

Advisory Council on Employee Welfare and Pension Benefit Plans

Report to the Honorable Thomas E. Perez,
United States Secretary of Labor

PBM COMPENSATION AND FEE DISCLOSURE

November 2014

NOTICE

This report was produced by the Advisory Council on Employee Welfare and Pension Benefit Plans, usually referred to as the ERISA Advisory Council (the "Council"). The Council was established under Section 512 of ERISA to advise the Secretary of Labor on matters related to Welfare and Pension Benefit Plans. This report examines PBM Compensation and Fee Disclosure. The contents of this report do not represent the position of the Department of Labor (DOL).

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ABSTRACT

The 2014 ERISA Advisory Council examined whether Pharmacy Benefit Managers (“PBMs”) should be required to disclose fees and compensation to sponsors of ERISA health plans in order for sponsors to satisfy their obligation to pay only reasonable compensation to entities that provide goods and services to ERISA plans. *See* ERISA, Section 408(b)(2). In 2012, the U.S. Department of Labor (“Department”) issued regulations requiring providers to disclose direct and indirect compensation to pension plans (“Section 408(b)(2) Regulations”). The Department reserved the question of whether the Section 408(b)(2) Regulations should apply to welfare plans. After receiving testimony and information from multiple sources, including representatives of PBMs, plan sponsors, plan consultants, plan auditors, pharmacy groups, governmental agencies, and other interested persons, the Council recommends that the Department should consider making Section 408(b)(2) Regulations applicable to welfare plan arrangements with PBMs, and thereby deem such arrangements reasonable only where PBMs disclose direct and indirect compensation, including compensation paid among related parties such as subcontractors, in a manner consistent with current Section 408(b)(2) Regulations. The Council also recommends that the Department should consider issuing guidance to assist plan sponsors in determining whether to and how to conduct a PBM audit of direct and indirect compensation.

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I. INTRODUCTION

Section 406(a)(1)(C) of the Employee Retirement Income Security Act of 1974, as amended (“ERISA”), prohibits the furnishing of goods, services, or facilities between a plan and a party in interest. Because any person or entity providing goods or services to an employee benefit plan is considered a party in interest, ERISA Section 3(14)(B), a service relationship between a plan and the provider is considered a prohibited transaction under the statute.

Because Congress recognized that employee benefit plans need to purchase goods and services in order to administer plans and provide benefits to participants and beneficiaries, it established an exemption from the prohibited transaction rules in Section 408(b)(2). That Section provides that a plan may purchase goods and services from a party in interest so long as (a) the arrangement is reasonable, (b) the goods and services are necessary for the establishment or operation of an employee benefit program, (c) and “reasonable compensation is paid therefor.” The issue before the Council focuses on this third element, i.e., how a fiduciary may determine whether “reasonable compensation” is being paid for goods and services. This issue arises not only under Section 408(b)(2), but also under ERISA Section 404(a)(1), which requires plan fiduciaries to act prudently and solely in the interests of the plan’s participants and beneficiaries and for the exclusive purpose of providing benefits and defraying reasonable expenses of administering the plan.

In 2010, the U.S. Department of Labor (“The Department”) held hearings entitled “Hearings on Reasonable Contracts or Arrangements for Welfare Plans under 408(b)(2) – Welfare Plan Fee Disclosures” (“2010 Welfare Plan Hearings”). The Department heard testimony from various sources regarding the need for and potential scope of mandatory compensation and fee disclosures from providers who offer goods and services to employee welfare benefit plans. A significant portion of the testimony related to services provided by Pharmacy Benefit Manager (“PBM”) organizations to ERISA-governed health benefit programs. Witnesses requested 408(b)(2) regulatory relief because of expected Regulations under the newly enacted Affordable Care Act (“ACA”).

On February 3, 2012, the Department issued final 408(b)(2) Regulations, 29 C.F.R. Section 2550.408b-2. The Regulations generally require providers of goods and services to disclose both direct and indirect compensation to enable pension plan fiduciaries to determine whether they are paying reasonable compensation for those goods and services. The Regulations specifically reserve for future consideration disclosure of compensation in the welfare plan context. *Id.* at Section 2550.408b-2(c)(2). In part, this may reflect the Department’s determination following the 2010 Welfare Plan Hearings that “there are significant differences between service and compensation arrangements of welfare plans” and “the Department should develop separate, more specifically tailored, disclosure requirements under ERISA Section 408(b)(2) for welfare benefit plans.”

Now that nearly four years have passed since the Department’s hearing and two years have passed since the issuance of 408(b)(2) Regulations governing disclosure of compensation to pension plans, the Council has examined the current status of the necessity and scope of compensation and fee disclosures to welfare plans and has done so specifically in the context of PBM services. In considering this issue, the statutory requirements of 408(b)(2) and 404(a)(1) require that the focus of the Council must be solely on the nature and scope of the information that welfare plan fiduciaries need to satisfy their obligations under ERISA.

During the course of its investigation, the Council and witnesses used various terms that may or may not be subsumed within the term “compensation” as it is applied to PBMs, including “fees,” “price spreads,” “profits,” “revenue streams or sources,” “costs or cost information” and other terms. There was much discussion about which of these terms should be used to describe PBM “compensation” for disclosure purposes. For purposes of this report, the Council uses the term “compensation” as it is used in the 408(b)(2) Regulations and will refer to “direct compensation” and “indirect compensation” as those terms are defined in the Regulations issued by the Department under that Section.¹

The Council focused its attention on the regulatory balance which the Department struck in 2012 when the 408(b)(2) Final Regulations were issued. The 408(b)(2) Regulations provide that the required disclosure of a “description of compensation” may be by “formula” or “if the compensation cannot reasonably be expressed in such terms, by any other reasonable method.”² The Council found particularly helpful the Department’s 408(b)(2) sample disclosure form which permits a service provider to disclose compensation by referring to sections of its contract with the plan sponsor or to websites where compensation information is made available. Much of the testimony at the Council hearings dealt with far broader policy issues such as transparency in health care pricing, managing health care costs while protecting patients, the impact that disclosure has on competition, audit disputes, and other issues. The Council concluded that many of the concerns of the Industry³ and its critics went far beyond the more limited scope of the Council’s issue statement and what is required by the 408(b)(2) Regulations.

¹ The 408(b)(2) Regulations define “direct” compensation as “compensation received directly from the covered plan.” 29 U.S.C. Section 2550.408b-2(c)(1)(viii)(B)(1). “Indirect” compensation is defined as “compensation received from any source other than the covered plan, the plan sponsor, the covered service provider, or an affiliate. Compensation received from a subcontractor is indirect compensation, unless it is received in connection with services performed under the subcontractor’s contract or arrangement described in paragraph (c)(1)(viii)(F) of this section.”

² Section 2550.408b-2(c)(1)(viii)(B)(3).

³ As explained more fully below, the Council received written submissions and oral testimony from two witnesses on behalf of the Pharmaceutical Care Management Association (PCMA) and a written submission from Express Scripts, which is a large PBM. Throughout this report, the testimony and written submissions received from the PCMA witnesses and Express Scripts is sometimes collectively referred to as the “Industry.”

II. RECOMMENDATIONS AND FINDINGS

Recommendation No. 1: The Department should consider making Section 408(b)(2) Regulations applicable to welfare plan arrangements with PBMs, and thereby deem such arrangements reasonable only where PBMs disclose direct and indirect compensation, including compensation paid among related parties such as subcontractors, in a manner consistent with current Section 408(b)(2) Regulations.

Findings Related to Recommendation No. 1

- Plan sponsors of group health plans who testified at the Council hearings were unanimous in their view that they face many challenges managing pharmacy benefits on a cost effective basis. However, plan sponsors uniformly testified that PBM services are a valuable part of this effort .
- Testimony submitted to the Council revealed that drug pricing methodologies and PBM compensation are complex and evolving, including rebates, price spreads, discounts, and other payments from retail pharmacy chains and manufacturers. Substantial evidence was submitted to the Council from ERISA plan sponsors and others that many PBMs do not fully disclose compensation in a manner which is readily understandable to even the most sophisticated plan sponsors and consultants.
- Testimony before the Council indicated that some forms of PBM compensation have the potential for creating conflicts of interest. Sponsors of ERISA health plans may or may not be aware of these potential conflicts.
- ERISA group health plans that contract directly with PBMs frequently use consultants to assist in negotiations with the PBM. Testimony was submitted to the Council that it is common for consultants to receive indirect compensation. The payment of indirect compensation to consultants who are advising plan sponsors in negotiations with the PBM may create the potential for conflicts of interest that may be adverse to the plan sponsor. Sponsors of ERISA health plans may or may not be informed of such indirect compensation.
- Plan sponsors testified that disclosure of PBM compensation would better enable them to comply with their obligations to determine reasonable compensation under Section 408(b)(2). Nondisclosure creates the potential for impediments to plan sponsors' ability to comply with 408(b)(2).
- Voluntary efforts to address PBM direct and indirect compensation disclosure through accreditation and certification are not currently providing a workable alternative to most plan sponsors. In 2010, the Pharmaceutical Care Management Association (PCMA) testified before the Department that "many plan sponsors belong to third-party accreditation programs, like the URAC Pharmacy Benefits Management Standards and the Pharmacy Coalition of the HR Policy Association." The Council heard testimony

from representatives of the HR Policy Association that their certification program is no longer functioning. With respect to compensation disclosure, the URAC PBM guide is not available to the public and does not provide detailed guidance on the disclosure of direct and indirect PBM compensation.

- The Council received testimony that for plan sponsors to understand the reasonableness of PBM fees, plan sponsors need to know what services are being outsourced by the PBM and what is paid for the outsourced services.
- The Council wishes to thank the Federal Trade Commission (FTC) for its assistance in helping the Council understand the relationship between PBM compensation disclosure and competition in the area of prescription drug pricing. The Council received conflicting August 19, 2014 letters from representatives of the FTC: One letter was signed by the Director of Policy Planning, the Director of Bureau of Economics, and the Director of Bureau Competition (Staff Letter); and the second letter was signed by Commissioner Julie Brill (Brill Letter). The Staff Letter and the Brill Letter came to different conclusions on whether the FTC has made findings which remain valid on competition in the PBM industry and the impact that the disclosure of PBM direct and indirect compensation would have on competition. The Council asked the FTC to consider the impact on competition of existing 408(b)(2) Regulations which requires the disclosure of direct and indirect compensation in the financial services industry. The Council learned that such a study has not been made by the FTC.
- Responding to concerns expressed by the Industry, anti-competitive effects of suggested disclosures could be mitigated by confidentiality agreements. Testimony was presented to the Council that such agreements are already commonly used. To the extent disclosures under 408(b)(2) Regulations include proprietary or competitively sensitive information in some circumstances, the Department might consider providing guidance on plans agreeing to maintain confidentiality of the information. As for additional costs to PBMs and/or plans, to the extent plans seek more detailed cost or related PBM information, they can contract for it and incur whatever costs they deem appropriate under the circumstances. As for concerns about the potential for price fixing by pharmacies and/or collusion among drug manufacturers, again the nature of the disclosures required by 408(b)(2) would not seem to raise such concerns. Furthermore, PBMs are already responding to such concerns when voluntarily contracting to provide compensation information to plans by requiring confidentiality agreements.
- While the Council's Scope Statement was limited to PBMs, the Council received evidence that similar compensation and disclosure issues exist for other types of service providers to ERISA covered group health plans. The Department or the Council may wish to evaluate the application of the 408(b)(2) Regulations to other types of welfare plan arrangements in the future.

Recommendation No. 2: The Department should consider issuing guidance to assist plan sponsors in determining whether to and how to conduct a PBM audit⁴ of direct and indirect compensation.

Findings related to Recommendation No. 2.

- Testimony presented to the Council suggested that plan sponsors face considerable obstacles in conducting meaningful and cost-effective audits to determine compliance with PBM contracts including direct and indirect PBM compensation contract terms, which can result in PBM audits being expensive (estimated costs of PBM audits range from \$15,000 to \$200,000), lengthy (some PBM audits take up to two years to complete) and not meaningful for plan sponsors. Problem areas may include:
 - The exclusion of auditors who the PBM believes hold hostile views.
 - On-site audits are required at PBM headquarters.
 - PBMs limit the auditor to transcribing notes of documents.
 - Confidentiality agreements can be overly broad and put unnecessary burdens on the parties when they prohibit disclosure of information by an auditor to its client plan.
 - PBMs will not disclose documents requested by some auditors such as PBM contracts with retail pharmacies and drug manufacturers.
 - Access to claims data is restricted.
 - Audit rights restricted to limited periods (such as 2 years).
 - Some necessary data sources such as AWP pricing are not public and access is expensive (estimated at \$25,000 for Medi-Span AWP pricing) and disclosure is limited.
- Until either the Department or the private sector provide greater guidance on PBM audit standards, the Council suggests that audits not be required when plan sponsors retain PBMs.

⁴ The term “PBM audit” was used by a number of witnesses to refer to reviews by an auditor or consultant on behalf of the plan of PBM records to determine whether the PBM was in compliance with its plan contract. Susan Hayes from Pharmacy Outcomes Specialists was the one PBM auditor to testify before the Council; Ms. Hayes has a background in consulting with plans on PBM issues. The term “PBM audit” should not be confused with the requirement under ERISA Section 103(3)(A), 29 U.S.C. 1023, that certain employee benefit plans must have an annual “examination,” which is frequently referred to as an audit, by an independent qualified accountant.

III. BACKGROUND

A. Overview Of PBM Services, Compensation and Drug Pricing

Dr. Patricia M. Danzon, Celia Moh Professor at The Wharton School, The University of Pennsylvania, provided the Council with a primer on drug pricing, the parties involved in the sale of prescription drugs, and the terminology used in the industry. PBMs provide valuable services to employee benefit plans. PBM services can be broken down into three general areas:

- PBMs organize pharmacy networks and negotiate with the network pharmacies to obtain favorable pricing for prescriptions. PBMs are able to use the promise of steering large quantities of business to network pharmacies in order to obtain favorable pricing on prescriptions drugs. Pharmacies then fill the prescriptions with drugs they purchase from pharmaceutical manufacturers and wholesalers.
- Some PBMs also operate their own mail order, specialty drug, and retail pharmacies. In these cases, PBMs negotiate directly with pharmaceutical manufacturers to purchase prescription drugs, and in some case receive rebates from the manufacturers. Again, PBMs use their size and purchasing power as leverage to obtain discounted pricing on such drugs, agreeing to include such drugs in the formularies they offer to employee benefit plans.
- PBMs provide other administrative services to employee benefit drug programs, including general recordkeeping of drug purchases and usage, creation and maintenance of drug formularies, pharmaceutical utilization review, adjudication of drug claims, participant communications, and other services.

In a typical situation where a benefit plan participant seeks to fill a drug prescription, the role of the PBM is illustrated as follows: The participant visits a network pharmacy, the pharmacy checks with the PBM to confirm participant eligibility, coverage and copayment information, the participant pays the copayment and purchases the drug, the PBM then reimburses the pharmacy at the negotiated network rate less the copayment, and the PBM then bills the plan at the rate negotiated for that drug.

There are six entities potentially involved in a purchase of a single prescription drug: (a) the participant; (b) the participant's health plan; (c) the pharmacy; (d) the PBM; (e) the drug wholesaler; and (f) the drug manufacturer. All or only some of these entities may be involved in any given prescription drug transaction. For example, in a typical situation where a participant fills a prescription at a network pharmacy, the transaction may involve all of these entities: the participant buys the drug from the pharmacy, the pharmacy buys the drug from a wholesaler who purchases the drug from the manufacturer, the pharmacy interacts with the PBM as discussed above, and the PBM bills the health plan. However, where a participant purchases the drug directly from the PBM as part of a mail order program, for example, the pharmacy and wholesaler may not be involved at all. At any point in this process, drugs are priced and sold.

1. Commonly Used Terms

Drug pricing is exceedingly complex with its own lexicon of imprecise terms. In some cases, there are no standardized definitions. A few of the PBM price terms and what appear to be their common usage are:

- Wholesale Acquisition Cost (“WAC”): The price at which drug manufacturers sell branded drugs to wholesalers, net of any discounts for prompt pay, etc. This is typically the manufacturer’s list price.
- Average Wholesale Price (“AWP”): A price calculated by third party database companies such as Medi-Span, which is usually equal to WAC+20%. AWP frequently provides the basis for pricing between PBMs and pharmacies and between PBMs and plan sponsors. Retail pharmacies make a profit by (a) charging more than their purchase price for drugs and keeping the difference, and (b) charging a dispensing fee. PBMs negotiate discounts on pricing and dispensing fees (e.g., the price of a drug may be based on AWP, less a percentage, plus a dispensing fee), and are reimbursed based on a negotiated contract price with the benefit plan (e.g., AWP less a percentage). Much of a PBM’s revenue is based on the “retail spread” between the price paid to the pharmacy and the price received from the benefit plan.
- Maximum Allowable Cost (“MAC”): A pricing mechanism used for generic drugs. Unlike AWP, MAC pricing is set by PBMs. MAC pricing is used to set the price at which a PBM will reimburse a pharmacy for a generic drug. According to information provided by Professor Danzon, the majority of PBM contracts with plan sponsors base generic drug pricing on MAC; other billing arrangements are based on a discount off AWP. PBMs keep the difference between what they pay the pharmacy and what they receive from the plan. Pharmacies keep the difference between the MAC and what they pay for generic drugs.

Other terms which are frequently used in a discussion of PBM compensation are:

- Traditional or lock-in PBM contract: Under this contract model, the PBM agrees to provide drugs to the plan at a specified aggregate rate which is usually stated as AWP minus a percentage.
- Pass through or transparent contract: Under this contract model, the PBM agrees to “pass through” to the plan the PBM’s actual drug costs. However, as testified to by Professor Danzon, PBMs will not disclose the prices they pay related to pharmacies or drug acquisition costs from manufacturers.
- Mail Order Pharmacies: Many PBMs operate their own mail order pharmacies, selling prescription drugs directly to plan participants. By doing so, they can sell drugs at a

lower than retail rate and eliminate the margin and dispensing fees paid to retail pharmacies.

- Manufacturer Rebates: In return for preferred formulary placement and a resulting increase in the sale of their drugs, manufacturers pay rebates to PBMs. Plan sponsors may or may not contract to receive some or all of these rebates, which are based on actual usage of a given drug. Professor Danzon suggested that in recent years, rebates have declined as a percentage of PBM profits. She posits several potential reasons for this decline: (a) expiration of patent protection for several blockbuster drugs and the rise of generics; (b) increasing use of specialty drugs for which there are limited substitutes and therefore little incentive for manufacturers to pay rebates; (c) Medicare Part D requires transparency and pass through of rebates, which may lower the incentive of PBMs to seek rebates; and (d) litigation has reduced PBMs' capture of rebates and competition among PBMs promotes pass-through of a significant portion of these rebates to plan sponsors.
- Price spreads: Price spreads are discussed below. Generally, the price spread is the difference between what the plan pays the PBM, and what the PBM negotiates with either the retail pharmacy or the drug manufacturer.
- Flat Administrative Fees: Some PBMs charge per member or per transaction fees (somewhat analogous to pharmacies charging per transaction dispensing fees), which may or may not be in lieu of spread margins or rebates.
- Consulting Fees or Other Services: PBMs may offer specific services to plan sponsors, such as specialty formularies, claims data auditing to seek out cost saving opportunities, disease management programs, or other specialty services on a fee basis.

2. PBM Compensation

PBMs have developed multiple sources of compensation. Professor Danzon testified that the supply chain for pharmaceuticals in the United States has evolved into a complex network involving multiple agents. Pharmaceutical manufacturers such as Pfizer or Merck typically sell their drugs to wholesalers such as McKesson and Cardinal Health, which in turn distribute the drugs to pharmacies, including independent and chain retail pharmacies and PBMs' mail order pharmacies, which dispense the drugs to patients. PBMs contract with and reimburse the retail pharmacies, contract with and collect rebates from drug manufacturers, and dispense drugs through the PBMs' own mail order pharmacies. PBMs are compensated by plan sponsors for these services.

A graphic description of the complexity of PBM compensation was provided by Professor Danzon in her written description to the Council. At a very macro level, it can be said that "the functions of PBMs include managing the choice of drugs for the formulary and also controlling the costs of this distribution chain." As one would expect, with multiple agents involved, "each stage of this supply chain incurs costs and adds a markup or margin. PBMs are

contracted as intermediaries by plan sponsors . . . to manage the coverage of drugs dispensed to plan members by retail pharmacies.”

In order to provide a pharmaceutical benefit, a plan sponsor can structure the benefit in one of three ways: (1) the sponsor may retain the services of a health benefit administrator that has its own captive PBM; (2) the sponsor may contract out pharmaceutical services separately with a PBM; and/or (3) the sponsor may perform some PBM functions in-house and contract out other functions, such as basic pharmacy network management and claims processing. In addition to a PBM’s most basic function of claims processing, that is paying pharmacies for the drugs that they dispense to plan participants and beneficiaries, PBMs generally also actively manage pharmacy benefits with a view to reducing the overall cost to the plan of the covered drugs, assuring quality and value for money. Examples of services offered by some PBMs include:

- Creating a network of retail pharmacies.
- Processing pharmacy claims. In processing claims PBMs determine (1) whether an individual was an eligible participant; (2) whether the prescribed drug was covered by the plan; (3) whether the participant met his or her deductible; and (4) what the participant’s co-payment would be if required by the plan.
- Creating drug formularies (a formulary is a list of drugs that are covered by the plan).
- Negotiating drug rebates with pharmaceutical manufacturers.
- Mail-order pharmacy dispensing.
- Specialty pharmacy dispensing and related services.
- Drug utilization review (DUR).
- Compliance and therapy management programs.

For providing these services, the PBM is paid an administrative fee.

PBMs create networks of retail pharmacies for benefit plans, negotiate to pay the pharmacies a fee for dispensing medications, and contract with the network of pharmacies to determine what the pharmacies are reimbursed for drugs dispensed. There is a price spread between the agreed upon charge with the retail pharmacy and the agreed upon charge to the plan. Also, PBM negotiate with the drug wholesalers or manufacturers for purchase prices of drugs which results in another price spread. Further, PBMs receive rebates from manufacturers or wholesalers for inclusion of a brand or a specific manufacturer as the approved generic. These rebates and discounts are related to the volume of purchases made.

Professor Danzon provided a description of how a brand drug is priced by the manufacturer. Variation in pricing can be seen depending on whether a drug is a single-source branded drug, a generic drug or a specialty drug. “Pharmaceutical manufacturers typically sell their on-patent brand drug to wholesalers at the manufacturer’s list price, usually Wholesale Acquisition Cost (WAC), net of any discounts for prompt payment, etc. Manufacturers also supply their list price(s) to third party database companies, such as Medi-Span. According to Medi-Span’s official pricing policy, drug manufacturers most often provide a Wholesale Acquisition Cost (WAC) but sometimes a Direct Price (DP) and/or Suggested Wholesale Price (SWP). The third-party database companies calculate AWP based on the standard formula of $WAC + 20\%$. If the manufacturer lists both a WAC and an SWP, Medi-Span states that it will set AWP at the manufacturer’s SWP. Thus for on-patent brand drugs there usually is a strong relationship between AWP and WAC, but not necessarily strict proportionality.”

Professor Danzon went on to explain how a PBM pays a retail pharmacy. “[T]he PBM may reimburse pharmacies for drugs at AWP minus 18% plus a \$2.00 dispensing fee. These arrangements are not generally known to plan sponsors. The PBM may contract for reimbursement from the sponsor at AWP minus 16% plus a \$3.00 administration fee per script. The difference between the sponsor’s payment rate to the PBM and the PBM’s payment rate to the pharmacy, commonly known as the retail spread, is a significant source of PBMs’ net revenue.” Additionally, the periods over which industry pricing markers such as AWP are computed, may be different in the contracts of dispensing pharmacies and plan sponsors, giving rise to additional spread differentials for the PBM.

Professor Danzon explained that generic drugs generally are priced using different pricing markers than are used for the single-source branded drugs. “PBMs typically reimburse pharmacies for generics based on a maximum allowable cost (MAC), which is the same for any generic product (defined by molecule-dosage form-strength). MAC reimbursement incentivizes pharmacies to use the lowest cost generic available, as this will provide them with the greatest margin. Over time, PBMs revise down the MAC, thereby capturing (some of) the savings from competitive discounting by generic manufacturers to pharmacies. Unlike AWP, which is a list price schedule set by a third-party, each PBM negotiates its own MAC reimbursement prices with pharmacies.” As the marketplace has shifted and generic drugs have come to represent a much larger share of the drugs that are dispensed to plan participants, the overall drug spend associated with and based upon MAC pricing has grown.

Larger PBMs typically own and operate their own mail order pharmacies. Unlike the network retail distribution system where the PBM does not directly purchase actual drugs from manufacturers, when operating a mail order pharmacy, the PBM actually purchases drugs from wholesalers/manufacturers and dispenses pharmaceuticals to patients through the mail. Mail order pharmacies have traditionally focused upon supplying medications to patients with chronic illnesses who require ongoing drug regimens. Dispensing drugs by mail order eliminates the additional mark ups, margins and dispensing fees associated with purchase through a retail pharmacy. Using the mail order distribution channel allows the PBM to play a more active role in encouraging patient compliance with treatment regimens and enforce formulary compliance by switching patients from non-preferred to preferred brand drugs. The PBM also captures the

discounts on generic drugs. This has become an increasingly important source of PBM revenue as generic share (of overall drug spend) has grown to over 80 percent of drugs dispensed.

3. Potential PBM Conflicts of Interest Related to Compensation

The topic of potential conflicts of interest that may arise from PBM compensation arrangements was repeatedly raised during the Council hearings. In a balanced discussion of this issue, it is important to consider both the FTC's 2005 comprehensive study of the impact on prescription drug prices resulting from PBMs owning mail order pharmacies and therefore being both the purchaser and seller of drugs, and voluntary efforts by the PBM industry to insulate PBM formulary decisions from considerations of PBM compensation. Both of these topics are discussed in other sections of this Report. Professor Danzon and several other witnesses identified areas of potential conflicts of interest for PBMs:

- Manufacturer rebates to PBMs occur when a drug manufacturer's product is included in a formulary and utilized by plan participants. Allegedly, PBMs have incentives to encourage utilization of certain drugs based on the availability of rebates rather than ultimate cost to the plan.
- Because price spreads are related to drug costs, PBMs allegedly have less incentive to restrain drug price escalation. Mitigating the effect of this incentive, some witnesses argued that the PBM industry is highly competitive and that failure to control drug costs would result in PBMs losing clients to more aggressive PBMs seeking to reduce client costs. Testimony by the Consumers Union did point to some instances where certain medications were less costly when purchased by individuals outside a group health plan.
- Because PBMs establish "reimbursement rates for both competitor retail pharmacies and their own captive mail order pharmacies, they have incentives to steer utilization" between these two distribution channels maximizing their own profits." Professor Danzon referred the Council to a 2007 article written by Lawrence W. Abrams which argued that large PBMs artificially keep retail pharmacy reimbursements for generic drugs high in order to protect margins in their mail order business, which is the more profitable channel for PBMs.⁵ Professor Danzon also referred the Council to a 2013 study of the Pharmacy Benefit Management Institute ("PBMI") which reported that plans pay "slightly higher" prices through mail order on generic drugs, although the difference was not statistically significant.⁶ As discussed in another section of this Report, the FTC found lower prices on mail order pharmacies owned by PBMs.
- PBM are on both sides of a business transaction when they manage a formulary and serve as owners of a network of retail pharmacies, a mail order dispensing operation or a high-cost specialty drug pharmacy. A PBM could potentially be in a situation where it is

⁵ Abrams, Lawrence W. (January 20, 2007), "Pharmacy Benefit Managers As Conflicted Countervailing Powers," Watsonville: Nu-Retail.

⁶ Pharmacy Benefit Management Institute (PBMI) 2013, "2013-2014 Prescription Drug Benefit Cost and Plan Design Report."

determining which drugs will be covered by the plan, establishing the MAC list commonly utilized for generic drug reimbursement and also charging the plan sponsor for filling scripts for covered participants.

- The complexity of rebate arrangements with drug manufacturers and pricing spreads which are subject to continuous fluctuation, make it difficult for plan sponsors to monitor pricing.
- There may be financial incentives when PBMs design a formulary and switch drugs on a formulary.

B. Summary of Case Law on Fiduciary or Other Legal Status of PBMs

There are few reported cases on the ERISA fiduciary status of PBMs. In *Pegram v. Heredich*, 530 U.S. 211, 2000 U.S. Lexis 3964 (2000), involving an HMO, not a PBM, based upon ERISA pre-emption, an HMO sought removal of a state court medical malpractice action over the failure to treat an appendix rupture. The U.S. Supreme Court held that treatment decisions made by HMO physicians do not constitute ERISA fiduciary acts, that an HMO's "discretionary authority over its own HMO business" does not make an HMO a fiduciary unless it exercises discretion over the plan, and that "mixed eligibility decisions" were not intended as ERISA fiduciary acts.

In what is likely the leading case on the issue of whether a PBM is a fiduciary under ERISA, at least with respect to a "traditional" PBM contract where the PBM assumes the risk of the contract with the plan sponsor, *Chicago District Council of Carpenters Welfare Fund v. Caremark*, 474 F.3d 463 (7th Cir. 2006), the Court of Appeals for the Seventh Circuit reviewed whether a PBM acted as an ERISA fiduciary where the PBM promised to provide drugs at AWP less an agreed upon discount, and to pay a fixed dollar amount for each rebate. The court first looked to the PBM's agreement with the plan, which stated that the PBM was not an ERISA fiduciary, and then concluded that the PBM lacked discretionary authority over plan terms or assets where the terms of price spreads and rebates were spelled out in the contract. The court also addressed the PBM's control over the drug formulary. Citing *Pegram*, the Court concluded that the formulary and drug switching features of the formulary were contract terms, and that the PBM had not acted as a fiduciary when it entered into the formulary contract with the plan.

Consistent with the *Chicago Carpenters* decision, at least two federal district courts have dismissed ERISA fiduciary actions against PBMs. See *Moeckel v. Caremark*, 622 F. Supp. 2d 663 (MD TN 2007) (PBM's control over formulary and the negotiation of prices with retail pharmacies does not give rise to ERISA fiduciary status); *Bickely v. Caremark*, 361 F. Supp. 2d 1317 (N.D. Al 2004) (in derivative fiduciary action brought by a plan participant, court finds PBM acts are ministerial and do not give rise to ERISA fiduciary status). However, another federal district court dismissed common law claims against a PBM, but permitted ERISA fiduciary claims to go to trial. See *Express Scripts, Inc. v. PBM Litigation*, 2008 U.S. Dist. Lexis 26127 (E.D. Mo. 2008) (On motion to dismiss, court dismisses common law claims related to

PBM business practices with respect to undisclosed rebates and price spreads in lawsuit brought by health plan, but states that ERISA fiduciary claim may proceed to trial).

C. Federal Trade Commission Studies and Opinions on Competition in the PBM Industry and the Impact of PBM Compensation Disclosure

At the June 19, 2014 hearing, several witnesses submitted both written⁷ and oral testimony that the Federal Trade Commission (FTC) had definitively reported on the state of competition in the PBM industry and the impact that mandatory disclosure of PBM compensation might have on competition and, ultimately, on the price of drugs to employee benefit plans. Generally speaking, witnesses supportive of the Industry testified that based upon prior FTC reports, the Industry is highly competitive and that mandatory disclosure of compensation under ERISA Section 408(b)(2) would hurt competition and result in increased drug prices. On the other hand, witnesses who favored full disclosure of PBM compensation opined that the Industry is highly concentrated, with a significant majority of the business concentrated with a few PBMs,⁸ that disclosure of compensation would promote competition and that the FTC reports were not dispositive of the issues before the Council.

The FTC provided considerable assistance to the Council in understanding the competition related issues. The FTC has reported on competition in the PBM industry on a number of occasions over the past 9 years. In 2005, the FTC issued a report to Congress on the impact of competition resulting from PBM's ownership of mail order pharmacies (2005 FTC Report).⁹ The 2005 FTC Report is 240 pages and addressed six questions: (1) Assessment of price differences in payment amounts incurred by employee benefit plans and participants for prescription drugs dispensed by mail-order pharmacies owned by PBMs compared to non-owned mail-order pharmacies and retail pharmacies; (2) Whether employee benefit plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees; (3) Whether mail-order pharmacies that are owned by PBMs dispense fewer generic drugs compared to single-source drugs within the same therapeutic class than mail-order pharmacies that are not owned by PBMs; (4) Whether mail-order pharmacies that are owned by PBMs switch patients from lower priced drugs to higher priced drugs more frequently than mail-order pharmacies that are not owned by PBMs; (5) Whether mail-order pharmacies owned by PBMs sell a higher proportion of repackaged drugs or repackaged drugs at higher prices than mail-order pharmacies not owned by PBMs; and (6) Whether competition or drug pricing behavior by PBMs would be affected if PBMs were to bear financial risk for drug spending. While it is impossible to summarize the 2005 FTC Report in a few sentences, as confirmed by Professor Danzon in her written testimony, the FTC did not find competition or conflict of interests problems related to PBM owned mail-order pharmacies.

⁷ See "Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market, Vol. 99:1 Cornell Law Review (2013) (Professor Joanna Sheppard).

⁸ Professor Danzon submitted written testimony that in 2012, the market shares of the three largest PBMs were: Express Scripts, 33%; CVS/Caremark, 26%; and Optum RX, 12%.

⁹ See Fed. Trade Comm'n, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies 58 (2005). The 2005 FTC Report is available at the FTC website.

In addition to the 2005 FTC Report, the FTC staff has issued letters to several states on state legislative proposals involving mandatory PBM compensation transparency requirements such as disclosure of proprietary price discounts, and their likely effect on competition.¹⁰ In 2012, the FTC completed an investigation to determine whether some pricing and pharmacy reimbursement practices of CVS/Caremark constituted unfair methods of competition or unfair or deceptive acts of practices.¹¹ Also, in 2012, the FTC investigated the merger of Express Scripts and Medco which was projected to result in a 40% market concentration with the merged PBM.¹²

Between the June and August 2014 Council hearings, the Council solicited the input of the FTC on the impact that PBM compensation disclosure under ERISA Section 408(b)(2) would have upon competition. The questions submitted by the Council to the FTC appear in the Appendix to this Report.

In response to these questions, the Council received two letters dated August 19, 2014, from representatives of the FTC.¹³ The Council received a letter from the FTC Director of Office of Policy Planning, the Director of the Bureau of Economics and the Director of the Bureau of Competition (FTC Staff Letter).¹⁴ The FTC Staff Letter reviewed more recent letters issued in response to state laws seeking to regulate the disclosure of PBM compensation, and the FTC investigations of CVS and the 2012 Express Scripts/Medical merger discussed above. The FTC Staff Letter explained that plan sponsors “can also choose varying levels of disclosure” [of indirect payments] and cautioned that if a “standard level disclosure is imposed on all plans, thus denying plan sponsors the ability to negotiate their preferred level of disclosure, plans will be unable to use the level of disclosure as one element of a negotiating strategy.” The FTC Staff Letter also cautioned that “if the Council determines that additional transparency may be desirable, we urge the Council to consider whether and how mandatory disclosure might be tailored narrowly to present useful and meaningful information to plan administrators while mitigating the risk of competitive harm.”

In addition to the FTC Staff letter, the Council received a letter and an Appendix from FTC Commissioner, Julie Brill, who had written a dissenting opinion on the 2012 Express Scripts/Medco merger decision. Commissioner Brill stated that the FTC 2005 PBM study was too old to offer much guidance or information on the current state of competition in the PBM

¹⁰ See e.g., Letter from FTC staff to Hon. James Seward Concerning N.Y. Senate Bill 58 on Pharmacy Benefit Managers (PBMs) (March 2009) available at FTC’s website.

¹¹ See *In the Matter of CVS Caremark Corp.*, FTC File No. 112 3210 (Jan. 12, 2012) (consent order settling charges that CVSC misrepresented the prices of covered Medicare Part D prescription drugs); and *In the Matter of CVS Caremark Corp.*, FTC File No. 091 0106 (closing letter sent Jan. 12, 2012), both documents available at FTC’s website.

¹² See Statement of the Fed. Trade Comm’n Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc., FTC File No. 111-0210 (April 2012) available at FTC website.

¹³ Both letters are available to the public by contacting EBSA’s Public Disclosure Room.

¹⁴ The Staff Letter included the following footnote 1: “This letter expresses the views of the Federal Trade Commission’s Office of Policy Planning, Bureau of Economics, and Bureau of Competition. The letter does not necessarily represent the views of the Federal Trade Commission (“Commission”) or any individual Commissioner. The Commission, however, has voted to authorize us to submit these comments. Commissioner Brill dissented on authorizing Commission staff to submit these comments, and she is writing separately to the Council to express her views.”

industry. She also contended that the 2012 FTC majority's conclusion that competition in the PBM industry is "intense" is both debatable and irrelevant to the Council's deliberations. Commissioner Brill suggested that the 2012 investigations did not focus on the competitive effect of different PBM plan designs and suggested that the level of competition that the majority found in those investigations may be because of rather than in spite of, state efforts to require mandatory transparency of PBM fees and compensation. Commissioner Brill took issue with the FTC staff's conclusion that plan design is a significant dimension of competition among PBMs that plans can negotiate, noting that smaller plans are at a significant competitive disadvantage in negotiating with large PBMs and even lack the knowledge necessary to determine the issues for negotiation. Commissioner Brill concluded by asking the Council "to consider the FTC's current level of knowledge regarding the competitive effects of different plan designs in today's market, as well as the FTC's current level of knowledge regarding whether the forces at play in the current market are competitive and adequate to protect consumers of PBM services."

In her Appendix, Commissioner Brill specifically addressed each question submitted by the Council. Commissioner Brill stated that the FTC had not specifically issued guidance on the impact on competition if rebates and price spreads were disclosed under ERISA Section 408(b)(2); that the 2005 FTC study of the Industry is not current; that the FTC had not considered the impact on competition of current practices on the disclosure of PBM compensation or that the benefit consultants which assist plan sponsors in negotiating with PBMs frequently receive indirect compensation; that the FTC had not studied the impact of competition on the financial service industry resulting from the Department's 2012 Section 408(b)(2) Regulations; and that the FTC had not studied the impact on competition of post-2005 state laws which sought to regulate the disclosure of PBM compensation.

D. Summary of Efforts by States to Regulate Disclosure of PBM Rebates and Price Spreads

During the June 19, 2014 hearing, the Council heard general testimony about settlements between state attorney generals and the Industry. After the close of the June 19 hearing, the Council requested that representatives of the Industry and advocates for greater PBM compensation disclosure educate the Council regarding these settlements. In response, the Council received an executed document titled "Assurance of Voluntary Compliance and Discontinuance," dated May 15, 2008, between Express Scripts and various states and the District of Columbia (2008 AVC). Among other provisions not related to the disclosure of PBM compensation, the 2008 AVC appears to have required that Express Scripts disclose aggregate information about manufacturers' rebates to a "Client Plan" at both the "contracting stage" and during the periods of contract compliance. At the August 20, 2014 hearing, Stephanie Kanwit, appearing on behalf of the Pharmaceutical Care Management Association (PCMA), submitted written testimony that the 2008 AVC "is still in place" and that "none of the participating states has felt the need to undertake enforcement action for one primary reason: the market for PBM services has changed radically in the 11 years since the AVC."

In addition, Emory Law Professor Joanna Sheppard submitted her law review article with citations to laws in a number of states which attempted to regulate the disclosure of PBM

compensation.¹⁵ As observed by Professor Sheppard: “Typically, these regulations are relatively benign and only require PBMs to disclose publicly available financial statements from the preceding year. However, a growing number of states require PBMs to disclose more detailed financial information that could impair PBMs bargaining position vis-à-vis pharmaceutical manufacturers, pharmacies, and health plan sponsors.”¹⁶ The Council located a website of an organization titled “PBM Watch” which provides online summaries of laws in 21 states regulating PBMs, including the disclosure of PBM compensation with citations to state codes.¹⁷

None of the witnesses appearing before the Council identified reported court decisions related to the enforcement of PBM compensation disclosure under state law. In addition, as explained elsewhere in this Report, the FTC staff has issued letters to state legislators about the impact on competition resulting from state mandated disclosure of PBM compensation.

E. ACA Regulation of PBM Compensation Disclosure for Medicare Part D and Plans on the Exchanges

The Patient Protection and Affordable Care Act (“Affordable Care Act” or “ACA”) includes provisions requiring greater transparency in PBM contracts with Medicare Part D plans and plans on healthcare exchanges. The ACA requires PBMs to provide the following information: (1) percentage of all prescriptions that were provided through retail versus mail order pharmacies and the percentage of prescriptions for which a generic drug was available and dispensed that is paid by the health plan; (2) the aggregate amount, type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization and the aggregate amount of the same that are passed through to the plan sponsor and the total number of prescriptions that were dispensed; and (3) the aggregate amount of the difference that the health plan pays the PBM and the amount the PBM pays the retail pharmacies, the mail order pharmacies, and the total number of prescriptions that were dispensed.¹⁸ The ACA provides that the disclosed information is subject to confidentiality preventing disclosure of the information. The confidentiality provisions also apply to the CMS with respect to disclosure of the specific PBM, plan, or prices charged for drugs. Failure by the PBMs to timely or accurately disclose the requisite information will subject the PBM to penalties.¹⁹ Proposed²⁰ and Final²¹ Regulations on PBM compensation transparency were issued by CMS. The Regulations discuss

¹⁵ See “Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market, Vol. 99:1 Cornell Law Review (2013) at Section II(A) pps 11-13 (Professor Joanna Sheppard).

¹⁶ Id at page 11.

¹⁷ The PBM Watch website with the summary of state laws is located at: <http://www.pbmwatch.com/pbm-legislation.html>.

¹⁸ 42 U.S. Code, Section 1320b-23(b).

¹⁹ Id at Section 1320b-23(c).

²⁰ Proposed rule: <http://www.gpo.gov/fdsys/pkg/FR-2011-10-11/pdf/2011-25844.pdf> (preamble starting on page 63033, Proposed Regulations text on page 63087).

²¹ Final rule: <http://www.gpo.gov/fdsys/pkg/FR-2012-04-12/pdf/2012-8071.pdf> (starting on page 22093, Regulations text on page 22171).

both lock-in and pass-through PBM pricing models.²² Professor Danzon testified that the ACA requires pass through pricing for Medicare Part D, and identified a 2011 Office of Inspector General Report that PBMs administering Part D plans retained less than 1% of rebates.²³

F. Review of Efforts to Establish Private Sector Accreditation Standards for the Disclosure of PBM Compensation and PBM Audits

During the Department’s 2010 hearings and the 2014 Council hearings, it was noted that most PBMs are evaluated by third party accreditation programs. Accreditation of health care providers is a type of nongovernmental regulatory mechanism that has been and continues to be widely utilized throughout the world. With respect to the Industry, two organizations were noted in 2010 as providing PBM accreditation: the HR Policy Association and URAC, now known by its initials but formerly known as the Utilization Review Accreditation Commission. The Council received testimony from representatives of the HR Policy Association that its accreditation program was no longer in operation. The Council was advised in testimony supplied by the Pharmaceutical Care Management Association (PCMA), the Industry’s trade group, that “all of PCMA members were fully accredited under URAC’s Pharmacy Benefit Management Standards.” Testimony supplied by PCMA indicated that the URAC Pharmacy Benefit Management Standards were developed by a Standards Advisory Committee comprised of 30 stakeholders over the course of more than a year. The standards that are currently in force were released in 2007. Additionally, a PBM Purchasers’ Guide was released by URAC in 2009. The Chair and Vice Chair for this issue received a copy of the URAC Pharmacy Benefit Management Standards and Guide for their review. The Guide is not available to the public. With regard to compensation disclosure, the URAC Standard and Guide do not provide detailed guidance on PBM compensation disclosure.

IV. SUMMARY OF WITNESS TESTIMONY

A. Testimony of PBM Industry Witnesses

At the June 2014 hearing, on behalf of the PCMA, the Council heard from William J. Kilberg. Mr. Kilberg testified in the 2010 Department hearings on the application of the Section 408(b)(2) Regulations to service providers. In addition, at the August 2014 hearing, the Council heard from Ms. Kanwit, appearing on behalf of the PCMA. On July 18, 2014, with the approval of the Council Chair, the Chair of the PBM Issue was provided a tour of the mail order facility at the Express Scripts headquarters in St. Louis Missouri. He met with several Express Scripts representatives and was provided a book titled “Briefing Book and Key PBM Issues,” which was included in the Council’s record of proceedings.

²² The citations for the portions of the Regulations which discuss lock-in and pass-through pricing are: 74 Fed. Reg. 1505, 1544 (Jan. 12, 2009); 74 Fed. Reg. 1544 (Jan. 12, 2009); 74 Fed. Reg. 1505–1506 (Jan. 12, 2009); and 42 CFR § 423.100.

²³ OIG Report, “Concerns with Rebates in Medicare Part D Programs” (March 2011).

The Industry's view is based in large part on the premise that the PBM industry is intensely competitive, has generated \$2 trillion dollars in savings to the public and private health care plans in the United States, has driven substantially lower increases in costs when compared to other areas of the U.S. healthcare system, and has been responsible for one of the few positive trends in the U.S. health care system, which otherwise is characterized by runaway costs.²⁴

In response to critics who say that the Industry is concentrated in the largest PBMs, the Industry relies considerably upon studies and letters from the FTC which have been published over the last nine years and are discussed in another section of this Report, as well as other arguments.²⁵ In addition, the Industry argues it is regulated by the States.²⁶ State regulation of PBMs and related state litigation is discussed in another section of this Report. The Industry also argues that the URAC has "developed both detailed PBM Accreditation Standards (released in 2007), as well as a useful PBM Purchasers Guide (released in 2009) in conjunction with the National Business Coalition on Health (NBCH)." Private industry certification and accreditation of PBMs are discussed in another section of this Report. The Industry also argues that its most vocal critics, community pharmacies, have continued to thrive.²⁷ The Industry points out that it has adopted procedures to ensure that the formularies are based on expert medical opinions as to the efficacy of drugs and not on PBM compensation.²⁸ The Industry states that PBMs offer plan sponsors various options for the pricing of PBM services with differing levels of compensation transparency, depending on the needs and desires of plan sponsors.²⁹

The Industry also maintains that with the assistance of consultants, ERISA plan sponsors have the wherewithal to enforce transparency where needed or desired as part of a free market

²⁴ The Briefing Book (herein "ESI Briefing Book") supplied by Express Scripts included an article titled "An Overview of Pharmacy Benefit Managers: Focus on Consumers" (herein "An Overview") at page 6, dated June 1, 2012 and written by University of Missouri St. Louis, College of Business Administration Professors Edward C. Lawrence, Jane Qing-Jiang Qu, and Ellen N. Brisken which refers to a recent report that annual increases of spending on prescription drugs had fallen from 5.1% in 2009 to 2.3% in 2010. The ESI Briefing Book included a Graph purportedly prepared by CMS, Office of the Actuary, National Health Statistics Group showing that in 2010 RX drug spending for "private health insurance benefits" increased .5%, in 2011, .8%, and in 2012, minus 2.1%.

²⁵ The ESI Briefing Book includes a graph titled "Company Profit Margins" from Yahoo Finance which shows a profit margin of 1.29% for ESI, 1.39% for CVS/Caremark, and much higher profit margins for other sectors of the health care industry.

²⁶ See "An Overview", cited at Note 1. at page 14 which states "States have exercised the ability to regulate PBMs in different ways." "These PBM laws cover such issues as licencing, investigation, duties to clients, disclosure of financial terms with manufacturers, or the extent to which savings must be passed on to consumers." "Common themes include . . . requiring PBMs to submit to audits."

²⁷ See An Overview, cited at Note 1, at pages 14 which states: "Community and independent pharmacies have been vocal in their opposition to PBMs. . . . Contrary to community pharmacy perceptions, though, the number of community pharmacies continues to increase, and pharmacies themselves are thriving."

²⁸ The ESI Briefing Book included a document titled "White Paper: Formulary Development at Express Scripts" which describes how formularies at Express Scripts are reviewed by a Therapeutic Assessment Committee made up of pharmacists and physicians employed by Express Scripts, and a National Pharmacy and Therapeutics Committee, which is made up of independent pharmacists and physicians who are not permitted to consider rebates, discounts and costs of the drug.

²⁹ The ESI Briefing Book includes a document titled "PBM Contracting Models: Lock-In or Pass-Through Pricing." This document states "commercial clients often choose lock-in pricing because it provides certainty of costs-protecting it from cost increases or decreases in rebates and provider discounts . . . " and that "government and labor clients often choose pass-through pricing because they favor unit cost-plus contracting and know that the PBM's profit is fixed under this arrangement."

system. A witness for the PCMA testified that “PBM-plan sponsor negotiations today are primarily driven by these consultants who are chosen by, paid by, and act in the interests of their client health plans.” However, the Council received conflicting testimony from witnesses on behalf of plan sponsors that consultants frequently receive indirect payments from PBMs, which may have the potential to misalign a consultant’s incentives. A witness for the PCMA testified that “the contracting process is highly transparent.” On the other hand, the Council received conflicting testimony from witnesses on behalf of consultants and plan sponsors that they experience difficulty in obtaining disclosure of PBM compensation. By way of example, the Industry contends that plan sponsors can negotiate for pass-through pricing and thereby achieve transparency of PBM pricing. Professor Joanna Shepherd testified that many PBM contracts already provide for full disclosure, albeit with strict confidentiality provisions. Alternatively, where plans deem it more advantageous, they can negotiate for fixed pricing, where the PBM takes more of the pricing risk and plans may be less concerned about PBM compensation because the plans’ costs are fixed. There are also variations on these types of arrangements. The Industry points out that currently the vast majority of drug manufacturer rebates are shared with benefit plans. Professor Shepherd suggested that in most markets consumers do not have or need cost information and are still able to obtain competitive pricing on products and services. In sum, the Industry argues that the free market system is more than adequate to achieve the transparency that regulation would otherwise require.

The Industry also suggests that mandatory disclosure of confidential pricing information, including rebates and discounts, could lead to several undesirable results:

- Harm to competition: According to Professor Shepherd and others, if confidential pricing information becomes public, (a) pharmacies will use the information to avoid providing their best price to PBMs when pharmacy competitors are offering less favorable pricing, and thus (b) making information public may lead to collusion among drug manufacturers, who will provide less favorable pricing. These points appear to be based on the premise that sellers of goods and services have more incentive to bid aggressively against an “unknown” price than against a “known” price. The Industry argues that mandatory disclosure of PBM compensation information (presumably in a manner that would make it public) could result in increased drug prices for benefit plans.
- Increased costs to PBMs: The Industry contends that mandatory disclosure will require additional administrative costs because PBMs would be required to produce data that otherwise would not be produced or the data would be in a form not otherwise required. The Industry urges that these increased costs would be passed on to ERISA plans.
- Increased costs to ERISA plans: The Industry contends that mandatory disclosure of pricing information will lead to higher costs as plan sponsors are forced to analyze data they would not otherwise have and, in many cases, would be required to incur additional expenses for consultants to provide assistance with the analysis. There is also the suggestion that mandatory disclosure may establish a “floor” for fiduciary

conduct, requiring plans to push for full disclosure and 100% pass-through of rebates and discounts even though ultimate costs may be lower in a given case were the plan to enter into a fixed price arrangement.

The Industry points out that some form of aggregate compensation disclosure is required under the Affordable Care Act for Medicare Part D plans offered through the exchanges, but notes that this disclosure is accompanied by strict confidentiality requirements. The Industry argues that broader disclosure to all ERISA health plans, even with confidentiality requirements, would still create the potential for negative results because enforcement of confidentiality could be problematic. Specifically, the Industry suggests that disclosure to a broader array of plan sponsors would make breaches of confidentiality agreements more likely.

B. Testimony of Plan Sponsor Witnesses

The Council heard testimony from representatives of plan sponsors, including multiemployer plans, large single employer plans, ERISA and non-ERISA group medical plans, and consortiums of group medical plans that were established to negotiate better terms with PBMs. The common theme in the testimony of these witnesses was the difficulty of determining the types and levels of compensation received by PBMs. These witnesses testified that this lack of information creates an impediment when plan sponsors negotiate contracts with PBMs and when they seek to monitor compliance with contract terms. The report provides only a summary of the testimony from plan sponsor witnesses. For those interested in this topic, the Council suggests a careful review of the written witness testimony.

Plan sponsor witnesses identified the following specific problems they have experienced in determining PBM compensation and the impact of this lack of information on their ability to (a) determine whether they are paying reasonable compensation for PBM services, (b) monitor PBM contract arrangements, and (c) determine whether PBM compensation arrangements create the potential for conflicts between the PBMs' financial interests and the interests of covered persons under group health plans.

- Plan sponsors uniformly testified about the difficulties in obtaining the disclosure of PBM compensation, and how this interfered with their efforts to negotiate and monitor PBM contracts.³⁰ Randy DeFrehn, Executive Director of the National Coordinating Committee for Multiemployer Plans, testified that a plan sponsor's bargaining position "is strengthened by simply understanding the extent of the PBM's financial involvement with" manufacturers and retail pharmacies. Allison Klausner, Assistant General Counsel-Director of Benefits for Honeywell International, Inc., testified that "there is a very complex multi-dimensional system that supports the delivery of prescription drugs to individuals covered by a company sponsored health plan" and that "an understanding of the fees and compensation earned by a PBM cannot be fully known by a plan sponsor

³⁰ The problems testified to by plan sponsors are difficult to reconcile with claims of Industry advocates that such problems do not exist: "Finally, health plans are already able to negotiate contract terms that include disclosure and audit rights when they want them and are willing to pay the additional resulting administrative costs." See "Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market," Vol. 99:1 Cornell Law Review (2013) (Professor Joanna Sheppard) .

until the PBM discloses how that system is leveraged and utilized.” Keith Bruhnsen, Assistant Director of Benefits Administration at the University of Michigan, testified that “Asking a PBM to disclose all sources of revenue is complex as they may define revenue as a discount, rebate, data fee, a credit, or some other administrative or education fee.” Linda Nilsen, Executive Director of Benefits and Compensation at Princeton University testified that “At this time, PBM contract negotiations which set pricing guarantees and volume steering thresholds occur without the employer having a full understanding of all income the PBM experiences based on the employer’s plan participants utilization.” Robert Restivo, Director of Benefits at General Dynamics testified that “the cost of pharmaceuticals now occupies a very large percentage of the overall health care spend for large employers, that large employers have become very frustrated by the lack of transparency in the pharmaceutical procurement process,” and that “there will be increased pressure by large employers as well as their employees and dependents to develop far more transparent systems around pharmaceutical purchasing.” A plan sponsor witness with a large health plan testified that it is a conflict of interest for a PBM to be both negotiating drug prices on behalf of plans and to own portions of the supply chain such as retail, mail order and specialty drug pharmacies.³¹ Another plan sponsor witness testified that PBMs may reimburse retail pharmacies less than the plan is being charged for the same drug through the PBM’s mail order pharmacy. A plan sponsor witness testified that when a brand drug goes generic, often the manufacturer has been granted a six month exclusivity period to market the generic. In exchange for substantial rebates, manufacturers approach PBMs for an exclusive extension of their brand drug, which blocks competing generics.

- A plan sponsor testified that the exclusion of a drug from the PBM formulary may impact patient treatment and may mean that the patient can no longer afford the drug. For example, if a covered person has diabetes, high cholesterol, and high blood pressure, and is using multiple drugs in different therapeutic classes to effectively manage the medical condition, it can be potentially life threatening to change the balance of drugs that are working well together. PBM contracts normally provide 120 days notice of a change in a formulary, which frequently is not enough time for a patient and the treating physician to evaluate the new formulary, adjust treatment and/or file an appeal.
- A plan sponsor witness testified that consultants to plan sponsors frequently have preferred relationships with certain PBMs which may call into question the consultants’ independence. For example, another plan sponsor witness testified that PBMs use different price schedules to increase the compensation paid to consultants when the consultant’s client base with the PBM increases.
- A plan sponsor witness testified that in a competitive retail market, retail pharmacy vendors who are looking to generate foot traffic may provide significant savings on certain prescription drugs. However, in some cases plan sponsors and PBMs have been slow to adjust to the savings to be realized by this approach, in part because of the alignment of interests between plan consultants and PBMs.

³¹ See Section of Report on the Federal Trade Commission’s review of the impact of Caremark/CVS ownership of retail pharmacies. The FTC did not find an adverse impact on drug pricing.

- A plan sponsor witness testified that compensation arrangements may give PBMs a financial incentive to manage their formularies. An example was provided to the Council that within a year of Drug X losing patent protection, a PBM would be incentivized to change its formulary to remove Drug X as the designated brand-name drug for that therapeutic class and replace it with Drug Y, which was not losing patent protection for some time, and thereby maintain rebate dollars from Drug Y's manufacturer.
- A plan sponsor witness testified that when plan sponsors seek bids for PBM services, some PBMs will not provide claims data to the sponsor, citing privacy and contractual constraints.
- A plan sponsor witness testified that PBMs use complex pricing algorithms to show that the PBM met an agreed upon price guarantee as determined on an aggregate basis. In determining the price guarantee (such as a percentage off AWP), some PBMs will exclude certain claim types from the calculation that would hurt the PBM's performance and include others that alter the performance calculation.
- A plan sponsor witness testified that if the PBM overcharged the plan sponsor during the course of the year, the PBM contract may condition any refund of the overcharge on the PBM contract not being terminated.

Plan Sponsor witnesses identified a number of what they considered "best practices" related to PBM compensation and disclosure which appear in the Appendix to this Report.

C. Testimony of Consultant and Auditor Witnesses

At the August 20, 2014 hearing, the Council received written and oral testimony from two PBM consultants serving plan sponsors in negotiations with PBMs: Michael Miele from Arthur J. Gallagher, who testified primarily on PBM contract terms, and Susan Hayes from Pharmacy Outcomes Specialists, who testified primarily on audit of PBM contracts by plan sponsors.

Mr. Miele testified that there are a number of challenges for plan sponsors in the negotiation of PBM contract terms:

- There are multiple possible definitions of AWP which needs to be specified in the contract. Generally, the definition of AWP should be tied to an outside service such as MediSpan and updated weekly as opposed to permitting the PBM to select the AWP price list. In addition, the PBM contract may define AWP by the package (bottle) size as "smallest" as opposed to the "actual" size dispensed to the plan participant. Generally speaking, the larger the package size, the greater the AWP discount. A similar issue about package size exists for generic drugs.
- A PBM may seek to retain the right to designate or delay when a drug is considered brand or generic which can impact price guarantees and pass through savings. The

definition of generic should be tied to some outside source such as the MediSpan's Generic Product Indicator. The plan should verify in its rebate report that the drugs classified as generic show up on the rebate report as generic. The contract should specify that a drug will be reclassified from brand to generic immediately after the drug is reclassified and not after a six month delay set by the PBM.

- Some drugs cost less than the plan's copays. The PBM contract should specify the prices that will be charged to the participant. The Council heard testimony from Ms. Hayes that under some PBM contracts, the charge to the participant is higher than the PBM formulary, and the PBM "claws back" the copay paid by the participant and received from the retail pharmacy with no reimbursement to the plan.
- The PBM may seek to exclude some manufacturer rebate dollars from the plan by re-characterizing rebates as administrative or service fees.
- The plan sponsor should consider that the rebate program may incentivize the PBM to substitute higher priced brand drugs with higher rebates which can result in overall higher costs to the plan.

Ms. Hayes testified that plan sponsors may face challenges in seeking to audit PBMs to determine compliance with the contract between the PBM and the plan sponsor:

- Cost estimates for PBM audits can range from \$15,000 to over \$200,000 depending on the size of the plan, and the scope of the audit. Ms. Hayes estimated that PBM audits can take between 100 to 500 hours of consultant time. An audit of the top 10 rebate contracts may take one to two weeks of on-site time. Auditors need to be familiar with the complexities of the contract between the PBM and the plan sponsor. As a result, many plans are too small to justify the cost of a PBM audit. Plans with less than \$10 million in "spend" may be prohibited by some PBM contracts from conducting audits.
- Basic data to conduct the audit is expensive. For example, MediSpan is the supplier of AWP price guidelines. MediSpan charges \$25,000 or more a year for access to its AWP guidelines. MediSpan limits the rights of an auditor to disclose AWP data.
- Some PBM contracts require that the plan's auditor be "mutually acceptable" to the PBM. This may result in a PBM requiring that the plan sponsor not use its regular accounting firm or consultant to conduct the audit.
- Some PBMs will not disclose the contracts with the retail pharmacies and manufacturers which set the prices being paid by the PBM to the pharmacy or the manufacturer. When rebate contracts are disclosed, a review of the contract can take 4 to 5 hours of auditor time per contract. The auditor is not given a separate copy of the contract, but is required to take notes from the contract.
- Some PBMs require that an audit be on-site at the PBM's headquarters.

- Some PBM contracts condition audits on the execution of a confidentiality agreement. Some PBM contracts seek to restrict communications between the auditor and the plan sponsor on the basis of confidentiality.
- Some PBM contracts limit audits to the two prior years.

D. Testimony of Consumer Advocate Witness

Consumers Union provided testimony concerning the issue of Pharmacy Benefit Manager (PBM) disclosure. Noting that a significant amount of our nation’s health spending is for outpatient prescription drugs, the consumer advocates highlighted a need for clear, transparent information about clinical effectiveness and pricing. Specifically, the consumer advocates asserted that “PBMs could better protect consumers’ and employers’ interests by improving the transparency of their business practices, thus allowing plan sponsors to ensure that prescription drugs are fairly priced and formulary designs reflect appropriate safety, efficacy and value considerations.” While crediting the PBM industry for streamlining and modernizing current practices in pharmaceutical management, the consumer advocates noted that the PBM industry has “come under fire” for certain practices including: “opaque rebate schemes, opaque pricing spreads, formulary designs and drug switching driven by PBM profits, and mail order pharmacies that utilize these practices.” The consumer advocates recounted significant legal settlements involving PBMs and provided examples of inconsistent drug pricing where drugs with equivalent clinical efficacy were priced very differently. These examples were referenced to indicate potential harms to consumers. In conclusion, the consumer advocates supported: 1) removal of the exemption for employee welfare benefit plans in Section 408(b)(2) of ERISA’s Final Regulations; and 2) inclusion of PBMs as a covered service provider in same. The consumer advocates asserted that such action would “provide employers and other plan sponsors with information they need to assess reasonableness of total compensation, both direct and indirect, received by the PBM service provider, its affiliates, and/or subcontractors; and identify potential conflicts of interest inherent in certain PBM practices.” (Quincy, 8)

E. Testimony of Community Pharmacy Witness

The National Community Pharmacists Association (“NCPA”) suggested: (a) Extend the current 408(b)(2) regulatory disclosure requirements to PBMs with a modification of the definition of indirect compensation to include “all financial benefits the PBM receives, including but not limited to all: rebates, discounts, credits, fees, grants, chargebacks, or other payments or financial benefits of any kind,” combined with a confidentiality requirement applicable to the plan; or (b) Require PBMs to disclose the same aggregated information currently required to be disclosed under Medicare Part D, again with a confidentiality requirement. The NCPA also suggested that audit requirements and criteria be liberalized to allow plans broader options for a choice of auditor and giving auditors broader access to information.

V. CONCLUDING OBSERVATIONS

In conclusion, the Council agrees with the regulatory balance that the Department struck in 2012 when it permitted service providers to disclose a compensation formula or any other reasonable method of disclosing compensation such as a reference to sections of a contract between the plan sponsor and the service provider. Applying the 408(b)(2) Regulations to PBMs would provide assistance to plan sponsors in fulfilling their statutory duties to determine that compensation paid for PBM services is reasonable. Based upon the experience of applying the 408(b)(2) Regulations to the financial services industry, and considering the flexibility provided in the Regulations for disclosing compensation, the Council believes that the application of the Section 408(b)(2) Regulations to PBMs will greatly enhance the ability of plan sponsors to provide prescription drug benefits to participants and beneficiaries, with minimal or no adverse impact on PBMs. Also, assuming that Industry advocates are correct that disclosure of PBM compensation is currently available to plans in the market place upon request, the type of disclosure required by the Section 408(b)(2) Regulations should not adversely impact PBMs.

VI. APPENDIX

A. Council's Questions Submitted to the Federal Trade Commission

The following questions were submitted by the Council to the FTC for comment:

- Describe existing published guidance by the Federal Trade Commission (FTC) on the impact that disclosures by PBMs of rebates and spreads between contract price for prescription drugs and actual cost of prescription drugs (indirect compensation) have on competition.
- Has the FTC conducted further study of the PBM industry since 2005? Have there been changes in the PBM industry that have impacted the competitive nature of the industry since 2005? How does the FTC respond to critics that the 2005 FTC study is not current? Also, Julie Brill, FTC Commissioner at the time of the Medco/Express Scripts merger said in a minority opinion that "this merger is, in fact, a duopoly with few efficiencies in a market with high entry barriers--something no court has ever approved." Have there been any new additional studies on the duopoly issue?
- Is the FTC aware that the PBM industry currently discloses indirect compensation by means of "pass through pricing" contracts, and "transparent" audit rights both of which are commonly offered to plan sponsors? If not, assume that this is true. Would the voluntary disclosure of indirect compensation by the PBM industry in response to market pressures by plan sponsors change the FTC's conclusion about the anti-competitiveness related to Government required disclosure of indirect compensation? Please explain. Does it make a difference if the PBM industry provides voluntary disclosure of indirect compensation under "pass through pricing" contracts, but does not provide such information under other contractual arrangements with plan sponsors?
- Is the FTC aware that in negotiations between the PBM industry and plan sponsors it is a common practice for a consultant to represent the plan sponsor, for the consultant to be paid by indirect compensation from the PBM, and that the disclosure of such indirect compensation is a matter of contract between the PBM and the plan sponsor? If the FTC is not aware of this, assume that it is true. Is the potential of undisclosed indirect compensation to the PBM and undisclosed indirect compensation to the consultant from the PBM relevant to the FTC's conclusion that the mandatory disclosure of indirect PBM compensation is anti-competitive?
- In 2012, the Department issued Regulations requiring retirement plan service providers in the financial services industry to disclose indirect compensation. See DOL Reg. Section 2560.408b-2. Has the FTC considered the impact on competition in the financial services industry of the Department's 2012 regulation? If so, please explain. Has the FTC concluded that if the Department mandated disclosure of PBM indirect compensation in a manner similar to the Department's Regulation for the

financial service industry when providing services to retirement plans, such disclosures would be anti-competitive? If so, please explain.

- In July 2014, the National Academy of Social Insurance issued a report titled “State Policies on Provider Market Power” which is located at: http://www.nasi.org/sites/default/files/research/State_Policies_Provider_Market_Power.pdf. Has the FTC studied the impact on competition of State laws related to the disclosure PBM compensation transparency and similar disclosures for hospitals and other health care providers? If so, please explain.

B. PBM Best Practices from Plan Sponsor Witnesses

Plan sponsor witnesses provided a number of recommendations of best practices related to compensation when contracting with PBMs. The Council does not endorse these “best practices” or suggest that they should be considered as minimum requirements in negotiating PBM contracts. Such recommendations would be outside of the Council’s scope statement.

1. Best practices related to Requests for Proposals (RFPs)

- A plan sponsor witness testified that the plan sponsor should obtain disclosure of all entities in the drug supply chain as well as information as to whether they are the PBM’s subsidiaries or affiliates or whether they are the PBM’s subcontractors or agents. If there is outsourcing or subcontracting, the PBM should disclose to the plan sponsor the services that have been outsourced and the amount of the PBM fee or compensation being shared with the third party. Another plan sponsor witness testified that a PBM may outsource the negotiation of rebate contracts with incentive compensation to the subcontractor, which is not disclosed or shared with the plan.
- A plan sponsor witness testified that while there may be advantages to pass through or transparent pricing, under this arrangement, the PBM may not provide the plan with its best contract pricing with the retail pharmacy. PBMs may have complex financial arrangements with retail pharmacies that are based upon aggregate financial obligations to the retailer and that permits steeper discounts for separate employer contracts. This can result in a transparent contract subsidizing a traditional contract, or small and medium size plans subsidizing larger plans. In addition, with a transparent contract, it was suggested that PBMs may reclassify rebates as purchase order discounts or administrative fees to avoid sharing rebates with the plan sponsor.
- Three plan sponsor witnesses testified that in spite of the potential for disruption to plan participants, large plans or consortiums of plans conduct a PBM market pricing exercise or RFP every few (3 to 5) years. A large plan requires that its consultants disclose any conflicts of interest or collusive arrangements with PBMs. In a PBM RFP, a large plan requires disclosure of rebates, purchasing discounts, sales of data, price protections, manufacturers administrative fees, administrative processing fees on a per transaction per member per month (PMPM) basis, projected rebate revenue, fees for clinical programs such as prior authorizations, step therapy, appeal services, coding, e-prescribing fees,

member mailings, paper claims, ID cards, data extracts and electronic connectivity, and system training. PBM owned mail order and specialty pharmacies are often entitled to contractual benefits from drug wholesalers and manufacturers such as volume purchase or early payment discounts which may not be shared with the plan. It is difficult but essential to develop a metric for an “apples to apples” comparison to determine best PBM cost, services and savings.

- Two plan sponsor witnesses testified that due to concerns over both conflicts of interest and their ability to obtain reasonable pricing, large plans consider the disaggregation of PBM services such as mail order and specialty provider.

2. Best practices related to PBM contract language

- A plan sponsor witness testified that a PBM contract should clearly define contract terms such as rebates, revenue, transparency, AWP, MAC (Maximum Allowable Cost) list pricing, audit guidelines, and termination rights. Define whether 100% of the rebates are reduced by fees paid by the PBM to other entities in the supply chain. Pricing may differ based upon the delivery channel (retail/mail) and supply levels (30 days vs. 90 days). The PBM may be purchasing the drug in lots of 50,000 plus at substantially lower prices.
- A plan sponsor witness testified that a PBM contract should include transparency provisions that illuminate all of the entities in the supply chain, whether they are the PBM’s subsidiaries or affiliates or whether they are the PBM’s subcontractors or agents.
- A plan sponsor witness testified that a PBM contract should include a most favored nations pricing clause.
- A plan sponsor witness testified that a PBM contract should include termination “without cause” language to protect the plan from being locked into a longer term unfavorable contract.
- A plan sponsor witness testified that a PBM contract should include language that plan participants are not required to pay a full copay where the drug cost plus dispensing fee is less than the plan copayment. This avoids the potential for PBM “clawback,” which was described as occurring when a plan participant may be charged a higher rate at the pharmacy than the participant’s plan is required to pay for a certain drug, where the participant is paying the entire cost of the drug, such as in the case of a high deductible plan where the deductible has not been met.
- A plan sponsor witness testified that the PBM contract should include audit language with the right to audit for no less than 24 months and specify the documents to be produced in the audit.
- A plan sponsor witness testified that the PBM contract should include limits on the number of times per year that a PBM may make changes to the formulary or preferred-drug list, along with requiring prior notification of any changes.