Testimony of Susan Hayes

Before the Employee Benefit Security Administration
Advisory Council on Employee Welfare and Pension Benefit Plans
U.S. Department of Labor

Hearing on PBM Compensation and Fee Disclosure

August 20, 2014
Executive Summary – Oral Testimony

I appreciate the opportunity to testify before you today in regards to “PBM Compensation and Fee Disclosure.” As was suggested in the appearance letter, I have responded to your many of questions regarding PBM compensation and fee disclosure in my written testimony. Briefly, here is a summary of my written testimony:

I am a benefits consultant with over 35 years’ experience in the industry. For the last 18 years, I have owned my own firm, Pharmacy Outcomes Specialists. Pharmacy Outcomes Specialists assists health plans and employers with their pharmacy benefits programs and we employ Certified Public Accountants, Pharmacists, Pharmacy Technicians and Fraud Investigators in our practice. I have consulted to over 1,000 plan sponsors. Our clients range from the largest health plans in the country, such as WellCare, to the smallest 100 employee companies who are self-insured. I am the lead pharmacy consultant for one of the largest brokerage firms in the United States. My firm performs audits of pharmacy benefit managers (PBMs), assist clients in finding new PBMs or negotiate renewed arrangements with PBMs. I have been an expert witness in many cases involving the PBM industry including the landmark deceptive practices case against Merck-Medco. The United States Government sued Merck-Medco over deceptive practices in regards to rebate payments and won a large settlement requiring reforms to Medco’s Corporate Integrity Policies.1 We also assist plan sponsors in the detection and recovery of pharmacy fraud. I have a bachelor’s degree in Criminal Justice and am currently pursuing a Master’s Degree in Criminal Justice. I am an Accredited Health Care Fraud Investigator and a Certified Pharmacy Technician. For the last eight years, my firm has conducted at least one annual Pharmacy Benefits Academy that teaches plan sponsors about the PBM industry where hundreds of clients have been educated about topical issues relevant to the PBM industry.

There are four areas of concern:

- Plan sponsors are not allowed reasonable access to audit their PBMs to determine if the PBM is properly performing under contract terms. Plan sponsors must hire an auditor who is deemed “acceptable” by the PBM, the auditor must proceed with the audit that is under the terms stipulated by the PBM which in turn causes the audit to be expensive, pricing audits out of reach for many plan sponsors. Because of this, plan sponsors have no idea if the financial terms are being met by their PBM. That is problem when trying to exercise your fiduciary responsibilities to manage the plan effectively and for the benefit of beneficiaries.

- PBMs routinely decline to disclose that they are being paid by adding costs on to prescription drug claims. If they do disclose that spread pricing is occurring, the amount of spread is not disclosed. No one has a problem with PBMs making money or making a profit. But not knowing what the PBM is charging a client makes it nearly impossible to evaluate the quality of the services provided against the cost of those services.

- Clawbacks, which take money back from pharmacies which the pharmacy has collected as a copay, simply enriches the PBM, fools the pharmacy into believing temporarily that the pharmacy is being paid fairly and does not encourage consumerism by beneficiaries. The practice is deceitful to pharmacies, beneficiaries and plan sponsors.

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1 UNITED STATES OR AMERICA ex rel. George Bradford Hunt, Walter W. Gauger, and Joseph Piacentile, v. MERCK-MEDCO MANAGED CARE L.L.C., MEDCO HEALTH SOLUTIONS, INC., MERCK MEDCO RX SERVICES OF FLORIDA, NO. 2, L.C., MEDCO HEALTH SERVICES OF FLORIDA, L.C., MERCK-MEDCO RX SERVICES OF NEVADA, INC., MERCK MEDCO RX SERVICES OF TEXAS, L.L.C., Case No. 00-CV-737
Having your PBM monitor pharmacy fraud is like having the fox watch the hen house. Simply put, adding costs to claims as a source of administrative fees, encourages more claims. There is therefore, no incentive for PBMs to reduce the number of claims, whether the claims come from the most honest pharmacy or a pharmacy that routinely sends in phantom claims – claims for which a prescription order, patient or physician do not exist.

Thank you and I look forward to your questions.
Written Testimony

On the outset of this testimony, I would like to be very clear. Newer transparent pass-through PBMs, like Envision, Navitus and EHIM are based on business models that guarantee that much of the conduct that I will be discussing today does not occur. Even some of the older, traditional PBMs like Express Scripts, Catamaran and Caremark have saved plan sponsors billions of dollars in discounts, clinical management and mail delivery programs. Frankly, these entities save lives every day, be it at a contracted retail pharmacy or in shipping high cost specialty drugs to patients suffering from horrible diseases. However, plan sponsors under ERISA deserve to know what they are paying for these valuable services and PBMs need to make a profit, albeit a disclosed profit. Buying prescription drugs is not like buying a car. A car dealer does not have to tell me, a consumer, what he makes when I buy my next car. Under ERISA, benefit plans are established for the sole benefit of employees and corporations receive tax credits for offering these programs. Plan sponsors are therefore obligated to understand that the costs associated with these programs are market competitive.

There are four key areas that I will discuss today relevant to the topic. The first area concerns plan sponsor audit rights.

1. **Plan Sponsor Audit Rights**

Plan sponsors enter into agreements with PBMs for the provision of pharmacy benefits for the plan sponsor’s members. These agreements typically list the overall financial performance that is expected from the PBM. Financial performance guarantees are broken out by retail brand and generic, and mail order brand and generic discounts off Average Wholesale Price (AWP) and Maximum Allowable Cost (MAC) price guarantees and dispensing fee arrangements. Specialty drugs, typically the very high cost drugs, may be listed with an overall “default discount arrangement” or a price list. Rebates are either expressed as a percentage shared arrangement or a flat dollar guarantee, or a combination of both. Administrative fees are documented for various programs and general PBM services. (I have included a sample redacted PBM “rate sheet” as Exhibit One). But plan sponsors have substantial difficulty in ensuring that these financial arrangements are properly adhered to by the PBM.

PBMs often allege that there is “transparency” and “disclosure” because plans can audit the PBM. This is simply not the case. First, in order to conduct an audit, plans must contract with audit firms, like Pharmacy Outcomes Specialists (POS). These audits are expensive and can range from $15,000 to over $200,000 depending on the size of the client and scope of the audit. The result is that it is cost prohibitive for smaller employers, which make up the bulk of plan sponsors today, to audit PBMs. Why are these audits so expensive? Because firms like mine have to buy Average Wholesale Price guides that cost $25,000 or more a year. AWP price is the only bit of information that you cannot google and there is no “app” for. MediSpan is the only pricing guide that publishes AWP. By keeping a monopoly on AWP pricing, MediSpan can demand whatever price it wants. And, MediSpan’s primary “clients” are the PBMs who have a vested interest in keeping this information out of the public’s eye. In fact, under my company’s agreement with MediSpan, we cannot disclose AWP information to anyone; we can simply use it to form an opinion. Second, in addition to the cost to the plan sponsor, each audit may take 100 to 500 hours to complete. Audit firms must comb through line by line claims transaction data to ensure that

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claims have been priced correctly. Complicated rules are written into PBM contracts that make auditing difficult even for seasoned professionals.

Taking a step back, the above ONLY occurs IF the auditing firm is allowed to audit. Many PBM contracts have provisions that make audits near impossible to conduct. For example, one such provision requires the auditor to be “mutually acceptable” to both the PBM and the plan sponsor. On its surface this seems like a reasonable request. A PBM would not want an audit firm conducting an audit when the firm knows nothing about the PBM industry. However, instead of keeping auditors “out” that do not know anything about the PBM industry, the term is used to keep auditors that do know something about the PBM industry away from auditing them. If the audit firm has “secret knowledge” from one audit, they are barred for a lifetime of auditing, simply because they are considered “not mutually acceptable” by the PBM. For example, Express Scripts barred my firm for over 10 years from conducting further audits. Why? ESI barred POS because we had been named as a fact witness in a lawsuit, which occurred because the PBM was unwilling to pay recoveries to the client on an audit. This case was stuck in court for over 10 years. When the client dismissed the case, suddenly, POS was considered an acceptable auditor. I have attached the letter from Express Scripts as Exhibit Two. I have also attached this mutually acceptable auditor language and audit protocol from a PBM contracts as Exhibit Three.

Lastly, PBMs make it near impossible to audit both their “secret agreements” for rebates with pharmaceutical companies and retail network agreements with pharmacy chains. If the PBM is acting on behalf of the plan sponsor to negotiate rebates or network arrangements, why keep the rebate agreements secret from the entity you are working for? If you do want to keep the agreements secret, both the client and the auditor should sign confidentiality agreements. Further, these agreements are “secret” because the drug company generates the document, not the PBM…it is not the PBM’s contract to keep secret.

Smaller plan sponsors, firms with a pharmacy spend of less than $10 million, a majority of companies in the United States, are contractually prohibited from conducting a rebate audit or a retail network audit. In the case of a large managed health care plan or a large employer that has the clout to negotiate such an arrangement, here are the “rules of the industry:"

- Auditors are required to go on-site to the PBM’s headquarters for the audit.
- PBMs may provide any and all correspondence relative to a given PBM/rebate or PBM/network contract which may entail four to five reams of paper. An average rebate contract can take up to 4 to 5 hours to read and review.
- Instead of providing copies, the auditor must manually and oftentimes without a laptop computer, take down the contract terms. These contract terms may take 4 or 5 hours to manually transcribe. Auditors are put in rooms with no phones and “baby sat” with PBM representatives in the room to ensure that the agreements are not copied.
- An audit of the top ten rebate contracts or retail network contracts may take one to two weeks of on-site time.
- This on-site time is costly for clients to pay and makes auditing costly.
- When the audit is completed, the PBM simply states that the auditor took down the wrong terms because it was manually done and no work papers exist.
- When the auditor reports to the client any amounts owing, the PBM claims that the auditor breached confidentiality to its own client.

The above described situation could be easily remedied if, under confidentiality agreements, copies of the rebate or retail network agreements are sent to the audit firm, eliminating on-site time, chance of errors and establishing irrefutability of the findings. Why is this important? Because without the ability to audit,
it is impossible to know if the PBM is really “passing through” rebates and retail network discounts. Why is it so heavily guarded? Because PBMs do not want the amount of spread disclosed.

The Department of Labor can fix this situation. We believe it is imperative to issue to plan sponsors a “Best Practice” guide to auditing. This guide would include when to audit and how an audit should take place. For example, we believe audits should take place each time a PBM contract is renewed, typically every three years. Guidelines for auditors should be established so that “fly by night” auditors are not allowed to audit. Like Private Investigators in Illinois, auditors should either “apprentice” with seasoned auditors or be required to pass an exam. And PBMs should not have such prohibitive rules for auditing. Copies of rebate contracts and retail network agreements should be allowed to be sent to auditors who sign confidentiality agreements and those auditors that breach these agreements should be subject to sanctions. PBMs not following these guidelines should be sanctioned. Auditors should not be sanctioned, however, on a whim by a PBM or as “revenge” for finding recoveries for clients.

2. Disclosure of Spread Pricing

Spread pricing generally occurs in one of two ways: (1) when the PBM reimburses pharmacies a lower amount than it charges a plan sponsor; and, (2) when rebates from drug manufacturers are not passed back in full by the PBM. As an example of the first spread pricing condition, David Balto, an antitrust attorney who testified before this Council in June cited a case involving a large health plan, Meridian, which discovered vast differences in the amount it was paying its PBM for amoxicillin versus what the PBM was paying pharmacies for that same drug. The difference in a single prescription of amoxicillin was $65.62. In other words Meridian was being billed for generic amoxicillin at $92.53 for every employee prescription; however Express Scripts was paying only $26.91 to the pharmacy to fill these same prescriptions.4 Our own studies and audits reveal similar situations in which drug costs to plan sponsors are needlessly increased at the expense of clients and consumers and to the benefit of PBMs.5 Unfortunately, I am unable to discuss these examples for fear of being sued by a PBM for breach of a confidentiality agreement that I may have signed.

Rebate spread pricing might even be more egregious than the first example. A Chief Operating Officer at a PBM recently told me that drug manufacturers of specialty drugs, the highest cost drugs with therapies as expensive as $100,000 a year are now offering to pay the PBM $5,000 per member to fund nurses on call lines who will ensure that the members stay on these high cost drugs as long as possible. These programs have two costly functions: (1) they promote unnecessary use of high cost drugs, and (2) they divert manufacturer funds from “shared” rebates with clients to reduce the cost of overhead for PBMs.

The result of spread pricing has detrimental effects for plan sponsors. Because the PBM takes an undisclosed amount for its administrative fees, plan sponsors perceive the cost of PBM administration as “free.” But nothing could be further from the truth. The nature of the undisclosed amount makes it impossible to determine the real cost effectiveness of a PBM’s services. The ability of the PBM to alter the amount of spread on a claim by claim basis means that plan sponsors cannot project the cost of administrative fees in the future and plan sponsors will never know the true cost of administration of the program. Therefore, it is difficult if not impossible to evaluate one PBM’s services, and the cost to perform those services, against another PBM.


5 See David Balto, Increasing Competition and Choice, New America Foundation (March 2014), http://newamerica.net/sites/newamerica.net/files/policydocs/Balto_IncreasingCompetitionAndChoice.pdf (Discusses conflicts of interest among PBMs leading to increased costs to plan sponsors and consumers. “PBMs may favor drugs in which they receive a greater margin because they are dispensed by mail order, even though the plan sponsor or consumer may pay more.”).
How can plan sponsors exercise their fiduciary responsibility to evaluate a PBM’s services and related costs if the plan sponsor does not know the cost of administration of the PBM’s services?

The Department of Labor has the ability to cure this situation. Under Medicare Part D, PBMs are required to report spread pricing as an administrative fee on the Prescription Drug Event (PDE) files, and to which the plan sponsor of the Medicare Part D program are not reimbursed by the government. This forces the PBM to (hopefully truthfully) separate (a) what the “cost” for reimbursing the pharmacy is, and (b) what is taken as spread or administrative fees. If the plan sponsor then wants to pay exorbitant fees to the PBM as spread pricing, so be it. But at least the plan sponsor now knows under Medicare Part D what the cost of doing business is from PBMs that are not “pass through.”

A similar mechanism can be set up for ERISA employer plans. The programming for PDE reporting now exists with most all PBMs. It would not be a costly endeavor to “turn on” PDE-like reporting for employers. PBMs should be required to provide PDEs to all ERISA plan sponsors which would show on a claim by claim basis what was reimbursed to the pharmacy on the plan sponsor’s behalf and what was added on to the claim as a form of administrative fees. At the end of the year, a plan sponsor would know precisely what was charged for administration of the plan.

Of course, PDE reports presume two important factors. The first factor presumes PBMs are fully disclosing administrative fees. Since it is a fiduciary responsibility to audit, the amount broken out as spread pricing could be verified by auditing a sample of reimbursement files back to the pharmacies. The Department of Labor should incorporate these standards in the “Best Practices” guidelines discussed above. The second presumption is that rebates are being properly defined. As with Medicare Part D, rebates should be defined as Direct and Indirect Remuneration (DIR) to encompass all forms of payment for direct (i.e. money) and indirect (such as provision of a nurse) remuneration from drug manufacturers.

3. **Clawbacks**

A new PBM phenomenon, called “clawback” is increasing costs directly to plan beneficiaries. While information about spread pricing has been around for some time now, a recent phenomenon has been observed in the PBM auditing community. This new phenomenon not only raises the cost of prescription drugs but has the effect of duping average consumers of prescription drugs into unwittingly funding PBM profits.

The proliferation of front end health insurance deductibles was designed to encourage consumers to make smart choices. If a consumer has a $2,500 front end deductible, the idea is that since they are spending their own money in this deductible, a patient will choose, for example, a generic over a brand formulation of the same drug. In a “clawback” situation, the patient presents a prescription at a pharmacy. The claim is processed and the pharmacist is instructed to collect $100 as the cost of the drug. The entire prescription is paid for by the patient. Two weeks later, when the pharmacist receives reimbursement from the PBM, his remittance statement shows that the PBM has taken back (clawed-back) $75. This leaves just enough so that the pharmacist may make a few dollars profit on the claim. What happens to the $75 difference? The PBM retains this amount as “spread” paid for by the patient.


7 Per [42 C.F.R. 423.308](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/downloads/PDEDataElements.pdf), direct and indirect remuneration (DIR) is any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug. Thus, DIR includes discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, and coupons. DIR also includes goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. Retrieved from: [http://www.medicarelink.com/pdf/2009_DIR_Rep_Reqs%20Apr%202013%2010.pdf](http://www.medicarelink.com/pdf/2009_DIR_Rep_Reqs%20Apr%202013%2010.pdf)
the “clawback” was because the PBM did not have a financial relationship with the patient and “could charge a prevailing price” for the drug. Asked where the “prevailing price” came from, the PBM admitted it was a price made up by the PBM.

Following is a recent example of another clawback situation. A small independent pharmacy in the Midwest, who asked not to be identified for fear of the PBMs “shutting off his contracts for reimbursement,” provided me information for the month of June. Various PBMs throughout the country, for his patients, asked him to collect $5,667 in copays. Then, these PBMs proceeded to deduct $1,830 from his other reimbursements or 32% of the collected copays. Therefore, 32% of the out-of-pocket amount that his patients paid went into the pockets of the PBMs, when the PBM had no role in the pharmacy services provided these patients. While this pharmacist is not willing to be named here, he is willing to speak to any member of the Department of Labor privately to verify my testimony.

The clawback situations I describe unwittingly dupe patients into funding the PBM’s profits. Patients believe they are paying the total the cost of the drug in their front end deductible. If the largest companies in America cannot afford to buy AWP information, then certainly patients have no way of knowing that they are paying reasonable costs. Even if the patient were to go from Walgreens to CVS to Rite Aid, the PBM would “charge” the clawback price and take money away from any of these pharmacies. So shopping around has no effect on this situation. Plan sponsors are not made aware of these arrangements. I have reviewed thousands of contracts between PBMs and employers. Not one mentioned that member claims were not subject to the same discounts and pricing as employer funded claims. In fact, it is the absence of language that “allows” PBMs to create the clawback opportunity.

The DOL can fix this situation. Legislation must be passed to protect ERISA beneficiaries in the same spirit of the original legislation in 1974. ERISA was designed to protect plan beneficiaries. This practice is an intentional deception of the most vulnerable. It is time to bring an end to this practice now widely employed by the PBMs. While passing legislation might be outside of what this council can do, I am asking that the Department of Labor adopt regulations to fix this situation by either preventing it or requiring all PBMs to disclose any recoupments of copays or deductible payments made to pharmacies to both the plan sponsor and the beneficiary.

4. Fraud, Waste and Abuse

As an Accredited Healthcare Fraud Investigator, I am intensely interested in elimination of fraud in the health care system. I believe fraud committed by pharmacy staff ultimately leads to public health and safety risks. Plan sponsors retain PBMs to assist them in the detection of pharmacy fraud. By 2016, it is estimated that health care spending will exceed $4.14 trillion, representing 19.6% of the GDP. Prescription drug costs represent $263.3 billion of health care dollars spent. According to the National Health Care Anti-Fraud Association (NHCAA)⁸, health care fraud is estimated conservatively at 3% of health care spending, or $68 billion. Other estimates by officials and law enforcement agencies place pharmacy fraud related losses as high as 10%, or $230 billion is lost to fraud (www.fbi.gov⁹).

PBMs are supposed to contract with pharmacies on behalf of the plan sponsor. However, since the contracts are between the pharmacies and the PBM, not the PBM and the pharmacy on behalf of the plan sponsor.

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sponsor, the PBM retains the right to audit claims submitted by the pharmacy. The PBM is supposed to ensure that only legitimate claims are paid. However, with the practice of spread pricing, fraudulent claims are overlooked. If the PBM pays the pharmacy the “cost” of a phantom prescription, but then adds 5% to 10% to the cost of that prescription, what happens when the PBM discovers the prescription is “phantom?” The spread that the PBM retains also disappears.

Most large PBMs would argue that all have staff dedicated to fraud investigation. And that is true. Many of the staff investigators in PBM fraud units are hardworking and dedicated to finding fraud and eliminating it. But these staff investigators really have too much work and too little time to make a dent. Some of the largest PBMs have less than 10 staff including investigators. Considering the billions of transactions a year, and 65,000 pharmacies in America, there is just not enough time in the day to even audit 1% of the network. If one investigator could audit two pharmacies a day, every day, it would take a year and a half to audit only 1% of the network, without accounting for a sick day or travel time, preparation time or reporting writing time. Realistically, PBMs staff these positions to catch only the most blatant fraud schemes. Narcotic abuse, waste of using brands over generics and false submissions of claims go undetected and unmonitored by the nation’s PBMs.

Fraud also happens in mail order facilities, like any pharmacy. However, mail order pharmacies are often owned by the PBM who does not allow plan sponsors to audit the facilities and plan sponsors are not informed when fraud occurs in mail order facilities. This is truly the fox watching the hen house. Plan sponsors who use PBM-owned mail order should require the PBM to disclose any suspected fraud and the plan sponsor should be able to audit the PBM’s operations for suspected fraud. Several years ago, we uncovered Liberty Pharmacy in Las Vegas. When we came on-site, Liberty Pharmacy had a license to operate from the State of Nevada as a pharmacy but had no product and in fact was nothing more than a pharmacist in an office in Medco’s mail order pharmacy. Liberty’s pharmacist transferred all of the prescriptions to the Medco facility. Why? So that Medco could actually be a pharmacy in competing PBMs networks.\(^{10}\)

In 35 years of consulting, I have only seen one PBM, OptumRx, report to its clients what it saved as a result of fraud intervention and only at the insistence of the client after a serious problem with controlled substances. For the last five years, however, the amount recovered has been less than 1% of spend – a drop in the bucket compared to what experts estimate fraud to be in pharmacy programs.

Again, I would ask that the DOL allow ERISA fiduciaries to audit fraudulent claims – whether in retail or mail order, like CMS allows plan sponsors under Medicare Part D and require PBMs to report suspected fraud to the FBI’s Healthcare Fraud Unit and other law enforcement agencies. It is only with a concerted effort by PBMs, plan sponsors and government agencies working together that we can battle pharmacy fraudsters and not endanger the public.

Conclusions

I want to thank you for the opportunity to testify today and present this written testimony. I represent the many plan sponsors who are my clients who are frustrated with the lack of ability to do the job that they signed up to do; namely, to be ERISA fiduciaries. Clients want to do the right thing. But the lack of transparency, the depth of deception and overworked Human Resource department personnel combine to make exercising fiduciary responsibility with respect to PBMs very difficult. Simple steps taken at the Department of Labor level will greatly assist in leveling the playing field between thousands of plan sponsors.

\(^{10}\) The address of both Liberty Pharmacy and the Medco Pharmacy is 6225 Annie Oakley Dr, Las Vegas, NV 89120. Both Liberty and Medco are separately licensed under the Nevada Board of Pharmacy.
sponsors against a PBM industry rooted in keeping a closed door to undisclosed profits. In summary, these steps include:

- A best practices manual for auditing PBMs
- PDE reporting for commercial plans,
- Barring “clawbacks” at the retail pharmacy level by PBMs
- Requiring reporting of fraud investigations.

Thank you again for your time.
Exhibit One – Redacted Pricing Sheet