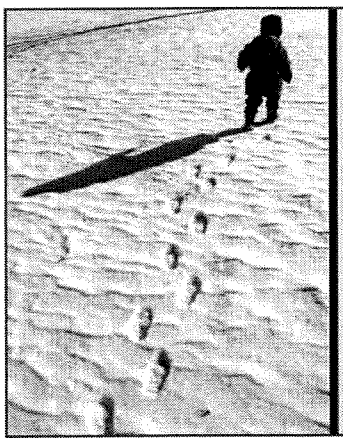

Beginning Steps for PBM Reform

by David A. Balto

Probably no other market faces the amount of litigation and myriad government investigations as the pharmaceutical benefit manager (PBM) market. PBMs are intermediaries in the delivery of pharmaceutical benefits. As in many healthcare markets, intermediaries may improve the delivery of benefits by bringing new network relationships and streamlining processes. PBMs also have engendered significant controversies, however, because of the appearance of conflicts of interest.

In recent years, there have been numerous federal and state investigations into the PBM market. In April 2004, the Attorneys General of 20 states and the U.S. Attorney settled charges against Medco Health Solutions, Inc. (Medco) and Merck-Medco Managed Care, L.L.C. for alleged violations of various consumer protection and unfair trade practice statutes.[1] The settlement imposed far-reaching legal obligations on the company relating to its drug-switching practices, and is likely to serve as a blueprint for future regulation of PBMs.

The Complaint

Medco Health Solutions, Inc., the corporate successor to Merck-Medco Managed Care, L.L.C., provides PBM services to healthcare plans nationwide. Medco also operates prescription drug mail order pharmacies under the names of various wholly-owned subsidiaries. Medco is the nation's largest PBM, with 2002 net revenues of more than $32 billion and a network of more than 55,000 pharmacies.[2]

Virtually all health insurance plans include a pharmacy benefit component that pays for prescription drugs for the plan members. This pharmacy benefit often is managed by a PBM. The PBM is engaged in the business of administering the pharmacy benefit for the client health plans, and performs some or all of the following tasks for its clients: a) organizing a network of retail pharmacies that agree to fill prescriptions, and negotiating prices at which to fill those prescriptions; b) operating mail order pharmacies that sell prescription drugs directly to patients; c) processing and paying prescription drug claims on behalf of its clients through a computerized system; d) providing patients, physicians, and clients with information about available pharmacy benefit and prescription drug plans; and e) providing advice regarding the development of so-called "formularies," which are lists of preferred drugs that a plan agrees to pay for its member patients. Medco's Pharmacy & Therapeutics Committee (P&T Committee), composed of independent physicians and pharmacists, is obligated to use its professional judgment to determine which drugs should be included in Medco's formularies.

The complaint alleged that Medco represented to its clients that it saved them money by providing prescription drugs at a contractual discount off the average wholesale price (AWP). In addition, the complaint alleged that Medco also promised cost savings for its clients by a) negotiating and obtaining "rebates" from drug manufacturers for including their branded drugs in Medco's formularies; and b) conducting so-called "therapeutic interchange programs," which allowed Medco to switch prescription drugs to ensure greater compliance with Medco's formularies. Critical to Medco's cost-savings claims, the complaint further alleged, was its promise to "pass through" such manufacturer rebates to its clients.

The complaint also alleged that Medco's formulary decisions, as well as its drug switching programs, were influenced

largely by its desire to receive money from the drug manufacturers, not by the desire to save clients' money. The complaint further alleged that Medco actively encouraged pharmacists and prescribers to switch patients to different prescription drugs, but failed to pass on the resulting savings to patients or their healthcare plans. The drug switches generally benefited only Medco, despite Medco's claims that it saved money for both patients and health plans. Moreover, Medco did not disclose to prescribers or patients that the proposed drug switches would increase rebate payments from drug manufacturers to Medco. Finally, the complaint alleged that the drug switches resulted in increased costs to health plans and patients, including additional costs for follow-up doctor visits and tests.

In particular, the complaint alleged that Medco's proposed drug switches "either favored target drugs that were more expensive than drugs originally prescribed, or had the effect of favoring drugs without a generic equivalent over drugs with a generic equivalent."[3] Because Medco engaged in conduct designed to maximize revenues for itself without passing through those revenues to its clients, the complaint alleged, both Medco's formulary decisions and its drug switching programs were "driven by Medco's conflicted interest, not by cost savings for the client."[4]

Moreover, the complaint alleged that Medco's proposed drug switches required clients and patients to pay substantial additional costs. For certain drug therapies, a switch from one to drug to another often requires additional doctor visits and/or medical tests to ensure the new drug's efficacy. Medco did not pay for these additional costs. Often these switch-related costs outweighed the incremental cost savings, if any, resulting from the drug switches.

Principal Provisions of Consent Decrees

To remedy Medco's conduct, the Consent Order set forth several categories of prohibited drug switches. The Order carved out the following four specific instances in which Medco may *not* make drug switch solicitations to physicians and prescribers:

(1) when the cost of the proposed drug exceeds that of the current drug;
(2) when the current drug has generic equivalents, while the proposed drug does not have generic equivalents (except in situations in which the proposed drug is cheaper than *all* of the generic equivalents of the initially-prescribed drug);
(3) when the patent for the current drug expires within six months, or the proposed drug switch would have the effect of avoiding competition from future generic equivalents; and
(4) when—within the past two years—a patient either already has switched a drug in the same therapeutic class in response to Medco's solicitations or subsequently has reversed such a switch. This "two-year rule" does not apply if all of the proposed drugs were not part of the prior drug switch solicitation by Medco.

The Order also established a number of affirmative obligations for Medco during permissible solicitations for drug switches to prescribers, including:

(1) identifying the person and the entity (e.g., Medco) making the solicitations;
(2) clearly disclosing to prescribers both the annual minimum or actual cost savings of proposed drug switches and the effect of such proposed drug switches on patients' copayments (even if the drug switch does not alter copayments, Medco must communicate this to patients);
(3) clarifying whether—and under what circumstances—patients' healthcare plans will continue to cover the current drug (should the patient decide to stay with the current drug);
(4) disclosing whether Medco receives any payments from manufacturers for promoting drug switches;
(5) disclosing the right to reimbursement for all out-of-pocket healthcare costs incurred by a drug switch (e.g., costs for return doctor visits and additional laboratory tests necessitated by the drug switch); and
(6) describing any material differences in side effects between the initial and the proposed drug.

With respect to reimbursing patients for their out-of-pocket healthcare costs imposed by a drug switch, the Order requires Medco to:

(1) allow patients and prescribers—as well as physicians—to initiate reimbursement requests either by phone or in writing;
(2) provide a *single-page* claims form to be filled out; and
(3) reimburse patients for all out-of-pocket costs within 30 days of receiving a claims form.

If the drug-switch costs to be reimbursed by Medco exceed $500, the Order permits Medco to designate a third party to review the costs submitted by patients and prescribers.

The Order also requires Medco to follow specific procedures when implementing permissible drug switches that comport with the above obligations. Before switching to a

proposed drug, the Order requires Medco to obtain express, verifiable authorization from the prescriber for the switch of the current drug. Such authorization can be communicated either to Medco directly by the prescriber (verbally or in writing), or by another person who affirms the prescriber's authorization. The Order requires Medco to maintain all records of such authorization.

After obtaining authorization, the Order requires Medco to issue a *written* confirmation of the switch to the prescriber. For patients receiving home delivery prescriptions, Medco must issue patients a written *and* a telephonic confirmation of the switch (only written confirmation will suffice for non-home delivery prescriptions). Among other things, written confirmations must:

(1) state that Medco, *not* the prescriber, requested a drug switch;
(2) disclose all relevant items noted above (e.g., cost savings, copayment differences, and the existence of manufacturer payments); and
(3) advise the patient that he or she may decline the proposed drug switch.

The Order expressly allows patients to reject Medco's proposed drug switches. If the patient declines the proposed drug switch, the Order requires Medco to honor such requests and to provide the initially-prescribed drug. In addition, Medco also must maintain a toll-free phone number to receive and process such requests. Following the drug switch, Medco must monitor the effects of the new drug on the patient at least on a quarterly basis, and must report its findings to the P&T Committee.

The Order also imposed on Medco a number of affirmative disclosure obligations for its clients that are aimed at promoting price transparency with respect to the manufacturer payments it receives. Medco must make quarterly *and* annual disclosures (Manufacturer Payments Report) to its client health plans that account for all compensations from drug manufacturers that such health plans have contracted to receive. In addition, any time Medco enters into a contractual relationship with a healthcare plan—whether new or renewing clients—it must disclose: 1) Medco's policy of soliciting, receiving, and passing through manufacturer payments; 2) information contained in the Manufacturer Payments Report for the most recent fiscal year; and 3) Medco's policy of publishing quarterly and annual payments reports. Furthermore, Medco may not refuse proposals or bids from a potential health plan client simply because the proposal does not use AWP or prohibits the use of AWP in pricing terms. Medco also may not conceal relative prices of drugs by using symbols or other indirect means.

To further ensure that Medco conducts its business in an open and fair manner, the Order required Medco to adopt the code of ethics of the American Pharmacists Association (APhA),[5] and to provide these documents to its entire staff of pharmacists to ensure compliance. Medco also must make these documents available to its client health plans as well as to its patients.

The Order required Medco to pay $20.2 million to the 20 states, either in cash or through free prescription medications targeted for the low-income, the elderly, and the disabled. Medco also will pay another $6.6 million to the states to cover their investigation costs. Finally, the Order required Medco to establish a $2.5 million fund to reimburse patients $25 for additional costs (e.g., for medical tests or follow-up visits to their physician) attributable to any medication switch by Medco.

Conclusion

With more than 150 million Americans using a pharmacy benefit component of healthcare and the critical role PBMs will play in the new Medicare pharmaceutical benefit, the *Medco* Order provides a framework for improving the working of PBM markets. According to Pennsylvania Attorney General, Jerry Pappert, PBM reforms will lead to greater competition, more transparency, and ultimately, lower drug costs for consumers.[6] Δ

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[1] The states included in the settlement are Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington. Ohio and West Virginia are in litigation with Medco, while Tennessee has expressed an interest in pursuing negotiations with the PBM.

[2] Complaint at 3, State of Maine v. Merck-Medco Managed Care, L.L.C. et al., (2003)(CV-04___), *available at* http://www.maine.gov/ag/dynld/documents/medcocomplaint.pdf (last accessed May 28, 2004).

[3] *Id.* at 10.

[4] *Id.*

[5] *See* American Pharmacists Association, Code of Ethics for Pharmacists (adopted Oct. 27, 1994), *available at* www.aphanet.org (click on "About APhA," then "Code of Ethics") (last accessed May 18, 2004).

[6] Press Release, PA Press Office, AG Pappert Sues 13 Major Drug Companies for Unlawful and Deceptive Pricing and Sales Practices; Alleges Illegal Conduct Caused Pennsylvanians to Pay Higher Prices for Prescription Medications (Mar. 10, 2004), *available at* http://www.attorneygeneral.gov/press/release.cfm?p=35A2F8C9-017B-3BF1-703540A339D7DC11 (last accessed May 28, 2004).