retail Pharmacy Refunds (UF VARR) program for prescriptions filled at community retail pharmacies. This is a total of \$976 million in cost avoidance for DoD in FY 2007.

The preferred reference for the pharmaceutical pricing structure for federal agencies is the June 2005 Congressional Budget Office (CBO) paper called "Prices for Brand-Name Drugs Under Selected Federal Programs". Likewise, the preferred reference for pharmaceutical pricing in the commercial sector is the June 2007 CBO Report called "Prescription Drug Pricing in the Private Sector". Both documents are extremely helpful to understanding the complex pricing structure of pharmaceuticals in both the federal and private sectors.

After the carve-out initiative, DoD was able to create beneficiary outreach programs to encourage use of the cost-effective TMOP. As a result, TMOP use increased from \$106 million in annual expenditures in FY 2000 before carve-out to \$347 million in 2002 after carve-out, and was just short of a billion dollars (\$955 million) in FY 2008. To date, overall cost increases are down from 48% in 2002 to 6% in 2008, and retail cost increases are down from 88% in 2002 to 8% in 2008. As access to federal discounts is finally achieved in FY 2009, these cost increases will continue to diminish.

A significant benefit of the carve-out is the ability to create a central data warehouse of all outpatient prescriptions dispensed to DoD beneficiaries. This worldwide centralized data system called the Pharmacy Data Transaction Service (PDTS) not only identifies potential drug-drug interactions, but provides DoD the ability to conduct outcomes studies and research projects, some of which have produced peer reviewed articles for publication.

Best Commercial Practices

Employers overwhelmingly choose to carve out their pharmacy benefit plans. In fact, the larger the plan, the more likely it will carve out the pharmacy benefit. A survey of the Fortune 500 in 2008 by Express Scripts, Inc. found that each of the top ten companies had carved out their pharmacy benefit and that 80% of the top 100 had done so. Within the Fortune 300, fully 75% had carved out the pharmacy benefit.

A June 2007 article appearing in Drug Benefit News confirms the findings of the Express Scripts survey. According to the article: "Despite renewed efforts by health plans to recapture their pharmacy benefit plan business lost to stand-alone PBMs – and even attract new Rx management business from outside of their membership – several recent surveys indicate that most large employers and other groups continue to favor contracting with stand-alone PBMs."

In May 2007, J. P. Morgan Securities, Inc., surveyed 50 large employers and found that they continue to favor stand-alone PBMs and are not interested in carving back in the pharmacy benefit. They cited price and services as the top two benefits of carving out drug spending.

According to J. P. Morgan analyst Lisa Gill, 64% of large employers used Medco Health Solutions, Inc., Express Scripts, Inc. or Caremark (now part of CVS Corp.). In addition,

between 80% and 90% of large employers carve out the pharmacy benefit. Gill explained that employers favor stand alone PBMs based on several factors: PBMs focus 100% on managing pharmacy costs rather than entire medical costs, a perception of greater transparency around PBM costs, and the greater choice of offerings from PBMs, such as specialty pharmacy and step therapy programs.

DoD's current managed care support contractors receive the pharmacy data they need for integration into a disease management or a case management program they may be conducting. The single national contract under one Pharmacy Benefits Management office consolidated the retail benefit from the previous multiple MCSC contracts into one management entity, providing a fully portable benefit unrestricted by regional boundaries with centralized pharmacy claims processing, which reduced administrative fees by more than 70% per claim. In addition, the carve-out enabled the government to establish more favorable and guaranteed reimbursement rates for the network retail pharmacies.

Health Outcomes

DoD actively participates in disease management (DM) and appropriate polypharmacy management and believes they are the ultimate goals of successful managed health care and pharmacy benefit management for improving health outcomes. These goals remain achievable through a carved out pharmacy benefit and are independent of the various distribution processes.

DoD shares pharmacy data with the TRICARE managed care support contractors and welcomes the opportunity to continue to work with them to ensure the accurate and timely flow of data. In addition, DoD has included requirements in the next generation of TRICARE contracts and the newly awarded T-Pharm contract to formalize the processes of pharmacy data sharing and DM. The contracts require a formal Memorandum of Understanding (MOU) between the managed care support contractors and the TRICARE

pharmacy contractor for the purpose of establishing the necessary cooperation for data exchange, coordination of care for patients receiving specialty pharmacy services, third-party liability, and claims issues. The MOU will specifically address the frequency and format of pharmacy data that will be provided to the managed care support contractors by the pharmacy contractor.

Conclusion

Hand in hand with the military mission itself, the highest priority in the DoD is the protection of the health of the men and women in uniform and the provision of the best possible care to those who become ill or injured. The DoD pharmacy benefit plays a critical role in that effort. Mr. Chairman, thank you for the opportunity to discuss the DoD Pharmacy Program and our efforts to continue to provide a world class and cost effective benefit to all of our beneficiaries.

Mr. LYNCH. Thank you, Admiral. Mr. Dicken, you are now recognized for 5 minutes.

STATEMENT OF JOHN E. DICKEN

Mr. DICKEN. Great. Thank you, Mr. Chairman and members of the subcommittee. I am pleased to be here today as you examine approaches to control rising drug spending within the Federal Employees Health Benefits Program [FEHBP].

Prescription drug spending has been one of the fastest growing segments of health care spending in both the public and private sectors. Notably, prescription drug spending has been a significant contributor to FEHBP costs and premium growth. Projected increases in the cost of prescription drugs alone, would account for about a 3 to 5 percent annual increase in FEHBP premiums from 2002 to 2007.

The Office of Personnel Management predicts that prescription drugs will continue to be a primary driver of program costs. Other Federal programs also continue to face unsustainable increases in prescription drug spending, and use varying approaches in an effort to control the spending.

My remarks today, based on prior GAO work, and updates from other congressional and Federal sources, will describe the approach used by FEHBP to control prescription drug spending. I will also broadly summarize approaches used under Medicare, the Department of Veterans Affairs, the Department of Defense and Medicaid.

As you have already heard today from other expert witnesses, representing several of these Federal programs, my comments will step back to describe at a higher level, the general approaches these programs use in controlling drug spending. In short, the primary difference among these programs, is that FEHBP and Medicare Part D, rely on competition between health plans to control prescription drug spending, while VA, DOD and Medicaid use other methods, such as statutorily mandated prices for drug negotiations with drug suppliers.

For FEHBP, competition aims to give plans an incentive to reign in prescription drug costs, and to leverage their market share to obtain favorable prices. Like most private employer-sponsored health plans, most FEHBP plans contract with PBMs to help administer the prescription drug benefit.

We have outlined key approaches that PBMs use in an effort to achieve savings for the health plans. These include: One, negotiating rebates with drug manufacturers and passing some of the savings to the plans; two, obtaining discounts from retail pharmacies, and dispensing drugs at lower costs through their own mail order pharmacies; three, using such techniques as prior authorization and generic substitution to reduce utilization of certain drugs, or substitute other less costly drugs; and four, developing and managing formularies to encourage enrollees to use preferred drugs and to influence price negotiations with manufacturers.

While OPM itself does not negotiate drug prices or discounts for FEHBP, it attempts to limit spending through annual premium and benefit negotiations with plans, including the encouragement of spending controls, such as benefit designs that provide incentives for increased use of generic drugs.

Medicare Part D uses a model similar to the FEHBP, by relying on competing health plans and their PBMs to control drug spending. In part, plan sponsors compete on their ability to negotiate prices and price concessions with drug manufacturers and with pharmacies. Even though the Centers for Medicare and Medicaid Services is not involved in negotiations, plans are required to report price concessions to CMS, to help determine the extent to which they are passed on to beneficiaries.

In contrast, VA and DOD use statutorily mandated discounts as well as direct negotiations with drug suppliers, to limit drug spending. They have access to a number of prices to consider when purchasing drugs, paying the lowest. These include the Federal supply schedule prices that VA negotiates with drug manufacturers. These prices are intended to be no more than those manufacturers charge their most-favored, non-Federal customers under comparable terms and conditions.

Finally, Medicaid is subject to aggregate payment limits and drug payment guidelines set by CMS. Medicaid does not negotiate drug prices with manufacturers, but reimburses retail pharmacies for drugs dispensed to beneficiaries at set prices. An important element of controlling Medicaid drug spending is the Medicaid drug rebate program, under which drug manufacturers are required by law, to provide rebates for certain drugs covered by Medicaid. Under the rebate program, States take advantage of prices manufacturers receive for drugs in the commercial market, that reflect discounts and rebates negotiated by private payers.

In addition, Medicaid, like each of the other programs I discussed, uses techniques such as prior authorization, generic substitution, utilization review, and cost sharing requirements to limit drug spending. Mr. Chairman, this concludes my statement. I will be happy to answer any questions that you, or other members of the subcommittee, may have.

[The prepared statement of Mr. Dicken follows:]

United States Government Accountability Office

GAO

Testimony
Before the Subcommittee on Federal
Workforce, Postal Service, and the District of
Columbia, Committee on Oversight and
Government Reform, House of Representatives

For Release on Delivery
Expected at 10:00 a.m. EDT
Wednesday, June 24, 2009

PRESCRIPTION DRUGS

Overview of Approaches to Control Prescription Drug Spending in Federal Programs

Statement of John E. Dicken
Director, Health Care



GAO-09-819T

June 24, 2009



Highlights of GAO-09-819T, a testimony before the Subcommittee on Federal Workforce, Postal Service, and the District of Columbia, Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

Millions of individuals receive prescription drugs through federal programs. The increasing cost of prescription drugs has put pressure to control drug spending on federal programs such as the Federal Employees Health Benefits Program (FEHBP), Medicare Part D, the Department of Veterans Affairs (VA), the Department of Defense (DOD), and Medicaid. Prescription drug spending within the FEHBP in particular, which provides health and drug coverage to about 8 million federal employees, retirees, and their dependents, has been a significant contributor to FEHBP cost and premium growth. The Office of Personnel Management (OPM), which administers the FEHBP, predicted that prescription drugs would continue to be a primary driver of program costs in 2009.

GAO was asked to describe approaches used by the FEHBP to control prescription drug spending and summarize approaches used by other federal programs. This testimony is based on prior GAO work, including *Prescription Drugs: Oversight of Drug Pricing in Federal Programs* (GAO-07-481T) and *Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs* (GAO-07-358T) and selected updates from relevant literature on drug spending controls prepared by other congressional and federal agencies.

View GAO-09-819T or key components. For more information, contact John E. Dicken at (202) 512-7114 or dickenj@gao.gov.

PRESCRIPTION DRUGS

Overview of Approaches to Control Prescription Drug Spending in Federal Programs

What GAO Found

FEHBP uses competition among health plans to control prescription drug spending, giving plans an incentive to rein in costs and leverage their market share to obtain favorable drug prices. Most FEHBP plans contract with pharmacy benefit managers (PBMs) to help administer the prescription drug benefit. In a 2003 report, GAO found that the PBMs reduced drug spending by: negotiating rebates with drug manufacturers and passing some of the savings to the plans; obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail-order pharmacies operated by the PBMs; and using other techniques that reduce utilization of certain drugs or substitute other, less costly drugs. While OPM does not negotiate drug prices or discounts for FEHBP, it attempts to limit spending through annual premium and benefit negotiations with plans, including the encouragement of spending controls such as generic substitution.

Other federal programs use a range of approaches to control prescription drug spending.

- Medicare—the federal health insurance program for the elderly and disabled—offers an outpatient prescription drug benefit known as Medicare Part D that uses competition between plan sponsors and their PBMs to limit drug spending, in part through the ability to negotiate prices and price concessions with drug manufacturers and pharmacies. Plans are required to report these negotiated price concessions to the Centers for Medicare & Medicaid Services (CMS), to help CMS determine the extent to which they are passed on to beneficiaries.
- VA and DOD pharmacy benefit programs for veterans, active duty military personnel, and others may use statutorily mandated discounts as well as negotiations with drug suppliers to limit drug spending. VA and DOD have access to a number of prices to consider when purchasing drugs—including the Federal Supply Schedule prices that VA negotiates with drug manufacturers—paying the lowest of all available prices.
- The Medicaid program for low-income adults and children is subject to aggregate payment limits and drug payment guidelines set by CMS. Medicaid does not negotiate drug prices with manufacturers, but reimburses retail pharmacies for drugs dispensed to beneficiaries at set prices. An important element of controlling Medicaid drug spending is the Medicaid drug rebate program, under which drug manufacturers are required by law to provide rebates for certain drugs covered by Medicaid. Under the rebate program, states take advantage of prices manufacturers receive for drugs in the commercial market that reflect discounts and rebates negotiated by private payers.

In addition, Part D, VA and DOD, and Medicaid use techniques similar to FEHBP to limit drug spending, such as generic substitution, prior authorization, utilization review programs, or cost-sharing requirements.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here as you examine approaches to control the rising spending for prescription drugs within the Federal Employees Health Benefits Program (FEHBP). As you know, the FEHBP provides health coverage, including prescription drug coverage, to about 8 million federal employees, retirees, and their dependents. As with other public and private employer-sponsored health plans, prescription drug spending has been a significant contributor to FEHBP cost and premium growth. Projected increases in the costs of prescription drugs alone would have accounted for about a 3 to 5 percent annual increase in FEHBP premiums from 2002 through 2007. The Office of Personnel Management (OPM), the federal agency that administers the FEHBP, predicted that prescription drugs would continue to be a primary driver of program costs in 2009.¹

Because of the importance of controlling prescription drug spending by the federal government, you asked us to describe prescription drug spending control approaches used by the FEHBP and summarize the approaches used by other federal programs. Accordingly, my testimony today will describe the approach used by FEHBP to control prescription drug spending and summarize approaches used under Medicare, the Department of Veterans Affairs (VA), the Department of Defense (DOD), and Medicaid. My remarks are based on prior work performed from 2003 to 2009 on federal programs that purchase or cover prescription drugs, with selected updates from relevant literature on drug spending controls prepared by other congressional and federal agencies.² We used various methodologies to complete our work; please see the individual products for the details. Our work was performed in accordance with generally

¹OPM, *News Release: OPM Announces Open Season for Health Benefits, Dental and Vision Insurance, and Flexible Spending Accounts* (Sept. 25, 2008).

²A list of related GAO products is included at the end of this statement. For other reports we reviewed, please see, for example, Congressional Budget Office, *Budget Options Volume 1: Health Care* (Washington, D.C.: Dec. 2008); Congressional Budget Office, *The Health Care System for Veterans: An Interim Report* (Washington, D.C.: Dec. 2007); Congressional Research Service, *Medicare Part D Prescription Drug Benefit: A Primer* (Washington, D.C.: Aug. 20, 2008); Congressional Research Service, *Prescription Drug Coverage Under Medicaid* (Washington, D.C.: Feb. 6, 2008); Congressional Research Service, *Pharmaceutical Costs: A Comparison of Department of Veterans Affairs (VA), Medicaid, and Medicare Policies* (Washington, D.C.: Apr. 13, 2007); Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Washington, D.C.: Aug. 2005); and Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Mar. 2009).

accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The FEHBP is the largest employer-sponsored health insurance program in the country. Through it, about 8 million federal employees, retirees, and their dependents received health coverage—including for prescription drugs—in 2008. Coverage is provided under competing plans offered by multiple private health insurers under contract with OPM, which administers the program, subject to applicable requirements. In 2009, 269 health plan options were offered by participating insurers, 10 of which were offered nationally while the remaining health plan options were offered in certain geographic regions. According to OPM, plans must cover all medically necessary prescription drugs approved by the Food and Drug Administration (FDA), but plans may maintain formularies that encourage the use of certain drugs over others.³ Enrollees may obtain prescriptions from retail pharmacies that contract with the plans or from mail-order pharmacies offered by the plans. In 2005, FEHBP prescription drug spending was an estimated \$8.3 billion.

Medicare—the federal health insurance program that serves about 45 million elderly and disabled individuals—offers an outpatient prescription drug benefit known as Medicare Part D. This benefit was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) beginning January 1, 2006.⁴ As of February 2009, Part D provided federally subsidized prescription drug coverage for nearly 27 million beneficiaries. The Centers for Medicare & Medicaid Services (CMS), part of the Department of Health and Human Services (HHS), manages and oversees Part D. Medicare beneficiaries may choose a Part D plan from multiple competing plans offered nationally or

³Formularies include lists of prescription drugs, grouped by therapeutic class (groups of drugs that are similar in chemistry, method of action, and purpose of use), that health plans or insurers encourage physicians to prescribe and beneficiaries to use.

⁴Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152 (codified at 42 U.S.C. §§ 1395w-101 to 1395w-152). MMA redesignated the previous part D of title XVIII of the Social Security Act as part E and inserted a new part D after part C.

in certain geographic areas by private sponsors, largely commercial insurers, under contract with CMS. Part D plan sponsors offer drug coverage either through stand-alone prescription drug plans for beneficiaries in traditional fee-for-service Medicare or through Medicare managed care plans, known as Medicare Advantage. In 2009, there were over 3,700 prescription drug plans offered. Under Medicare Part D, plans can design their own formularies, but each formulary must include drugs within each therapeutic category and class of covered Part D drugs. Enrollees may obtain prescriptions from retail pharmacies that contract with the plans or from mail-order pharmacies offered by the plans. Medicare Part D spending is estimated to be about \$51 billion in 2009.

The VA pharmacy benefit is provided to eligible veterans and certain others. As of 2006, about 8 million veterans were enrolled in the VA system.⁸ In general, medications must be prescribed by a VA provider, filled at a VA pharmacy, and listed on the VA national drug formulary, which comprises 570 categories of drugs. In addition to the VA national formulary, VA facilities can establish local formularies to cover additional drugs. VA may provide nonformulary drugs in cases of medical necessity. In 2006, VA spent an estimated \$3.4 billion on prescription drugs.

The DOD pharmacy benefit is provided to TRICARE beneficiaries, including active duty personnel, certain reservists, retired uniformed service members, and dependents.⁹ As of 2009, there were about 9.4 million eligible TRICARE beneficiaries. In addition to maintaining a formulary, DOD provides options for obtaining nonformulary drugs. Beneficiaries can obtain prescription drugs through a network of retail pharmacies, nonnetwork retail pharmacies, DOD military treatment facilities, and DOD's TRICARE Mail-Order Pharmacy. In 2006, DOD spent \$6.2 billion on prescription drugs.

⁸Of the almost 8 million veterans enrolled, about 5 million received health care services. Additionally, there were over 4 million pharmacy users in VA in 2006.

⁹DOD provides health care through TRICARE—a regionally structured program that uses contractors to maintain provider networks to complement health care provided at military treatment facilities.

Medicaid, a joint federal-state program, finances medical services for certain low-income adults and children.⁷ In fiscal year 2008, approximately 63 million beneficiaries were enrolled in Medicaid.⁸ While some benefits are federally required, outpatient prescription drug coverage is an optional benefit that all states have elected to offer. Drug coverage depends on the manufacturer's participation in the federal Medicaid drug rebate program, through which manufacturers pay rebates to state Medicaid programs for covered drugs used by Medicaid beneficiaries. Retail pharmacies distribute drugs to Medicaid beneficiaries and then receive reimbursements from states for the acquisition cost of the drug and a dispensing fee. Medicaid outpatient drug spending has decreased since 2006 because Medicare Part D replaced Medicaid as the primary source of drug coverage for low-income beneficiaries with coverage under both programs—referred to as dual eligible beneficiaries.⁹ In fiscal year 2008, Medicaid outpatient drug spending was \$9.3 billion—including \$5.5 billion as the federal share—which was calculated after adjusting for manufacturer rebates to states under the Medicaid drug rebate program.

FEHBP Uses Competition between Health Plans to Control Prescription Drug Costs

FEHBP uses competition among health plans as the primary measure to control prescription drug spending and other program costs. Under an annual "open season," enrollees may remain enrolled in the same plan or select another competing plan based on benefits, services, premiums, and other such factors. Thus, plans have the incentive to try to retain or increase their market share by providing the benefits sought by enrollees along with competitive premiums. In turn, the larger a plan's market share, the more leverage it has for obtaining favorable drug prices on behalf of its enrollees and controlling prescription drug spending.

⁷Medicaid consists of 56 distinct programs created within broad federal guidelines and administered by state Medicaid agencies. The 56 Medicaid programs include 1 for each of the 50 states; the District of Columbia; Puerto Rico; and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, and the Virgin Islands. Within a framework established by federal statutes, regulations, and policies, each state (1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program.

⁸Approximately 6 million of the 63 million Medicaid beneficiaries were 65 years or older in 2008.

⁹Part D includes different levels of premium and cost-sharing assistance for dual eligible beneficiaries as well as assistance for other eligible beneficiaries who have low incomes and modest assets but do not meet the eligibility requirements for Medicaid.

Similar to most private employer-sponsored or individually purchased health plans, most FEHBP plans contract with pharmacy benefit managers (PBMs) to help them administer the prescription drug benefit and control drug spending. In a 2003 report reviewing the use of PBMs by three plans representing about 55 percent of total FEHBP enrollment, we found that the PBMs used three key approaches to achieve savings for the health plans:

- negotiating rebates with drug manufacturers and passing some of the savings to the plans;
- obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail-order pharmacies operated by the PBMs; and
- using other intervention techniques that reduce utilization of certain drugs or substitute other, less costly drugs.¹⁰ For example, under generic substitution PBMs substituted less expensive, chemically equivalent generic drugs for brand-name drugs; under therapeutic interchange PBMs encouraged the substitution of less expensive formulary brand-name drugs for more expensive nonformulary drugs within the same drug class; under prior authorization PBMs required enrollees to receive approval from the plan or PBM before dispensing certain drugs that are high cost or meet other criteria; and under drug utilization review PBMs examined prescriptions at the time of purchase or retrospectively to assess safety considerations and compliance with clinical guidelines, including appropriate quantity and dosage.

The PBMs were compensated by retaining some of the negotiated savings. The PBMs also collected fees from the plans for administrative and clinical services, kept a portion of the payments from FEHBP plans for mail-order drugs in excess of the prices they paid manufacturers to acquire the drugs,

¹⁰GAO, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, GAO-03-196 (Washington, D.C.: Jan. 10, 2003).

and in some cases retained a share of the rebates that PBMs negotiated with drug manufacturers.¹¹

While OPM does not play a role in negotiating prescription drug prices or discounts, it does attempt to limit prescription drug spending through its leverage with participating health plans in annual premium and benefit negotiations. Each year, OPM negotiates benefit and rate proposals with participating plans and announces key policy goals for the program, including those relating to spending control. For example, in preparation for benefit and rate negotiations for the 2007 plan year, OPM encouraged proposals from plans to continue to explore the appropriate substitution for higher cost drugs with lower cost therapeutic alternatives, such as generic drugs, and the use of tiered formularies or prescription drug lists. OPM also sought proposals from plans to pursue the advantages of specialty pharmacy programs aimed at reducing the high costs of infused and intravenously administered drugs.¹² In preparation for 2010 benefit and rate negotiations, OPM reiterated its desire for proposals from plans to substitute lower cost for higher cost therapeutically equivalent drugs, adding emphasis to using evidence-based health outcome measures.¹³

Other Federal Programs Use a Range of Approaches to Control Prescription Drug Spending

Medicare Part D uses a competitive model similar to FEHBP, while other federal programs use other methods, such as statutorily mandated prices or direct negotiations with drug suppliers.

¹¹In the private market, one of the key ways PBMs influence price negotiations with manufacturers is through formulary development and management. PBMs may assist health plans in developing or managing a formulary that the health plan will cover. Manufacturers pay PBMs through rebates or other payments to be included on plan formularies and to capture greater market share for their drugs.

¹²U.S. Office of Personnel Management Insurance Services Program, *Federal Employees Health Benefits Program Call Letter No. 2006-09* (Washington, D.C.: Apr. 4, 2006).

¹³U.S. Office of Personnel Management Insurance Services Program, *Federal Employees Health Benefits Program Call Letter No. 2009-08* (Washington, D.C.: Apr. 20, 2009).

**Medicare Part D Uses
Competing Prescription
Drug Plans**

Medicare Part D follows a model similar to the FEHBP by relying on competing prescription drug plans to control prescription drug spending. As with the FEHBP, during an annual open season Part D enrollees may remain enrolled in the same plan or select from among other competing plans based on benefit design, premiums, and other plan features. To attract enrollees, plans have the incentive to offer benefits that will meet beneficiaries' prescription drug needs at competitive premiums. The larger a plan's market share, the more leverage it has for obtaining favorable drug prices on behalf of its enrollees and controlling prescription drug spending. As a result, Part D plans vary in their monthly premiums, the annual deductibles, and cost sharing for drugs. Plans also differ in the drugs they cover on their formulary and the pharmacies they use.

Part D uses competing sponsors to generate prescription drug savings for beneficiaries, in part through their ability to negotiate prices with drug manufacturers and pharmacies. To generate these savings, sponsors often contract with PBMs to negotiate rebates with drug manufacturers, discounts with retail pharmacies, and other price concessions on behalf of the sponsor. MMA specifically states that the Secretary of HHS may not interfere with negotiations between sponsors and drug manufacturers and pharmacies.¹⁴ Even though CMS is not involved in price negotiations, it attempts to determine whether beneficiaries are receiving the benefit of negotiated drug prices and price concessions when it calculates the final plan payments. Sponsors must report the price concession amounts to CMS and pass price concessions onto beneficiaries and the program through lower cost sharing, lower drug prices, or lower premiums. Similar to OPM, CMS also negotiates plan design with participating plans and announces key policy goals for the program, including those relating to spending control. For example, in preparation for 2010 benefit and rate negotiations, CMS noted that one of its goals is to establish a more transparent process so that beneficiaries will be able to better predict their out-of-pocket costs.

Part D sponsors or their PBMs also use other methods to help contain drug spending similar to FEHBP plans. For example, most plans assign covered drugs to distinct tiers, each of which carries a different level of cost sharing. A plan may establish separate tiers for generic drugs and

¹⁴The Secretary may also not require a particular formulary or institute a price structure for the reimbursement of Medicare Part D drugs. Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2098 (codified at 42 U.S.C. § 1395w-111(f)).

brand-name drugs—with the generic drug tier requiring a lower level of cost sharing than the brand-name drug tier. Plans may also require utilization management for certain drugs on their formulary. Common utilization management practices include requiring physicians to obtain authorization from the plan prior to prescribing a drug; step therapy, which requires beneficiaries to first try a less costly drug to treat their condition, and imposing quantity limits for dispensed drugs. Additionally, all Part D plans must meet requirements with respect to the extent of their pharmacy networks¹⁵ and the categories of drugs they must cover.¹⁶ Plan formularies generally must cover at least two Part D drugs in each therapeutic category and class, except when there is only one drug in the category or class or when CMS has allowed the plan to cover only one drug.¹⁷ CMS has also designated six categories of drugs of clinical concern for which plans must cover all or substantially all of the drugs.¹⁸

VA and DOD Use Statutorily Mandated Prices and Negotiate Directly with Drug Suppliers

While FEHBP and Medicare Part D use competition between health plans to control prescription drug spending, VA and DOD rely on statutorily mandated prices and discounts and further negotiations with drug suppliers to obtain lower prices for drugs covered on their formularies.

VA and DOD have access to a number of prices to consider when purchasing drugs, paying the lowest available.

- *Federal Supply Schedule (FSS) prices.* VA's National Acquisition Center negotiates FSS prices with drug manufacturers, and these prices are available to all direct federal purchasers.¹⁹ FSS prices are intended to be

¹⁵All prescription drug plans must have a contracted pharmacy in their network that is within 2 miles of 90 percent of urban beneficiaries, 5 miles of 90 percent of suburban beneficiaries, and 15 miles of 70 percent of rural beneficiaries. 42 C.F.R. §423.120(a)(1)(2008).

¹⁶Under the MMA, prescription drug plans must cover drugs within each therapeutic category and class of Part D drugs. Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2085 (codified at 42 U.S.C. § 1395w-104(b)(3)(C)).

¹⁷42 C.F.R. §423.120(b)(2)(2008).

¹⁸Part D plan formularies must include all or substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic drug categories.

¹⁹VA and DOD directly purchase drugs from manufacturers for their beneficiaries. FEHBP, Medicare Part D, and Medicaid provide reimbursement for drugs dispensed to beneficiaries.

no more than the prices manufacturers charge their most-favored nonfederal customers under comparable terms and conditions. Under federal law, drug manufacturers must list their brand-name drugs on the FSS to receive reimbursement for drugs covered by Medicaid.²⁰ All FSS prices include a fee of 0.5 percent of the price to fund VA's National Acquisition Center.

- *Federal ceiling prices.* Federal ceiling prices, also called Big Four prices, are available to VA, DOD, the Public Health Service, and the U.S. Coast Guard. These prices are mandated by law to be 24 percent lower than nonfederal average manufacturer prices.²¹
- *Blanket purchase agreements and other national contracts.* Blanket purchase agreements and other national contracts with drug manufacturers allow VA and DOD—either separately or jointly—to negotiate prices below FSS prices. The lower prices may depend on the volume of specific drugs being purchased by particular facilities, such as VA or military hospitals, or on being assigned preferred status on VA's and DOD's respective national formularies.

In a few cases, individual VA and DOD medical centers have obtained lower prices through local agreements with suppliers than they could have through the national contracts, FSS prices, or federal ceiling prices.

In addition, VA's and DOD's use of formularies, pharmacies, and prime vendors can further affect drug prices and help control drug spending. Both VA and DOD use their own national, standard formulary to obtain more competitive prices from manufacturers that have their drugs listed on the formulary. VA and DOD formularies also encourage the substitution of lower cost drugs determined to be as or more effective than higher cost drugs. VA and DOD use prime vendors, which are preferred drug distributors, to purchase drugs from manufacturers and deliver the drugs to VA or DOD facilities. VA and DOD receive discounts from their prime vendors that also reduce the prices that they pay for drugs. For DOD, the discounts vary among prime vendors and the areas they serve. As of June

²⁰See 38 U.S.C. § 8126(a)(4).

²¹See 38 U.S.C. § 8126(a)(2). The nonfederal average manufacturer price is the weighted average price of a single form and dosage unit paid by wholesalers to a manufacturer, taking into account cash discounts or similar price reductions. Big Four prices, in general, do not apply to generic drugs.

2004, VA's prime vendor discount was 5 percent, while DOD's discounts averaged about 2.9 percent within the United States. Additionally, similar to FEHBP and Medicare Part D, DOD uses utilization management methods to limit drug spending including prior authorization, dispensing limitations, and higher cost sharing for nonformulary drugs and drugs dispensed at retail pharmacies.

Medicaid Uses Aggregate Payment Limits, Drug Pricing Guidelines, and Required Rebates

Unlike VA and DOD, Medicaid programs do not negotiate drug prices with manufacturers to control prescription drug spending, but reimburse retail pharmacies for drugs dispensed to beneficiaries at set prices. CMS sets aggregate payment limits—known as the federal upper limit (FUL)—for certain outpatient multiple-source prescription drugs.²² CMS also provides guidelines regarding drug payment. States are to pay pharmacies the lower of the state's estimate of the drug's acquisition cost to the pharmacy, plus a dispensing fee, or the pharmacy's usual and customary charge to the general public; for certain drugs the FUL or the state maximum allowable costs may apply if lower.²³

In addition to these retail pharmacy reimbursements, Medicaid programs also control prescription drug spending through the Medicaid drug rebate program.²⁴ Under the drug rebate program, drug manufacturers are required to provide quarterly rebates for covered outpatient prescription drugs purchased by state Medicaid programs. Under the rebate program, states take advantage of the prices manufacturers receive for drugs in the commercial market that reflect the results of negotiations by private payers such as discounts and rebates. For brand-name drugs, the rebates are based on two price benchmarks per drug that manufacturers report to

²²Federal regulations set specific limits for multiple-source drugs for which there are two or more therapeutically equivalent products.

²³States may establish their own methodologies for estimating retail pharmacies' drug acquisition costs. Most states choose to estimate these costs by taking a percentage discount from the average wholesale price. The usual and customary charge for a drug is the full retail price that individuals without prescription drug coverage pay when purchasing drugs at a retail pharmacy. Some states also administer a maximum allowable cost program for selected multiple-source drugs with the maximum price at which the state will reimburse those medications.

²⁴See 42 U.S.C. § 1396r-8.

CMS: best price²⁶ and average manufacturer price (AMP).²⁷ The relationship between best price and AMP determines the unit rebate amount and thus the overall size of the rebate that states receive. The basic unit rebate amount is the greater of two values: the difference between best price and AMP or 15.1 percent of AMP. If the brand-name drug's AMP rises faster than inflation as measured by the change in the consumer price index, the manufacturer is required to provide an additional rebate to the state Medicaid program. In addition to brand-name drugs, states also receive rebates for generic drugs. For generic drugs, the basic unit rebate amount is 11 percent of the AMP. A state's rebate for a drug is the product of the unit rebate amount plus any applicable additional rebate amount and the number of units of the drug paid for by the state's Medicaid program. In addition to the rebates mandated under the drug rebate program, states can also negotiate additional rebates with manufacturers.

Like FEHBP and Medicare Part D participating plans, Medicaid programs also use other utilization management methods to control prescription drug spending including prior authorization and utilization review programs, dispensing limitations, and cost-sharing requirements.

Mr. Chairman, this concludes my prepared remarks. I would be happy to answer any questions that you or other members of the Subcommittee may have.

²⁶Best price is the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, or nonprofit or government entity, with some exceptions. Among other things, sales made through the FSS, single-award contract prices of any federal agency, federal depot prices, and prices charged to DOD, VA, Indian Health Service, and Public Health Service are not considered in determining best price.

²⁷AMP is defined by statute as the average price paid to a manufacturer for a drug by wholesalers for drugs distributed to the retail pharmacy class of trade. Under the rebate agreement manufacturers negotiate with HHS, AMP does not include prices to government purchasers based on the FSS, prices from direct sales to hospitals or health maintenance organizations, or prices to wholesalers when they relabel drugs they purchase under their own label.

**Contacts and
Acknowledgments**

For future contacts regarding this testimony, please contact John E. Dicken at (202) 512-7114 or at dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Randy DiRosa, Assistant Director; Rashmi Agarwal; William A. Crafton; Martha Kelly; and Timothy Walker made key contributions to this statement.

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Mr. LYNCH. Thank you, Mr. Dicken.

I now recognize myself for 5 minutes. Ms. Kichak, in your testimony, admittedly you said that transparency doesn't always result in lower prices; however, for the oversight committee, for us, it is not an option. Oversight cannot go forward without transparency, so we don't have a choice of not having transparency, even if we didn't think the value of transparency was something that we put a high value on, let us say. It has just got to happen. We have to have it statutorily—

Ms. KICHAK. Right.

Mr. LYNCH [continuing]. And through our congressional mandate, it is to have transparency.

Ms. KICHAK. Well, we support transparency, which is why with every suggestion or every time our Inspector General makes suggestions to us, we consider them very carefully. And we have done two significant things, which I had in my opening statement, that we got from work when the Inspector General came back to us and raised problems.

One was what we call the large provider contract regulations, which gives the Inspector General full access to the full PBM contract. I understand that it is now not digging down as far as they would like to go. What was described in the previous panel, is an industry problem, where the PBMs are not making their costs and their operations public to anyone. It is not just an FEHB problem, but within the FEHB, we have given full access to the contracts that are available to our Inspector General.

Mr. LYNCH. Understood.

Ms. KICHAK. Yes.

Mr. LYNCH. Understood, but the pharmacy benefit managers have made this system so opaque and so complex, that even when I sit an auditor right on there, have them go, these are professionals now—

Ms. KICHAK. Right.

Mr. LYNCH [continuing]. They can't figure out what things cost and whether I am getting a good deal or not.

Ms. KICHAK. And we would agree with you.

Mr. LYNCH. Right. OK. So that is a problem. That is a huge problem. We can't operate that way anymore. The administration is looking for savings, and we are trying to help the administration, and we think this is an area that is very fertile ground for savings.

When we compare what TRICARE is paying, what others are paying, and we look at the discount TRICARE, up around 50 percent, VA up around 60, somewhere in that range, and then we look at OPM getting about 12 percent with the FEHBP, Federal Employees Health Benefits Plan, that simply is not acceptable.

Now we need to dramatically change this. Part of one solution would be to classify PBMs as subcontractors, subject to the Federal acquisition regulations. Now that is not a simple system either, as someone who has spent far too many trips to Iraq and Afghanistan trying to figure out how we manage those contracts.

Those are not simple either, but they are a walk in the park compared to trying to figure the system that we have now with the Federal Employees Health Benefits Plan. It is actually structured and operated in a way that is meant to block oversight and block

auditing. We cannot have that any more. There are even procedural limitations on the auditors; they are not allowed to copy information, that whole system is built on—there is no competitive model, in your competitive model.

The system that is set up at the Federal Employees Health Benefits Plan is basically increase complexity, to the degree that it is not understandable, hide information from the consumer and from the auditors, and from the U.S. Congress Committee on Oversight. Basically deny information that would allow people to make that competitive decision on pricing, and basically charge as much as you possibly can in that atmosphere and in that framework of concealing information and making it so complex. That is the system we have right now. And we can't continue to operate that way.

So what we think is one way to clarify is to classify these folks as contractors. At least we put them in a system where we can keep score and we can figure out whether they are giving us a raw deal or not. And as I understand it, we can do that by Executive order, we can do that by regulation right now at OPM. Is that something that you are open to?

Ms. KICHAK. We believe that there is definitely more information that should be available, but we do not believe that we have the regulatory authority to do that. We think that what we have done through regulation—you see, OPM contracts with the health plans. The health plans contract with the PBMs. We are not direct contractors for the drug services, so we don't have the same authority we would if we were a direct contractor.

In order to become a direct contractor with a PBM, it would require a statute change, in our opinion, not a regulation change. We believe, but we will continue to explore it, because we explore everything our Inspector General suggests to us, but we believe the regulation we changed giving the Inspector General full access to PBM contracts, was the extent of the authority that we could do through regulation.

So this is a question of law that needs further exploration, because we certainly believe in transparency and we would like to further that to the extent that we can.

Mr. LYNCH. Well, I have to say that in trying to figure this whole system out, there is nothing more complex than what you have over there at the Federal Employees Health Benefits Program. This is really very convoluted, and I am an attorney. I have done contract law.

But you have a system over there that is meant to deceive, and to keep the truth and information from getting to the public and to the beneficiaries. We don't even know what stuff costs, and so you may say you are for transparency, but take a good hard look at that system, and that doesn't even have the beginnings of any transparency and we are supposed to be trying to save money here.

And I am very disappointed to hear you say that, because we think you do have the regulatory power. I will file legislation to have these folks classified as subcontractors. I am going to do that. I think you are making me work harder than I need to. I think you have that power already, but maybe my filing this legislation will light a fire under somebody.

Ms. KICHAK. Well, we would be glad to get back to you with an explanation of what we think our authority is. Because if we have that authority, then we will not make you work harder than you have to. We will see what we can do to exercise that.

Mr. LYNCH. God bless you.

Ms. KICHAK. OK.

Mr. LYNCH. Thank you. All right. Now, look, you are new over there, you have to be new.

Ms. KICHAK. Thank you.

Mr. LYNCH. No, but this is probably a question beyond your own experience, but do you have any idea why we might have 256 contractors that we deal with?

Ms. KICHAK. Because we have HMOs in most of the States in the Nation. We only have about 13 Government-wide plans that service everybody. And even out of those 13, a certain segment of them, a very important segment of them, are to just limited groups of people like foreign service officers, or rural letter carriers. But we have HMOs in California, in Florida, New York, etc.

Mr. LYNCH. I see.

Ms. KICHAK. And they deliver care locally.

Mr. LYNCH. And there are only a handful of the larger ones that are national? Most of these are regional or local?

Ms. KICHAK. Most of them are regional.

Mr. LYNCH. OK.

Ms. KICHAK. Most of the big numbers come from the regional plans.

Mr. LYNCH. OK.

Ms. KICHAK. And again, the national plan is open to everybody. I think it might be about seven and then another five are to special groups.

Mr. LYNCH. OK. Now you have 7.7 million, that I gather, that are within your group there?

Ms. KICHAK. Right.

Mr. LYNCH. Let me turn to Rear Admiral McGinnis now. I think you have 9 million, but you have 7 million that are actually participants in your pharmacy plan, and those folks are spread out all over as well, aren't they?

Admiral MCGINNIS. That is correct, sir. They are all over the world. We have about 9.5 million beneficiaries today, and about 7 million use the pharmacy benefit.

Mr. LYNCH. Now in your testimony, you also described that you have a limited number of contractors. Is that correct, or did I mishear you?

Admiral MCGINNIS. No. You are correct. We have one contractor currently, that provides the retail pharmacy benefit for us. One contractor that provides the mail order pharmacy benefit for us. It happens to be the same contractor, ExpressScripts. We saw duplications yet in that, and beginning November 4th, there will only be one contractor providing both the retail and pharmacy benefit.

Mr. LYNCH. How did you do the competition for that one contract?

Admiral MCGINNIS. We used the Federal Acquisition Regulations, sir. We put out our requirements, requests for proposals. They are submitted, we review them internally, and award that

contract on many different aspects. Past performance, we go out to commercial clients who use this PBM and ask them, how are they doing for you?

Mr. LYNCH. Right.

Admiral MCGINNIS. And we take that into consideration when we award this contract. It is a 1-year contract with four option years.

Mr. LYNCH. It is interesting. You have a situation where you are using one contractor. You are I think, perhaps putting all your chips on one bet, but you are getting a 50 percent discount or something of that magnitude. And when we dice it up, we are getting a 12 percent discount. I am just wondering if there is a proximate cause there, a direct relationship on that point.

Mr. Dicken, you addressed that a little bit in your opening statement, about the fact that there are two models here. Maybe it is apples and oranges I am comparing here, but what do you think?

Mr. DICKEN. Well, I think certainly the differences there are in part because some of the prices that TRICARE are able to get, are statutorily set. That they are able to choose the lowest of prices. They are defined by statute, that set ceiling prices.

Those ceiling prices in exchange are based on some of the best prices that are able to be negotiated by non-Federal payers. And so there is a certain guarantee of a level of prices that then TRICARE can negotiate below if they are able to. On the other hand, FEHBP, in its contracts with the multiple plans, those are individual contractual relationships where the plans and their PBMs will negotiate on behalf of each plan. And there is no guarantee in the way that there would be for TRICARE of a ceiling price.

Mr. LYNCH. OK. I understand, Ms. Kichak, that OPM attempted to control drug spending in 2000 by introducing a pilot plan with SAMBA?

Ms. KICHAK. Correct.

Mr. LYNCH. Do you recall that?

Ms. KICHAK. Yes, I do.

Mr. LYNCH. Now I have been reading up on this so I might be wrong on this, but as I understand it, SAMBA is the Special Agents Mutual Benefit Association.

Ms. KICHAK. Correct. Mostly FBI agents and Secret Services agents.

Mr. LYNCH. Just a few thousand people at the time?

Ms. KICHAK. Yes.

Mr. LYNCH. OK. And my understanding is that you tried to do a pilot program that would allow the special agents and their families, just a few thousand beneficiaries, to purchase their drugs off of the Federal supply schedule.

Ms. KICHAK. That is correct.

Mr. LYNCH. OK. And if again, I am correct, at the threat of that pilot program, we had three drug companies, big ones, refuse to participate and supply drugs to that program.

Ms. KICHAK. I can't attest to the exact number, but that is what happened. It was a concern of the drug industry. We were trying to try a new approach and get better discounts. It was a concern of the drug industry, that if that was the nose under the tent, and

we were going to move 8 million people, onto those Federal supply schedules, with those major discounts, the pharmaceutical companies would not be able to sustain the discounts they had promised to a big group, but more limited than ours. And they opposed it, and said that they would not honor their contract on the Federal supply schedule if we went forward. And we were forced to withdraw that proposal.

Mr. LYNCH. Wow. The formulary that would have been available to the special agents, was that a full formulary of proprietary drugs as well as generics?

Ms. KICHAK. That was the full spectrum of drugs on the supply schedule. Yes.

Mr. LYNCH. I am just wondering why we didn't call their bluff, in terms of their refusal to supply those drugs. It seems like sort of a brash and confrontational way to deal with the problem.

Ms. KICHAK. It was definitely a very stressful situation, because, of course, our responsibility is to make sure, and we take this very seriously, that Federal employees have access to health care. And every year they have the option to select new. But we wanted to have that plan in place and coverage continuing, and the manager of the Federal supply schedule at that time, VA, was very concerned that this pilot was jeopardizing care to other members of the VA, or other Federal purchasers from that schedule, and really asked us to withdraw the pilot.

I think that we pushed it very, very hard. It delayed our getting ready for open season and negotiating rates and benefits, because we had to get somebody else. We had open season on time, but we, at some point, had a point at which we had to enter into a contract with SAMBA to go forward with these coverages or they would not have been in the program in the following year. And so we chose to withdraw the pilot.

Mr. LYNCH. OK. Now, and I understand you don't remember how many companies were involved?

Ms. KICHAK. I really don't.

Mr. LYNCH. From my readings, it was three larger pharmaceutical companies. Now I am just wondering if you remember what percentage of the drugs on the formulary would have been affected by these three companies, or four companies, however, in terms of the program going forward?

Ms. KICHAK. Ninety percent.

Mr. LYNCH. Ninety percent?

Ms. KICHAK. So they were three large companies.

Mr. LYNCH. OK. Yes.

Ms. KICHAK. That I have confirmed.

Mr. LYNCH. I am just trying to replay that in my mind. I know it was Pfizer, Parke-Davis and Merck. That is the information that I have. I am just wondering if a similar pilot program would work if we just used generics. That way, if something is generic, it is out there, it is not subject to patent control, and if you have real competition, and you get a lot of people that could produce that drug at a reasonable cost, do you think a pilot program just focusing on generics, where three big players can't come in and say embargo this whole deal.

Ms. KICHAK. Well, let me say, as we have said before, this is a very complex program, and drugs are very complex, retail, mail order, generic, etc.

Mr. LYNCH. Tell me about it.

Ms. KICHAK. And so I am uncomfortable, but I am going to take a stab at it anyway.

Mr. LYNCH. OK.

Ms. KICHAK. Where you really need to save your money in drugs is on the non-generic. The generic are really, in my opinion and in my experience, are pretty low priced anyway.

Mr. LYNCH. All right.

Ms. KICHAK. And to make it worthwhile, I think you would have to go for the brands.

Mr. LYNCH. That is a great point. That is a great point. Thank you. Admiral McGinnis, the success that you have had over there, at TRICARE, has there been any attempt to expand beyond your existing population?

Admiral MCGINNIS. No. We have only covered members of the seven uniform services, so we have not been asked to look any further than that. We have expanded the benefit to virtually every pharmacy in the country today.

Mr. LYNCH. OK. In the testimony earlier today, Ms. Kichak, we heard from Mr. McFarland that the transparency and the data for them to make determination, was not available, and yet you say there has been a new effort to do just that, to free that up. There seems to be a little bit of difference in your views and Mr. McFarland's views, the Inspector General, in terms of the access to the information, the transparency of the organizations themselves. Do you know what might cause that difference of opinion?

Ms. KICHAK. I think what is happening here is, at one point when one of our plans subcontracted with a PBM, the subcontract was not available for audit. So now that actual subcontract is available, there is definitely improvement. What I believe that our Office of Inspector General would like and find very helpful, and what all of the previous panels asked for, was more basic. How much profit, where is the money going, the whole under workings within the drug companies.

That doesn't become a part of the contract, or the subcontract, and that is not yet available. And as I was saying before, I am not sure, and I promise to get you an answer, that we have the authority, through our regulatory process, to demand that kind of information. But I will find out. At one point, the contract wasn't even available. Now the contract is fully available, but the underlying workings still have not been opened up. In the same manner, that all the previous witnesses said, the drug companies do not make this information available.

Mr. LYNCH. OK. Let me jump back. My idea originally was to look at the generics, because I saw that problem you had with the SAMBA Program. Is there any appetite—I know the earlier incident was in 2000, is there any appetite at OPM to look at another pilot program where we might expand the access to the Federal supply schedule for others?

Ms. KICHAK. Well, as you know, at OPM we have a new director, who is taking a top-down look at everything. We have a new focus

on data driven analysis, which is also looking at that stuff, and we are looking at every health plan with a fresh look. Now the new administration, by the time they got here, we were already engaged in negotiations for 2010, because the process starts early. But that is certainly something—we have an appetite right now for looking at everything. We are bottom-up delving into whether these schedules are the right way to go, whether we should carve out drugs. Everything is on the table, how much data we can get from our carriers is also on the table. So we are taking a fresh look, and I would say, therefore, we are definitely going to consider that along with many other options.

Mr. LYNCH. OK. You know one of the other things, when I read through that case of the SAMBA plan, it puzzled me. Now under the statutory and regulatory guidance, these carriers should not be receiving any financial benefit from the carved out pharmacy plans. That is the way it is supposed to work. Now why do you think we have such opposition from the carriers when we try to introduce—if there is no financial benefit, why all the opposition?

Ms. KICHAK. Well, change is difficult for everybody, first of all. Second, administratively, particularly in this day and age where we are trying to do so many health care programs, wellness programs, that is the wrong word, but case management programs. For example, diabetes, where you are trying to track prescription drugs, the usage of the right drugs, what are health care outcomes, and we are pushing our plans to do things like that, I think that is an incentive, or one of the reasons why the plans want to be able to have access to that data. I think the other thing they are trying to do is, in the competitive environment, they think they can come up with the best design. And we do have different designs.

We have people today that are waiving the copays on generic drugs to try to get people to switch. We have other people, other plans that get you in generic drugs by a plan manager who looks at that. We have plans that are trying to be more cost-effective through e-prescribing and getting you to generic that way. Or trying to get you to the most effective drug that way. So I think the plans are trying to use the drugs as part of their health care initiatives, and that is one of the reasons for the resistance.

Mr. LYNCH. Fair enough.

Mr. DICKEN, I have not bothered you that much. Let me shift to you. Has GAO encountered any difficulty, in other instances, obtaining access to data as we had described with Ms. Kichak in trying to fulfill its role in assuring that the Federal Government does not overpay for prescription drugs?

Mr. DICKEN. Yes. I would be glad to describe GAO's experience. I think the panelists in the first panel, well-described the challenges that oversight agencies have in transparency in this area. GAO in 2003, did examine the experience of three FEHBP plans with their PMBs, and we were able to look at particular contracts, or financial reports that were specific to those FEHBP plans and their PBMs.

I would like to make a distinction though, that while we were able to look at that, I think that was much of the issue that Ms. Kichak was talking about for what is being made available to the Inspectors General. There is a much larger book of business that

the PBMs have where FEHBP is a significant part, but not the entire part. And that affects their contracts more broadly with manufacturers and with pharmacies. And so while we were able to look at the information specific to FEHBP, we did not obtain information for that broader book of business that could affect things like the prices they are requiring for mail order drugs, or the total rebates that they are getting on their entire book of business, not just those allocated to FEHBP.

Mr. LYNCH. Let me drill down a little bit on that. You had a chance to review the pharmacy benefit managers. In your analysis, or attempted analysis, what information was there that you did not have access to that you think might have been helpful in judging their effectiveness?

Mr. DICKEN. I think the distinction really is, we were able to look at what was specific to the FEHBP book of business, but not information that was broader across their entire book of business that would then affect rebates they may be getting that would include, for example, their FEHBP lives, as well as all of their commercial lives that PBM would be negotiating with manufacturers on their behalf.

Mr. LYNCH. So that was considered proprietary, the relationships they had with, in other words, these rebates that are—call them what you may, these other financial incentives that they were getting, those arrangements were not subject to your review.

Mr. DICKEN. If they were not rebates specifically dedicated to FEHBPs, so we were able to look at what rebates the PBMs promised to pass on to the FEHBP plans, but that they may also be getting rebates that are much broader for their entire book of business. And that is the part that we did not obtain.

Mr. LYNCH. OK. But FEHBP, you have 7.7 million people?

Mr. DICKEN. Yes.

Mr. LYNCH. Well, I guess you can't assume that any percent of the volume of their business is dedicated. But it would be nice to get that information to find out their full menu of revenue sources, and find out whether or not the employees, the members of the FEHBP are getting the benefit of some of those rebates.

As I did earlier with the previous panel, I am going to ask you, you know obviously I didn't exhaust the entire landscape of issues that we could have addressed. But, and again, I am going to allow other Members who are not in attendance to ask you questions in writing, and I would appreciate your cooperation in answering those if they do come. Why don't we start with Mr. Dicken, since we have been down at Ms. Kichak's end, for most of the hearing? Take 2 minutes, if there are issues that we did hit on here, that you think are important, we would like to hear about them.

Mr. DICKEN. Well, I think the hearing has well-addressed some of the challenges that oversight faces within the context of FEHBP and the plan's contracts with PBMs. I guess I would just note that this is not an issue that is unique to FEHBP. I can speak to GAO's experience also.

For example, with Medicare Part D. That is an area where we have been working since 2007. In that case, plans are required to report price concessions or rebates they may get to CMS; however, CMS and HHS have interpreted the legislation that created Medi-

care Part D as not allowing to disclose that to GAO. GAO has been working with committees, including this committee, for legislative clarification that GAO indeed, would have access to that information for Medicare Part D, in fact.

Mr. LYNCH. You said a legislative fix? Or is that a regulatory fix?

Mr. DICKEN. It is a legislative, well because there is a—HHS has interpreted the legislation. We are seeking legislative clarification that GAO does have access, under its broad authority.

Mr. LYNCH. Is there a bill out there right now that gives you that access?

Mr. DICKEN. There is a bill, HR2646.

Mr. LYNCH. Who is sponsoring that?

Mr. DICKEN. Pardon me?

Mr. LYNCH. Who is the sponsor?

Mr. DICKEN. I can get back to you on that.

Mr. LYNCH. OK. We will figure it out. I thought you might know. OK. Thank you. I didn't mean to interrupt, but please go ahead.

Mr. DICKEN. I think that is what I wanted to highlight. Thank you.

Mr. LYNCH. OK. Thank you. That was helpful.

Rear Admiral McGinnis.

Admiral MCGINNIS. Mr. Chairman, I think that transparency is probably the most important thing on both sides. Our PBM must pass through all rebates benefits. They are not able to even negotiate rebates. Everything is a pass through to the Government. We negotiate the rebates with the pharmaceutical company. Everything on our side also has to be transparent. We put our formulary on the open Web, everybody can see our formulary. Our formulary committee minutes are put up on the Web. We have a beneficiary advisory panel, advising us on that formulary. Bringing things to our attention to consider, before we make changes to that formulary.

We have good feedback from that beneficiary organization. We incentivise our PBMs properly so that they come back consistently with a 95 percent or better beneficiary satisfaction rating to get the monetary incentives that we put in our contract. And we feel that these types of things work very well for us. The formulary placement of medications has brought us great results with the pharmaceutical industry. They have been willing to give us much better pricing than the Federal ceiling price for that formulary placement.

Mr. LYNCH. Very good. Thank you, Admiral. And thank you for your service to our country.

Ms. Kichak, 2 minutes.

Ms. KICHAK. We are very concerned about drug costs, because they are 30 percent of our program, and we want to know everything we can about drug costs so that we can find the best way to deliver them and the most cost-efficient way to serve the Federal employees and retirees. We are working with our Federal partners. We are working with TRICARE to understand their system.

We are exploring all options, including options we have tried before and didn't fail. And we are responding as quickly as we can to suggestions to make more information available to our Inspector Generals. So we are going to keep working on this problem until we make it better in some fashion or another.

Mr. LYNCH. Thank you, Ms. Kichak. I want to thank you all for your willingness to come before the committee and help us with our work. And you can tell Director Berry that we appreciate the participation and cooperation of OPM as well. Thank you all, and have a good day.

Ms. KICHAK. Thank you.

Mr. LYNCH. Thank you for your patience. I know it has been a long day. It is the custom of this committee, that all witnesses to testify are to be sworn. Could I ask you to please rise and raise your right hands?

[Witnesses sworn.]

Mr. LYNCH. Let the record indicate that all the witnesses have answered in the affirmative. I am going to offer brief introductions of each of the witnesses, and then you will be allowed 5 minutes for an opening statement.

Dr. Jack Needleman is currently an associate professor in the Department of Health Services of the UCLA School of Public Health. In 2007 he was inducted as an honorary fellow of the American Nursing Academy. Before beginning his tenure at UCLA, Dr. Needleman was a member of the faculty of the Harvard School of Public Health.

Dr. Ralph de la Torre is a nationally renowned cardiac surgeon and an innovative health care businessman. Dr. Ralph de la Torre became the president and CEO of Caritas Christi Health Care, three facilities in my district, a matter of disclosure. In April 2008, with 12,000 employees, Caritas Christi is the 11th largest employer in Massachusetts. As CEO, Dr. de la Torre's mission is to revolutionize the delivery of health care in the region by moving integrated clinical services out into the communities where patients live. In addition to his clinical endeavors, Dr. de la Torre has served as a health care consultant.

Mr. Mark Merritt is the president and CEO of the Pharmaceutical Care Management Association. The National Association Representing America's Pharmacy Benefit Managers, lower prescription drug costs for more than 200 million Americans, and managed about 70 percent of the more than 3 billion prescriptions dispensed in the United States each year. Mr. Merritt has served as a senior strategist with America's health insurance plans and the pharmaceutical research and manufacturers of America.

Welcome, gentlemen. Dr. Needleman, you now have 5 minutes for an opening statement.

STATEMENTS OF DR. JACK NEEDLEMAN, ASSOCIATE PROFESSOR IN THE DEPARTMENT OF HEALTH SERVICES OF THE UCLA SCHOOL OF PUBLIC HEALTH; DR. RALPH DE LA TORRE, PRESIDENT AND CEO, CARITAS CHRISTI HEALTH CARE; AND MARK MERRITT, PRESIDENT AND CHIEF EXECUTIVE OFFICER, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

STATEMENT OF DR. JACK NEEDLEMAN

Dr. NEEDLEMAN. Chairman Lynch, members of the subcommittee, thank you for inviting me to testify. Let me add just one item to the biography that you provided, which is, prior to going to Har-

vard, I was vice president/co-director of the Public Policy Practice at Lewin-ICF, now the Lewin Group, a thing that has some meaning in these halls. You have my written testimony, so I simply want to highlight a few key points from it, some of which have been made today, but perhaps deserve one more hammer hitting the nail.

The first point is simply that the Federal Employees Health Benefits Plans, by and large, are using the current standard practice of contracting with PBMs for their drug benefits. And measured against a standard of what you would pay if you were strictly retail, there is substantial savings.

The industry-sponsored study published in 2008, or put out in 2008, that estimated that about 28 percent discount from retail, which I would say given its industry sponsor, should be treated as an upper bound. You know, that is a considerable savings, but it is not appropriate to be measuring the benefits of the PBMs structure in FEHBP, against retail. That is the wrong standard.

We have seen some discussion today about other more appropriate standards, and I think it is very clear, that compared to other large Federal purchasers, there is considerable evidence to date that the FEHBP plans are getting smaller discounts than other Federal purchasers. We can't tell how substantial those discounts are, or what PBMs are being paid for their services because of a lack of transparency in PBM billing plans.

To put it very simply, the PBMs buy on one schedule, they bill to the Federal Government and other health plans, on a different schedule. As has been discussed by prior participants, prior panel members, for generic drugs, the purchasing is built on an MAC, a Maximum Allowable Cost schedule, which will vary from PBM to PBM, and may vary from where they are getting the drugs across the plans, plus administrative fees. For unpatented, branded, sole-source drugs, they are paying a negotiated price. And that negotiated price has a whole variety of discounts and rebates that are potentially associated with them.

The size of those discounts are a function of the bargaining power of the PBM. And in part, that includes the threat of whether or not to include the drug in the formulary or how well tiered it will be within the formulary of a plan. That is where the bargaining power to negotiate the discount comes from.

The historic practice of the PBMs for actually billing the folks who have contracted with them to conduct these services, is either an aggregate amount or a percentage of wholesale, or some other measure, which may or may not make clear, typically doesn't make clear what was paid as costs for the drugs themselves, and what is being charged for administrative services.

That lack of transparency has been heavily criticized by purchasers and consumer groups, and there have been some efforts to address it. The Human Resources Policy Association, the group of human resource managers for large businesses, have developed standards for transparency in pharmaceutical purchasing, which include charging the acquisition costs, both at retail and mail order for drugs. Passing through all rebates for manufacturers and other pharmaceutical manufacturer revenues that the PBMs are receiv-

ing, and the right to audit, that those practices have been fully implemented.

These represent minimum standards, and many of the largest PBMs, including the key PBMs in the FEHBP Program, have actually signed on to that. However, the PBMs offer the plans the option of traditional pricing, or transparent pricing. And the pricing they have offered under transparent pricing, according to Ms. Hayes, who was here earlier, has been substantially higher.

Clearly, as many industry observers have noted, there should be some skepticism about the industry's willingness to meet the commitment it has formally signed on to for transparency. If you ask for my recommendations on directions to go in, I would say that at a bare minimum, the FEHBP Plans should demand and enforce contract billing provisions for costs, separated from the administrative charges and profits that are being made. So, separate billing provides for a clear accounting of the costs of the drugs, the administrative costs and fees being paid to pharmacies and other third parties, and the administrative profits and fees associated with the PBMs services.

The FEHBP Plans, either collectively or individually, need to negotiate hard for appropriate administrative fees, and consider either make versus buy decisions, or going to a single vendor as TRICARE has in order to get a good deal for the Federal Government. They should also consider whether to use scheduled Federal prices, or negotiated prices, for FEHBP in lieu of going with the PBM negotiated prices.

It is clear that PBMs provide a variety of services beyond negotiated prices, enrollment and eligibility determinations, claims paying, checks for drug/drug interactions, patient education, facilitating therapeutic interchange and appropriate use of generics. With more transparent pricing we would be in a far better position to access the cost and value of these services, rather than simply including them as the full package at a price that is not clear.

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

[The prepared statement of Dr. Needleham follows:]



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.) In 2006, 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 (TIPPSSM) 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
<i>Fee for Service Plans</i>		
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
<i>Experience-Rated HMO PBM's</i>		
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 Pharmacy Services	Blue Shield Pharmacy Services
Blue Shield of Calif. (SJ)	Wellpoint Pharmacy	Wellpoint Pharmacy
BlueChoice of MO (9G)	AdvancePCS	AdvancePCS
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	53
Medicaid Net Manufacturer Price	51
340B Ceiling Price	51
Federal Ceiling Price	50
Price Available to the "Big Four"	49
VA Average Price	42

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.

The Omnibus Budget Reconciliation Act of 1980 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.

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.

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 75 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.

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.

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.

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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 formulators. The MTF average price takes into account all the various pricing schedules and contracts under which DoD purchases drugs.

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 60 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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Mr. LYNCH. Thank you, Doctor.
Dr. de la Torre, you are recognized for 5 minutes.

STATEMENT OF DR. RALPH DE LA TORRE

Dr. DE LA TORRE. Thank you.

Mr. Chairman, I want to thank you for inviting me to participate in this hearing. The rising cost of health care, as we all know, is dealing a crippling blow to employers across the United States. Escalating premiums suffocate not only the employees but employers who struggle to provide a benefit to their employees. At the forefront of this escalation is the cost of prescription drugs. Controlling prescription drug costs is essential to containing health care costs.

Unlike many other contributors to the cost of health care, prescription drugs serve not only in the treatment of illness but as a preventive measure. This is especially true in the treatment of chronic illness. Many recent reports document how escalating copays on pharmaceuticals lead to noncompliance on behalf of patients. This non-utilization can lead to the escalation of chronic illness, and the subsequent grave implications to patient and employer. As a specific example, patients who fail to comply with medications that control blood sugar or hypertension, are more likely to develop atherosclerosis which can lead to heart attack and stroke. For all these reasons, to describe but a few, it is imperative that an employer, through the benefits offered its employees, control prescription drug costs.

Within the context of my comments, the Federal Government is the largest employer in the United States of America. Like all large employers the Federal Government should capitalize on its purchasing power to lower its cost of goods and services. In fact, this concept is at the very essence of our capitalist economy. Health care should be no different. When the largest employer in the United States addresses the cost of providing prescription drugs to its employees, the first step seems obvious. The Federal Government should use its purchasing power to secure preferential pricing for its insurance plans and for its employees.

The next question is how? What method? What means does the Federal Government have to secure such pricing, without a time-consuming overhaul in health care delivery? In review of our current practice, I will propose one, but obviously not the only solution to stimulate some discussion.

In 1991 section 340B of the Public Health Service Act was enacted. This act requires drug manufacturers to provide outpatient drugs to certain covered entities at a reduced price. This process was further simplified through the creation of a prime vendor. This process routinely yields pharmacy savings of 25 to 50 percent for the covered entities, beyond that of PBMs or GPOs. Rather than create a second parallel process for group purchasing, we should look to expand participation in this program to benefit some or all Federal employees and the U.S. Government.

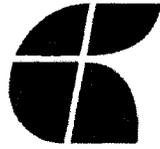
One relatively simple solution would be to modify section 340B of the Public Health Service Act, and the subsequent Pharmacy Affairs Branch definition of what constitutes a patient, at a disproportionate share hospital, to simply include Federal employees within a geographical region. A qualifying entity could then estab-

lish an outpatient pharmacy, complete with mail order and internet capabilities, to provide prescription drugs at markedly discounted prices.

In fact, many 340B hospitals already do this same thing. Since these entities are not allowed to resell or markup 340B prices, a minimal processing and handling fee would be the only incremental cost added to the below wholesale prices. This would not only provide markedly reduced prices, but a highly transparent pricing mechanism. This decreased pharmaceutical cost would be incorporated into the various health plans available to Federal employees, without limiting their choice of insurance product. These savings could then pass through to the employer, in the form of decreased premiums, and to the patient/employee in the form of decreased premiums and decreased co-pays.

Mr. Chairman, I want to reiterate my thanks for inviting me to this hearing. I also pledge my assistance and the assistance of my organization, Caritas Christi Health Care, in combing through this difficult struggle of ensuring access, maximizing quality and minimizing costs in health care.

[The prepared statement of Dr. de la Torre follows:]



Caritas

CARITAS CHRISTI HEALTH CARE

Testimony of Dr. Ralph de la Torre
President & CEO
Caritas Christi Health Care

June 24, 2009

Subcommittee on Federal Workforce, Postal Service
and the District of Columbia

Mr. Chairman, Members of the committee, I want to thank you for inviting me to participate in this hearing. The rising cost of health care, as we all know, is dealing a crippling blow to employers across the United States of America. Escalating premiums suffocate not only the employees but employers who struggle to provide a benefit to their employees. At the forefront of this escalation is the cost of prescription drugs. Controlling prescription drug costs is essential to containing health care costs. Unlike many other contributors to the cost of health care, prescription drugs serve not only in the treatment of illness but as a preventive measure. This is especially true in the treatment of chronic illness. Many recent reports document how escalating co-pays on pharmaceuticals lead to non-compliance on behalf of patients. This non-utilization can lead to the escalation of chronic illness and the subsequent grave implications to patient and employer. As a specific example, patients who fail to comply with medications that control blood sugar or hypertension are more likely to develop atherosclerosis which can lead to heart attack and stroke. For all these reasons, to describe but a few, it is imperative that an employer through the benefits offered its employees control prescription drug costs.

Within the context of my comments, the Federal government is the largest employer in the United States of America. Like all large employers the Federal government should capitalize on its purchasing power to lower its cost of goods and services. When the federal government secures pricing on an airplane, the price varies significantly on the quantity of the order. In fact, this concept is at the very essence of our capitalist economy. Health care should be no different. When the largest employer in the United States addresses the cost of providing prescription drugs to its employees, the first step seems obvious. The Federal government should use its purchasing power to secure preferential pricing for its insurance plans and for its employees.

The next question is how. What means does the federal government have to secure such pricing without a time consuming overhaul in health care delivery. In review of our current practice such a system already exists. In 1992 section 340B of the Public Health Service Act was enacted. This act requires drug manufacturers to provide outpatient drugs to certain covered entities at a reduced price. The process was further simplified through the creation of a "prime vendor." This process routinely yields pharmacy savings of 25-50% for the covered entities. Rather than create a second parallel process for group purchasing we should look to expand participation in this program to benefit federal employees and the United States government. One relatively simple solution would be to modify section 340B of the Public Health Service Act and the subsequent Pharmacy Affairs Branch definition of what constitutes a "patient" at a disproportionate share hospital to include federal employees within a geographic region. A qualifying entity could then establish an outpatient pharmacy, complete with mail order and internet capabilities, to provide prescription drugs at markedly discounted prices. Since these entities are not allowed to resell or mark-up 340b prices, a minimal processing and handling fee would be the only incremental cost added to the below wholesale prices. This decreased pharmaceutical cost would be incorporated into the various health plans available to federal employees without limiting their choice of insurance product. Using a conservative reduction of 30% in pricing and 90% employee compliance, this methodology could save the federal government near \$750 million per annum. These savings could then pass through to the employer, in the form of decreased premiums, and to the patient/employee in the form of decreased premiums and decreased co-pays.

Members of Congress, I want to reiterate my thanks for inviting me to this hearing. I also pledge my assistance and the assistance of my organization, Caritas Christi health care, in helping comb through the difficult struggle of ensuring access, maximizing quality, and minimizing costs in health care.

Extending 340B Discount Drug Pricing to Federal Employees

Background

- The 340B Drug Pricing Program mandates that pharmaceutical manufacturers provide discounts off normal and customary rates when selling to certain healthcare providers – primarily those serving large numbers of low income and indigent families and individuals
 - Established through Public Law 102-585, The Veterans Health Care Act of 1992 (which codified as Section 340B of the Public Health Service Act
 - Manufacturers provide the discounts, no State or Federal tax revenue is used to support this program
 - Greater discounts than Medicaid programs on average
 - Drugs purchased through 340B are exempt from “Medicaid Best-Price Agreements” established by 42USC 1396 R-8

Background

- Qualifying entities:
 - Federally funded “330 Community Health Centers” (:FQHC”)
 - Federally-qualified “look-alike” health centers
 - Some, but not all, disproportionate share hospitals
 - Private, non-profit hospitals with DSH adjustment factors > 11.75%
 - Hemophilia Treatment Centers
 - Ryan White Programs
 - STD and TB Programs
 - Title X Family Planning Clinics
 - Urban 638 Tribal Programs

- Administered by HRSA’s Office of Pharmacy Affairs

Background

- Discounts are off “cost”, i.e. upfront upon acquisition, no backend rebates
- Manufacturers MUST provide 340B pricing if their drug is to be covered by Medicaid
 - Cannot sell covered drugs above 340B ceiling to covered entities
- Discounts vary by drug but generally:
 - Generally, 340B prices are 50% of the “Average Wholesale Price” (“AWP”)

Proposed Structure

- Amend Section 340B to extend the definition of “patient” to include civilian federal employees:
 - allowing “340B Providers” to provide discounted pricing to federal employees
- Establish regional 340B Providers as “designated” pharmacy benefit providers for federal employees:
 - Providers:
 - Must have “retail -like” locations
 - Must provide mail order options with throughput capabilities
- Pay the 340B Providers a small *portion of the savings* as an administrative & handling fee. Dual benefit:
 - Reducing Federal expenditures for insurance / prescription drugs by extending 340B
 - Infusing (by *sharing the savings*, i.e. NO additional federal expenditures) additional capital into 340B Providers, which by definition serve a disproportionate amount of low income and indigent individuals and families

Potential Savings

Total Federal Government Employees	(1)	2,730,050
Average prescriptions per capita	(2)	12.6
Average cost per prescription	(2)	\$ 69.91
Estimated cost of prescriptions for all civilian federal employees		\$ 2,404,808,223
Estimated benefit of 340B drug pricing discounts	(3)	30.0%
Estimated potential savings by applying 340B program to civilian federal employees		<u>\$ 721,442,000</u>

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(1) Census Bureau data (December 2007)

(2) Kaiser Family Foundation: "Prescription Drug Trends", September 2008

(3) Estimated range based on hospital acquisition cost

Potential Savings

	% of Civilian Federal Employees Utilizing This Service		
	50%	75%	90%
(1) Total Federal Government Employees	2,730,050	2,730,050	2,730,050
(2) Average prescriptions per capita	126	126	126
(2) Average cost per prescription	\$ 69.91	\$ 69.91	\$ 69.91
Estimated cost of prescriptions for all civilian federal employees	\$ 2,404,808,223	\$ 2,404,808,223	\$ 2,404,808,223
(3) Estimated benefit of 340B drug pricing discounts	30%	30%	30%
Est. savings by applying 340B program to federal employees	\$ 721,442,000	\$ 721,442,000	\$ 721,442,000
Estimated % of federal employees accessing services via this method	50%	75%	90%
Estimated savings	\$ 360,721,000	\$ 541,082,000	\$ 649,298,000

(1) Census Bureau data (December 2007)

(2) Kaiser Family Foundation: "Prescription Drug Trends", Sept 2008

(3) Estimated range based on hospital acquisition cost

Mr. LYNCH. Thank you, Doctor.
Mr. Merritt, you are now recognized for 5 minutes.

STATEMENT OF MARK MERRITT

Mr. MERRITT. Good afternoon, Chairman Lynch and thank you for your time. My name is Mark Merritt. I am president of the Pharmaceutical Care Management Association, the PBM Association. It sounds like I have my work cut out for me. But that is what we do. We are proud of what we do. We work for the large employers' unions, Government agencies, Medicare Part D, FEHBP of course, and so forth.

And our clients aren't small players. They are big, sophisticated, savvy people who we negotiate very hard against, folks like the drug manufacturers. So it is kind of odd for everybody else to seem like the victim. We often feel that way ourselves as we are negotiating for lower prices, pushing for more generics, pushing for biogenerics and so forth.

But we use a number of tools and strategies, to increase generic utilization. It is a lot more than just the unit cost of the drug that we are involved in. It is all of pharmacy costs. And we view ourselves not as the cause of the complexity of the system, but a result of it, in an attempt to help payers sort through it. To sort through everything from manufacturers retailers, wholesalers, everything that is involved using technology, e-prescribing, different forms of delivery, like mail service delivery and so forth. All of which, in different forms, FEHBP uses.

But we are hired to create these benefit packages for different reasons, I would say, for instance in VA, or Medicaid, because we are hired by clients who want us to create good benefit packages that will retain and attract employees. Particularly the FEHBP, which competes against the private sector all of the time. So to use, I know this maybe a marginal example, but to use a tool like VA uses, of limited formularies of pharmacies, of which they can be dozens of miles away, is not the kind thing that FEHBP would want to use, even though it may well save them money.

Again, it is the client's choice. And clients choose all kinds of different ways to save money. But for the record, the GAO and others have looked at what we do. The GAO has looked at what we have done at the FEHBP, as we have heard earlier. We do save money to the tune of hundreds of millions of dollars a year. The OPM has noted how much we save for them, and that we do it in a consumer friendly way. These aren't the old HMOs of 10 or 15 years ago that saved money by keeping you from doing things and getting you what you need. We provide broad formularies, broad access, generous packages, lots of retail pharmacies, 60,000 retail pharmacies, and so forth.

I should note that PBMs are accustomed to a great degree of accountability. We expect it. We get it on the front end, and the back end, and during the process. These sophisticated purchasers that work with us, not only are working through their HR departments, they hire very expensive lawyers and very savvy consultants to look over all of these contracts before they sign anything with us.

And the Federal trade commission is noted as a very competitive process. There are lots of different PBMs. I know all of these guys

are not very fond of each other. They will steal business in a moment from each other for any little extra bit of fat that is left on there. So the competition drives prices down more than you might think.

It is important to note on the transparency issue, that it is something to be careful with. Intuitively it seems like the more you see the better off you would be. But we went through this during Medicare Part D, where there is a provision to make everything transparent in Medicare drug pricing. And the reason it was considered, I think it was by Senator Grassley and others, is because we need to save money and pay for the drug benefit, much like the discussions we are having now.

They were surprised when it went to the Congressional Budget Office, and they found, not only didn't it save money, but actually increased costs by 10 percent. I think about \$40 billion. And people wondered why. And it was because, ironically, with transparency, especially when it is public, when any of the information can be made public through any means, the beneficiaries aren't the consumers, but it is all of the people we negotiate against. All the people who we play off against each other. The drug makers, drug stores and so forth. They are all competing with each other.

And if they know what their competitor's pricing is, basic economics, so it is not really basic, it is a little more complex than that, but the basic practice is, that economists agree happen, is it reduces any interest to underbid their opponents because they know exactly how low they can go. And if they knew how low we got some of their opponents or some of their competitors, they would be surprised and they would price accordingly.

So transparency, we are for it. There is no uniform definition of it. Different clients want it at different degrees. Some clients don't care at all as long as you hit your numbers. Others really want to pore through the books and see all kinds of different information. That is the client's decision. They can decide on the front end.

But in conclusion, I would say that not only do we look forward to working with you and being helpful, we know this is complicated. That is why we are in existence. We hope that any future discussions of transparency, in FEHBP or elsewhere, focus not just on PBMs, but all of the providers in FEHBP, hospitals, physicians, nursing homes, independent drug stores, drug manufacturers, wholesalers and so forth.

Because we are about 10 percent of the spend, and we are happy to be looked at, but if you are looking at a holistic view of this, everybody should be looked at. And I would also hope that any related legislative proposals that you do consider, that you consider maybe getting them scored from CBL on the front end, to see maybe how they can be made better, and also to make sure that the costs are fully understood, if there are costs.

Thank you very much for your time.

[The prepared statement of Mr. Merritt follows:]



Testimony of Mark Merritt

President & Chief Executive Officer

Pharmaceutical Care Management Association

Before the

**UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
SUBCOMMITTEE ON THE FEDERAL WORKFORCE, POSTAL SERVICE,
AND THE DISTRICT OF COLUMBIA**

“FEHBP’s Prescription Drug Benefits: Deal or No Deal?”

June 24, 2009

Introduction

Good Morning Chairman Lynch, Ranking Member Chaffetz, 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).

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.

In addition to drug rebates, there are several other key reference points for measuring drug 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.

Value of PBMs in FEHBP

PBMs have played a major role in creating broad access to prescription drugs while generating significant savings for health plans and enrollees. Just as they do for all payers, in FEHBP, PBMs 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.

These methods have proven to be successful in lowering the overall costs of drugs. A *Health Affairs*-published report, "National Health Spending in 2007: Slower Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998," found that prescription drug spending growth slowed from 8.6 percent in 2006 to just 4.9 percent in 2007. This was due in part to an increase in generic dispensing from 63 percent of prescriptions in 2006 to 67 percent in 2007, which was encouraged by PBMs through lower or waived copayments and formulary compliance programs such as step therapy. Generic dispensing rates are generally higher in plans administered by PBMs than in other federal programs. This is significant, because every 1 percentage point increase in the generic fill rate can translate into a 1 percentage point reduction in drug costs without shifting costs to members.¹

Success in Medicare Part D

In Part D, PBMs have played a key role in reducing overall program costs well below expectations by generating high levels of generic utilization, offering broad choice of drugs, access to over 60,000 pharmacies, and attaining a continually high rate of beneficiary satisfaction. 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.² According to analysis conducted by PricewaterhouseCoopers, overall savings of Prescription Drug Plans (PDPs) in Part D are also comparable to levels achieved by PBMs in the Federal Employees Health Benefits Program.³

¹ Express Scripts, "Optimizing the Copayment Differential: Impact on Generic Fill Rate," available at <http://www.express-scripts.com/industryresearch/outcomes/onlinepublications/>, accessed September 2008.

² Centers for Medicare and Medicaid Services press release, "Medicare Part D Plan Premiums for 2008 Show Continued Impact of Strong Competitions," August 13, 2007.

³ PricewaterhouseCoopers, "Medicare Part D: An Assessment of Plan Performance and Potential Savings," analysis prepared for the Pharmaceutical Care Management Association, January 2007.

The Role of PBMs in FEHBP and other Commercial Payers

In 2003, the Government Accountability Office (GAO) found that PBMs were successfully managing drug costs while maintaining high levels of access to FEHBP enrollees. Specifically GAO noted:

- PBMs “are central to most FEHBP plan efforts to manage their prescription drug benefits, and PBMs have helped the FEHBP plans reduce what they would likely otherwise pay in prescription drug expenditures while generally maintaining wide access to most retail pharmacies and drugs.”
- PBMs contributed to an 18 percent reduction in the average price for brand-name drugs for Federal Employees Health Benefit Program (FEHBP) enrollees. This, in turn, caused a total annual reduction in drug spending of between 3 and 9 percent for FEHBP plans.⁴

In fact, the Office of Personnel Management (OPM) concurred with the GAO’s findings, stating that “PBMs do help keep costs down while offering excellent access to prescriptions for our consumers.”

OPM has implemented rigorous oversight and transparency requirements on PBM contractors and consistently audits and reviews all details of the pharmacy benefit contract and practices. The information provided by the PBMs to OPM includes financial and utilization information related to the benefit, information on pharmacy network fees, and rebates and discounts received by manufacturers on a drug by drug basis.

The balance that OPM has struck with respect to transparency and competition has enabled the protection and maintenance of proprietary information. The Federal Trade Commission (FTC) and Congressional Budget Office (CBO) both have demonstrated that

⁴ Government Accountability Office, “Federal Employees’ Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies,” GAO-03-19, January 2003.

ensuring confidentiality of proprietary information – e.g., the drug acquisition prices and detailed rebate information – are critical to maintaining price competition among drug manufacturers.⁵

The FTC has warned several states that legislation requiring the wrong type of disclosure could increase costs and “undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford.”⁶ In addition, the Department of Justice and the FTC issued a July 2004 report noting that “states should consider the potential costs and benefits of regulating pharmacy benefit transparency” while pointing out that “vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms.”⁷

Congress also rejected the inclusion of a PBM disclosure mandate as part of the Medicare Modernization Act when the CBO determined such a mandate would cost taxpayers \$40 billion over 10 years.⁸

Comparing Manufacturer Rebates of Commercial Coverage and Part D to Medicaid and Veterans Administration (VA)

When comparing unit price discounts achieved by PBMs 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:

⁵ US Federal Trade Commission & US Department of Justice Antitrust Division, “Improving Health Care: A Dose of Competition,” July 2004; Congressional Budget Office, “Cost Estimate: S 1, Prescription Drug and Medicare Improvement Act of 2003,” page 15. July 22, 2003

⁶ Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004)

⁷ US Federal Trade Commission & US Department of Justice Antitrust Division, “Improving Health Care: A Dose of Competition,” July 2004

⁸ Congressional Budget Office, “Cost Estimate: S 1, Prescription Drug and Medicare Improvement Act of 2003,” page 15. July 22, 2003

- 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, vertically integrated 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 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.⁹ 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.”¹⁰
- 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.¹¹

⁹ Congressional Budget Office. “Pricing for Brand-Name Drugs Under Selected Federal Programs,” June 2005.

¹⁰ Congressional Budget Office. Letter to the Honorable Debbie Stabenow, April 16, 2007.

¹¹ 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 the prices PDPs negotiate in Medicare Part D from the calculation of Medicaid best price. CBO estimated that this exemption – which freed manufacturers to negotiate below best price – reduced spending in the Part D program by 1.6 percent.¹²

According to CBO, “[f]or 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,”¹³ 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].”¹⁴

Biogenics: A Policy That Saves Consumers and Payers Money

Additional savings are possible in managing prescription drug costs using common-sense measures that can be implemented by Congress and utilized by OPM. These include establishing a clean regulatory pathway for biogenics removing loopholes that prevent generics from entering the market and enhancing mail-service pharmacy options. PCMA and the PBM industry look forward to working with you on these and other measures that would provide high levels of access, improve efficiency, and save money for FEHBP and its beneficiaries.

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 FEHBP, Department of Defence, VA, Medicare, and Medicaid billions of dollars. For this reason, PCMA supports H.R. 1427, the Promoting Innovation and Access to Life-Saving Medicine Act. This legislation meets what we believe to be the most important criteria for any biologics legislation Congress considers by:

¹² Avalere Health. “Follow the Dollar: Understanding Drug Prices and Beneficiary Choices Under Medicare Part D,” April 2006.

¹³ Congressional Budget Office. “A Detailed Description of CBO’s Cost Estimate for the Medicare Prescription Drug Benefit,” July 2004.

¹⁴ Congressional Budget Office. Letter to the Honorable John D. Dingell, Chairman of the House Energy and Commerce Committee, January 10, 2007.

- Empowering the Food and Drug Administration (FDA) to use its expertise to determine on a case-by-case basis what scientific data they need to approve comparable and interchangeable products;
- 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 prohibiting frivolous suits that restrict access and delay competition.

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 for their long-term maintenance medications 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.¹⁵ Today, about 20 percent of prescription volume in Medicare Part D 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.¹⁶

¹⁵ 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.

¹⁶ Ibid.

Conclusion

By using PBMs' proven strategies within FEHBP, the commercial market and the competitive Part D framework, these payers have achieved significant savings and value for their beneficiaries in their drug benefits, which provide wide access to medications and pharmacies at affordable prices.

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 all payers.

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.

Mr. LYNCH. Thank you, Mr. Merritt.

Let me start with Dr. Needleman. In your testimony, which was very helpful and we thank you for it. In your written testimony, you cited there were two different reports there, I believe. In trying to do an assessment on the Federal Employees Health Benefits savings from contracting with PBMs. The 2003 GAO report, I think estimated 18 percent, and then there was another report, called the PCMA Report, that had estimated savings at 28 percent.

Dr. NEEDLEMAN. Right.

Mr. LYNCH. That is like a 33 percent difference. What do you think might attribute to that different assessment?

Dr. NEEDLEMAN. It all goes back to the cost base. The PriceCoopersWaterhouse Report, the 2008 report, was working off of retail prices. GAO was just looking at drug pricing, not taking into account the other services, but was looking at wholesale prices as their benchmark.

Mr. LYNCH. I see. Now the suggestion that you made, that folks breakout the costs and the profit administratively, have you seen other plans that break it out that way? And has it been helpful in those instances?

Dr. NEEDLEMAN. Well, one of the questions I would have asked the Rear Admiral if I had had a chance to ask him, was exactly what the pricing looks like under the TRICARE contract. And I would hope you do that since they, in fact, have straight FSS, or other negotiated prices for the drug components. There must be explicit pricing for the other components of the contract as well.

Mr. LYNCH. OK. Dr. de la Torre, thank you as well for coming down at my request, basically. I have to ask you, I was reading the Boston Globe this morning, and I saw that the unfortunate story on the severe budget cuts for Commonwealth care, and this is something that we are all dealing with, and it is that situation that puts pressure on us here to try to find savings in these different program. But this action in Massachusetts will no doubt have implications on the national health care debate. I think we are looking at different examples, different models, and as a participant of that program, do you have certain observations that might be instructive to us during our debate here. What went wrong? And what perils we might avoid?

Dr. DE LA TORRE. Sure. Thank you. I think that the fundamental problem is that there is really three components to health care reform, or health care delivery. Which is really access, cost and quality. And you can't deal with one, i.e., access, without really intertwining the other two, cost and quality. You can't, without addressing the structure of health care delivery say, OK we are going to open the doors to everybody, and not expect the cost to choke everybody or the quality to become abysmal.

So I think the very discussion that is happening in this room, looking at other methods, other structures of providing health care, is the discussion that needs to be had across all of the components of health care. So I applaud you and the committee for looking at this very thing, but I think that is what needs to happen. We have to look at health care's entire structure, not just demand increased access and expect it to not choke us.

Mr. LYNCH. Unfortunately, we have a tendency to look at the fastest mover, and what we are seeing is the price of pharmaceuticals rising at a much faster rate, than say hospital-based care. And I know some of that, at least some of that, is due to higher utilization rates. These new products, new pharmaceuticals actually substituting for what was previously in-house care.

Let me ask you that. You were on one of those financial shows the other day, CNBC, or something like that, and they asked you what are the drivers of costs and you mentioned utilization.

Dr. DE LA TORRE. Yes.

Mr. LYNCH. And for your facilities, your system, I am very familiar with that, how is that a driver? We were looking at the unit costs and product costs, as Mr. Merritt mentioned, how is that utilization rate a driver of costs?

Dr. DE LA TORRE. If you look at the actual per episode health care delivery, there is not a lot of profit in it. Most nonprofit hospitals have margins of 1 percent, 2 percent. Last year I think in Massachusetts, the average community hospital net margin was less than 1 percent. So I mean, those are not margins that drive the Exxons of the world, obviously.

So what is driving this? What is going on? You know, a lot of us think it is utilization. It is, we are using too much health care. It is not that the price of every unit, let us put prescription drugs aside as too high. And what drives that? Well, there are three basic components that drive utilization. One is, which we have heard a lot about, is preventative, it is defensive medicine. It is physicians who over-order studies, who do too many tests, too many examines to kind of prevent themselves from getting sued.

Another component is what I call medicine as a vocation versus a business. And Dr. Atul Gawande had a great article in the New Yorker not long ago, The Cost Conundrum, which I encourage all to read, which addresses this. Which is in some how and in some locations, a group of health care providers, physicians or hospitals, medicine stopped being a vocation and became a business. And if it is a business, then obviously increased utilization makes the business more profitable. And that becomes a driver in and of itself. It becomes the culture of the location.

And then the third component is society-driven utilization. We as a society, and this is where drugs really come into play, we as a society are convinced that if it is newer and more expensive, it has to be better. We as a society spend 25, I have heard estimates up to 30 percent of all health care costs in the last 6 months of life, because as a society we want to live forever. We as a society are very proactive on high end surgery, high end medicines, have to be better than just basic care and preventative care.

So I think those three components really drive utilization, and are really driving the cost of health care across the United States, including pharmaceutical benefits through the roof.

Mr. LYNCH. Let me ask you then, as an employer, I think in your introduction I said that Caritas was 7th or 8th in size of employer, you mentioned this before in our meeting a few weeks ago, how do you address the needs as an employer for your folks?

Dr. DE LA TORRE. Well, the things that we are doing is we are going heavily into primary care. Trying to really emphasize the

preventative medicine. Try to emphasize the contacts with the primary care physician rather than being tertiary driven. We have our own insurance plan, and interestingly enough, we run 340B pharmacies through it, which is a marked reduction in cost.

Mr. LYNCH. Explain how that works, because I think just for someone who is listening and not terribly familiar with the process.

Dr. DE LA TORRE. So on the 340B program, as I was saying, it entails us to buy drugs in disproportionate share hospitals, certain high end disproportionate share hospitals, at a markedly reduced price, statutorily. Some would say an unfairly reduced price. That is a separate discussion. And what we do, is since our employees become our patients in a limited network product, then they become patients of the hospital. They buy pharmaceuticals, and we can give them pharmaceuticals through our hospital pharmacies, which get the 340B pricing.

And that is a marked reduction, well below anything that we can get through PBMs and GPOs for our whole hospital, and we have a fair amount of purchasing clout, as you know. We do between 250 and 300,000 emergency room visits in our system. We do about a million outpatient visits. We do 80 to 100,000 discharges, ballpark figures. So we have a fair amount of market clout. But the 340B pricing really allows us to take it to the next level down.

Mr. LYNCH. Now do you have a gatekeeper type feature on your own health benefit plan, or even pharmaceutical?

Dr. DE LA TORRE. We don't really establish a gatekeeper philosophy. We are trying to, and we are in the process of really incorporating IT. We are spending, as you probably know, \$70 million over 3 years in IT to go completely paperless. Not only the hospitals, but all 1,200 of our Caritas Christi network physicians are going to be on electronic health records within the next year, 18 months. And all of that is going to be tied to our pharmacies also.

We are also bringing in, we have just signed a partnership deal with Microsoft, that is going to provide health log benefits to all of our patients so they can manage and be part of their own health care. I think a lot of this is, in health care overall, is pushing it out to the home. Pushing it out to the patients, out to the communities, where care is. It can be centered, be more preventative and also be more cost-effective. You know how much it costs to provide health care in Boston, not because anybody is ripping anybody off, but because a parking space recently sold in Boston for \$300,000, so cars have to be put somewhere.

Mr. LYNCH. Right.

Now, Mr. Merritt, I understand the competitive model that is referred to with pharmacy benefit managers; however, in practice, or at least from where I sit, there is so much complexity there, that it is difficult to see how folks could compete on price, when you can't even figure out what the price is. And it is especially difficult for some of these plans that might not have the degree of sophistication that is necessary. I mean, when my auditors can't figure out what the price is, and they are professionals in that specific area, how does that competitive model actually work if you have such complexity there and lack of transparency?

Mr. MERRITT. Well, first of all, not many people do what you are doing right now, and I applaud you for it. Really taking the time

to try to learn it. It is very complex. But the savings are real, because it is not just about the drug unit costs, it is about relationships with drug stores, and wholesalers and manufacturers. It is about using technology.

We championed a bill last year on electronic prescribing and Medicare, which the president added more funding to in the stimulus package, which we really appreciate. It is a people don't know what their drugs are, they don't know what drugs are out there that they are taking, they don't know the cost share, and they don't know the alternatives. The doctors don't know. So there is a big lack of knowledge there in the physician community.

In terms of how drugs are negotiated, you are right, going up against the pharmaceutical industry isn't easy. But it is a competitive system. And I always say this, people don't have to use a PBM, and I don't say that in a kind of snide way, it is just that we add real value and people pay us to do things and they wouldn't do that unless the savings were really big. And again, these unions and automakers, these are not pushovers, and the Medicare Part D program, which has rigorous transparency, rigorous accountability, lots and lots of regulations.

So we can deal with that because we do add value. But the only thing I can say, and the specific answer to your question is, our job is always to remain on the cutting edge in finding out where any fat is. We are kind of like the shark in the eco sphere, nobody really wants us there, but we play a vital role of keeping things going, keeping folks honest. And it is very hard.

But it is very effective. The savings are real and most of the things that are said about PBMs are said by folks from either the drug store community or a pharma or others, and then honest people, who just sincerely are trying to figure it out. But when folks like GAO or the Federal Trade Commission or others look into it, really do a thorough, exhaustive study, the results are usually pretty good and usually validate what we do and that it adds real value.

Mr. LYNCH. That has never been in question. I believe you were here for the testimony of the Inspector General for the Office of Personnel Management, and despite his description of the difficulties that he was having in ascertaining value and wading through the complexity of it, he said that the pharmacy benefit managers were a good deal, a good model to use and were of high value. But we did say we have a lot of work to do in order to make it more transparent so that we can be assured of that.

Mr. MERRITT. Can I give you one more example? I don't mean to belabor this but, there are a lot of tools that don't get used because of special interests, for instance, home delivery. Seniors love it in Medicare, a 90 day supply, it saves a ton of money, increases adherence, people love it. Medicare could save probably \$30 billion over 10 years if they used that more aggressively. I am sure FEHBP and other programs could too. But because of pressure from various special interest groups who don't want that to happen, like the independent drug store or a lot of your others, it is always held back.

Mr. LYNCH. I am sorry, Mr. Merritt. What are they not taking advantage of?

Mr. MERRITT. Home delivery, mail service delivery.

Mr. LYNCH. Oh. I see. Yes.

Mr. MERRITT. Some retailers use it. PBMs use it. It saves a fortune. Very, very popular with consumers, and we are always encouraging clients to use it. More clients are using it now in these economic times because it saves money and they realize their people like it. But sometimes policymakers have a tough time addressing that because of other concerns. And so we would say that on issues like that, on issues like bio-generics, which we strongly, strongly support, there are policies that can help move this along. And we want to do our part, as PBMs, but we also want to offer any counsel we can of ways that we think can help finance health reform or other things that you are looking to finance.

Mr. LYNCH. I appreciate that.

Dr. Needleman, earlier, in your written testimony anyway, you mentioned that the HR Policy Association certifies PBMs that comply with certain standards. Do you know if the larger pharmacy benefit managers like Medco and CareMark, ExpressScripts, that were mentioned earlier, did these folks have that same certification?

Dr. NEEDLEMAN. The short answer is yes. A large number of them do. There is actually on their Web site, which is cited in my testimony, there is a list of which PBMs have been certified by the program, and it includes a number of the large ones that are currently operating within FEHBP.

Mr. LYNCH. And if they agree to meet those standards, are they required to do so across business lines. Can they do it in one area and be in noncompliance in another?

Dr. NEEDLEMAN. Based upon the conversation I had with Ms. Smith, yes, on the first panel—

Mr. LYNCH. Oh. Sue Hayes.

Dr. NEEDLEMAN. Yes. Prior to the first panel, what she indicated is the PBMs are offering transparent pricing, and they were also offering traditional pricing. And the net prices that are coming out for some reason that cannot explain by any economics I have been trained in, the transparent pricing is coming out higher.

Mr. MERRITT. I can explain that, if you are interested, but that is another issue.

Mr. LYNCH. Mr. Merritt, do you want to take a crack at that?

Mr. MERRITT. I will. I will. I am sorry. If I don't do it nobody else will.

Mr. LYNCH. That is why you are here.

Mr. MERRITT. That is why I am here. I will play my role here. The reality is the market dictates what we do. These companies are not fans of one another, these PBMs. They are looking to steal business all the time. If clients want a transparent product that is cheaper and it can be priced for that, they are going to get it. All of this implies that there is some sort of conspiracy to avoid transparency—

Mr. LYNCH. You have to admit, it doesn't look good. When you have to pay extra for transparency.

Mr. MERRITT. I know. But the reality is all of our companies would say they have transparent products that are better than their competing companies. They are transparent in different ways.

But we do know this, the marketplace is very agnostic on transparency, mostly they just want to hit their numbers. I mean in other words, they see transparency as a subset of the cost issue. When costs go up, they want to say, hey, why are the costs going up. Where is the fat in the system? I want to know what is going on.

If there is transparency and it doesn't reduce costs, and this gets back to what CBO and others have said, that is a problem. If there were more transparent products that save money, our companies would be all over it. They know what folks like you are looking at, and regulators and policymakers. They want to be as transparent as possible. They want to position themselves as the transparent, cheaper company. So to the degree that they are able to do that, they will. Where they are not willing to go, is a situation that will open up all of the pricing strategies with drug companies and the drug stores, to the drug companies and the drug stores, either through consultants or others. They put us in a position when we are negotiating, of playing poker against these guys with all of cards facing up, and we can't negotiate any savings.

So just from pure market, pure selfishness, pure market forces, any of our companies would love to offer a transparent product that was much cheaper, if one existed, and to the degree there are those, they are going to offer them.

Mr. LYNCH. OK. Earlier today we were talking about the possibility of classifying the PBM as a subcontractor, requiring them to—and I am actually going to introduce legislation to do just this, get them into that Federal Acquisition Regulation, because I can't understand the system you are using now, so I am actually trying to translate what you are doing into an understandable format, so that we can figure out what we are paying here.

It seems like a lot to do, to just get some clarity on this, but I am willing to do it because I don't think there are that many more options. What is your response to that? How do you think your PBMs will respond to that? Being put, all of them, not just some, but all of the PBMs competing in that Federal acquisition regulatory format?

Mr. MERRITT. Well, we do a lot of different subcontracting work. I would have to brush up on what exactly the details were here. And I would also want to see, again, that it really saved money. And if there were transparency provisions that actually helped you get where you are going and generate a real savings. That is something that we would want to take a look at.

We would mention, however, and this is an obvious point, I don't mean to go back to it but, FEHBP, despite everything we have heard today is a very popular program, including the drug benefit. People like it. You don't hear a lot of people, and maybe you do. I am not in FEHBP and you probably are. I don't hear a lot of people saying, gosh, I hate that FEHBP plan. I hear them saying, hey, it is pretty good. I am a Federal employee. It is one of the perks. It is why I am there.

Mr. LYNCH. But the taxpayer is picking up the tab.

Mr. MERRITT. Yes.

Mr. LYNCH. Do you know what I mean?

Mr. MERRITT. No, no. I agree.

Mr. LYNCH. They are not paying for it, so sure, it is a good deal.

Mr. MERRITT. You know it is a good deal, but then the FEHBP is always competing for employees and doing it on their benefits, so they don't want to skimp too much either. So we will give skimpy benefits, or generous benefits, depending on how much people want to pay and what they want to accomplish. But to answer your question, we would take a look at it is all I can say. I am not that familiar with it, but we would be happy to take a look at it and work with you and your staff on it.

Mr. LYNCH. OK. Well, as I have with the other two panels, obviously I didn't hit all of the landscape of issues that could arise in this, but I am going to ask you, if there is some area that we missed, or some area you wish to amplify or emphasize, just take 2 minutes, starting with Dr. Needleman.

Dr. NEEDLEMAN. Thank you.

First I want to just reiterate the point that has been made by me, Mr. Merritt, others of the potential of real value added from the PBMs. They have real expertise in claims administration, drug/drug interaction, working with the pharmacies, working with patients, all of which should be acknowledged and is a service that is probably worth paying for. Having said that, everything that Mr. Merritt said about the role of the PBMs in dealing with clients, and providers and negotiation could also be said about health insurance and managed care providers, all operating under administrative service only contracts, with far more transparencies than we see in the PBM contracts.

If we are looking at transparency, there are models. I would encourage the committee to take a closer look and get more information about exactly how TRICARE is paying for the administrative services under its PBM contract, given that it is paying clearly scheduled prices for the drugs themselves.

Those are my specific comments about the nuts and bolts. I think one of the issues that the committee needs to think about, is the nature of the FEHBP program. It has been run as essentially a private sector program with the Federal Government operating as a private sector employer, in terms of the way it contracts with health plans. Some of the changes that I have heard discussed today, some of which I would possibly endorse, if with additional study, involve changing that relationship. The DOD relationship, the VA relationship is all very different than an employer relationship with health plans. So you need to think about whether you are really prepared to walk down that road in order to achieve cost savings.

And finally, in that regard, part of the way in which the plans get cost savings, DOD, VA, is through a quite explicit use of formularies for sole-source, branded, patented drugs. The PBMs are also doing that and the individual health plans within FEHBP are doing that. So it is not unusual to see formularies in Federal plans, but in order to achieve some of the kinds of negotiated price savings that potentially you are talking about here, if you are going with a single point of entry for the Federal employees, you will have to be prepared to negotiate a well-constructed, well-thought through formulary that will apply to all of the Federal employees rather than the individual formularies that you are seeing in the

FEHBP plans. You need to think about whether you are prepared to take that route.

Mr. LYNCH. Very helpful. Thank you, Dr. Needleman. Dr. de la Torre.

Dr. DE LA TORRE. Sir, I want to begin by just echoing what Dr. Needleman just said, about centralizing a formulary and really using the purchasing power of the Federal Government to its benefit. I think as we sit where we are now in health care, fundamental change needs to happen. It can't be small incremental change. We need to do something big and drastic.

We have to get used to the fact as citizens, that we can't have everything all of the time in the most convenient location. It is just too expensive. I think it comes down to something very simple. I mean what is the cost of the drug, what do you pay the pharmacy, and the markup. And then everything else is a benefit or a potential service that is provided.

And I think we just need to look at it that simply. I mean, the big pharma said, we are going to help provide \$80 billion over 10 years. Well, if you use the FSS schedule, or if you use 340B, hey, I just found the first \$5 to \$10 billion for them. They only have \$70 more to find on their own. So I would take them up on it.

Mr. LYNCH. That is a great point. Thank you, Doctor.

Mr. MERRITT. First, I should have mentioned this earlier, but I did use to live in Norwood.

Mr. LYNCH. I knew there was something I liked about you, Mr. Merritt.

Mr. MERRITT. No. I was born in Virginia, but my next door neighbor was Chet Curtis, to age myself, I think he was married to Natalie Jacobson, I am not sure if it was before or after.

Mr. LYNCH. We won't go there.

Mr. MERRITT. We won't go there, but anyway, it is too late now but I thought I would throw it in there. I would just say, in conclusion, thanks for your time, thanks for all of your focus on this. Spending hours on this. I don't think I have ever seen a Member of Congress spend this much time on this. I really appreciate that. We feel like the more people learn about us, the better. We are not hiding from that. It is just difficult to explain this sometimes.

I would just suggest that whatever solutions you offer in regards to transparency, that you don't make the mistake that the rest of the Medicare Program has made with doctors and hospitals, where you move to a cost plus basis. Where you say, well, I don't care what you do, and I am just going to pay you a little percentage on top, I just want to see everything you do.

The danger in that, and again we have seen this with doctors and hospitals, but in the drug space the danger is, you want to make sure we have incentives to generate even more savings and for PBMs to compete against each other to generate more savings. You don't want a situation where we get paid the same amount if we dispense a generic or a brand. Or that if we don't care if it is delivered by mail or just at a drug store. If we are going to get paid anyway, why do we care. That is the one reason why the only part of Medicare that was saving money, is the one that we administer, Medicare Part D, which is coming 30 percent under budget, which is unheard of for a Federal program.

Now Med D is interesting because it is the biggest, probably the most successful Federal initiative that neither party wants to take credit for, but for whatever reason, it is working and we are part of it. And it is counterintuitive, but I would just make sure that the incentives are really strong. Because we can save a lot more money than we are right now. And hopefully, if there is a silver lining to this whole era of all of the deficits and so forth, it will let people and policymakers take a second look at other ways we can save money. So we would be happy to work with you on ways to do that. Thank you for your time.

Mr. LYNCH. Thank you. And on that note, we do appreciate your willingness to come here and help us. And this is an ongoing process. And the bottom line for us is the bottom line. We want to save money. There are no good guys and bad guys in this thing, we have an obligation here, to try to provide these products in health care at the lowest responsible price that we can for our Federal employees.

But again, I want to thank you each for your testimony. You did a great job, helped the committee a great deal, and I want to thank you for your time here. Have a good day.

Mr. MERRITT. Thanks, Mr. Chairman.

Mr. LYNCH. This hearing is now adjourned.

[Whereupon, at 6:23 p.m., the subcommittee was adjourned.]

