UNITED STATES OF AMERICA

FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition

April 17, 2007

Nellie Pou
Assemblywoman, 35th District
Chair, Appropriations Committee
New Jersey General Assembly
100 Hamilton Plaza, Suite 1405
Patterson, NJ 07505

Dear Assemblywoman Pou:

The staffs of the Federal Trade Commission=s Office of Policy Planning, Bureau of Competition, and Bureau of Economics[1] are pleased to respond to your request for comments on the likely competitive effects of the Assembly Committee Substitute for Assem

Bill attempts to address are not prevalent. To the contrary, the Commission's recent study of the PBM industry suggests that HBPs can, and do, protect themselves from potential conflicts of interest in arms-length contracts with PBMs.[4]

Interest and Experience of the Federal Trade Commission

Congress has charged the Federal Trade Commission ("FTC" or "Commission") with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[5] Pursuant to its statutory mandate, the FTC seeks to identify business practices and regulations that impede competition without offering countervailing benefits to consumers. For several decades, the FTC and its staff have investigated the competitive effects of restrictions on the business practices of health care providers.[6] The FTC and its staff have issued reports and studies regarding various aspects of the pharmaceuticals industry,[7] and the FTC has brought numerous enforcement actions against entities in that industry.[8]

In particular, the FTC has extensive recent experience with PBMs. The FTC and the Department of Justice Antitrust Division ("DOJ") considered diverse competition and consumer protection issues raised by health care markets in joint hearings conducted over the course of twenty-seven days in 2003 ("Health Care Hearings"). Given the concerns regarding PBM activities reflected in then-pending lawsuits, PBM practices, in particular, were a focus of those hearings.[9] In 2004, the FTC and DOJ issued a report based on the

---

Because these duties to disclose or remit rebates allegedly arise under existing legal obligations, it is unclear how A-320's additional legal requirements that, e.g., PBMs disclose sensitive financial information to various parties, serve as fiduciaries of HBPs, and limit therapeutic interchange and mail-order usage, are likely to serve as direct or effective means of improving

hearings, a 2002 the FTC-sponsored workshop, and independent research.[10] Also in 2004, FTC staff commented on proposed PBM legislation in several states, including North Dakota[11] and California,[12] and the FTC investigated the competitive implications of a proposed merger between two PBMs, Caremark and AdvancePCS.[13] In response to a request from Congress in 2003, the FTC undertook a substantial "Conflict of Interest Study" regarding PBM practices.[14] In the course of that study, the FTC analyzed data on PBM pricing, generic substitution, therapeutic interchange, and repackaging practices, and examined whether PBM ownership of mail-order pharmacies served to maximize competition and lower prescription drug prices for plan sponsors.[15] In its 2005 report

that regard, the stipulation that a PBM "shall have all responsibility attendant to a fiduciary as established by law,"[19] may implicate a broad set of common law fiduciary obligations beyond those contemplated in contracts for PBM services. In addition, the imposition of fiduciary duties may conflict with or complicate express contractual or statutory duties that, otherwise, are relatively straightforward. In doing so, the fiduciary provision imposes additional litigation risks that may be costly ones, and further limits the abilities of HBPs and PBMs to design and implement certain cost-saving practices for distributing pharmaceuticals. Moreover, by imposing liability risks and related fiduciary costs on independent PBMs that are not imposed on insurer-affiliated PBMs, the Bill confers a competitive advantage on integrated HBP/PBM organizations. This may distort present competition in the PBM industry and may, in turn, raise costs by encouraging vertical integration – new or sustained HBP/PBM affiliations – to an extent that would not be cost-effective, but for the regulation.[20] This section briefly sketches the general obligations of a fiduciary, and identifies some of the potential effects of imposing such obligations on PBMs.

A fiduciary is required "to act primarily for the benefit of another in matters connected with his undertaking."[21] As its fiduciary, a PBM would owe an HBP duties of service, obedience and loyalty.

particular, a fiduciary may owe its principal a "duty to give information" that is independent of any express disclosure requirements that may be imposed under contract or statute,[25] as well as a "duty to account for profits" that may require the pass-through of payments to the principal.[26] Moreover, although a fiduciary relationship generally may be defined by the terms of a contract between the fiduciary and its principal, "even specific agreements … must be interpreted in the light of the principles which are applicable to the relation of principal and agent."[27]

In general, fiduciary duties exist in situations where contracting to address potential conflicts of interest may be prohibitively expensive, often because one party has superior information about the true nature of his or her performance.[28] In such cases, fiduciary duties can ameliorate potential market failures by providing some protection against opportunistic behavior. As we found in the PBM Study, however, HBPs tend to be sophisticated repeat purchasers of PBM services. HBPs – often employing consultants – negotiate contracts through an iterated competitive bidding process that addresses both price and non-price dimensions of service.[29] Through that process, HBPs appear able to avoid potential conflicts of interest with PBMs.[30] For example, HBPs negotiate the pass-through of pharmaceutical payments, audit rights, and protections against cost-increasing therapeutic interchange.[31] Thus, A-320's imposition of extra-contractual fiduciary duties on PBMs appears unwarranted.

Under a mandatory fiduciary duty, future PBM/HBP contracts might need to account for several categories of new costs. Among them is an increased risk of legal liability for PBM services. For example, A-320 would provide an HBP the right to bring a tort action against a PBM for breach of fiduciary duty, in addition to any liability claims

---

[25] A-320 expressly imposes certain disclosure requirements independent of any general disclosure obligations that may be found under agency principles. *See* text accompanying notes 52-53, *infra* (disclosure requirements for substitutions) and text accompanying notes 63-71, *infra* (disclosures of financial information).

[26] *See* RESTATEMENT (SECOND) OF AGENCY §§ 381 (duty to give information) and 388 (duty to account for profits arising out of employment, subject to contract, general duty to convey profits to principal). With regard to disclosure, "contracts or transactions which in their essential nature are 'intrinsically fiduciary' and 'necessarily call [] for perfect good faith and full disclosure without regard to any particular intention of the parties." *United Jersey Bank v. Kensey*, 704 A.2d 38, 44 (N.J. Super. Ct. App. Div. 1997) (quoting *Berman v. Gurwicz*, 458 A.2d 1311 (N.J. Ch. Div. 1981) *aff'd*).

[27] RESTATEMENT (SECOND) OF AGENCY at Chapter 13, introductory note; *President*, 814 A.2d at 1184 ("Of course, we enforce ambiguous insurance contracts in accordance with the reasonable expectations of the insured"; that is, with the principal, as against the fiduciary.)

[28] For example, fiduciary duties often arise in situations involving professional services. *See, e.g.*, *Carluccio*, 57 A.2d at 452, 453 (real estate agents); *Packard-Bamberger & Co*, 771 A.2d at 1203 (attorneys); *Fasolo v. Bd. of Trustees of Div. of Pensions*, 464 A.2d 1180, 1187 (trustees).

[29] *See* PBM STUDY, *supra* note 3, at 8.

[30] *See id.*, at 9-10 (diversity of PBM/HBP contracts).

[31] *See, e.g., id.* at 57-59 (diverse pass-through, payment sharing, and audit arrangements) and 90-94 (potential benefits of interchange and plans contract for diverse protections against costly interchanges).

that might arise under their contract.[32] This increased legal liability is likely to entail legal and administrative costs, and some of these costs may be passed on to clients in the form of higher fees.

Also, liability concerns may make a PBM less willing to engage in cost-reducing practices, such as employing incentives to guide beneficiaries to its own mail-order pharmacy or contracting with plan sponsors that want to provide limited networks of retail pharmacies or place few preferred drugs in each therapeutic class on their formularies. For example, because a fiduciary cannot profit at the expense of its principal, a PBM might be concerned that ownership or management of a mail-order pharmacy could create at least the appearance of self-dealing and that co-payment plans or other incentives for beneficiaries to use such pharmacies could trigger claims that the PBM breached duties of loyalty owed to the beneficiaries themselves; at the same time, if network discounts, manufacturer rebates, or formulary design appear to depart from best industry practices, PBMs may be exposed to claims for breach of duties of care and

Absent a well developed body of case law regarding the duties of PBM fiduciaries in particular, the limits of future tort liability are unclear. Also unclear is the extent to which PBMs will go to minimize their exposure to such tort claims, as the case law develops. Still, at the outset, the risk of liability based on general principles of agency law may be substantial. Removing the fiduciary obligation would reduce the cost of uncertainty in HBP/PBM contract formation, and would permit HBPs and PBMs greater latitude to explore business arrangements that may be more efficient generally, or may better suit the needs of individual HBPs. In addition, when all PBMs are able to tailor their prices – and pricing mechanisms – based on each HBP's preferences, PBMs may be forced to compete more vigorously for each contract.[37]

Restrictions on Requiring Mail-Order Pharmacy Usage

The Bill also may limit HBPs' abilities to require or encourage, through financial incentives, beneficiary use of mail-order pharmacies for certain prescriptions. Because the potential cost-savings from the mail-order provisionm(tia)TjETBT/TT0 1 Tf12 0 0 12 1463 70 12 290.28

programs have the potential to increase usage of less expensive, but therapeutically effective, branded drugs or their generic equivalents, such restrictions may raise the cost of drug benefits. Severa

costs for health plan sponsors that use them.[57] Furthermore, interchange programs can play a useful role in the negotiation of discounts with manufacturers.[58] At the same time, it is unclear how these restrictions on HBP/PBM contracting are likely to provide countervailing benefits. As the PBM Study found, HBPs appear able to protect themselves from cost-raising substitutions.[59]

Further, although New Jersey may wish to further a policy goal of insulating physicians against repetitive therapeutic interchange authorization requests, the Bill's required two-year waiting period on a second authorization request for a given drug nonetheless appears artificially restrictive.[60] First, because therapeutic interchange is not frequently undertaken by PBMs,[61] the potential benefits of a restriction on the frequency of authorization requests may be slight. Second, it appears that the restriction is over-broad as a limitation on repetitive authorization requests, because the two-year moratorium appears to apply independent of questions whether the drug is being prescribed for the same indication or significant new data on drug choice has emerged; the restriction appears to apply without regard to whether the drug is being prescribed by a different physician.

Disclosure of Financial Information

Explicit statutory provisions and the fiduciary requirement also would require PBMs to disclose sensitive financial information to HBPs; such disclosures may facilitate collusion, raise price, and harm the patients the bill is supposed to protect. In addition to disclosure requirements that would pertain to PBMs generally under the Bill's Sections 9

provides confidentiality protections for information disclosed to purchasers, under Section 9, and prospective purchasers, under Section 10, it is unclear whether such protections would extend to disclosures to purchasers, under Section 12.b., or any additional disclosures that would be required under common law fiduciary duties.[64] In

manufacturers, however, are just one factor among many that determine PBM pricing – in essence, the payments function as manufacturer discounts on the cost of drug products. Thus, the disclosure requirements are analogous to requirements that firms reveal aspects of their cost structures to customers. There is no theoretical or empirical reason to assume that consumers require sellers' underlying cost information for markets to achieve competitive outcomes.[69] At the same time, our analysis of PBM/HBP contracts shows that HBPs already are able to negotiate contract terms – including diverse information disclosure and audit rights – that protect them from conflicts of interest.[70] Press reports too suggest that many contracts

At the same time, there does not appear to be any compelling reason to restrict competition to protect HBPs. While some lawsuits have raised concerns about certain PBM conduct, as we concluded in the PBM Study, HBPs appear able to protect themselves from potential conflicts of interest for PBMs already through arms-length contracts.

We urge the New Jersey General Assembly to consider the adverse effects on competition and consumer welfare that A-320 will likely produce. We appreciate this opportunity to share our views and welcome any further discussions regarding competition policies.

(Feb. 2002), *available at* http://papers.nber.org/papers/W8802.

Respectfully submitted,

Maureen K. Ohlhausen
Director
Office of Policy Planning

Michael A. Salinger
Director
Bureau of Economics

Jeffrey Schmidt
Director
Bureau of Competition