FTC Report Partially Addresses PBMs and Medicare . . . But Does Not Clarify Formulary Policies

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An unpublished report on pharmacy benefit managers (PBMs), issued this past August by the Federal Trade Commission (FTC), made me think of all those reports on the vulnerabilities of New Orleans that were ignored in advance of Hurricane Katrina in August/September. Mandated by Congress, the FTC report was supposed to determine whether PBMs, based on their past behavior, would favor their mail-order subsidiaries when the new Medicare outpatient drug benefit begins on January 1, 2006.

PBMs alone or in conjunction with insurance companies or, perhaps, with retail pharmacy companies, will participate in both the stand-alone companies and Medicare Advantage plans that provide drug benefits. When Congress approved the new Medicare drug benefit, it considered prohibiting participation by PBMs with mail-order subsidiaries because of a concern about self-dealing. Those concerns were sparked by a study published in October 2003 by two former FTC officials, James Langenfeld and Robert Maness. They concluded that self-dealing could cost Medicare beneficiaries up to $30 billion during the period 2004–2013. These arrangements purportedly would provide PBMs an opportunity to manipulate drug dispensing at their mail-order pharmacies to enhance their own profits at the expense of health plans and their members through generic substitution, interchanges to more expensive brand products, and repackaging of drugs into higher-priced units.

Instead of banning PBMs with mail-order arms, Congress mandated the FTC study. But the FTC’s August study goes only partway toward accomplishing what Congress asked it to do—to learn whether PBM ownership of mail-order pharmacies affects the cost that enrollees pay for drugs and whether health insurance plans that use PBMs with mail-order subsidiaries are “acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees” (MMA).

The FTC studied four types of PBMs:

1. Three large, major players: Medco Health Solutions, Inc.; Express Scripts, Inc.; and Caremark Rx, Inc.
2. Small and insurer-owned PBMs, such as Aetna, Inc., and Cigna Corp.
3. Retailer-owned companies (e.g., Eckerd Health Systems and Pharmacy Care Management Services)
4. Stand-alone retail pharmacies, such as the ones run by CVS Corporation and Longs Drug Stores Corp.

On the basis of 2002 and 2003 data, the FTC basically concluded that there was “strong evidence” in those years that the PBMs’ ownership of mail-order pharmacies generally did not disadvantage plan sponsors. (The report does not examine enrollees per Congress’s directions.) But even that conclusion was pickled in caveats. The data obtained by the FTC from the individual PBMs in each category were aggregated; this forced the FTC to admit that the total numbers do not address whether each plan sponsor has negotiated the best deal possible or whether each PBM has fulfilled its contractual obligations. Moreover, the data do not indicate whether, in individual instances, a PBM might have favored its mail-order pharmacy in ways contrary to a plan sponsor’s interests. However, the commission dismissed those study shortcomings by hypothesizing that competition in this industry could afford plan sponsors with sufficient tools to safeguard their interests.

In some instances, the FTC inadvertently raises questions on subjects that were not even posed to the agency. For example, the FTC found that drug manufacturer rebates to PBMs—which were intended to get those drugs favored positions on formularies—did not result in PBMs charging higher prices for those drugs from their mail-order pharmacies, compared with a retail drug store—so no favoritism there. However, the report then says that PBMs received an average of $6.34 in rebates per prescription in 2003, generally for a handful of single-source, brand-name drugs, the most expensive drugs on the formulary, which accounted for 50% of drugs that were dispensed to plan members. Thus, rebates can cause enrollees to use higher-priced drugs than necessary and can cause the federal government to pay more than it needs to. Recent Justice Department lawsuits against PBMs underline the potential pitfalls in the current rebate scene.

The FTC refers only briefly to the consent agreement with Medco Health Solutions in April 2004. Medco had agreed to pay $29 million to 20 states and the U.S. for damages, fees and restitution. The FTC report was published a few weeks before the Justice Department settlement with Caremark Rx, Inc. Caremark had agreed to pay $137.5 million to settle lawsuits claiming that Advance PCS, Inc., which Caremark acquired in March 2004, took kickbacks from drug manufacturers, which raised costs to several federal health care programs.

Unfortunately, the FTC provides no guidance on how rebates should be controlled so that Medicare formularies are not unduly influenced by them. I guess the FTC could fairly argue that providing such guidance went beyond its charge. But one wonders whether that issue—not self-dealing by PBMs—is the gathering storm posing the biggest threat to the Medicare drug benefit.