Pharmacy Benefit Manager Conflict of Interest Study
Public Notice

Section 110 of the Medicare Prescription Drug and Improvement Act (the Act) requires the Federal Trade Commission to produce a "Conflict of Interest Study" that examines whether the cost to group health plans of using mail-order pharmacies integrated with Pharmacy Benefit Managers (PBMs) is more than that of using non-integrated mail-order pharmacies or over-the-counter retail pharmacies. The Commission has authorized the use of compulsory process to collect information and data from industry members so that it can complete the Congressionally-mandated Conflict of Interest Study in a timely manner.

Congress specifically asked the Commission to investigate whether, in the course of managing pharmacy benefits for their clients (*e.g.*, group health plans), PBMs make decisions on various matters in a manner that increases the PBMs' profits while raising the costs of pharmacy benefits for their clients. These decisions could include decisions on generic substitution, therapeutic interchange, and drug repackaging practices. A previous public study has worked with high level public data and has found evidence suggesting that the frequencies with which PBMs employ some of these activities in their mail-order pharmacies differ from the frequencies with which they are employed when prescriptions are dispensed through other channels (over-the-counter at a retail pharmacy or through a mail-order pharmacy not integrated with a PBM). This finding has raised issues as to whether there is a conflict of interest.[1] It is the purpose of the Commission's study to obtain specific information to determine if the concerns are warranted.

The Commission envisions using a two-stage process to collect the company-specific information and data necessary to complete the study. In the first stage, the Commission is seeking high level business documents relating to these issues, and aggregate data concerning three business practices (generic substitution, therapeutic interchange, and repackaging of drugs) identified specifically in the Conference Report accompanying the Act. The Attachment contains a more detailed listing of the type of information sought. The information from the first stage will enable the Commission to determine whether a more detailed empirical study would be feasible and useful to answer the questions posed by Section 110 of the Act. If so, the Commission would issue a second round of information and data requests.

For the first round of information collection, the Commission has identified approximately 20 companies, including independent PBMs, PBMs integrated with health plans, PBMs integrated with retail pharmacies, and retail pharmacies, to receive the information and data requests. Responses to these data collection requests will be due May 14, 2004.

The FTC will obtain the information sought by interrogatories and document requests under Section 6(b) of the FTC Act, 15 U.S.C. § 46(b). The documents and information obtained through these Section 6(b) orders will help the FTC address whether there exists a conflict of

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[1]James Langenfeld and Robert Maness, "The Cost of PBM 'Self-Dealing' Under a Medicare Prescription Drug Benefit" (2003), *available at* http://www.mpaginc.com/news/pbmreport.pdf.

interest between PBMs and the group health plans to which they provide their services. Although law enforcement is not the primary purpose of the information and data collection, the information collected could merit law enforcement action. The Commission chose the PBMs and retailers subject to the first stage of data collection to ensure a robust analysis of the issues Congress has requested that the FTC examine. The Commission will protect confidential business and financial information collected in this study to the extent it is legally authorized. 15 U.S.C. § 46(f).

It should be noted that subsequent to this notice, any destruction, removal, mutilation, alteration, or falsification of documentary evidence that may be responsive to this information collection within the possession or control of a person, partnership or corporation subject to the FTC Act is subject to criminal prosecution. 15 U.S.C. § 50; *see also* 18 U.S.C. § 1505.

Attachment

1. *Data to Be Collected From All Respondents*: Company documents, business plans, strategic plans, planning documents, industry studies, and higher level pricing documents that relate to the company's strategies and business practices for lowering the net price that they pay for pharmaceutical products (*i.e.*, documents that discuss how to maximize pharmaceutical rebates and/or fees paid by the pharmaceutical manufacturer to the PBM).

2. *Data From PBMs*. Each PBM would be asked to provide monthly data for the period 2001-2003 (if applicable) for each of the following data items:

   a. Gross drug spend by dispensing channel (mail-order, retail).

   b. Top 10 selling drugs by dollars and scripts by dispensing channel.

   c. Demographics by dispensing channel, if available.

   d. Averages on co-pays and co-insurance for different channels and by formulary tier.

   e. Average prices for enrollees and plan sponsors by dispensing channel and by formulary tier.

   f. Generic substitution rates and generic dispensing rates by dispensing channel .

   g. Frequency of dispensed as written prescriptions by dispensing channel, and any statistics on authorizations obtained to switch these prescriptions to generics or therapeutic equivalents.

   h. Frequency of therapeutic substitution by channel (with information on reasons if available - e.g., on formulary); and lists of drugs for which the PBM engages in therapeutic interchange and the contracts with the pharmaceutical manufacturers for these drug products.

   i. Frequency of repackaging, the drug products for which it occurs, and the associated acquisition costs and prices charged to customers.

   j. An accounting of payments due and made to the 10 largest pharmaceutical manufacturers (by sales and prescriptions) which includes gross amounts due less rebates, administrative fees, and other discounts to determine a net amount paid.

   k. Details on rebate pass-throughs to plan sponsors.

   l. Documents relating to Medicare legislation that analyze the Medicare prescription drug benefit, discuss competition in the provision of PBM services as it relates to the Medicare drug benefit, and discuss utilization of PBM services.

m. Dollar amounts paid by the PBM to health plans (i.e., changeover fees) and customer acquisition costs.

n. List of top 10 customers (plans/employers) and revenues by customer (and contracts with the top customers).

o. Lists of 10 customers with the lowest and highest proportions of drug spend going through mail-order (and associated contracts).

p. Lists of 10 customers with lowest and highest generic dispensing rates in mail and retail (and associated contracts).

q. List of 10 top selling drugs via mail-order and retail. Also note the therapeutic category of each drug, and whether any generic was available in that category.

r. Information on the time periods for which the PBM maintains detailed information by plan and drug category.

s. List of top 10 pharmacy companies who dispense prescriptions under all of the PBMs' plans, listed separately for retail and mail-order pharmacies.

3. *Data From Retailers.* Each retailer would be asked to provide monthly data for the period 2001-2003 (if applicable) for each of the following data items. To the extent that it is possible, the responses should be separated between cash paying and third party payer customers:

a. Gross sales by dispensing channel (mail-order, retail).

b. Top 10 selling drugs by dispensing channel.

c. Average prices per prescription by dispensing channel.

d. Generic substitution rates and generic dispensing rates by dispensing channel.

e. Frequency of dispensed as written prescriptions by dispensing channel, and any statistics on authorizations obtained to switch these prescriptions to generics or therapeutic equivalents.

f. Frequency of therapeutic substitution by channel (with information on reasons if available - e.g., on formulary); lists of drugs for which the retailer engages in therapeutic interchange; and any documents summarizing the revenue received from pharmaceutical manufacturers or PBMs in compensation for these programs.

g. Frequency of repackaging, the drug products for which it occurs, and the associated acquisition costs and prices charged to customers.

h. Total revenues from rebates. Also, total revenues from administrative fees and other sources from pharmaceutical manufacturers or PBMs.

i. Documents relating to Medicare legislation that analyze the Medicare prescription drug benefit, discuss competition in the provision of pharmacy services as it relates to the Medicare drug benefit, and discuss utilization of pharmacy services.

j. List of top 10 customers (PBMs or health plans) and revenues by customer.

k. Lists of 10 customers with the lowest and highest proportions of drug spend going through mail-order.

l. Lists of 10 customers with lowest and highest generic dispensing rates in mail and retail.

m. List of top 10 selling drugs via mail-order and retail. Also note the therapeutic category of each drug, and whether any generic was available in that category.

n. Information on the time periods for which the retailer maintains detailed information about pharmacy sales.