UNITED STATES OF AMERICA



FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

Office of Policy Planning Bureau of Economics Bureau of Competition

August 8, 2011

Hon. James L. Seward Senator, 51st District Legislative Office Building Albany, NY 12247

Dear Senator Seward:

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 New York Assembly Bill 5502-B ("A-5502-B" or "the Bill"), which regulates the use of mail order pharmacies by health plans offering prescription drug coverage.²

FTC staff recognize that the Bill seeks to enhance New York consumers' ability to choose how and where their prescriptions are filled. We are concerned, however, that the Bill will have the unintended consequence of harming consumers. By reducing competition between pharmacies, this legislation likely will raise prices for, and reduce access to, prescription drugs, which are an increasingly important component of medical care.

The Bill will limit a health plan's ability to steer beneficiaries to a lower cost mail order vendor of maintenance drugs,³ via financial incentives or other terms of coverage, whenever a competing retail pharmacy is willing to fill prescriptions at "comparable" prices. By restricting a health plan's ability to offer favorable treatment to a low cost mail order pharmacy, the Bill undercuts pharmacies' incentives to bid aggressively for a share of that health plan's business. Reducing those incentives is likely to raise the prices that consumers pay for the prescription drugs that their health plans cover. Some cost increases may be passed on to plan beneficiaries in the form of higher out-of-pocket prices. In some cases, plans may respond to higher costs by reducing the scope of prescription drug coverage, or by eliminating prescription drug coverage entirely. For those reasons, FTC staff recommend that the Bill not be enacted.

I. Interest and Experience of the Federal Trade Commission

Congress has charged the Federal Trade Commission ("FTC" or "Commission") with enforcing the FTC Act, which prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. ⁴ Pursuant to its statutory mandate, the

FTC seeks to identify business practices and government regulations that may impede competition without offering countervailing benefits to consumers.

Competition is at the core of America's economy,⁵ and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, more choices, and greater innovation. Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct in health care markets has long been a key target of FTC law enforcement,⁶ research,⁷ and advocacy.⁸ Of particular relevance to our analysis of A-5502-B is the Commission's 2005 "Conflict of Interest Study" regarding pharmacy benefit managers ("PBMs"). In response to a 2003 Congressional request, the FTC analyzed data on PBMs and, in particular, on price competition and other issues regarding the use of mail order pharmacies by PBMs and others. In its 2005 report based on the study, the FTC found, among other things, that mail order pharmacies typically are less expensive than retail pharmacies for both health plans and their members⁹

II. The Bill and "Any Willing Provider" or "Freedom of Choice" Laws

A. A-5502-B's Restrictions on Mail Order Pharmacies.

The Bill imposes parallel restrictions on any policy or insurer that provides coverage for prescription drugs. Such policies and insurers are subject to two basic limitations, which apply whenever a competing pharmacy is willing to accept prices that are "comparable" to those charged by a health plan's preferred mail order pharmacy. First, the plan must permit each covered person to fill any mail order prescription at the pharmacy of his or her choice – at any retail (non-mail) pharmacy in the plan's network, or at any mail order pharmacy at all, independent of network participation. Competing pharmacies need only offer to accept prices that are "comparable" to those charged by a health plan's preferred mail order pharmacy. Second, plans cannot impose higher copayments or deductibles when a covered individual chooses to fill a prescription at a non-preferred pharmacy.

B. "Any Willing Provider" and "Freedom of Choice" Regulations.

A-5502-B limits a health plan's ability to require or encourage the use of any particular mail order pharmacy. These limits are akin to those found generally in "any willing provider" ("AWP") and "freedom of choice" ("FOC") laws. AWP laws require health plans to include in their networks any provider that is willing to participate in accordance with the plan's terms. ¹³ FOC laws are similar, but are directed at health plans instead of providers. FOC laws require plans to reimburse for health care goods or services obtained from any qualified provider, even if the provider is not one of the plan's preferred providers, or is not a member of the plan's network. ¹⁴ More than thirty states have adopted AWP or FOC laws in some form, and more than a dozen have adopted such laws for pharmacy services in particular. ¹⁵

FTC staff have expressed concerns about potential anticompetitive effects and consumer harms associated with AWP and FOC laws before. These laws can make it more difficult for health insurers or PBMs to negotiate discounts from providers; if plans cannot give providers any assurance of favorable treatment or greater volume in exchange for lower prices, then the incentive for providers to bid aggressively for the plan's business – to offer better rates – is undercut. AWP and FOC laws also can limit competition by restricting the ability of insurance companies to offer consumers different plans, with varying levels of choice. These restrictions on competition may result in insurance companies paying higher fees to providers, which, in turn, generally results in higher premiums, and may increase the number of people without coverage. Both economic theory and the available empirical evidence suggest that AWP/FOC provisions are likely to have these negative effects. 18

III. Likely Effects of A-5502-B

Mail order pharmacies can offer substantial cost savings, especially with respect to prescriptions for "maintenance" drugs, which are taken for long periods of time, on a regular basis. ¹⁹ Limits on the use of mail order may, therefore, raise the cost of providing prescription drug benefits to New York health care consumers. Although the Bill attempts to provide consumers with a choice among available pharmacy providers, it may have the unintended consequences of curtailing prescription drug coverage and increasing out-of-pocket payments.

FTC research has found that mail order pharmacies typically are less expensive than retail pharmacies, ²⁰ for both health plans and consumers. ²¹ For this reason, health plans, insurers, and PBMs use a variety of incentives to encourage the use of mail order pharmacies, especially for beneficiaries taking maintenance medications. ²² For example, plans may offer lower co-payments for mail order drugs, or charge deductibles for retail purchases, or impose limitations on the number of times a prescription may be refilled at a retail pharmacy. ²³ Some health plans even have "mandatory mail order" programs that reimburse beneficiaries for maintenance medications only if the beneficiaries fill those prescriptions by mail. ²⁴

These restrictions sometimes limit choices, but they help keep costs down for consumers because they help the health plans get better prices from the pharmacies. Pharmacies often offer lower prices for higher customer volume – in other words, they offer bigger discounts to health plans or PBMs that give their members an incentive to use those pharmacies. Also, if health plans are able to exclude a pharmacy from their network or channel customers elsewhere, that creates a strong incentive for pharmacies to bid aggressively and offer better deals. All of these factors help consumers get lower prices.

A-5502-B limits the abilities of health plans and PBMs to employ both of these strategies for reducing costs. First, to the extent that the Bill restricts a health plan's ability to create incentives for customers to choose one pharmacy rather than another, ²⁷ it undercuts the ability of the plan to negotiate favorable terms with any particular mail order pharmacy: there is no incentive for a mail order pharmacy to bid aggressively for a share of a health plan's business if the pharmacy has no reason to expect that a lower bid will result in a higher

share. Second, costs will increase further – once those negotiations are concluded – if a health plan cannot create incentives for its beneficiaries to use a relatively low-cost mail order pharmacy. When costs increase there are negative effects for all those who pay for health care – individuals, companies, and all levels of government. As a Maryland study has shown, statutory impediments to mail-order provision of, for example, maintenance drugs, can be very costly for a state and its citizens. ²⁸

We are also concerned about the use of the term "comparable" in the Bill's FOC provision. The term is ambiguous, which will make it difficult for health plans to assess when an offer is close enough to trigger the requirements of the bill. This ambiguity will likely increase the time and cost of negotiating and also may lead to litigation. Second, the use of "comparable" has the potential to add costs beyond those normally associated with FOC laws: a plan's ability to negotiate a favorable contract with a mail order pharmacy is undercut to begin with; and then, competing mail order pharmacies – and competing participating non-mail order pharmacies – need not even match the negotiated prices. They need only accept prices that are "comparable."

IV. Conclusion

FTC staff appreciate that A-5502-B seeks to enhance consumers' ability to fill their prescriptions at the pharmacies of their choice. We are concerned, however, that the Bill impedes a fundamental prerequisite to consumer choice: healthy competition between retail and mail order pharmacies, which constrains costs and maximizes access to prescription drugs. We are concerned that, in the end, higher costs will lead to higher prices and fewer choices for New York health care consumers. For some consumers, increased costs may mean higher out-of-pocket prices for prescription drugs. For other consumers, it may mean that prescription drug benefits are curtailed or eliminated. Scaled-back drug benefits are likely to create pressing financial concerns for many consumers, and may even lead to additional health problems. 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." "

For these reasons, we urge the legislature and the Governor to seek alternative means to preserve consumer choice in the purchase of prescription drugs. We appreciate this opportunity to share our views and welcome any further discussions regarding competition policy.

Respectfully submitted,

Susan S. DeSanti, Director Office of Policy Planning

Joseph Farrell, Director Bureau of Economics

Richard A. Feinstein, Director Bureau of Competition

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 Hon. James L. Seward to Susan S. DeSanti, Director, Office of Policy Planning, Federal Trade Commission (June 24, 2011).

³ Maintenance drugs are prescription drugs that are used to treat chronic illnesses or conditions and prescriptions for maintenance drugs often are written for long terms and/or repeat fills. Mail order pharmacies chiefly fill maintenance drug prescriptions, and incentives to use mail order tend to focus on such prescriptions. *See, e.g.*, FEDERAL TRADE COMMISSION, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 16-19 (Aug. 2005) [hereinafter FTC PBM STUDY], *available at* http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

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

⁵ See Standard Oil Co. v. FTC, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy long has been faith in the value of competition.").

⁶ See generally, e.g., FTC, An Overview of FTC Antitrust Actions In Health Care Services and Products (Sept. 2010), available at http://www.ftc.gov/bc/110120hcupdate.pdf; see also FTC, Competition in the Health Care Marketplace: Formal Commission Actions, available at http://www.ftc.gov/bc/healthcare/antitrust/commissionactions.htm.

⁷ See, e.g., FTC & U.S. DEP'T OF JUSTICE ("DOJ"), IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Ch. 7 (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf. The 2004 Report was informed by extensive hearings on health care markets – including pharmaceutical and insurance markets – that were jointly conducted by the FTC and DOJ in 2003, as well as an FTC-sponsored workshop and independent

research. Information on the 2003 Hearings on Health Care and Competition Law and Policy is *available at* http://www.ftc.gov/bc/healthcare/research/healthcarehearing.htm.

- FTC and staff advocacy may comprise letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, amicus briefs, or reports. *See, e.g.,* FTC Staff Letter to Hon. Mark Formby, Mississippi House of Representatives, Concerning Mississippi Senate Bill 2445 and the Regulation of Pharmacy Benefit Managers (Mar. 2011), *available at* http://www.ftc.gov/os/2011/03/110322mississippipbm.pdf; FTC and DOJ Written Testimony before the Illinois Task Force on Health Planning Reform Concerning Illinois Certificate of Need Laws (Sept. 2008), *available at* http://www.ftc.gov/os/2008/09/V080018illconlaws.pdf; FTC Amicus Curiae Brief in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* Concerning Drug Patent Settlements Before the Court of Appeals for the Federal Circuit (Case No. 2008-1097) (Jan. 2008), *available at* http://www.ftc.gov/os/2008/01/080129cipro.pdf; FTC & DOJ, A DOSE OF COMPETITION, *supra* note 7.
- ⁹ See FTC PBM STUDY, supra note 3, at 25, 31-36; see also GENERAL ACCOUNTING OFFICE, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 9 (Jan. 2003) [hereinafter GAO REPORT], available at http://www.gao.gov/cgi-bin/getrpt?GAO-03-196 (reporting average mail-order prices "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.").
- ¹⁰ A-5502-B (amending § 3216 of the insurance law with regard to any "policy," § 3221 with regard to any "insurer," and § 4303 with regard to "any policy issued by a medical expense indemnity corporation, a hospital service corporation or a health services corporation which provides coverage for prescription drugs" with exceptions, in each case, for policies that result from collective bargaining agreements between employers and recognized or certified employee bargaining organizations).

- ¹⁵ See, e.g., Anne Carroll and Jan M. Ambrose, *Any-Willing-Provider Laws: Their Finanical Effect on HMOs*, 27 J. Health Pol., Pol'y & L. 928, 931 (2002) (noting thirteen states with pharmacy AWP laws). As Carroll and Ambrose note, AWP laws vary widely in their particulars, id. at 929, and FTC staff have not undertaken a current survey of AWP/FOC laws under any particular characterization.
- ¹⁶ See, e.g., FTC Staff Comment to the Hon. Nelie Pou Concerning New Jersey A.B. A-310 to Regulate Contractual Relationships Between Pharmacy Benefit Managers and Health Benefit Plans (Apr. 2007) [hereinafter New Jersey Comment], available at http://www.ftc.gov/be/V060019.pdf; FTC Staff Comment to the Hon. Terry G. Kilgore Concerning Virginia House Bill No. 945 to Regulate the Contractual Relationship Between Pharmacy Benefit Managers and Both Health Benefit Plans and Pharmacies (Oct. 2006), available at http://www.ftc.gov/be/V060018.pdf; Letter from FTC Staff to Patrick C. Lynch, Rhode Island Attorney General, and the Hon. Juan M. Pichardo, Rhode Island State Senate (Apr. 8, 2004) [hereinafter Rhode Island Comment], available at http://www.ftc.gov/os/2004/04/ribills.pdf.
- ¹⁷ See New Jersey Comment, supra note 16, at n. 36 and accompanying text; Rhode Island Comment, supra note 16, at 6; see also Aaron S. Edlin & Eric R. Emch, The Welfare Losses from Price-Matching Policies, 47 J. IND. ECON. 145 (1999). Such negotiations on behalf of health plans often are handled by PBM companies or by insurer-owned, or retailer-owned, providers of PBM services. See generally FTC PBM STUDY, supra note 3, at Ch. 1.
- ¹⁸ For example, one study found that expenditures rise when AWP or FOC laws are enacted, and tend to rise more with stronger laws. Vita, *supra* note 13, at 966 (panel data showing, e.g., that states with highly restrictive AWP/FOC laws spent approximately 2% more on healthcare than did states without such policies). As Vita notes, empirical studies of the effects of such laws are few. *Id.* at 956. A 2005 Maryland study, however, examined in particular the effects of these types of statutory impediments to mail order provision of, e.g.,

¹¹ Id

¹² *Id*.

¹³ Michael Vita, Regulatory Restrictions on Selective Contracting: An Empirical Analysis of 'Any Willing Provider' Regulations, 20 J. HEALTH ECON. 955, 956 (2001).

¹⁴ See, e.g., id.

maintenance drugs. According to the Maryland report, greater use of mail order maintenance drugs – 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) [hereinafter MARYLAND REPORT]; *cf.* Carroll and Ambrose, *supra* note 15, at 939-40 (examining data from the early 1990s and finding pharmacy AWP laws associated with higher costs).

¹⁹ See supra note 3.

²⁰ See FTC PBM STUDY, supra note 3, at 25 (mail order prices lower, even after controlling for prescription size and drug selection); see also GAO REPORT, supra note 9, at 8-11 (reporting that PBMs negotiate substantial discounts with retail pharmacies, but achieve much greater savings using mail order pharmacies).

²¹ FTC PBM STUDY, *supra* note 3, at 35-36 (comparing prices for both 30- and 90-unit prescriptions, for each of three drug types filled by retailer-owned PBM mail order pharmacies, with those filled by retail non-mail pharmacies, and finding, e.g., that "[f]or 30-unit prescriptions dispensed by retailer-owned PBMs, both members and plans paid lower average prices at mail than at retail for each of the three drug types. For G [generic], MSB [multi-source brand], and SSB [single-source brand] drugs, the total average not-owned retail price was higher than the owned mail price by 27.6%, 14.4%, and 10.6%, respectively.").

²² See FTC PBM STUDY, supra note 3, at 17-19. It should also be noted that prices vary across mail order pharmacies. See, e.g., id. at 29-30 (prescription prices typically lower at PBM-owned mail order pharmacies than at non-PBM-owned mail order pharmacies). Hence, incentives to patronize a particular mail order pharmacy may be important to cost saving strategies.

²³ See id. at 18-19.

²⁴ See id. at 19.

²⁵ See id. at 36-37.

²⁶ Rhode Island Comment, *supra* note 16, at 4 n.11; *see also* Vita, *supra* note 13 (finding that AWP laws lead to higher drug prices).

²⁷ The Bill prohibits, in particular, an insurer or plan from requiring that "*any* mail order covered prescription" be filled by a mail order pharmacy, much less any particular mail order pharmacy, and it prohibits any different "copayment fee or other condition" imposed on purchases that are made from an alternative provider. *See* text accompanying notes 10-12, *supra*.

²⁸ 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* MARYLAND REPORT, *supra* note 18, at 2-3.

²⁹ The use of "comparable" in the Bill directly addresses those pharmacies at which a beneficiary may fill a prescription – that is, at any mail order or any network retail pharmacy willing to accept comparable prices. According to the Bill, copays cannot differentiate among any such pharmacies, whether they are willing to accept comparable prices or not.

³⁰ William Sage, David A. Hyman & Warren Greenburg, *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31, 35 (Mar./Apr. 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, National Bureau of Economic Research Working Paper W8802, Table 5 (Feb. 2002), *available at* http://papers.nber.org/papers/W8802.