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Before Employee Benefits Security Administration
U.S. Department of Labor

Hearing on
Section 408(b)(2) Regulation
Fee Disclosures to Welfare Benefit Plans

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I appreciate the opportunity to come before you today and testify about fee disclosures to welfare benefits plans under Section 408(b)(2). The Employee Retirement Income Security Act (ERISA) welfare benefit plans include a wide range of services across the health care industry. I submit the following comments on a specific segment of the health care industry: pharmacy benefit managers (PBMs).

As my testimony outlines, extending the fee disclosure provisions to PBMs will benefit ERISA beneficiaries by enabling plans to have the full set of information necessary to make PBM markets work effectively and secure benefits at the lowest cost. Greater disclosure will give plans the necessary tools to detect and prevent conflicts of interest and secure all the appropriate compensation, including undisclosed indirect compensation. Plans currently do not fully benefit from PBM cost control efforts because of conflicts of interest and the ability of PBMs to hide undisclosed indirect compensation, such as rebates from drug manufacturers. Extending the fee disclosure provisions will enable plans to secure the full benefit of compensation received on their behalf.

I am a Senior Fellow at the Center for American Progress Action Fund and have practiced antitrust law for over 25 years, both in the government and in private practice. Prior to entering private practice, I was the Policy Director of the Office of Policy and Evaluation for the Bureau of Competition of the Federal Trade Commission and attorney advisor to Chairman Robert Pitofsky and helped direct the first antitrust cases against PBMs.[1] I have counseled health plans, PBMs, pharmacies, and consumers on PBM competition and consumer protection issues. My comments are based on those decades of enforcement and real world experience.

Today's hearing comes as a result of EBSA's efforts to thoroughly understand and effectively reform the fee disclosures to welfare benefit plans under Section 408(b)(2). The recent hearings leading up to the release of the interim final rule on disclosure fees and conflicts of interest affecting retirement plans spurred debate on the appropriate level of disclosure by PBMs. I have testified before Congress on how transparency can improve competition in PBM markets.[2] The PBM market is highly concentrated, PBM contracting practices are complex and the markets are opaque. This provides a fertile environment for deceptive and fraudulent practices – in the past 6 years the three major PBMs have settled 4 major cases brought by state attorneys generals resulting in over $370

[1] Merck & Co. Inc. and Merck-Medco Managed Care, L.L.C, FTC Agreement Containing Consent Order. File No. 951 0097. Available at http://www.ftc.gov/os/1998/08/9510097agr.htm. Eli Lilly and Company, FTC Order Opening and Setting Aside Order, File No. C-3594. Available at http://www.ftc.gov/os/1999/05/elililly.htm.
[2] David Balto. "The Effects of Regulatory Neglect on Health Care Consumers." Testimony before the Consumer Protection, Product Safety and Insurance Subcommittee of the Senate Committee on Commerce, Science and Transportation hearing on "Competition in the Health Care Marketplace." July 16, 2009.

million in penalties and fines. Much of the concern raised in these cases involved undisclosed indirect compensation of the type addressed in the proposed rule. Thus, I argue that the disclosure improvements established by the interim final rule should be applied to welfare plans and PBM services. Greater disclosure is needed in the PBM industry to protect plans, consumers and reduce costs.

I. PBMs no longer serve as "honest brokers" and engage in a wide range of anticompetitive conduct.

Although PBMs offer a great deal of promise in terms of the potential to control pharmaceutical costs, there is a pattern of conflicts of interest, self-dealing and anticompetitive conduct, all of which ultimately means that consumers pay far more for drugs than necessary. The three dominant PBMs (Medco Health Solutions, CVS Caremark and Express Scripts) have been plagued with opaque business practices, limited market competition and widespread allegations of fraud. The facts are clear: while PBMs may well prove a necessary expedient in lowering the cost of healthcare, measures must be taken to ensure that they operate as they are supposed to.

The fundamental elements for a competitive market are transparency, choice and a lack of conflicts of interest. This is especially true when dealing with health care intermediaries such as PBMs and health insurers where information may be difficult to access, there are agency relationships and securing adequate information may be difficult.

Why are choice, transparency, and a lack of conflicts of interest important? It should seem obvious. Consumers need meaningful alternatives to force competitors to vie for their loyalty by offering fair prices and better services. Transparency is necessary for consumers to evaluate products carefully, to make informed choices, and to secure the full range of services they desire.

When dealing with intermediaries, it is particularly critical that there are no conflicts of interest. A PBM is fundamentally acting as a fiduciary to the plan it serves. In the PBM market, the service a PBM provides is that of being an "honest broker" bargaining to secure the lowest price for drugs and drug dispensing services. When a PBM has an ownership interest in a drug company or a pharmacy chain, or has its own pharmacy dispensing operations, it is effectively serving two masters.

PBMs entered the health care market as "honest brokers" or intermediaries between heath care entities. Health plans and plan sponsors agree to a negotiated fee and contract with PBMs to administer drug claims and serve as a third-party broker with pharmaceutical manufacturers. PBMs can play an important function in health care markets by setting up pharmaceutical benefit networks and adjudicating pharmaceutical claims. However, the role of the PBM has evolved over time and increasingly PBMs have found sources of indirect compensation, and by failing to adequately disclose the compensation (typically from manufacturers), or engaging in misleading disclosures they are able to "play the spread" and pocket the indirect compensation. As a result PBM profits have skyrocketed. From 2003 to 2007, the three largest PBMs—Medco, Caremark and Express Scripts—nearly tripled their annual profits from $966 million to over $2.7 billion. In addition, there has been tremendous consolidation among PBMs, so the three major PBMs (CVS/Caremark, Express Scripts and Medco) now have over 80% of the national PBM market.[3]

Facing weak transparency standards, PBMs frequently engage in a wide range of deceptive and anticompetitive conduct that ultimately harms and denies benefits to consumers. Some PBMs secure rebates and kickbacks in exchange for exclusivity arrangements that may keep lower priced drugs off the market. PBMs may switch patients from prescribed drugs to an often more expensive drug to take advantage of rebates that the PBM receives from drug manufacturers. In addition, PBMs derive their enormous profits from the ability to "play the spread" between

[3] The American Antitrust Institute provided a white paper assessing the structural issues posed by the proposed Express Scripts/Caremark merger. *See* American Antitrust Institute, *Express Scripts' Proposed Acquisition of Caremark* (2007), *available at* http://www.antitrustinstitute.org/archives/files/AAI_Express%20Scripts_Caremark_2-14_021520071110.pdf.

pharmaceutical manufacturers, pharmacies, and health care plans. (All of these qualify as undisclosed indirect compensation.) Later in my testimony, I will go into mechanics of these deceptive pricing practices, but it is important to note that these pricing tactics ultimately lead to higher prices paid by plans and patients.

In the past 6 years alone, a coalition of over 30 state attorneys general have brought several cases attacking unfair, fraudulent and deceptive conduct. Between 2004 and 2008, the three major PBMs have been the subject of six major federal or multidistrict cases over allegations of fraud; misrepresentation to plan sponsors, patients, and providers; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. These cases listed below, resulted in over $371.9 million in damages to states, plans, and patients so far.

- United States v. Merck & Co., Inc., et.al – $184.1 million in damages for government fraud, secret rebates, drug switching, and failure to meet state quality of care standards.

- United States v. AdvancePCS (now part of CVS/Caremark) – $137.5 million in damages for kickbacks, submission of false claims, and other rebate issues.

- State Attorneys General v. Caremark, Inc. – $41 million in damages for deceptive trade practices, drug switching, and repacking.

- State Attorneys General v. Express Scripts – $9.5 million for drug switching and illegally retaining rebates and spread profits and discounts from plans.

II. A Lack of Transparency allows PBMs to "play the spread," leading to higher costs for plan sponsors and patients.

PBMs earn enormous profits by negotiating rebates and discounts with drug manufacturers in exchange for promoting certain drugs on their preferred formulary or engaging in drug substitution programs. PBMs also negotiate contracts with pharmacies to determine how much the pharmacists will be paid for dispensing medication and providing services. By paying a lower reimbursement rate to pharmacies, but failing to adequately disclose reimbursement rates PBMs can generate more revenue. In both respects, PBMs can play the spread by failing to disclose these forms of indirect compensation. The failure to disclose these payments denies purchasers important information that impacts their buying decisions. As a result, this lack of information often results in higher costs for consumers, health plans, employers, and other plan sponsors.

PBMs are free to "play the spread" between manufacturers, pharmacists and plans because of a lack of disclosure. Unclear and inadequate disclosure of rebates and discounts undermine the ability of plan sponsors to compare competing proposals. Because rebates, discounts, and other fee structures remain undisclosed, plan sponsors cannot clearly identify and choose PBMs offering the highest value services. PBMs' promise of controlling pharmaceutical costs has been undercut by a pattern of conflicts of interest, self-dealing, deception, and anticompetitive conduct. The dominant PBMs have been characterized by opaque business practices, limited market competition, and widespread allegations of fraud.

III. Increased disclosures by PBMs have resulted in price decreases and significant savings for health plans.

Because of the enforcement activity focusing on PBMs, there has been a great deal of attention surrounding transparency. Transparency is a somewhat ambiguous term, but in this context, David Calabrese in *Managed Care Executive* provides a useful definition:

> Transparency is a form of business practice involving full disclosure of costs and revenues, allowing the customer to make more well-informed decisions regarding purchases. In the PBM industry, transparency lays the groundwork for more simplified PBM-client business relations, more accurate financial modeling and performance metrics and a greater comfort level among PBM consumers. 'Transparency,' however, is a relative term used freely in the marketing efforts of many PBMs. The genuine commitment to transparency lies in the actual business practices the PBM invokes to support this claim. 'True transparency' is a model in which all PBM revenue streams [drug-level rebates, funding of clinical programs, administrative fees, service fees, management fees, research/educational grants, etc.] are fully disclosed to the payer; the full value of retail and mail-order pharmacy discounts is passed onto the client; data is shared with the client; and the client is given ultimate decision-making control over its drug benefit design and formulary management. It is this commitment to true transparency which has begun to differentiate newer PBMs.[4]

Responding to the numerous enforcement actions, both a handful of states and Congress[5] have taken measures to enact transparency provisions by requiring some degree of disclosure of rebates and other revenue.[6] In addition, in the multistate enforcement action against Caremark, 30 state attorneys generals required rebate disclosure.[7] Finally, some large sophisticated health plans have negotiated for greater transparency.

The most significant disclosure requirements are incorporated in The Patient Protection and Affordable Care Act of 2010. PPACA works to shine light on spread pricing and undisclosed manufacturer agreements by requiring additional data reporting from PBMs that manage contracts under Medicare Part D or the state Exchanges. These PBMs must provide regulators with data on the percentage of all prescriptions that are provided through retail pharmacies compared to mail-order facilities and the generic dispensing rates for each type. PBMs must also submit the aggregate amounts and types of rebates and discounts or price concessions that the PBM negotiates on behalf of a plan. Importantly, PBMs must disclose how much of these rebates and discounts are "passed through" to the plan versus kept as company profits. In addition to this information, PBMs must also supply regulators with the aggregate difference between the amount paid by the plan and the amount the PBM pays the retail and mail-order pharmacy and number of prescriptions dispensed.[8]

In addition to the disclosure provisions established by PPACA, many plans have recognized the importance of transparency, especially plans that represent government entities. Increasingly very powerful plans are negotiating for transparency and securing significant savings. Large plan sponsors, such as universities, states, and federal programs have recently learned that they can achieve substantial cost savings by opting for contacts with transparent PBMs that disclose negotiations with manufacturers or simply managing their own pharmacy benefit. For example, TRICARE, the federal health plan for military personnel and their families, anticipates savings of $1.67 billion by negotiating its own drug prices, including rebates, rather than going through a PBM. The University of Michigan has saved nearly $55 million by administering its own plan for the past six years. Similarly, New Jersey projects savings of $558.9 million over six years and Texas expects savings of $265 million by switching to a transparent PBM contract. Instead of managing drug benefits through a traditional PBM, TRICARE, University of Michigan, New Jersey and Texas are be able to engage in a more transparent negotiation process and reduce costs. Each of these examples demonstrates that disclosure can improve competition and reduce costs to plans and consumers.

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[4] Calabrese, David. *Managed Care Executive*. May 1, 2006.

[5] I will discuss the transparency provisions under PPACA. However, Under the MMA, PBMs that serve Part D Plans are also required to disclose to HHS all manufacturer rebates and price concessions.

[6] Less than a handful of states have enacted significant transparency standards for PBMs. Even in these cases, transparency provisions may only apply to state employee benefit plans such as the Texas State Employee Health Benefit Plan. Transparency regulation by states is inadequate to address the ongoing problems in the market.

[7] *See, e.g.*, State of Texas v. Caremark (2008).

[8] PPACA. Title VI, Subtitle A, Section 6005.

Some might suggest that if some states and the federal government are regulating and private parties can negotiate for transparency, that further regulation by DOL is unnecessary. They are mistaken. First, less than a handful of states have implemented transparency provisions. Second, the PPACA transparency provisions only apply to plans that are in the state Exchanges and the Medicare Part D program. Third, the fact that some powerful buyers can negotiate for certain levels of transparency does not mean that transparency regulation is unnecessary. These plans can negotiate for transparency because they have clout; but all plans and their subscribers need the protection of transparency. That is why regulation is necessary.

Some may suggest that disclosure provisions may lead to higher costs. The representatives of the PBM industry in an earlier filing argued transparency would increase costs citing a 2003 CBO report based on an a proposed amendment to the Medicare Modernization Act. There are several reasons why that argument should be dismissed. First, the CBO estimate is over 6 years old. Since that time there have been numerous multistate actions demonstrating ongoing fraud and deception. Second, in the *Caremark* case, over 30 state attorneys generals required transparency as part of their consent order. Third, since that time numerous plans have negotiated for transparency and have achieved significant cost savings. Finally, there is no evidence that any additional transparency from these private plans or state regulation have led to collusion or any other conduct to raise costs. Simply, if transparency was bad, why would Congress enact it, state attorneys generals require it, and plans, especially government plans, work so hard to secure it?

For similar reasons, the PBM industry's reliance on FTC studies or advocacy is misguided. For example, the PBM industry relies extensively on hearings conducted by the FTC in 2004 which suggested that the PBM market was competitive. In addition, they rely on other FTC letters to state regulators on PBM transparency provisions. Much of this advocacy including the hearings preceded the numerous attorneys general enforcement actions which uncovered significant evidence of ongoing fraud and deception involving all of the major PBMs. Moreover, the FTC's suggestion that some PBM clients may be able to secure accurate information on rebates does not discount the need for regulations to protect all purchasers of PBM services. Indeed the FTC notes that "large, sophisticated repeat-purchasers of health care services" can use useful tools to contract with PBMs. But smaller plans lack these tools and are more vulnerable to deception or conflicts of interest by PBMs.

The issue of whether transparency would lead to higher costs was debated during the enactment of PPACA in 2009 and PBM advocates asked CBO to reaffirm that transparency would lead to significantly higher costs. CBO rejected that position. In 2010, the CBO estimated that PBM transparency standards established by the PPACA would result in zero increased costs. The significant reduction in cost estimates represents that CBO recognizes the potential benefits and unlikely risks of greater transparency. Additionally, if concerns over the risks of disclosure still persist, confidentially provisions can be established to protect the flow of information from PBMs to plans and beneficiaries. The exchange of sensitive information between competitors can be reduced through confidentiality agreements and the disclosure of information to only regulatory agencies instead of market participants.

IV. The fee disclosures for retirement plans under 408(b)(2) established by the interim final rule should be applied to welfare benefit plans including PBM services.

The standards established by the interim final rule for disclosure fees and conflicts of interest affecting retirement plans should broadly apply to welfare benefit plans. PBMs operate with little transparency and engage in deceptive practices such as drug switching and spread pricing. Without transparency, PBM profits will continue to rise exponentially at the expense of plans and patients. Broadening fee disclosures will produce substantial savings for plans and decrease patient expenditure on premiums and prescription drugs.

When establishing transparency standards for PBMs, the term "compensation or fee" should be defined as broadly as possible. The following items should be included in the definition of "compensation or fee":

a. Discounts received by a PBM with respect to its acquisition of goods and services for resale or in connection with service to be rendered by the PBM and any related profits;

b. Income earned by a service provider with respect to the provision of plan benefits; and

c. Fees received by a service provider for services performed for or on behalf of a third party, provided that the services performed are part of an independent fee for a service relationship.

In addition to broadening the definition of "compensation or fee," we disagree with those who argue that a PBM should not be obligated to disclose specific information regarding its contracts and arrangements with third parties if the information constitutes a trade secret or if the information is not generally known to the public and affords the PBM a competitive advantage. This exemption would basically negate the value of requiring additional disclosure. PBMs claim that they use protected information such as rebates, discounts, and competitive reimbursement rates to achieve savings for plans. These payments which are sometimes considered "indirect compensation" should be subject to disclosure regulations. The savings experienced by TRICARE, University of Michigan, New Jersey and Texas demonstrate that this information can be disclosed without resulting price increases. Expanded fee disclosures with limited restrictions will ultimately foster competition and cost control within the PBM market.

Conclusion

I appreciate the opportunity to present my views on the crucial need for greater fee disclosure among the PBM industry. The establishment of standards to disclose otherwise undisclosed indirect compensation will help restore PBMs to their role as "honest brokers" and facilitate greater competition in health care markets. Thank you for your time.