UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition

October 2, 2006

Terry G. Kilgore, Member
Commonwealth of Virginia House of Delegates
General Assembly Building
P.O. Box 406
Richmond, Virginia 23218

Dear Delegate Kilgore:

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 Virginia House Bill No. 945 ("H.B. 945" or "the Bill"), which would regulate the contractual relationships between pharmacy benefit managers ("PBMs") and both health benefit plans ("HBPs" or "plans") and pharmacies. In your letter, dated August 11, 2006, you asked the FTC to "examine H.B. 945 to determine whether the proposed legislation is anti-competitive and will likely result in the increased cost of pharmaceutical care for consumers."[2]

H.B. 945 requires that contracts with PBMs contain certain terms, prohibits the use of certain contractual requirements, requires disclosure of proprietary information, and burdens therapeutic interchange and, to a lesser extent, generic drug substitution by PBMs. We believe that such restrictions, if enacted, will limit the ability of PBMs, HBPs, and pharmacies to enter into efficient, mutually advantageous contracts, and may increase prices for pharmaceuticals in Virginia. Ultimately, the restrictions may decrease the number of Virginia consumers with insurance coverage for pharmaceuticals, without producing offsetting benefits. Empirical evidence suggests that the potential problems that the Bill attempts to address are not prevalent. To the contrary, the findings in the Commission's recent study of the PBM industry suggest that HBPs can protect themselves from potential conflicts of interest in arms-length contracts with PBMs.[3]

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[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 Virginia Delegate Terry G. Kilgore to Maureen Ohlhausen, Director, Office of Policy Planning, Federal Trade Commission (Aug. 11, 2006).

[3] 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.

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.[4] Pursuant to its statutory mandate, the Commission seeks to identify business practices and regulations that impede competition without offering countervailing benefits to consumers. For several decades, the Commission and its staff have investigated the competitive effects of restrictions on the business practices of health care providers.[5] The FTC and its staff have issued reports and studies regarding various aspects of the pharmaceuticals industry,[6] and the Commission has brought numerous enforcement actions against entities in that industry.[7]

The FTC also has extensive recent experience with PBMs. On June 26, 2003, the Commission and the Department of Justice Antitrust Division held hearings on PBMs, as part of our Hearings on Health Care and Competition Law and Policy ("Health Care Hearings").[8] The report jointly issued by the Commission and the Antitrust Division on July 23, 2004, also addressed the issues raised by PBMs.[9] That same year, Commission staff commented on proposed Rhode Island legislation that would have affected PBMs' ability to contract with pharmacies[10] and on proposed California legislation that would have required PBMs to disclose information on their financial arrangements with

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[4] Federal Trade Commission Act, 15 U.S.C. § 45.

[5] *See* Federal Trade Commission, *FTC Antitrust Actions in Health Care Services and Products, available at* http://www.ftc.gov/bc/hcupdate031024.pdf.

[6] *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.

[7] *See* Federal Trade Commission, *FTC Antitrust Actions in Pharmaceutical Services and Products, available at* http://www.ftc.gov/bc/0310rxupdate.pdf.

[8] Health Care Hearings, June 26, 2003, *available at* http://www.ftc.gov/ogc/healthcarehearings/030626ftctrans.pdf. *See also* http://www.ftc.gov/ogc/healthcarehearings/03062526agenda.htm. All subsequent references to the hearings will identify a panelist, affiliation, and transcript page. Affiliations are as of the date of the hearing.

[9] Federal Trade Commission and Department of Justice, IMPROVING HEALTH CARE: A DOSE OF COMPETITION Chapter 7 (2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

[10] 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), *available at* http://www.ftc.gov/os/2004/04/ribills.pdf.

pharmaceutical manufacturers to covered entities and consumers.[11] Most recently, Commission staff commented on North Dakota legislation that would have restricted PBMs' contracting with pharmacies and PBMs' ability to effect certain drug substitutions.[12] Also in 2004, the Commission investigated the competitive implications of a proposed merger between two PBMs, Caremark and AdvancePCS.[13]

In August 2005, the FTC issued a report analyzing potential conflicts of interest raised by PBM ownership of mail order pharmacies ("PBM Study").[14] The Commission obtained data – including agreements between PBMs and plan sponsors, agreements between PBMs and pharmaceutical manufacturers, and data on generic substitution, therapeutic interchange, and repackaging practices – from several PBMs and pharmacies.[15] These data allowed the FTC to examine how PBMs price their services and how pharmaceutical manufacturers compete for preferred treatment on a plan's formulary. The PBM Study found strong evidence that PBMs' ownership of mail order pharmacies generally did not disadvantage plan sponsors and that competition in the industry appears to afford HBPs sufficient tools with which to safeguard their interests.

Background on PBMs

PBMs provide plan sponsors with a variety of services for managing pharmacy benefits. Principally, PBMs act as clearinghouses for HBPs, covered individuals, and retail pharmacies. When a plan beneficiary purchases a drug at a retail pharmacy, he or she presents a health plan card identifying the source of insurance coverage, and the pharmacy transmits the card information to the PBM.[16] The PBM then verifies the beneficiary's policy, whether the drug is covered by the plan, the direct payment the PBM owes the pharmacy, and the co-payment, if any, owed by the beneficiary. The PBM conveys this information back to the pharmacy, logs the payment information, and sends the billing information to health insurers (who will remit payment to the PBM). The PBM then pays the retailer.

PBMs also help plan sponsors manage the cost and quality of the benefits they

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[11] Letter from FTC staff to Rep. Greg Aghazarian (Sept. 7, 2004), *available at* http://www.ftc.gov/be/V040027.pdf.

[12] 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.

[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* note 3, *supra*.

[15] *Id*. at iii – iv.

[16] For mail-order prescriptions, the beneficiary also identifies him or herself and the source of the insurance coverage, if not by submitting the card itself.

provide to their enrollees. To varying degrees PBMs:

- negotiate rebates from pharmaceutical manufacturers.
- provide access to mail order pharmacies for health plan enrollees on maintenance medications.
- develop drug formularies[17] and help plan sponsors determine which drugs should be on the plan's formulary and whether and how to provide co-payment incentives to the plan's enrollees to use those drugs.
- provide drug utilization reviews that include analysis of physician prescribing patterns to identify physicians prescribing high cost drugs when lower cost, therapeutically equivalent alternatives are available.
- provide disease management services by offering treatment information to and monitoring of patients with certain chronic diseases.

The drug formulary is an important tool for PBMs. Because a formulary affects the mix of drugs used by beneficiaries, its design can affect significantly the cost of drugs to a plan sponsor. PBMs use generic substitution and therapeutic interchange procedures to attain better compliance with their formularies.[18] Because generic drugs typically are much less expensive than their brand-name counterparts, generic substitution lowers prescription drug costs. Therapeutic interchange also has the potential to increase usage of less expensive, but therapeutically effective, brand name drugs or their generic equivalents. Although therapeutic interchange represents a small percentage of prescriptions filled under PBM arrangements, it does tend to reduce plan sponsors' costs where it is employed and can serve as an important tool in PBM negotiations with manufacturers for higher

[17] A formulary is a list of plan sponsor-approved drugs for treating various diseases and conditions. This list will often be broken down into "tiers," which correspond to different co-payment levels for enrollees. For instance, a three-tier formulary may consist of a generic tier, a preferred brand tier, and a non-preferred brand tier. Whether a brand is preferred may depend on whether a generic alternative is available and also upon the financial terms available to the PBM on drugs in the same therapeutic class.

[18] In generic substitution, a pharmacy provides a drug that is pharmacologically identical to the name-brand drug indicated on the prescription. "A generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use." U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Generic Drugs: Questions and Answers, *available at* http://www.fda.gov/cder/consumerinfo/generics_q&a.htm (last checked Sept. 26, 2006). In therapeutic interchange, a pharmacy substitutes 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 (*i.e.*, two brand-name drug products, from the same therapeutic class, that treat the same ailment—such products may or may not have the same active moiety; that is, identical active compounds). *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.

pharmaceutical payments or allowance rates.[19]

PBMs enter into contracts with plan sponsors, retailers, and drug manufacturers. First, a PBM's contract with a plan sponsor covers the amount that the plan sponsor will pay for each prescription, via retail or mail order, and separate charges for the various PBM services that the sponsor may use.[20] In addition, the contract also specifies the details of how the client will share in payments obtained from pharmaceutical manufacturers.[21]

Second, PBMs negotiate drug prices with pharmacies participating in the PBMs' networks. A price typically is stated as a discount from a measure of a drug's wholesale price, plus a dispensing fee.[22] Retailers offer discounts depending on the type and number of clients covered by the PBM and the exclusivity of the network — the more exclusive the network, the higher the discount. By forming a preferred or exclusive network, a PBM is able to guide plan beneficiaries to certain pharmacies. The promise of increased customer volume creates an incentive for pharmacies to bid aggressively on drug prices.[23] A PBM may have several networks that differ in degree or scope of exclusivity.

Finally, PBMs negotiate with pharmaceutical manufacturers to determine payments from the manufacturers to the PBMs, based on the treatment of the manufacturers' products within the plans that the PBMs administer. Preferential placement on a formulary or reduced co-payments can give a drug product a higher

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[19] *See* notes 42-44, *infra* (PBM Study results regarding therapeutic interchange).

[20] Drug pricing in a typical contract between a PBM and a plan sponsor generally is specified as a discount off of the "average wholesale price" ("AWP") for branded drugs as reported in various public databases. So the price formula would be, for example, "AWP - 10% +$2.00." A discount off of AWP is sometimes also used for pricing of generic drugs, but it is also common for PBMs to develop "maximum allowable cost" ("MAC") lists that give prices for many of the most prescribed generic drug products.

[21] These payments are paid to the plan sponsor, retained by the PBM, or shared between them depending on the specifics of the contract between these parties. *See* PBM STUDY, *supra* note 3, at 59-60; John Richardson, Health Strategies Consultancy, Health Care Hearings, *supra* note 8, at 23-24 (PBMs "can be paid through administrative fees, share of rebates, or some combination."); Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 8, at 124. Typically, contracts also specify a plan's audit rights with respect to formulary and payment sharing. *See* PBM STUDY, *supra* note 3, at 58.

[22] *See* PBM Study, *supra* note 3, at 4.

[23] For example, the GAO Report noted that when Blue Cross Blue Shield introduced a plan with a smaller network of retail pharmacies, it included deeper discounts in its retail pharmacy payments. *See* 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. An extensive discussion of these issues is found in the Letter from FTC staff to Patrick C. Lynch, Rhode Island Attorney General and Juan M. Pichardo, Rhode Island Deputy Senate Majority Leader, *supra* note 10.

market share. Pharmaceutical companies compete for such placement by offering rebates and other financial rewards (collectively "pharmaceutical payments"). Because pharmaceutical payments reduce a PBM's costs, they tend to lower prices for health care consumers.[24]

Competition Among PBMs

Plan sponsors, sometimes with the help of consultants, typically procure PBM services through a bidding process, which may go through multiple iterations. PBMs compete for plan sponsors' business on a variety of price and non-price dimensions. One survey of plan sponsors using PBMs found that, although financial terms often were key determinants in the selection of the winning bid, sponsors also focused on non-price terms, such as benefit design, extent of the retail network, and quality of mail order service.[25] Further, plan sponsors' preferences for formulary design and pharmaceutical payment sharing vary considerably. At the Health Care Hearings, panelists stated that some sponsors want to maximize generic substitution, while others want to maximize payments from manufacturers.[26] Panelists also noted that some plan sponsors want to receive all payments from manufacturers, while others seek to negotiate deeper discounts on list prices by allowing the PBM to retain these payments — and many plan sponsors fall somewhere in-between.[27] An FTC analysis of a sample of contracts between HBPs and PBMs confirmed this diversity of contract terms.[28]

There are approximately 40-50 PBMs operating in the United States, with three large, independent, full-service PBMs of national scope: Medco, Express Scripts, and Caremark.[29] Some large insurers manage pharmacy benefits internally. Large retail supermarket/pharmacy chains own several PBMs, and several local and regional PBMs can compete with national PBMs for contracts with smaller employers or health plans that are geographically limited.[30] The three large national PBMs are the major players in

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[24] *See* GAO Report, *supra* note 23, at 11 (noting that rebates passed through to health plans reduced these plans' annual spending on prescription drugs by three percent to nine percent).

[25] *See* Health Care Financing Administration, STUDY OF PHARMACEUTICAL BENEFIT MANAGEMENT (Jun. 2001), *available at* http://www.cms.gov/researchers/reports/2001/cms.pdf.

[26] Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 8, at 65; Anthony Barrueta, Kaiser Foundation Health Plan, Inc., Health Care Hearings, *supra* note 8, at 105.

[27] John Richardson, The Health Strategies Consultancy, Health Care Hearings, *supra* note 8, at 18 ("A lot of PBMs don't retain any of the rebates; others retain a portion in addition to whatever percent of the revenue they will keep as their administrative fees. So again, that's going to differ in each arrangement that is out there."); John Dicken, General Accounting Office, Health Care Hearings, *supra* note 8, at 40 ("of those contracts -- not all, but some -- would have the PBMs retaining some portion of those rebates to cover their administrative services."); Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 8, at 58-59.

[28] *See* PBM STUDY, *supra* note 3, at 59-60.

[29] *See id.* at 2-3.

[30] *See* IMPROVING HEALTH CARE: A DOSE OF COMPETITION, *supra* note 9, at 14-15 (2004),

many regional markets, but typically one-third to one-half of each market is serviced by other, smaller PBMs. The FTC found, in its most recent antitrust investigation of the PBM industry, that competition among PBMs for contracts with plan sponsors is "vigorous."[31]

Description of H.B. 945's Provisions

Several provisions of H.B. 945 significantly restrict the provision of PBM services in ways that are likely to harm Virginia consumers. It may be useful to partition the Bill's provisions into three general categories: (1) contract restrictions; (2) mandatory disclosures of financial information; and (3) drug interchange and substitution burdens.

Contract Restrictions

H.B. 945's "non-discrimination" provisions (a) allow beneficiaries to obtain benefits from any pharmacy within a PBM's network, and (b) prohibit a PBM from requiring any beneficiary to obtain any pharmacy service from a mail order pharmacy rather than a retail pharmacy;[32] the Bill's "freedom of choice" provisions prohibit insurers and PBMs from barring access to the pharmacy of the beneficiary's choice, whether or not the pharmacy of choice is a preferred provider.[33] Furthermore, the Bill prohibits PBMs and HBPs from encouraging the use of either preferred provider or mail-order pharmacies via differential copayments or other financial incentives.[34]

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available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf; Kaiser Family Foundation, FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN, at 16 (Mar. 2005), *at* http://www.healthstrategies.net/research/docs/Follow_the_Pill.pdf.

[31] Commission Statement, *supra* note 13.

[32] *See id.* at § 38.2-1384.

[33] Insurers and PBMs cannot "prohibit *any* person receiving pharmacy benefits … from selecting, *without limitation*, the pharmacy of his choice to furnish such benefits. This right of selection extends to … nonpreferred providers … that have previously notified the insurer … of their agreement to accept reimbursement for their services at rates applicable to pharmacies that are preferred providers." § 38.2-4209.1 (emphases added); *see also id.* at § 38.2-4312.1. Disclosure provisions in the Bill (both as they address HBPs and as they address pharmacies) may further undermine a PBM's ability to form efficient network contracts. *See* text accompanying notes 37-40, and 71-72, *infra*, (regarding relevant disclosure provisions).

[34] Under the Bill's "freedom of choice" provisions, no "insurer or *pharmacy benefits manager* shall impose … 1. Any copayment, fee or condition that is not equally imposed upon all individuals … whether or not such benefits are furnished by pharmacies who are nonpreferred [*sic*] providers; 2. Any monetary penalty that would affect or influence any such person's choice of pharmacy; 3. Any reduction in allowable reimbursement for … nonpreferred [*sic*] providers; or *4. A different copyament, fee, or condition for persons wishing to have prescriptions filled at a participating pharmacy other than a mail order pharmacy, regardless of the number of months for which the prescription is written.*" H.B. 945 § 38.2-3407.7(B). Under the Bill's non-discrimination provisions, a PBM cannot "[u]se any financial or other disincentives, penalties, or other means to influence, coerce, or steer beneficiaries away from a retail or institutional

H.B. 945 also mandates a number of contract terms for contracts between PBMs and HBPs and for contracts between PBMs and pharmacies.[35] These terms include disclosure and payment timetable requirements, as well as a requirement that a PBM must act as a *fiduciary* of a pharmacy, on behalf of which the PBM receives payment.[36]

Disclosures

H.B. 945 mandates that PBMs disclose certain proprietary business information to pharmacies, prescribing physicians, beneficiaries, and health benefit plans. For example, PBMs must disclose formulary information to preferred and "nonpreferred [*sic*] or nonparticipating pharmacists" alike.[37] Contract terms regarding the reimbursement of network pharmacies must be disclosed to any out-of-network pharmacy wishing to take advantage of the Bill's "freedom of choice" provisions.[38] For drug substitutions proposed under principles of therapeutic interchange, the Bill requires PBMs to disclose *financial* information, as well as potentially relevant medical information, to prescribing physicians.[39] Although the Bill would provide that, *purchasers* of PBM services (chiefly, HBPs) would be subject to private confidentiality conditions, those provisions apply only to purchasers, and then only for information that would be disclosed under certain of the Bill's disclosure provisions.[40]

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pharmacy that can meet the same terms and conditions as a mail order pharmacy; or … [l]imit the quantity of drugs that a beneficiary may obtain at any one time from any type of pharmacy provider …." *Id.* at § 38.2-1384(C).

[35] For example, under new § 38.2-1379 are mandatory contract terms for all contracts executed by PBMs for the provision of PBM services. Certain general provisions regarding PBM contracts are found at § 38.2-1378 (Contracts; agreements must be approved; prohibited provisions); and provisions required of PBM/PP contracts are at § 38.2-1382.

[36] *Id.* at 38.2-1378(E).

[37] *See id.* at § 38.2-3407.9: 01

[38] *See id.* at § 38.2-4209.1, 4312.1.

[39] *See id.* at § 38.2-1381 (requiring disclosure not just of medical rationale for the substitution but, e.g., "cost savings for the purchaser [the HBP], if any," and the "existence of additional payments received by the pharmacy benefits manager that are not reflected in the cost savings to the purchaser").

[40] That is, HBPs would be subject to private contractual assurances for at least some of the information that would be disclosed directly to them. *See id.* at § 38.2-1375 (regarding "[p]rerequisites to disclosure[s]" under 1377-1378). We suppose that an apparent anomaly among these prerequisites is merely a formatting error soon to be (if not already) corrected. In this draft, the Bill provides for mandatory disclosure to a prospective purchaser under § 38.2-1376 and for mandatory disclosure to a purchaser under § 38.2-1377. However, the relevant confidentiality assurance for a PBM disclosing copious proprietary information is found at § 38.2-1375. That assurance provision—regarding "prerequisites to disclosure"—states that, "a pharmacy benefits manager need not make the disclosures required under *§§ 38.2-1377 and 38.2-1378* unless and until the prospective purchaser or the purchaser agrees in writing to maintain as confidential any proprietary information disclosed by the pharmacy benefits manager." *Id.* at

Therapeutic Interchange and Generic Drug Substitutions

H.B. 945's disclosure provisions also burden a PBM's ability to implement its clients' programs that promote the therapeutic interchange of one branded drug product for another. The Bill potentially burdens certain substitutions of generic drugs for brand name drugs as well. As noted above, very extensive disclosure obligations are required for therapeutic interchange under the Bill.[41] Although therapeutic interchange is not widely practiced by PBMs,[42] it tends to reduce health plan sponsors' costs where it is employed,[43] may play a useful role in the negotiation of discounts with drug manufacturers,[44] and may, in certain instances, serve therapeutic ends.[45] Even more importantly, the Bill imposes high threshold conditions for therapeutic interchange, such as requiring there be medical or financial benefits to purchasers.[46]

Likely Effects of H.B. 945

H.B. 945 likely would restrict the ability of HBPs to enter into the types of contractual relationships that best suit their needs. The Bill would undercut a PBM's

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38.2-1375 (emphasis added). On its face, the draft Bill neglects to provide "prerequisites" for disclosures to prospective purchasers required under its own § 38.2-1376. In any case, we note that the prerequisites expressly pertain only to disclosures made under two of the Bill's subsections.

[41] *See* text accompanying note 39, *supra*.

[42] 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." PBM Study, *supra* note 3, at 84. Although these figures do not include refills or renewals of interchanged prescriptions, and may not be representative of practices across the industry, they do suggest that therapeutic interchange represents a small share of filled prescriptions, if not a trivial number of prescriptions in absolute terms.

[43] *See id.* at 81.

[44] 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." *Id.* at 84.

[45] The PBM Study notes that adequate information was not available to determine when therapeutic interchange may be employed for drug safety reasons, e.g., to avoid adverse drug interactions. *See id.* at 82, n. 4.

[46] H.B. 945 § 38.2-1380 generally prohibits substitutions (generic substitution and therapeutic interchange), absent "medical reasons that benefit the beneficiary; or … financial savings and benefits to the purchaser." *Id.* Because, e.g., a plan's net cost for a drug with a higher Average Wholesale Price may be lower than its cost for the prescribed drug, once pharmaceutical payments or market share payments are taken into account, demonstrating compliance with this provision on a substitution-by-substitution basis may be at least complex and uncertain. *See* PBM STUDY, *supra* note 3, at 7 (regarding market share payments).

ability to negotiate provider networks for HBPs, require a PBM fully to disclose diverse proprietary information, and burden the ability of a PBM to employ therapeutic interchange and, potentially, to effect certain drug substitutions.. Additional disclosure and contract responsibilities, including the imposition of a fiduciary duty on a PBM in certain of its dealings with pharmacies, are likely to increase administrative costs and legal liability for performing the PBM's core functions. All of these legislative requirements are likely to cause the prices that PBMs charge for their services – and concomitantly, the price of pharmaceutical coverage – to rise.

Contract Restrictions

Several provisions of H.B. 945 significantly restrict PBM contracting in ways that are likely to be counter-productive for Virginia consumers.[47] In particular, the Bill's "freedom of choice" and "non-discrimination" provisions restrict the ability of a PBM to form service networks.[48] Service network contracts are central to PBM negotiations with pharmacies on price.[49] Network participation offers an incentive to pharmacies to bargain on price, because participation promises increased sales volume. The Bill, however, places very strong limitations on a plan's ability to steer beneficiaries to one pharmacy rather than another,[50] together with restrictions on a PBM's ability to enter into efficient contracts with pharmacies.[51] Thus, the Bill undercuts the likelihood or magnitude of sales that a PBM/Pharmacy contract may reasonably contemplate.[52]

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[47] Absent such restrictions, PBM business models and contracts tend to be diverse, as "PBMs compete on price and non-price dimensions to serve … varying client needs." PBM STUDY, *supra* note 3, at 8; *see also* PBM STUDY at ix, xiv, 8-10, 37-39, 48-60, 90-92 (contract terms between PBMs and manufacturers, and between PBMs and HBPs, show variation in payment terms, substitution incentives, reporting and disclosure requirements).

[48] *See* text accompanying notes 32-34, *supra*.

[49] *See* text accompanying notes 22-23, *supra*.

[50] *See* text accompanying notes 32-34, *supra* (regarding H.B. 945's "non-discrimination" and "freedom of choice" provisions generally); *see also* note 34, *supra* (regarding stipulations that plans cannot use differential financial incentives to encourage use of certain pharmacies).

[51] *See* notes 32-36, *supra* (regarding contract restrictions).

[52] Pharmacy choice provisions may have economic effects similar to those of "price matching" policies (whereby a seller guarantees that it will match the lowest available price) or "any-willing-provider" regulations (where the same sort of price matching guarantee is imposed on sellers by regulation). On their face, such policies may appear to be pro-competitive. In effect, however, they may tend to result in higher prices, because they reduce sellers' willingness to bid aggressively on price to begin with. *See, e.g.*, Aaron S. Edlin and Eric R. Emch, *The Welfare Losses from Price-Matching Policies*, 47 J. IND. ECON. 145 (1999). Empirical work on the effects of any-willing-provider regulations on managed care generally, bear this out. *See* Michael G. Vita, *Regulatory Restrictions on Selective Contracting: An Empirical Analysis of "Any-Willing-Provider" Regulations*, 20 J. HEALTH ECON. 955, 965 (2001) (panel data show expenditures rise when any-willing-provider laws are enacted, and tend to rise more with stronger laws).

Because any pharmacy may "free-ride" on a competitor's successful network proposal, pharmacies may be less willing to invest in the development of innovative, competitive proposals to begin with. While pharmacy choice provisions may seem superficially attractive, a likely effect of such provisions is the suppression of efficient service networks, not the expansion of real consumer choice. The higher retail prices that are likely to follow ultimately would be passed on to Virginia consumers.[53]

Similarly, H.B. 945 restricts the ability of a PBM to negotiate for discounted mail order provision of chronic use drugs, as plans may neither require the use of mail order pharmacies nor implement financial incentives to encourage it.[54] On the one hand, a beneficiary is only guaranteed access to a pharmacy willing to "meet the same terms and conditions as a mail order pharmacy."[55] On the other hand, the Bill makes it likely that those terms and conditions will be easier to meet.[56] Retail prices tend to exceed mail order prices on prescription drugs.[57] Moreover, data indicate that retail prices exceed mail order prices even after adjusting for prescription size.[58] Plan sponsors, on balance, can negotiate larger discounts in contracting with mail order pharmacies for any given reference drug.[59] The Bill's restrictions on the preferred use of mail order, however, undermine sponsors' abilities to promise larger volumes of purchasing in exchange for price reductions. As such, the restrictions are likely to diminish the prospect or magnitude of negotiated discounts.[60]

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[53] Data on any-willing-provider regulation of managed care show that both hospital and physician expenditures rise with strong any-willing-provider laws. *See* Michael G. Vita, *supra* note 53, at 962, 965 (states with the laws spent roughly 2% more on healthcare than states without). Although choice generally is beneficial to consumers, not all health care consumers prefer additional choices if they are costly ones. Many employers, for example, offer a choice between higher-cost/higher-benefit plans and lower-cost/lower-benefit plans, and many employees choose the latter. *See, e.g.*, Dennis P. Scanlon, et al., *Impact of Health Plan Report Cards on Managed Care Enrollment*, 21 J. HEALTH ECON. 19, 36-37 (2002); Nancy Dean Beaulieu, *Quality of Information and Consumer Health Plan Choices*, 21 J. HEALTH ECON. 43, 44, 55-57(2002) (employees respond to information on price and quality in choosing health plans).

[54] *Id.* at 38.2-1384(C).

[55] *Id.*

[56] As with retail pharmacy choice, the mail order provisions effectively operate as any-willing-provider regulations, which tend to raise, rather than lower, health care expenditures. *See* text accompanying notes 34, 47-51, and n. 53, *supra*.

[57] This appears to be partly, although not entirely, due to economies of scale in filling larger prescriptions. *See* PBM STUDY, *supra* note 3, at 23, 26-7 (mail order prescriptions less expensive and three times larger, economies of scale in filling larger prescriptions).

[58] *Id.* at 25.

[59] *Id.*

[60] H.B. 945 prohibits a PBM from requiring that a beneficiary obtain pharmacy services from a mail order pharmacy; it also prohibits the PBM from implementing "any financial or other disincentives, penalties, or other means to influence, coerce, or steer beneficiaries away from a retail or institutional pharmacy…." *Id.* The Bill also limits a PBM's ability to limit "the quantity of drugs that a beneficiary may obtain at any one time…." *Id.* Pharmacy choice provisions may

Disclosure Requirements

H.B. 945 mandates that PBMs disclose considerable proprietary business information to pharmacies, prescribing physicians, beneficiaries, and HBPs. Although PBM/HBP contracts would, under the Bill, bar HBPs from disclosing some of this proprietary information, there are no analogous protections for information disclosed to pharmacies, prescribing physicians, or plan beneficiaries. For example, therapeutic interchange would require that prescribing physicians receive information regarding manufacturer payments to PBMs.[61] In addition, provisions regarding pharmacy choice require at least certain PBM disclosures, and could be read as requiring broad, unprotected disclosures of proprietary information. As mentioned above, a beneficiary may elect to receive pharmacy benefits via a local pharmacy (instead of a mail order pharmacy) or a non-preferred provider (instead of a preferred provider).[62] Such pharmacy choice is unrestricted, provided that, (a) the non-preferred provider notifies the PBM of its willingness to confer benefits on the same terms as those offered to preferred providers,[63] and (b) a pharmacy shall, if requested to do so by the PBM in writing, execute "the direct service agreement or preferred provider agreement which the corporation or pharmacy benefits manager requires all of its preferred providers to execute."[64] A PBM is obligated to verify, promptly, "the terms of the reimbursement."[65] Unclear is the extent to which full contract terms with network pharmacies must be disclosed to non-preferred, or non-participating, pharmacies under these provisions. What does appear clear is that the Bill's contemplated protections for proprietary information apply only to two of the sections expressly requiring certain disclosures.

Consumers need accurate information on price and quality to make efficient purchasing decisions. For this reason, the FTC has challenged collusive attempts to obfuscate price information for consumers[66] and has opposed government regulation that

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have economic effects similar to those of "price matching" policies (whereby a seller guarantees that it will match the lowest available price). On their face, such policies may appear to be pro-competitive. In effect however, they may tend to result in higher prices, because they reduce sellers' willingness to bid aggressively on price to begin with. *See, e.g.*, Aaron S. Edlin and Eric R. Emch, *The Welfare Losses from Price-Matching Policies*, 47 J. Ind. Econ. 145 (1999).

[61] *See* notes 39-41, *supra*.

[62] *See* text accompanying notes 32-34, *supra*.

[63] Under the Bill's "non-discrimination" provisions, § 38.2-3407.7, pharmacies must agree "to accept reimbursement for their services at rates applicable to pharmacies that are preferred providers"; under the "freedom of choice provisions, pharmacies may provide services if they are willing to do so "at rates applicable" to preferred providers. § 38.2-4209.1(A).

[64] *See* § 38.2-4209.1(D). The proposed statutory language is unclear about the choice of contract obligations in the event that a PBMs preferred provider agreements vary.

[65] *Id.* at § 38.2-3407.7.

[66] *See 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

restricts advertising to consumers.[67] But there is a difference between protecting consumer access to the information required for a healthy benefits market and the mandatory disclosures that would damage it. The disclosure of pharmaceutical payment information required by H.B. 945 would not necessarily convey needed pricing information to PBMs' current or prospective clients. Pharmaceutical payments received by the PBM from manufacturers (along with costs such as amounts paid to network pharmacies for drugs dispensed, operating expense, etc.) are merely one factor among many that PBMs consider in determining competitive prices for their services. The payments can be thought of as discounts on the costs of drug products supplied to members of plans administered by the PBM. Therefore, the Bill's disclosure requirements are analogous to a requirement that a firm reveal aspects of its cost structure to its customers. Moreover, while consumers need accurate information on price and quality to make efficient purchasing decisions, there is no reason that consumers require the seller's underlying cost information for markets to achieve competitive outcomes.

The Commission found in its analysis of the Caremark/Advance PCS merger that the market for PBM services is competitive.[68] Further, plan sponsors – or the consultants they hire to assist them in contracting with PBMs – often are highly sophisticated, repeat purchasers of PBM services who, typically, award contracts based on sealed bidding.[69] Thus, there is no indication that the market provides PBM clients insufficient information to contract for, and purchase, competitively priced services; there are, however, substantial and clear reasons to worry that the Bill's mandatory disclosure provisions may harm, rather than improve, market outcomes.

Public disclosure of proprietary information can foster tacit collusion or otherwise undercut vigorous competition on drug pricing. If, for example, pharmaceutical manufacturers learn the particulars of rebates and other payments and incentives offered by their competitors, then tacit collusion among them may be more feasible. Inclusion in a PBM formulary offers pharmaceutical manufacturers the prospect of substantially

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Internet); *Cal. Dental Ass'n v. FTC*, 526 U.S. 756 (1999) (vacating appellate decision upholding FTC decision finding illegal a dental association rule that prohibited advertising on price). *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).

[67] *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), *at* http://www.ftc.gov/os/2004/05/040512dtcdrugscomment.pdf*; Letter from FTC to Supreme Court of Alabama (Sept. 30, 2002), 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), 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).

[68] *See* Commission Statement, *supra* note 13.

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

increased sales. Because particular products and their manufacturers can be excluded from formularies, manufacturers have powerful incentives to bid aggressively for inclusion. Knowledge of rivals' prices can dilute incentives to bid aggressively and facilitate tacit collusion, which increases prices.[70] Consequently, the required disclosures may lead to higher prices for PBM services *and* pharmaceuticals.

Similarly, disclosure of contract particulars in PBM/Pharmacy contracts may undercut competition or foster collusion between pharmacies. Pharmacies — including large pharmacy chains — compete on drug prices for network, or preferred provider, contracts with PBMs. Again, knowledge of rivals' prices can dilute incentives to bid aggressively and foster tacit collusion. The disclosure provisions may thus work in tandem with the pharmacy choice provisions to undercut the most efficient network contracts, leading to higher pharmaceuticals prices.[71]

As we found in the PBM Study, plan sponsors generally appear able to negotiate contract terms – including terms regarding information disclosure – to protect themselves from conflicts of interest. Press reports suggest that, as a result of competition to provide the best mix of price and quality, many PBMs offer contracts that provide both full disclosure and rebate sharing to their clients.[72] Further, it is common for contracts to provide for audit rights, so that HBPs can verify that pharmaceutical payments are being shared as per agreement.[73] Thus, there is no reason to suppose that competition between PBMs is less likely than government regulation to produce efficient levels of information disclosure. In brief, HBPs and pharmacies appear to be able to bargain for the information they need to participate effectively in the health care market. Regulation that damages competition by requiring anticompetitive disclosures is likely to harm consumers.

Burdens on Therapeutic Interchange and Certain Generic Drug Substitutions

H.B. 945 also would limit greatly a PBM's ability to implement its clients' therapeutic interchange, and may also stand as an impediment to certain generic drug substitution policies. The disclosures required for therapeutic interchange, for example, would likely result in not just the dissemination of proprietary information, but the

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

[71] *See* text accompanying notes 47-52, and n. 53, *supra* (regarding pharmacy choice and the economic effects of price-matching policies).

[72] *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. Panelists at the Health Care hearing also testified that PBMs compete on price and non-price dimensions to win contracts. *See* IMPROVING HEALTH CARE: A DOSE OF COMPETITION at 15-17 (2004); *see also* Health Care Financing Administration, STUDY OF PHARMACEUTICAL BENEFIT MANAGEMENT (Jun. 2001), *available at* http://www.cms.gov/researchers/reports/2001/cms.pdf.

[73] *See* PBM STUDY, *supra* note3, at 58.

imposition of significant administrative costs on otherwise efficient pharmacy practices. Collectively, such requirements may constitute an impediment or bar to interchanges that would lower health plan costs overall. In addition, certain threshold savings requirements for therapeutic interchange may be difficult to establish.[74] For example, a plan's net cost for a drug with a higher Average Wholesale Price may be lower than its cost for the prescribed drug, once pharmaceutical payments or market share payments are taken into account.[75] Overall, the PBM study indicates that, (a) health plans can benefit from therapeutic interchange,[76] (b) interchange with apparently more costly drugs need not harm plans or beneficiaries,[77] and (c) plans presently contract for diverse protections against interchanges that are actually costly.[78] The Bill's restrictions on therapeutic interchange are likely to limit PBMs' ability to obtain benefits, potentially resulting in higher costs for consumers. The regulatory protections contemplated by the Bill thus seem both unnecessary and expensive.

Conclusion

Allowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than mandating the terms through government regulation. By forcing health plan sponsors to accept contractual terms they would not otherwise bargain for, H.B. 945 will probably increase the price of pharmaceutical coverage; ultimately the number of Virginians who have pharmaceutical coverage, and the scope of coverage for those who have it, is likely to be suppressed. 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."[79]

At the same time, there does not appear to be any compelling reason to restrict competition to protect pharmacies or HBPs. As we concluded in the PBM Study, HBPs

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[74] Although those requirements pertain equally to generic substitutions, savings typically are likely more transparent when generic products are substituted for branded ones.

[75] Market share payments are used by pharmaceutical manufacturers to encourage PBMs to dispense their drugs, especially in crowded therapeutic classes. *See* PBM STUDY, *supra* note 3, at 7.

[76] *See id.* at 92-94.

[77] *See id.* at 94-95.

[78] *See id.* at 90-92.

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

appear well able to protect themselves from potential conflicts of interest for PBMs. If the Virginia General Assembly nonetheless is concerned that some plan sponsors may be unable to protect themselves through arms-length contracts, we would suggest that the General Assembly consider modifying H.B. 945 to allow plans sponsors to waive its requirements. This would allow those sponsors who want to employ PBMs on terms other than those in the Bill to do so.

We urge the Virginia General Assembly to consider the adverse effects on competition and consumer welfare that H.B. 945 will likely produce. We appreciate this opportunity to share our views and welcome any further discussions regarding competition policies.

Respectfully submitted,

Maureen K. Ohlhausen
Director
Office of Policy Planning

Michael A. Salinger
Director
Bureau of Economics

Jeffrey Schmidt
Director
Bureau of Competition