Federal Trade Commission Study of Pharmacy Benefit Managers

What is a 6(b) study?

A 6(b) study is a policy and research project. 6(b) studies have been used effectively to inform enforcement proceedings, promote competition, and protect consumers. A 6(b) study allows the FTC to issue an Order to file a Special Report. Those Orders can be extensive, and this Order requires the PBMs to respond in 90 days from the date of service. The PBMs response will come in the form of a special report containing the documents specified in the Order. The special report is required to be signed and sworn by an official of the receiving company who has overseen the preparation of the report and associated materials.

What PBMs are included in the FTC study?

CVS Caremark; Express Scripts, Inc.; OptumRx, Inc.; Humana Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.

What is the FTC studying?

The inquiry is aimed at shedding light on several practices that have drawn scrutiny in recent years including:

- fees and clawbacks charged to unaffiliated pharmacies;
- methods to steer patients towards pharmacy benefit manager-owned pharmacies;
- potentially unfair audits of independent pharmacies;
- complicated and opaque methods to determine pharmacy reimbursement;
- the prevalence of prior authorizations and other administrative restrictions;
- the use of specialty drug lists and surrounding specialty drug policies;
- the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

What type of items will the FTC request?

The FTC requires the PBMs to produce among other things, a list of all terms used by the PBMs in the ordinary course of business including various fee terms; variables and calculations used to determine the amount of money paid to and received from, and retained by the PBM; pharmacy network information; pharmacy reimbursement data for the top 100 drugs by annual total amount paid and then by specific class, e.g., 30-day equivalent prescriptions; network contracts, including negotiation strategies and communications; audit criteria and related audit information; formulary information, including where a brand or reference biologic was given a more favorable formulary tier; criteria for determining specialty drugs; information on steering to specialty or mail-order pharmacies; plan sponsors, including material financial terms on all contracts; and rebate contracts with manufacturers, including decisions around rebating and formulary placement.

How long will the study last, can the PBMs challenge it, and what can the FTC do when it is done?

Industry insiders think the study could last around 2-4 years, but the FTC is free to issue interim reports as it deems necessary. The PBMs may file a petition to limit or quash, and the Commission may seek a court order requiring compliance. If a PBM fails to comply with a 6(b) order after receiving a notice of default from the Commission, the Commission may commence suit in federal court under Section 10 of the FTC Act, 15 U.S.C. Sec. 50. After expiration of a thirty-day grace period, a defaulting party is liable for a penalty for each day of noncompliance. During and at the completion of the study, the FTC is free to undertake rulemaking, enforcement actions, and issue advisory opinions.