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Prescription for Transparency in Pharmacy Benefits: Corporations, Federal Government Hold Pharmacy Benefits Managers' Feet to the Fire

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Two recent developments threaten to wipe clear the cloudy barrier shrouding pharmacy benefits managers' (PBMs) administration of employer-sponsored health plans. For years, the federal government—along with select state governments and other employers—has demanded more transparency in PBM business practices. If recent events are indicative, they may finally get what they have been asking for.

THE PBM EXPLOSION

Pharmacy benefits managers exploded onto the health care scene in the 1990s. PBMs set out to provide pharmacy benefits and prescription drugs administration and services for many self-funded employee health plans. These health plans include plans sponsored by corporate entities, by state, federal, and municipal governments, and by non-governmental entities such as labor unions alike. Touting a unique positioning in the health care provider industry, along with enhanced bargaining power derived from volume dealings with drug manufacturers and retail

pharmacies, PBMs attempt to streamline the process by which many Americans fill prescriptions at the corner pharmacy. In so doing, PBMs have wedged themselves into the role of middle man between the health plan, the drug manufacturers, and the retail pharmacies. Currently, PBMs provide their services to an estimated 200 million covered "lives" in the United States.

In recent years, a number of improper PBM practices have been exposed through private lawsuits, whistleblower actions, and state and federal investigations. These unseemly PBM practices include the failure to pass through drug manufacturer and pharmacy rebates to which the health plan is entitled, inappropriate and costly drug "switching," mail order prescription manipulation, and the use of illicit pricing spreads, among other things.

TRANSPARENCY DEMANDED

The increased pressure and awareness resulting from these investigations and lawsuits now appears to be taking hold. First, in early August 2005, 52 large employers calling themselves the

Pharmaceutical Purchasing Coalition pooled their resources, size, and clout to demand that PBMs begin to operate in a more transparent manner.

Second, and perhaps more importantly, in early September 2005, AdvancePCS—now a wholly owned subsidiary of one of the nation's three dominant PBMs, Caremark Rx Inc.—agreed to pay \$137.5 million to settle a federal investigation and lawsuit relating to civil liabilities and kickback allegations. Together, these two events stand to change forever the manner in which PBMs do business in America, how the courts view PBMs, and how PBMs are able to influence consumer pharmaceutical use and pricing.

According to the Pharmaceutical Purchasing Coalition, the organization represents five million covered lives with the awesome collective drug spending power of over \$3.7 billion in 2003.¹ A part of the public policy group known as the HR Policy Association, the Pharmaceutical Purchasing Coalition includes such notable companies as Caterpillar, Inc., International Business Machines Corporation, Starbucks Corporation, and Verizon Communications Corporation. The Coalition “sought a restructured pharmacy benefit purchasing model in which financial incentives would shift from maximizing rebates from pharmaceutical manufacturers to promoting appropriate cost effective therapies, and one in which PBMs are paid for the services that they provide for their clients.”²

In an attempt to further this purpose, the Coalition solicited bids from PBMs that would be willing to operate under the more transparent model it created. Notably, only three PBMs were certified by the Coalition: Aetna Pharmacy Management, MedImpact Healthcare Systems Inc., and Walgreens Health Initiatives. The nation's most powerful PBMs—Medco Health Solutions Inc., Caremark Rx Inc., and Express Scripts Inc.—dropped out of the

bidding, according to *The Wall Street Journal*.³

JUSTICE'S ANNOUNCEMENT

Taken by itself, this development—while noteworthy—might be indicative of little more than a handful of powerful companies refusing to play ball on the PBMs' home court and under their standard terms. However, the heat on the PBMs increased exponentially with the US Department of Justice's September 8th announcement that AdvancePCS agreed to pay \$137.5 million to resolve civil fraud and kickback allegations stemming from an investigation into its now wholly-owned subsidiary, AdvancePCS.⁴ The AdvancePCS investigation had begun as early as 1999. According to Patrick L. Meehan, United States Attorney for the Eastern District of Pennsylvania, the settlement addresses “AdvancePCS's hidden financial relationships with drug manufacturers and health plans that influence what drugs we are prescribed and how much we pay for them.”⁵ Importantly, as a part of the settlement, AdvancePCS entered into a consent order of injunction and settlement which imposes certain obligations and duties on the company going forward.

Under the Corporate Integrity Agreement entered into as a part of the settlement, AdvancePCS (and Caremark, as its corporate parent) agreed to name a corporate compliance officer and a compliance committee, and agreed to adopt and adhere to a particular code of conduct. In addition to certain broad inspection, audit, and review rights granted to the Office of Inspector General of the United States Department of Health and Human Services, AdvancePCS also agreed to create an “Arrangements Database.” The database requires AdvancePCS to organize and disclose information to the federal government regarding its compensation arrangements, and is designed to ensure compliance with anti-kickback laws. AdvancePCS

further agreed to engage an independent review organization (such as an accounting, auditing, law, or consulting firm) to monitor AdvancePCS's compliance with the terms of the Corporate Integrity Agreement.

WHISTLEBLOWER SUITS AND INVESTIGATIONS

These developments and updated facts are catching the attention of the nation. A resultant PBM cumulative awareness effect is undeniable. Further evidence of the fire enveloping the PBM industry takes the form of various additional whistleblower lawsuits and other state and federal investigations. For example, in April 2004, 20 states settled allegations of inappropriate drug switching with Medco on consumer fraud bases. The settlement garnered over \$29 million. Medco remains the subject of a federal investigation. In late 2004, New York Attorney General Eliot Spitzer sued Express Scripts on behalf of New York's largest state employee and retiree plan, alleging that the plan had been deprived of as much as \$100 million in rebates and savings not passed through to the plan. Meanwhile, Caremark remains the subject of several *additional* whistleblower lawsuits (to say nothing of the state actions which remain pending after the recent settlement). One suit alleges that Caremark refused to cover prescriptions for people with dual coverage, inappropriately allowing those payment obligations to be passed along to government programs such as Medicaid or Veterans Affairs rather than channeling them through available private coverage. Another suit alleges that Caremark restocked and resold potentially damaged drugs without following appropriate testing protocols, and that Caremark altered dates on prescriptions and engaged in other misconduct in order to meet contractual turnaround deadlines and avoid monetary penalties.

It is becoming clear that PBM clients are no longer willing to stand

for certain conduct and are demanding the right to meaningfully audit these practices. For years, PBMs have conducted their business in a manner which does not allow the rest of the world—including their own clients—to see how the client money is being used within the opaque PBM box. PBMs have jealously guarded their complex rebate contracts and their agreements with drug manufacturers under the ruse that this is what allows them to keep prices down, or by arguing that the manufacturers would not allow them to disclose certain details. Such arguments are specious at best, as has been chronicled by some drug manufacturers going on record to distance themselves from any suggestion that it is the *manufacturers* who demand secrecy.⁶ Further, in the lucrative and increasingly common ‘PBM-as-vendor’ practice of retailing mail-order pharmaceuticals to plan beneficiaries—directly from PBM warehouses—it turns logic on its head to suggest that secrecy in wholesale pricing could ever lead to consumer advantage. Indeed, in this mail-order scenario, the PBM can hardly be called an agent or a middle man.

THE SHIFTING TIDE

Certain of these long-accepted and long-unregulated PBM practices have fostered a well-entrenched system characterized by an utter lack of transparency. To be sure, the murky water is deep and many PBMs are doing everything in their power to ensure that it does not clear. However, many of the existing investigations and lawsuits have spotlighted the

issues discussed herein and it now appears that the tide is shifting toward a more open marketplace.

According to the HR Policy Association press release discussed above, the three PBMs certified to operate under the new transparent model have specifically agreed to:

- charge employers the exact same amount that the PBM paid at the dispensing pharmacy for brand and generic drugs delivered at retail;
- provide acquisition cost of brand and generic drugs delivered via mail order;
- pass-through of any and all pharmaceutical manufacturer revenues that are associated with an employer’s drug utilization, including rebate dollars and revenue garnered by PBMs for data sales and marketing studies;
- an audit of contracts to verify compliance;
- provide point-of-sale rebates to employers and/or employees;
- design programs and services to manage chronic conditions to meet individual employer needs; and
- promote greater use of appropriate cost effective medications.⁷

The fact that large corporations are banding together to force agreement with the above standard, coupled with the fact that Caremark/AdvancePCS has agreed to operate with the federal government under the strict terms of the Corporate Integrity Agreement, indicates that health plans are beginning to have their PBM transparency concerns heard and addressed. If these large corporations are able to

cooperate with certain PBMs, why would not all corporations begin to demand the same? Why would not all PBMs agree to these terms? If Caremark/AdvancePCS has agreed to operate under a strict conduct agreement with the federal government, why would not all Caremark/AdvancePCS clients demand the same for their health plans?

Whether and to what extent these practices gain widespread traction in the industry remains to be seen, but these recent developments suggest that the nation is catching on to the PBM game. ☺

NOTES

1. A copy of the press release is available at http://www.hrpolity.org/press/2005/release_081005.htm.
2. *Id.*
3. See Vanessa Fuhrmans, “Employers Join to Push Drug Managers for Full Disclosure,” *The Wall Street Journal*, August 10, 2005.
4. Eleven states, along with the District of Columbia, remain plaintiffs in this whistleblower action, as their actions were not settled and remain pending.
5. A copy of the US Department of Justice press release is available at <http://www.usdoj.gov/usao/pae/News/Pr/2005/sep/PCS.html>.
6. See Milt Fraudenheim, “Critics Attack Secret Deals by Middlemen to Buy Drugs,” *The New York Times*, December 20, 2003.
7. HR Policy Association press release, August 10, 2005, *supra*.

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