



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 Economics¹ are pleased to respond to your request for comments on the likely competitive effects of the Assembly Committee Substitute for Assembly No. 320 ("A-320" or "the Bill"), which would regulate the contractual relationships between pharmacy benefit managers ("PBMs") and health benefit plans ("HBPs"). You asked the FTC to "examine A-320 to determine whether the proposed legislation is anti-competitive and will likely result in "increased costs of pharmaceutical care for employers, unions, and consumers."²

We believe that A-320, if enacted, will limit the ability of PBMs, HBPs, and pharmacies to enter into efficient, mutually advantageous contracts, and may increase pharmaceuticals prices in New Jersey. Ultimately, the restrictions may decrease the number of New Jersey consumers with insurance coverage for pharmaceuticals, without producing offsetting benefits. Although some lawsuits have challenged particular types of PBM conduct,³ empirical evidence suggests that the conflicts of interest that the

¹ This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics. The letter does not necessarily represent the views of the Federal Trade Commission (Commission) or of any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

² Letter from New Jersey Assemblywoman Nellie Pou to Maureen Ohlhausen, Director, Office of Policy Planning, Federal Trade Commission (Aug. 9, 2006).

³ See, e.g., *United States v. Merck-Medco Managed Care, L.L.C.*, Case No. 00-CV-737 (E.D. Penn. Dec. 9, 2003); *In re Pharmaceutical Industry Wholesale Price Litig.*, MDL No. 1456, Civ. Act. No. 01-cv-12257-PBS (D. Mass. 2002); *Ohio v. Medco Health Solutions, Inc.* (Dec. 22, 2003). Some complaints allege that failure to disclose or remit rebates either breached a contractual requirement or breached an asserted duty to disclose or remit rebates under some other existing law. See, e.g., *AFSCME v. AdvancePCS*, Case No. BC 29227 (Super. Ct. Cal. Mar. 18, 2003); *New York v. Express Scripts, Inc.* (N.Y. Sup. Ct. Aug. 4, 2002).

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 compliance with the existing obligations that have been subject to legal controversy.

⁴ See generally Federal Trade Commission, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (Aug. 2005) ("PBM STUDY"), available at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>.

⁵ Federal Trade Commission Act, 15 U.S.C. § 45.

⁶ See Federal Trade Commission, *FTC Antitrust Actions in Health Care Services and Products* (Oct. 2003), available at <http://www.ftc.gov/bc/hcupdate031024.pdf>.

⁷ See Federal Trade Commission, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* (July 2002); DAVID REIFFEN AND MICHAEL R. WARD, *GENERIC DRUG INDUSTRY DYNAMICS*, Federal Trade Commission Bureau of Economics Working Paper No. 248 (Feb. 2002), available at <http://www.ftc.gov/be/econwork.htm>; ROY LEVY, *THE PHARMACEUTICAL INDUSTRY: COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE*, Federal Trade Commission Bureau of Economics Staff Report (Mar. 1999), available at <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>.

⁸ See Federal Trade Commission, *FTC Antitrust Actions in Pharmaceutical Services and Products* (Oct. 2005), available at <http://www.ftc.gov/bc/0310rxupdate.pdf>.

⁹ See *Hearings on Health Care and Competition Law and Policy*, June 26, 2003, available at <http://www.ftc.gov/ogc/healthcarehearings/030626ftctrans.pdf>. ("Health Care Hearings") See also <http://www.ftc.gov/ogc/healthcarehearings/03062526agenda.htm>. Subsequent references to the hearings will identify a panelist, affiliation, and transcript page. Affiliations are as of the date of the hearing.

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 Dakota¹¹ 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 based on the study (“PBM Study”), the FTC found, among other things, that competition affords HBPs substantial tools with which to safeguard their interests.¹⁶ Most recently, the FTC staff commented on proposed Virginia legislation that would have restricted PBM contracts and drug substitution practices, while requiring disclosures to HBPs, consumers, and physicians.¹⁷

Likely Effects of A-320

Several provisions of A-320 regulate relationships between PBMs and HBPs, in ways that are likely to have an adverse effect on the prices that HBPs, and ultimately New Jersey consumers, pay for pharmaceuticals.

Fiduciary Duties

A-320 would make a PBM a fiduciary of any HBP with which it contracts.¹⁸ In

¹⁰ See Federal Trade Commission and Department of Justice, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf> (Chapter 7, especially, “Industry Snapshot and Competition Law: Pharmaceuticals”).

¹¹ Letter from FTC staff to North Dakota State Senator Richard Brown (Mar. 8, 2005), available at <http://www.ftc.gov/os/2005/03/050311northdakotacomnts.pdf>.

¹² Letter from FTC staff to Rep. Greg Aghazarian (Sept. 7, 2004), available at <http://www.ftc.gov/be/V040027.pdf>.

¹³ Statement of the Federal Trade Commission, *In re Caremark Rx, Inc./AdvancePCS*, File No. 0310239 (Feb. 11, 2004), available at <http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf>. The Commission closed the investigation because it concluded that the transaction was unlikely to reduce competition.

¹⁴ See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. I, § 110, 117 Stat. 2066, 2174 (2003) (codified at 42 U.S.C. § 1395w-101 (Historical and Statutory Note)).

¹⁵ See PBM STUDY, *supra* note 3, at i-iii.

¹⁶ See *id.*, at 55 (noting diverse audit rights and reporting under PBM contracts).

¹⁷ Letter from FTC staff to Virginia Delegate Terry G. Kilgore (Oct. 2, 2006), available at <http://www.ftc.gov/be/V060018.pdf>.

¹⁸ See A-320 at § 7. The obligation pertains to all PBMs that are not merely providing services for themselves or their affiliates. Risks, contract restrictions, and administrative costs that are imposed differently on insurer-affiliated and independent PBMs may raise competition concerns within the PBM industry. See text accompanying note 19, *infra*.

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.²² Under the duty of loyalty, a fiduciary “acts on behalf of the principal and only for his benefit”;²³ among the duties of service is a duty of care and skill, under which a fiduciary must “act with a standard of care and with all the care which is standard in the locality for the kind of work for which he is employed.”²⁴ In

¹⁹ *Id.*

²⁰ A PBM that is an affiliate of a carrier, and “provides [PBM] services solely to that carrier,” is exempted from the fiduciary duty requirement. A-320 at § 7. The three largest PBMs are independent. At the time of the PBM STUDY, insurer-owned or affiliated PBMs accounted for approximately 40% of covered persons in the U.S., although not all of these PBMs provided benefits solely to the carrier’s beneficiaries. See PBM STUDY at 3.

²¹ RESTATEMENT (SECOND) OF AGENCY § 13, comment *a*. See also *In re Estate of Vayda*, 875 A.2d 925, 929 (N.J. 2004) (discussing relative duties of loyalty and care for attorneys as fiduciaries) (citing *Packard-Bamberger & Co. v. Collier*, 771 A.2d 1194 (N.J. 2001)); *President v. Jenkins*, 814 A.2d 1173, 1185 (N.J. Super. App. Div. 2003) *aff’d in part, rev’d in part on different grounds*, 180 N.J. 550, 853 A.2d 247 (2004) (discussing fiduciary duty of care owed to insureds).

²² See RESTATEMENT (SECOND) OF AGENCY §§ 377-386 (regarding duties of care and obedience) and §§ 387-395 (duties of loyalty); J. Dennis Hynes, *Freedom of Contract, Fiduciary Duties, and Partnerships: The Bargain Principle and the Law of Agency*, 54 WASH. & LEE L. REV. 439, 443 (1997).

²³ RESTATEMENT (SECOND) OF AGENCY § 387, comment *a*; *Carluccio v. 607 Hudson St.*, 57 A.2d 452, 453 (N.J. 1948) (duty of “absolute loyalty” to principal); *Melveney v. McCrane*, 351 A.2d 385, 387 (N.J. Super. Ct. App. Div. 1976) (as fiduciary, broker “required to exercise fidelity, good faith, and primary devotion to the interests of his principal.”). Quoting Justice Cardozo, the New Jersey court has explained that, “[m]any forms of conduct permissible in a workaday world for those acting at arm’s length are forbidden to those bound by fiduciary ties ... Uncompromising rigidity has been the attitude of courts of equity when petitioned to undermine the rule of undivided loyalty by the ‘disintegrating erosion’ of particular exceptions. Only thus has the level of conduct for fiduciaries been kept at a level higher than that trodden by the crowd.” *Carluccio*, 57 A.2d at 454 (quoting *Meinhard v. Salmon*, 249 N.Y. 458, 464 (N.Y. 1928)).

²⁴ RESTATEMENT (SECOND) OF AGENCY § 379(1); *President*, 814 A.2d at 1185 (fiduciary duty of care is “degree of knowledge and skill requisite to the calling”) (quoting *Carter Lincoln-Mercury, Inc. v. EMAR Group, Inc.*, 638 A.2d 1288, 1288 (N.J. 1994)).

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 skill.³³ The PBM Study found that mail-order pharmacies typically are less expensive than retail pharmacies, even after controlling for prescription size and drug selection.³⁴ In addition, the PBM Study found that average total prices at mail-order pharmacies owned by large PBMs “typically were lower than at mail-order pharmacies not owned by PBMs.”³⁵ Further, many pharmacies trade higher customer volume for lower prices, by offering deeper discounts to PBMs with more exclusive networks,³⁶ and pharmaceutical manufacturers tend to offer higher payments in return for more prominent formulary presence. In response to litigation risk, PBMs may adopt defensive business practices that would curtail such cost-saving measures.

³² For example, in *Pickett v. Lloyd's*, the New Jersey Supreme Court recognized a private cause of action in a regulated insurance matter because, “[a]lthough the regulatory framework does not create a private cause of action, it does declare state policy and we do not think that finding a cause of action for the breach of the [fiduciary] duty of good faith and fair dealing would conflict with that policy.” 621 A.2d 445, 468 (N.J. 1993).

³³ Such concerns are not unrelated to those that gave rise to the PBM Study in the first place. See text accompanying notes 19-24, *supra*. Alleged breaches of fiduciary duty could occur, e.g., if a plan sponsor feels that a PBM negotiated pharmaceutical payments that are “too low,” or pharmacy reimbursement rates that are “too high,” relative to terms negotiated by the PBM in contracts with other plan sponsors or to the terms negotiated by other PBMs.

³⁴ See PBM STUDY, *supra* note 3, at 25; see also General Accounting Office, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* at 11 (Jan. 2003) (“GAO Report”), available at <http://www.gao.gov/cgi-bin/getrpt?GAO-03-196> (reporting that PBMs negotiate substantial discounts with retail pharmacies, but achieve greater savings using mail-order pharmacies, with an average mail-order price “about 27 percent and 53 percent below the average cash price customers would pay at a retail pharmacy for the selected brand name and generic drugs, respectively.” GAO Report at 8.

³⁵ PBM STUDY, *supra* note 3, at vi.

³⁶ Further, a credible threat to exclude a pharmacy from a network and channel customers elsewhere creates a strong incentive for pharmacies to bid aggressively. Letter from FTC staff to Patrick C. Lynch, Attorney General, and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations (Apr. 8, 2004), at 4 n.11, available at <http://www.ftc.gov/os/2004/04/ribills.pdf>. See also Michael G. Vita, *Regulatory Restrictions on Selective Contracting: an Empirical Analysis of “Any Willing Provider” Regulations*, 20 J. HEALTH ECON. 955 (2001) (finding that “any willing provider” laws lead to higher drug prices).

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 provision of maintenance drugs is substantial, such limitations may raise the cost of providing pharmaceutical benefits to New Jersey consumers.³⁸ For example, A-320 states that a PBM must disclose to purchasers “the availability of a voluntary mail-order service provided by the [PBM] for prescription drugs or specialty drugs, which shall be available to a covered person who chooses to use the service through an express written request submitted to the [PBM].”³⁹ The Bill also would permit a PBM, pursuant to a written contract with a purchaser, to provide mail-order pharmacy services to a covered person, “provided that the covered person chooses to use the mail-order service through an express written request submitted to the [PBM].”⁴⁰

Typically, as noted above, mail-order pharmacies are less expensive than retail pharmacies.⁴¹ Consequently, HBPs and PBMs have adopted diverse incentives to encourage the use of mail-order pharmacies, especially for beneficiaries taking maintenance medications.⁴² Such incentives include, among others, lower co-payments for mail-order drugs, deductibles for retail purchases, and limitations on the number of

³⁷ See James C. Cooper *et al.*, *Does Price Discrimination Intensify Competition? Implications for Antitrust*, 72 ANTITRUST L.J. 327, 332-42 (2005).

³⁸ See text accompanying note 34, *supra*, and note 42, *infra* (cost savings from mail-order) and note 47, *infra* (cost of statutory impediments to mail-order).

³⁹ A-320 at § 9.a.(8).

⁴⁰ *Id.* at §8.a.(2).

⁴¹ See text accompanying note 28, *supra* (savings remain after adjusting for Rx size and selection).

⁴² See PBM STUDY, *supra* note 3, at 17-19. Maintenance medications are “prescription drugs that treat chronic illnesses and conditions.” *Id.* at 17. It should be noted that, while mail-order usage tends to lower costs, and while “[m]ail-order distribution of prescription drugs has grown dramatically,” not all plans administered by PBMs have implemented incentives for beneficiaries to use mail-order. See *id.* at 17-18.

times a prescription may be filled, or refilled, at a retail pharmacy.⁴³ Certain health plans employ relatively strong incentives, such as “mandatory mail-order” programs that reimburse beneficiaries for maintenance medications only if the beneficiaries fill those prescriptions by mail.⁴⁴

On its face, A-320 appears to prohibit HBPs from adopting mandatory programs, and could be read to prohibit incentive-based programs that impose strong financial penalties on certain retail purchases. Although the findings and declarations section of the Bill prohibits “mandating the use of mail-order services,” the Bill does not define “mandating” or “mandatory mail-order,” which leaves unclear whether certain types of incentive-based programs would be prohibited. To the extent that A-320 impedes HBPs from creating incentives for beneficiaries to use mail-order pharmacies, the Bill is likely to increase drug prices for both HBPs and New Jersey consumers.⁴⁵ As a Maryland study has shown, statutory impediments to mail-order provision of, e.g., maintenance drugs, can be very costly for a State and its citizens.⁴⁶

Substitution Requirements

Although A-320 appears to allow PBMs and HBPs to engage in generic substitution⁴⁷ without triggering the Bill’s limitations on drug substitutions generally, it places several conditions on therapeutic interchange.⁴⁸ Because therapeutic interchange

⁴³ See *id.* at 18-19.

⁴⁴ See *id.* at 19.

⁴⁵ See text accompanying notes 28-30, *supra*. As noted above, the Bill is unclear about the extent to which the “voluntary,” expressly chosen nature of mail-order use, in itself, or bundled with fiduciary duties, may require that beneficiaries have access to local pharmacies under covered rates.

⁴⁶ According to the Maryland report, greater use of mail-order maintenance drugs, as would be enabled by liberalizing Maryland insurance law, would save Maryland consumers 2-6% on retail drug purchases *overall*, and third-party carriers 5-10%. See Md. Health Care Comm. and Md. Ins. Admin., *Mail-Order Purchase of Maintenance Drugs: Impact on Consumers, Payers, and Retail Pharmacies*, 2-3 (Dec. 23, 2005).

⁴⁷ Although the Bill does not define the terms “generic drug” or “generic substitution,” generic substitution is generally understood to be the provision of a drug that is pharmacologically identical to the name-brand drug indicated on the prescription. FDA, Office of Generic Drugs, *What are Generic Drugs?*, available at <http://www.fda.gov/cder/ogd/index.htm#Introduction> (last checked Nov. 20, 2006).

⁴⁸ See generally A-320 at § 12 (permitted and prohibited drug substitutions). Therapeutic interchange is the substitution of a drug that is designed to have similar therapeutic effects, and is approved by FDA for treatment of the same indication, but is in some regard pharmaceutically different. See R. Herdman & D. Blumenthal, eds., *DESCRIPTION AND ANALYSIS OF THE VA NATIONAL FORMULARY* (Institute of Medicine June 2000), available at www.nap.edu/books/0309069866/html. The Bill states that its provisions “shall not apply” when “the drug prescribed is being substituted with a generic drug or chemical equivalent, in accordance with the purchaser’s contract or in compliance with State law, unless the prescriber objects to the drug substitution on medically necessary reasons and the covered person is willing to pay any increase in co-payments or other out-of-pocket expenses for the originally prescribed drug.” *Id.* at §12.a.(3). Because the Bill does not define the term “generic drug,” there is some uncertainty about the meaning of both the statutory carve-out for generic drugs or chemical equivalents, under Section 12.a.(3), and the procedural prerequisites to non-exempt substitutions, under Section 12.b.(1)(e). That uncertainty could be resolved by appropriate statutory definition of terms.

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. Several of the Bill's restrictions on drug substitution practices appear to duplicate existing provisions under New Jersey law,⁴⁹ but other provisions may make therapeutic interchange more difficult.⁵⁰ The Bill requires PBMs to disclose substantial financial information, and imposes a default obligation on a PBM to obtain HBP authorization, for any substitution not otherwise prohibited under the Bill's paragraph 12.b.(1).⁵¹ Under the plain language of A-320, it appears that HBPs and PBMs may contract to waive the authorization requirement, but it is unclear whether parties may waive the disclosure requirements as well.⁵² The Bill also imposes a two-year waiting period, per patient per drug, on a second request for interchange authorization.⁵³

To the extent that A-320 reduces the incidence of cost-saving substitution, it is likely to increase pharmaceutical costs for HBPs. Therapeutic interchange programs⁵⁴ have the potential to increase usage of less expensive, but therapeutically effective, branded drugs or their generic equivalents (which are much less expensive than their brand-name counterparts).⁵⁵ The PBM Study noted that interchange programs are costly to implement and that, in practice, interchanges have been relatively rare.⁵⁶ Nonetheless, the Study data confirm that, if implemented, interchange programs should tend to reduce

⁴⁹ See, e.g., N. J. Stat. Ann. § 24:6E-7 (regarding, e.g., mechanisms whereby a prescribing physician can prevent a substitution or interchange and a beneficiary's ability to opt-out of a proposed drug substitution independent of coverage implications). Cf. PBM STUDY, *supra* note 3, at 81-82 (noting that interchange programs, while representing a very limited share of prescriptions, tend to be more prevalent in mail-order programs than retail ones, because the reduced time pressure facilitates physician authorization).

⁵⁰ Under the Bill's paragraph 12.b.(1), certain conditions are imposed among limitations, some partial and some absolute, on all drug substitutions. Under paragraph 12.b.(2)-(3), certain conditions are imposed on all drug substitutions not otherwise prohibited by 12.b.(1) or contract.

⁵¹ See *id.* at §§12.b.(2)-(4). Disclosures required "at the time of substitution," under Section 12(b)(4) are enumerated, and discussed more fully, together with the Bill's more general disclosure requirements, at notes 63-67, *infra*,

⁵² See text accompanying notes 24, 32-35, *supra*. Paragraph 12.b.(2)(1) provides that a PBM must have an HBP's authorization for each drug substitution not otherwise prohibited by the Act, "unless otherwise provided for in a contract for [PBM] services" The same paragraph subsequently states, in a separate sentence, that such otherwise non-prohibited substitutions require that substantial disclosures be made to the HBP, making no mention of the possibility of waiver. Further, waiver provisions that might be relatively straightforward, under contract law, for sophisticated corporate parties such as HBPs and PBMs, may be confounded by the imposition of unsettled fiduciary obligations.

⁵³ That is, if a prescribing physician has rejected a proposed interchange once, that interchange cannot be proposed again for two years. See A-320 § 12.b.(1)(f).

⁵⁴ See note 49, *supra*, for a definition of therapeutic interchange.

⁵⁵ See, e.g., PBM STUDY, *supra* note 3, at 28, Fig. II-2, and 61.

⁵⁶ Two large PBMs submitting data for the PBM STUDY under special orders employed therapeutic interchange in filling "less than one-half of one percent (0.5%) of prescriptions dispensed at retail and at PBMs' owned mail-order pharmacies." *Id.*, at 84. The data represent the practices of two large PBMs in 2002 and 2003 and may not represent the frequency of therapeutic interchange across the industry. See *id.*

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 and 10,⁶² Section 12 requires substantial additional disclosures of financial information whenever a PBM implements certain drug substitution programs.⁶³ Although A-320

⁵⁷ *See id.* at 81. Examining data regarding drug pairs for which PBMs had authorized a program to substitute (interchange) one member of the pair for the other provides some indication of the potential for therapeutic interchange to lower costs if implemented. "In the 10 therapeutic categories the Commission examined, study participants' data showed that the use of TI could reduce plan sponsors' costs in a majority of cases." *Id.* Therapeutic interchange may also, in certain instances, serve therapeutic ends, although the PBM STUDY lacked adequate information to determine the frequency with which therapeutic interchange may be employed for drug safety reasons, e.g., to avoid adverse drug interactions. *See id.* at 82, n. 4. Note, too, that the substitution restrictions imposed under § 12 of the Bill do not apply to substitutions "initiated for patient safety reasons." A-320 at § 12.b.(1).

⁵⁸ The PBM STUDY reports that "[o]ne PBM indicated that it regards the real value of [therapeutic interchange] programs as a negotiating tool with manufacturers to obtain higher pharmaceutical payments or allowance rates." PBM STUDY, *supra* note 3, at 84.

⁵⁹ *See id.* at 82 and n. 2.

⁶⁰ *See id.* at § 12.b.(1)(f) (imposing the restriction per drug, per patient).

⁶¹ *See* note 57, *supra*.

⁶² Substantial disclosure of information regarding a PBMs operating practices and financial arrangements with third parties are required for all PBM/HBP contracts under Section 9. Among other things, a PBM "shall disclose to a purchaser on a quarterly basis...the nature, type, and amount of non-purchaser remuneration that the [PBM] received during the reporting period" A-320 at § 9(b)(3).

⁶³ *See id.* at §§12.b.(2)-(4). For example, a PBM is to disclose to the HBP, "at the time of initiation of the

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 addition, there do not appear to be any safeguards for financial information that might be disclosed to beneficiaries under Section 12.b.(4).⁶⁵ To the extent that the Bill mandates the disclosure of proprietary business information without effective protection, the Bill increases the likelihood of proprietary business information becoming public knowledge. If pharmaceutical manufacturers know the precise details of rebate arrangements offered by their competitors, then tacit collusion among them may be more feasible.⁶⁶ Absent such knowledge, manufacturers have powerful incentives to bid aggressively for formulary position, because preferential formulary treatment offers the prospect of substantially increased sales. Unprotected disclosures thus may raise the price that New Jersey consumers pay for pharmaceutical coverage by softening competition among pharmaceutical companies for preferred formulary treatment.

Consumers need accurate information on price and quality to make efficient purchasing decisions. For this reason, the FTC has challenged collusive attempts to suppress price information for consumers⁶⁷ and has opposed government regulation that restricts advertising to consumers.⁶⁸ Pharmaceutical payments PBMs receive from

substitution ... (a) the cost savings as a result of the substitution; (b) any additional costs that will be incurred by the purchaser as a result of the substitution and the mechanism by which the [PBM] will reimburse the [HBP] for those costs, or, if applicable, a reiteration of the contract provision stating that the purchaser agreed to pay for any increase in costs ...; (c) any non-purchaser remuneration the [PBM] has received or will receive as a result of the substitution and how much, pursuant to the contract, the purchaser will receive; and (d) the date on which the [PBM] received approval from the prescriber to initiate the drug substitution.” *Id.* Disclosures to *beneficiaries* are to include “payments ... and any other remuneration or revenue received by a [PBM] in connection with a purchaser’s prescription drug benefits or drug utilization, regardless of how that remuneration or revenue is categorized.” *Id.* at § 12.b.(4).

⁶⁴ A-320 § 9.c. provides, for example, that a PBM “shall make the disclosures *pursuant to this section* upon receiving a written agreement from the purchaser that it will keep the information confidential.” (emphasis added) The plain language of the provision does not appear to condition other disclosures on such an agreement and leaves ambiguous the question whether such disclosures could be fully protected by contract. Also potentially unprotected are disclosures to other entities. Moreover, because the disclosures required under Section 9 are waived for insurer-affiliated PBMs, administrative and other costs they may entail could create an undue pressure toward excessive vertical integration—that is, in favor of new PBM/HBP affiliations that would not be efficient were it not for the regulatory cost or savings choice imposed under the Bill.

⁶⁵ See notes 52, 63, *supra* (regarding substitution disclosure requirements).

⁶⁶ See, e.g., Svend Albaek *et al.*, *Government Assisted Oligopoly Coordination? A Concrete Case*, 45 J. INDUS. ECON. 429 (1997).

⁶⁷ See, e.g., *Fair Allocation System, Inc.*, FTC Docket No. C-3832 (1998) (consent order) (challenging concerted action by auto dealers to restrict a competing dealer’s ability to advertise over the Internet); see also *FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447 (1986) (challenging a dental association rule that prohibited dentists from submitting x-rays to dental insurers in connections with claims forms).

⁶⁸ See, e.g., *Massachusetts Bd. of Registration of Optometry*, 110 F.T.C. 549 (1988); FTC Staff Comments in the Matter of Request for Comments on Agency Draft Guidance Documents Regarding Consumer-Directed Promotion, Before the FDA, Docket No. 2004D-0042 (May 10, 2004), *available at*

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 provide for full disclosure to client HBPs.⁷¹ With no evidence that PBM clients lack accurate information on the price and quality of the services that they purchase, it is unclear how requiring PBMs to reveal rebate information would improve on current market outcomes.

Conclusion

Allowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than contract terms mandated by government regulation. By forcing HBPs to accept terms they would not bargain for, A-320 will likely increase the price of pharmaceutical coverage; ultimately this may suppress the number of New Jersey consumers who have pharmaceutical coverage, and the scope of coverage for those who have it.⁷² As an article in *Health Affairs* noted, “when costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions.”⁷³

<http://www.ftc.gov/os/2004/05/040512dtcdugscomment.pdf>; Letter from FTC to Supreme Court of Alabama (*Sept. 30, 2002*), available at <http://www.ftc.gov/be/v020023.pdf>; FTC Staff Comments in the Matter of Direct-to-Consumer Promotion, Public Hearing before the FDA, Docket No. 95N-0227 (Jan. 11, 1996), available at <http://www.ftc.gov/be/v960001.htm>. See also THE EFFECTS OF RESTRICTIONS ON ADVERTISING AND COMMERCIAL PRACTICE IN THE PROFESSIONS: THE CASE OF OPTOMETRY, FTC Bureau of Economics Report (1980).

⁶⁹ The notion that health insurance beneficiaries should know the cost structure of the service that administers their pharmacy benefits, on behalf of their insurers, is more dubious still.

⁷⁰ See PBM STUDY, *supra* note 3, at 58.

⁷¹ See, e.g., Milt Freudenheim, *Employers Unite in an Effort to Curb Prescription Drug Costs*, N.Y. Times, Feb. 3, 2005; Milt Freudenheim, *Big Employers Join Forces in Effort to Negotiate Lower Drug Prices*, N.Y. TIMES, June 12, 2004.

⁷² In addition to costs that may be entailed by specific restrictions on established preferred contract terms, HBPs and PBMs may be concerned that numerous statutory restrictions on their ability to contract freely will harm their ability to develop and test innovations in this relatively new marketplace. See, e.g., Neil Model, *PBM transparency: More than meets the eye*, Employee Benefit News (Nov. 2006), available at <http://www.benefitnews.com/detail.cfm?id=9740> (regarding new contract provisions addressing pass-through pricing and disclosure and possible advantages and disadvantages to different contract options being explored).

⁷³ William Sage, David A. Hyman & Warren Greenburg, *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31, 35 (March/April 2003). Although estimates of the elasticity of demand for health insurance coverage vary, the empirical evidence is clear that higher costs result in less coverage. See David M. Cutler, HEALTH CARE AND THE PUBLIC SECTOR, NBER Working Paper W8802, Table 5

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.

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