NATIONAL COORDINATING COMMITTEE FOR MULTIEMPLOYER PLANS

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Mr. Larry Good
ERISA Advisory Council Executive Secretary
Frances Perkins Building
U. S. Department of Labor
200 Constitution Avenue, NW
Room N-5623
Washington, DC 20210

Re: Testimony of National Coordinating Committee for Multiemployer Plans
Presented to: 2014 ERISA Advisory Council Study Group Regarding
PBM Compensation and Fee Disclosure
Issue Chair: Jim Singer
Issue Vice-Chair: Mark Schmidtke
Drafting Team: Christine Hwang and Dennis Mahoney

Dear Mr. Good:

My name is Randy DeFrehn, and I am the Executive Director of The National Coordinating Committee for Multiemployer Plans (the "NCCMP"). Multiemployer plans are a product of the collective bargaining process and are vehicles whereby at least one labor organization and two or more employers provide health, pension and a variety of other employee benefits through negotiated contributions to trust funds maintained for the "sole and exclusive benefit" of plan participants. Multiemployer plans are jointly trusteed by both labor and management.

The NCCMP is the only national organization devoted exclusively to protecting the interests of the over 20 million active and retired American workers and their families who rely on multiemployer plans for retirement, health, and other benefits. The NCCMP's purpose is to assure an environment in which multiemployer plans continue their vital role in providing benefits to working men and women. The NCCMP is a nonprofit, non-partisan organization with members, plans, and contributing employers in a broad range of industries, including agriculture, building and construction, bakery and confectionary, entertainment, health care, hospitality, longshore, maritime, mining, retail food, service, steel, and trucking.

Introduction and General Discussion

NCCMP appreciates the opportunity to provide comments on the issue of compensation and fee disclosure relating to pharmacy benefit managers (PBMs). The Council's inquiry is a natural, and needed, extension of the Department of Labor's work on fee disclosure relating to retirement benefit plans. Throughout the process that led to the final fee disclosure rules for retirement plans under ERISA section 408(b)(2), the Department reiterated the underlying purpose of fee disclosure. The Department's own words express the issue well.

"[S]ection 404(a)(1) of ERISA [ERISA's core fiduciary standard] requires plan fiduciaries, when selecting or monitoring service providers, to act prudently and solely in the interest of the plan's participants and beneficiaries and for the exclusive purposes of providing benefits and defraying reasonable expenses of administering the plan. Fundamental to a fiduciary's ability to discharge these obligations is the availability of information sufficient to enable the fiduciary to make informed decisions about the services, the costs, and the service provider."[1] "The Department believes [and NCCMP agrees] that in order to satisfy their ERISA obligations, plan fiduciaries need information concerning all compensation to be received by the service provider and any conflicts of interest that may adversely affect the service provider's performance under the contract or arrangement."[2] "The Department believes [and NCCMP agrees] that fiduciaries and service providers to welfare benefit plans would benefit from regulatory guidance in this area for the same reasons that apply to defined contribution and defined benefit plans."[3]

In short, in order to properly discharge their duties to plan participants and beneficiaries, fiduciaries must have adequate information regarding PBM fees and compensation, including actual or potential conflicts of interest related to fees and compensation, in order to evaluate that compensation in light of the services provided and to make an "apples to apples" comparison across service providers.

There has been significant media attention placed on the interplay between PBMs and drug manufacturers. Many self-insured multiemployer funds enter into direct relationships with PBMs to oversee the dispensing drug utilization management of the participants' prescription needs. While providing prescription drug management services is a highly competitive arena in a marketplace which includes a number of service providers, it is an area that is dominated by a few very large entities whose compensation arrangements are anything but transparent. Unfortunately, without transparency, these arrangements may prevent plan sponsors of multiemployer plans, i.e., the joint board of trustees, from fulfilling their fiduciary responsibility of assuring that the fees paid for such services are "reasonable."

The financial relationships between drug manufacturers and the PBMs have profound impacts on the underlying economics of PBM pricing and the direct cost paid by plan sponsors. However, there is very little disclosure of those relationships. Drug manufacturers routinely offer rebates to PBMs as well as directly to providers in order to incent them to prescribe certain drugs. The specific financial details of these arrangements are closely guarded secrets by both the PBM and manufacturers. PBMs willingly enter into these rebate arrangements seeking enhanced financial terms based on the dispensing volume and efficacy of a manufacturer's drug versus competing drugs Likewise, drug manufacturers seek to entice individual providers, as well as PBMs, to recommend their drugs over competitors' by providing incentives to prescribers and dispensers of pharmaceuticals.

[1] 72 Fed Reg 70988 (Dec. 13, 2007); 75 Fed Reg 41600 (July 7, 2010).
[2] 72 Fed Reg 70988, at 70989 (Dec. 13, 2007).
[3] 77 Fed Reg 5632, at 5649 (Feb. 2, 2012).

Plan fiduciaries would be well served if PBMs were required to disclose all instances in which they receive financial remuneration from drug manufacturers, retail pharmacy providers, and data managers. The disclosure need not require detailed financial accounting. However, (remembering the "sole and exclusive benefit" obligation of plan fiduciaries) the disclosures need to be sufficient to allow trustees to assess whether, and to what extent, the deals offered by the PBMs are in the best interest of plan participants, rather than simply furthering the financial interests of the PBM. For most purposes, a plan sponsor's bargaining position (on behalf of plan participants) is strengthened by simply understanding the extent of the PBM's financial involvement with each of the above entities as well as the mechanics for how each program results in revenue to the PBM and how that revenue is used to reduce pricing with the plan.

PBMs often provide revenue sharing arrangements with plan sponsors to lower cost and drive participant behavior. However, because PBMs do not fully disclose the underlying terms it remains uncertain to the plan sponsor whether the revenue sharing arrangements, which may appear financially attractive, are primarily intended to steer plan participants to less cost effective treatments.

The primary use of this disclosed information would be for plan sponsors to gauge the willingness of the PBM to partner with them to control costs. For instance, requiring a listing of the programs (formulary, generic switching, etc.) in which a PBM is engaged with specific manufacturers, and for which a PBM receives financial remuneration, would be very useful information during the PBM selection process as well as monitoring the effectiveness of a PBMs performance. A plan sponsor looking to maximize generic drug utilization would be able to determine if a PBM was effectively managing and improving generic utilization, or if the PBM was disproportionately steering plan participants to drugs that resulted in a financial advantage to the PBM. Plan sponsors are currently unable to obtain this information from PBMs.

Response to Questions

The following information is provided in response to the specific questions asked by the Council.

Background on PBMs and PBM Services

The PBM market has experienced significant consolidation since the 2010 hearings held by EBSA. PBMs include very large corporations, such as Express Scripts (including the former PBMs operated as Medco, NextRx, Priority Health Care, CuraScript and NPA), CVS/Caremark (including Caremark and AdvancePCS), and Catamaran (including Catalyst Rx and InformedRx). Mid-size PBMs are also available, including EnvisionRx Options, Medimpact, and Benecard. Finally, PBMs may be owned by health plans, including Aetna Pharmacy Management, Human, and OptumRx (United Healthcare). A few other specialty PBMs are available, such as Navitus, PerformRx, and Sav-Rx.

PBM services vary from plan to plan, based both on the financial structure of the plan (e.g., fully-insured v. self-insured) and the number of services purchased from the PBM by the plan. Plan sponsors may purchase fully-insured products which include pharmacy services and which do not require a separate PBM agreement. Plan sponsors may also choose to fully-insure medical costs while self-insuring prescription drug benefits using a PBM. Finally, a self-insured

plan could have both self-insured medical benefits and self-insured prescription drug benefits using a PBM.

The financial arrangements between plan sponsors and PBMs vary widely. Sponsors can have a traditional PBM arrangement or a transparent one. These arrangements are discussed below. Right now, a majority of PBMs are the dispensing pharmacy and also the entity hired to contract with the dispensing pharmacy. This relationship and its financial consequences are often unclear to the plan sponsor.

PBMs may have various revenue streams from multiple sources, including but not limited to the following:

1. Retail and mail order reimbursement: average wholesale price (AWP) discounts, dispensing fees, and financial performance guarantees;

2. Drug manufacturer revenue streams: Formulary rebates, other rebates, and health and disease management programs;

3. Administrative fees: Fees paid by plan sponsors for routine PBM services and fees linked to transparency arrangements.

Formularies

Plan sponsors that retain PBMs generally choose a formulary from several options offered by the PBM. What is often unclear to the plan sponsor is which drugs are included on the formulary and whether the inclusions are based on clinical reasons or financial incentives. Plan sponsors need to understand whether formulary decisions are being made based on medical efficacy or financial considerations and, if financial, those considerations should be disclosed.

Comparative effective research as to the efficacy of various prescription drugs is not widely used. While the Affordable Care ACA (ACA) enacted the Patient Centered Outcomes Research Institute (PCORI) trust to conduct efficacy research, it is unclear whether that would facilitate understanding of prescription drug effectiveness.

One recent example of PBMs and the manner in which they use formularies is a strategy called "Price Inflation Protection," which involves the PBM negotiating price protections with pharmaceutical manufacturers for certain medications. Medications which are price-protected would be placed on the PBM's formulary, and those that are not would be excluded.

Contractual Arrangements

Contracts between a plan sponsor and a PBM are a critical tool in monitoring PBM performance and understanding the financial terms of the arrangement. Contracts are needed to ensure that terms (financial and non-financial) agreed upon during a PBM request for proposal are captured appropriately; identify pricing caveats demanded by the PBM; determine the competitiveness of a current PBM arrangement; and properly evaluate financial performance during an audit.

Some contract "best practices" are listed below, but the ability of the plan sponsor to achieve a "best practices" contract will depend on its size and bargaining ability. Each negotiation is unique and tradeoffs typically exist.

- Establish performance guarantees with enforceable penalties on various terms, such as generic dispensing rates;
- Clearly define contract terms such as rebates, revenue, transparency, AWP, audit guidelines, and termination rights;
- Most favored nation pricing clauses;
- Termination "without cause" language which prevents PBMs from locking plans into agreements for the full period of the contract (2 to 3 years);
- Assure that individual participants are not required to pay a copayment where the drug cost plus dispensing fee is less than the plan copayment;
- "Right to Audit" language with access to no less than 24 months of claims history;
- Assure that the plan sponsor will own all prescription claims data, other than proprietary pricing terms held by PBM;
- Address clinical programs and clearly define terms and pricing arrangements; and
- Limit the number of times per year that a PBM may make changes to Formulary or Preferred-drug lists, along with requiring prior notification of the changes.

The contraction in the number of PBMs affects contract negotiations because there may be few viable options particularly for large plans. Therefore, if the PBM refuses to change a contractual provision that a plan deems essential, the plan may have no effective alternative.

Monitoring PBM Compensation

Plan sponsors have a variety of tools that can be used to analyze prescription drug spending, including PBM compensation. These can include:

- A financial audit of the PBM during which pharmacy claims-level data is reviewed in order to verify that all contractual financial guarantees are met.
- A plan design audit to ensure that the plan document was followed.
- A pre-implementation audit prior to implementation of a new PBM to assure that the benefit has been properly set-up.
- Fraud and abuse review to detect abuse in the population and prescription utilization patterns.
- Reviews to determine the effectiveness of a PBM clinical review program.

- Utilizing an independent benchmarking database to analyze financial competiveness.

Transparency Contractual Arrangements

The Committee has asked what information is disclosed by PBMs under a "transparency" contractual arrangement and how disclosure impacts a health care benefit plan administrator's ability to determine reasonable compensation.

In general, there are two types of contractual arrangements for PBM compensation, "traditional" or "transparent." Traditional or "spread pricing" arrangements are commonly employed by PBMs. In these arrangements, PBMs negotiate aggressive contracted rates for retail and mail order drugs at lower prices and invoice their plan sponsor clients at higher contracted rates, profiting from the difference or "spread". For example, the price paid by the plan may be AWP-10. However, the PBM pays AWP-12. The "spread" is kept by the PBM and is not usually disclosed to the plan sponsor.

Transparent or "pass-through pricing" arrangements involve a contract in which a PBM charges a client a flat administrative fee per claim or per member, and the client pays the exact purchase price or reimbursement rate for the drug that the PBM has negotiated. However, it is important to define the terms subject to the transparency arrangement. For example, market share rebates or payments the PBM receives from a manufacturer for placing a drug on a formulary may be subject to the transparency arrangement, but fees paid to the PBM for clinical programs might not. A "spread" does not exist in a transparency arrangement. Transparency arrangements require greater oversight and monitoring by plan sponsors.

In some cases, a client with a "traditional" compensation arrangement may also be able to negotiate an additional arrangement where the PBM passes through 100% of all rebates. Whichever arrangement is selected, having clear, recognizable transparent terms is the key to oversight and must be spelled out clearly in the contract.

Key disclosures that should be made available in a transparent arrangement would include the following:

- Retail Provider Contracts
- Mail Order Drugs Purchasing Arrangements
- Manufacturer Rebate Contracts
- Reasons for changes in formularies

Audits

The Committee requests information regarding PBM audits. Specifically the Committee asks whether audits of PBMs are effective in terms of monitoring indirect compensation and taking into account the cost of the audit,

Plan sponsors may use a variety of audit techniques to audit PBMs. These may include a pre-implementation audit, which tests plan design and financial set-up of the PBM before it goes into

effect; a plan design audit, to ensure plan rules are being followed; and a financial audit, which reviews pharmacy claims-level data in order to verify that all contractual financial guarantees are met. PBM audits can be an effective tool, but are limited by a number of factors.

First, plan sponsor audit rights are limited by the terms of the applicable PBM contract. If audit rights have not been aggressively negotiated, they may be severely limited. Second, the plan sponsor can only audit those items to which the PBM will allow access under the financial terms of the contract. Consequently, for example, in a traditional PBM arrangement, the plan sponsor would not be allowed to audit the "spread" because that is not a financial term that is disclosed to the sponsor as part of the arrangement. They may, however, be able to audit rebates if that was negotiated in the contract. Third, the PBMs generally refuse to allow audits unless they pre-approve the auditor. Consequently, the plan sponsor's choice of auditor is often limited. Finally, PBM audits can be time-consuming and costly, and many plan sponsors may have limited resources to undertake this process.

State Law and ACA Disclosure Rules

The Committee has requested information concerning what compensation disclosures are currently required from PBMs under the ACA and/or state laws.

(a) ACA

ACA section 6005 amended the Social Security Act by imposing similar disclosure and transparency requirements with respect to prescription drug coverage for qualified health plans (QHPs) offered through the Marketplaces and Medicare. The Department of Health and Human Services (HHS) has issued regulations regarding these new requirements, which are summarized below. NCCMP is not familiar with any experience under these new rules and understands that the details may be further addressed in future guidance. Note that these disclosure requirements do not apply with respect to services provided by a PBM to self-funded plans or to fully-insured plans offered outside the Marketplaces created by the ACA.

HHS regulations (45 CFR § 156.295) require QHP issuers to provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies.
(2) The percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed, broken down by pharmacy type, which includes an independent pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public, that is paid by the QHP issuer or the QHP issuer's contracted PBM.
(3) The aggregate amount and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer or its contracted PBM negotiates that are attributable to patient utilization under the QHP.

"Bona fide service fees" for this purpose means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

(4) The aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

(5) The aggregate amount of the difference between the amount the QHP issuer pays its contracted PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

Information disclosed by a QHP issuer or a PBM under this requirement is confidential and cannot be disclosed by HHS or by a QHP receiving the information, except that HHS may disclose the information in a form which does not disclose the identity of a specific PBM, QHP, or prices charged for drugs, for certain specific enumerated purposes.

Similar disclosure is required under Medicare. See 42 CFR § 423.514(d).

(b) State law

Although we have not performed a detailed survey of State laws in this area, NCCMP is aware that various States regulate (or have attempted to regulate) PBMs in a number of ways, ranging from registration requirements to transparency requirements to requirements regarding the extent to which savings and rebates must be passed through by PBMs to plans. One of the issues with respect to State regulation of PBMs is the extent to which such regulation may be applied consistent with ERISA's preemption provisions. As States have become more active in the regulation of PBMs, litigation regarding preemption has also resulted. Case law is very fact specific, and different courts can sometimes reach different conclusions based on similar State laws. ERISA's general preemption of State law (and the costs associated with litigation under specific State statues) supports the need for appropriate regulation at the Federal level.

Conclusion

As noted throughout this statement, plan sponsors have a fiduciary duty to administer their plan solely in the interests of the plan's participants and beneficiaries. Consequently, fiduciaries must have adequate information regarding PBM fees and compensation in order to evaluate that compensation in light of the services provided. They must also be able to be able to compare those services across service providers. Requiring additional disclosure will assist plan fiduciaries in those duties.

We appreciate the opportunity to share this information with the Council and look forward to discussing these and other concerns raised by the Council in your upcoming meeting.

Respectfully Submitted,

Randy G. DeFrehn
Executive Director
NCCMP