UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
Washington, DC 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition

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This material is for reference only.

On July 20, 2023, the Federal Trade Commission issued a "Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports that No Longer Reflect Current Market Realities" cautioning the public and policymakers against relying on certain FTC materials. Accordingly, j 1against

In your letter dated January 19, 2005, you asked us to analyze the competitive implications of HB 1332 and discuss whether it "will likely result in the increased cost of pharmaceutical care for consumers." We believe that HB 1332, if enacted, may have the unintended consequence of increasing the price of pharmaceuticals and ultimately to decrease the number of North Dakotans with insurance coverage for pharmaceuticals. Specifically, we believe that HB 1332 may limit a PBM's ability to guide consumers to lower-cost pharmacies and would prohibit switching consumers to certain lower-priced drugs.[3]

Interest and Experience of the Federal Trade Commission

The Federal Trade Commission (Commission) is charged by statute with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[4] Pursuant to this 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 Commission has brought numerous enforcement actions against entities involved in the pharmaceutical industry,[6] and the Commission and its staff have issued reports and studies regarding various aspects of the pharmaceutical industry.[7]

The Commission also has extensive recent experience with PBMs. In 2004, Commission staff commented on proposed Rhode Island legislation that would have affected a PBM's ability to contract with pharmacies[8] and on proposed California legislation that would have required

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[3] Although our comment is addressed only to these provisions, the Bill also regulates PBMs in other ways. *See* note 14, *infra*. We note that HB 1332 has been amended once by eliminating a requirement that PBMs act as fiduciaries to covered entities with which they contract and reducing the scope of a PBM's mandatory disclosure of financial information. These amendments eliminated other provisions that likely would have produced adverse competitive effects.

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

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

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

[7] *See*

PBMs to disclose certain information to covered entities and consumers related to a PBM's financial arrangements with pharmaceutical companies.[9] Also in 2004, the Commission investigated the competitive implications of a proposed merger between Caremark and AdvancePCS.[10] On June 26, 2003, the Commission and Department of Justice Antitrust Division (Division) held a half-day of hearings on PBMs, as part of their Hearings on Health Care and Competition Law and Policy (Health Care Hearings).[11] The report jointly issued by the Commission and the Division on July 23, 2004 addressed the issues raised by PBMs as well.[12] Finally, Congress has required the Commission to analyze the prices that plan sponsors and participants pay for pharmaceuticals dispensed through different distribution channels.[13]

HB 1332 would allow the PBM to request the substitution of a "lower-priced generic or therapeutically equivalent drug" for a prescribed drug.[17] It is unclear in the Bill whether the term "therapeutically equivalent" drug refers to those drugs that are pharmaceutically equivalent or those that are pharmaceutically distinct, but are within the same therapeutic class.[18] To the extent that the Bill adopts the former narrower definition, HB 1332 would prohibit a PBM from requesting that the drug referred to in a patient's prescription be substituted for another drug that is designed to have similar therapeutic effects – but that is pharmaceutically distinct – unless the substitution is "for medical reasons that benefit the covered individual" and the prescribing physician approves the substitution.[19]

Background on PBMs

PBMs manage the pharmacy benefits of covered entities. At the Health Care Hearings, one panelist estimated that ninety-five percent of patients with prescription drug insurance coverage receive their benefits through a PBM.[20] There are approximately 60 PBMs operating in the United States today. There are three large, independent, full-service PBMs with national scope: Medco, Express Scripts, and Caremark. Some large insurers manage pharmacy benefits internally. A few PBMs are owned by large retail supermarket/pharmacy chains. In addition, there are many smaller, privately-held PBMs. The relative size and ranking of these companies varies according to the measure used. The three large national PBMs are the major players in many markets, but anywhere from one-third to one-half of the market is made up of the other types of PBMs listed above. In our most recent antitrust investigation in the PBM industry, the FTC found competition among PBMs for contracts with plan sponsors to be "vigorous."[21]

One important tool used by PBMs to manage pharmacy benefits is a formulary, which is a list of PBM-approved drugs for treating various diseases and conditions. Because a formulary affects the mix of drugs used by enrollees in a plan, its design significantly can affect the cost to the covered entity. Two procedures that PBMs use to attain better compliance with their formularies are generic substitution and therapeutic interchange.[22] Because generic drugs are

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[17] HB 1332 § 26.1-27.1.04(1)(a).

[18] For example, the FDA defines therapeutically equivalent drugs to be those that are pharmaceutically equivalent and have the same therapeutic equivalence codes. *See* http://www.fda.gov/cder/drugsatfda/glossary.htm#T

typically substantially less expensive than their brand-name counterparts, generic substitution lowers prescription drug costs. Therapeutic interchange also has the potential of increasing the utilization of less expensive brand name drugs.

Preferential placement on a formulary, accompanied with reduced co-payments, can give a drug product a higher market share within a drug plan. Pharmaceutical companies compete by offering rebates and other financial rewards based on some combination of a percentage of a reference price, achieving certain specified sales or market share targets, and preferred placement of certain drug products on a PBM's formulary. These rebates are either paid to the covered entity, retained by the PBM, or shared between them depending on the specifics of the contract between these parties.[23] Rebates can lead to lower health care costs.[24]

PBMs also enter into contracts with retail pharmacies to create a retail network. The contract generally specifies the amount the PBM will reimburse the pharmacy for dispensing a prescribed pharmaceutical, expressed as a discount from a reference price plus a dispensing fee. By forming an exclusive network, a PBM is able to guide a covered entity's participants to certain pharmacies. The promise of increased customer volume creates an incentive for pharmacies to bid aggressively with lower drug prices in exchange for membership in a network.[25] Pharmacies will be willing to compete more vigorously for inclusion in a network as the exclusivity of the network and the number of pharmacies in the relevant market increases.

Likely Effects of HB 1332

HB 1332 limits PBMs' freedom in contracting with retail pharmacies and prohibits certain drug substitutions. These provisions are likely to lead to higher prices for pharmaceuticals and health insurance, which in turn is likely to increase the number of North Dakotans who go without pharmaceuticals and/or health insurance. As a recent 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

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[23] John Richardson, Health Strategies Consultancy, Health Care Hearings, *supra* note 11, 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 11, at 124.

[24] *See* General Accounting Office, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* at 11 (Jan. 2003) ("GAO Report") (noting that rebates passed through to health plans reduced these plans' annual spending on prescription drugs by three percent to nine percent), *at* http://www.gao.gov/cgi-bin/getrpt?GAO-03-196.

[25] 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* GAO Report at 11.

cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions."[26] We provide details on our concerns below.

A. Restrictions on Contracting with Pharmacies

HB 1332 would prohibit PBMs from charging different copayments, coinsurance, or deductibles at various pharmacies within a plan's pharmacy network.[27] An important element of the design of pharmacy benefit plans administered by PBMs, however, is the determination of how the price for drugs will be split between the covered entity and its participants. This price sharing is achieved through the copayments, coinsurance, or deductibles that the participant pays to the pharmacy at the time the drug is dispensed.

Both a GAO study and an academic article reported that the prices charged to covered entities can vary substantially across different types of pharmacies.[28] This Bill, however, would prevent covered entities from designing benefit plans to encourage participants to use network pharmacies that provide drugs to the plan at a lower cost than other network pharmacies. Participants ultimately make the decision about where the drugs will be dispensed, but the covered entity bears most of the cost of the purchase. To encourage the participant to make efficient decisions, covered entities must be free to design plans that align its and the participants' interests.

The uniform copayments required by HB 1332, however, will prevent that alignment of interests and will likely generate inefficient decisions and higher drug costs. Under the Bill, participants would be less likely to use low-cost pharmacies than if they had been allowed to share in the cost savings via a lower copayment. Both the participants and the covered entity will miss out on the savings they could have shared from using the low-cost pharmacies. Only the high-cost pharmacies will benefit. A potential secondary effect of this uniform copayment structure is that low-cost pharmacies may lose the incentive to offer lower prices to covered entities. Pharmacies would not want to offer lower prices because doing so would generate no more sales than offering a high price under the legislation, since the final decision makers – the

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[26] 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), *at* http://papers.nber.org/papers/W8802.

[27] HB 1332 § 26.1-27.1-04(3).

[28] The study found that the lowest average prices for 30-day supplies were obtained when the drug was purchased through the PBM=s mail order pharmacy, and that cash-paying customers at retail pharmacies paid the highest prices. *See* GAO Report. Similar cost savings for PBM clients have been reported in another study. *See* Cindy Parks Thomas et al., *Impact of Health Plan Design And Management On Retirees= Prescription Drug Use And Spending, 2001,* Health Affairs Web Exclusive W2-408 (Dec. 4, 2002), *at* http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.408v1.

participants – are shielded from the price differences.

B. Prohibitions on Certain Drug Substitutions

HB 1332 may limit a PBM's ability to effect certain drug substitutions. It is unclear in the Bill whether "therapeutically equivalent" drugs are those that are pharmaceutically equivalent or those that are pharmaceutically distinct, but are within the same therapeutic class. To the extent that the Bill adopts the former narrower definition, HB1332 substantially would impair a PBM's ability to engage in price-reducing therapeutic interchange. Although North Dakota already requires physician approval before one branded drug may be switched for another, [29] HB 1332 further would limit substitutions to those that are "for medical reasons that benefit the covered individual." Consequently, the Bill would prevent a PBM from switching a prescription for one brand-name drug with a less expensive brand-name drug that is designed to have similar therapeutic effects, but that is pharmaceutically distinct, unless the switch was for medical reasons. To the extent HB 1332 makes safe and cost-reducing drug substitutions less common, it is likely to increase the cost of pharmaceuticals, which in turn is likely to increase health insurance premiums and reduce the availability of insurance coverage for pharmaceuticals.[30]

At the same time, it is unclear how the additional requirements in HB 1332 are likely to provide consumers with any additional countervailing benefits, because, as noted above, North Dakota requires prior prescriber authorization before a pharmacist is allowed to substitute one brand-name drug for another. Thus, existing safeguards appear sufficient to protect consumers from inappropriate therapeutic interchange.

Conclusion

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[29] *See* N.D. CENT. CODE § 19-02.1-02(14) (prohibiting "Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the express permission in each case of the person ordering or prescribing").

[30] Additionally, HB 1332 may reduce the value to a pharmaceutical company of securing a preferred spot on a PBM's formulary. When PBMs can use the formulary to guide consumers from one branded drug to another they can promote competition between pharmaceutical manufacturers, which is likely to result in reduced drug prices and/or insurance premiums. To the extent that HB 1332 reduces a PBM's ability to use therapeutic interchange, pharmaceutical companies may compete less vigorously for inclusion on the formulary, which could lead to higher drug prices.

HB 1332 is likely to limit a PBM's ability to reduce the cost of prescription drugs without providing consumers any additional protections. Any such cost increases are likely to undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford. Accordingly, we would urge the North Dakota legislature not to adopt HB 1332.

Respectfully submitted,

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