TAHP

Texas Association of Health Plans
Executive Committee Correspondence

February 16, 2016

The Honorable Ken Paxton
Attorney General of Texas
PO Box 12548
Austin, TX 78711-2548

Re: RQ-0092-KP: Request for Attorney General Opinion by Sen. Schwertner and Rep. Hunter regarding enforceability of "Any Willing Provider" pursuant to Tex. Ins. Code Art. 21.52B

Dear General Paxton,

The Texas Association of Health Plans ("TAHP") is a trade association composed of 28 health plans regulated by state law in Texas. Those plans have 4.5 million enrollees in the commercial market in Texas and 3.5 million Medicaid enrollees. The issues presented in the Request for Opinion ("RQ") are of vital importance to our member plans and the consumers they serve in Texas and will directly and adversely affect the cost of health plan coverage, whether for individuals or employer-sponsored groups. We respectfully offer this letter in opposition to the requestors' proposal for an Attorney General's opinion revalidating the Texas "Any Willing Pharmacy" statute.

The requestors have asked whether the Texas "Any Willing Pharmacy" (Texas "AWP") statute, found at Tex. Ins. Code Art. 21.52B, is currently enforceable and then argue that it is and that the Attorney General should opine to revalidate it. We submit that it is not enforceable based on the discussion and case law below.

In short, the RQ argues that a United States Supreme Court case dealing with Kentucky law interpreted by the 6th Circuit Court of Appeals "effectively overruled" a 5th Circuit Court of Appeals decision dealing with Texas law. *See Kentucky Association of Health Plans, Inc. v. Miller,* 538 U.S. 329 (2003) and *see Texas Pharmacy Association v. Prudential Ins. Co. of America*, 105 F.3d 1035, (5th Cir. 1997), respectively. The 5th Circuit case was not, in fact, overruled and is still authoritative. Further, there is no legal standard relating to "effectively overruling" a decision of a U.S. federal appellate court. The 5th Circuit opinion which declared the Texas AWP statute preempted still stands, and those parties seeking validation of the AWP statute should seek further relief from the legislature or the courts.

Background:

A. The Texas Any Willing Pharmacy Act

The Texas AWP statute was originally enacted in 1991. Acts 1991, 72nd Leg., ch. 182, § 1, eff. Sept. 1, 1991. The law prohibits a health insurer or health plan from denying any pharmacy the right to participate as a contract provider if it is willing to meet the terms of participation. In 1997, the 5th Circuit analyzed the Texas AWP law and held that the ERISA "savings clause[1]" did not save it from preemption by federal law. *Texas Pharmacy Assn.,* 105 F.3d 1035, 1036. The 5th Circuit decision in the Texas AWP law case has not been overruled. *See* Westlaw KeyCite attached as Exhibit A.

B. The 5th Circuit Decision is still binding in Texas

It is presumptuous to assume that a case based on Kentucky state insurance law "effectively overrules" a 5th Circuit decision based on Texas law. The U.S. District Court for the Western District of Texas, as recently as September 30, 2015, issued an opinion in a pharmacy-related case based on the Texas Insurance Code, albeit based on a different set of facts, wherein the court noted that the *Miller* case dealt with Kentucky law rather than Texas law when stating it did not apply in the case before the district court. *See Mission Specialty Pharmacy, LLC v. OptumRx, Inc.,* 2015 WL 9581866, *10 (W.D. Tex.2015).

Further, a Supreme Court decision must be "more than merely illuminating" with respect to a case before the 5th Circuit; a panel of the 5th Circuit may only overrule a prior panel decision if "such overruling is unequivocally directed by controlling Supreme Court precedent." *Martin v. Medtronic,* 254 F.3d 573, 577 (5th Cir.2001) (citing *United States v. Short,* 181 F.3d 620, 624 (5th Cir.1999)). The *Miller* case did not do that. Neither the 5th Circuit nor the Supreme Court have expressly held that the 1997 ruling in *Texas Pharmacy Assn.* was overruled by the Supreme Court's 2003 decision, and the *Miller* case did not specifically address the issue of whether any other state AWP statutes were saved from ERISA preemption.

While the 5th Circuit's 1997 *Texas Pharmacy Assn.* decision has received some subsequent "negative treatment" in later cases, it has not been overruled. *See* Exhibit A. Interestingly, the *Miller* case has also received a line of negative treatment. *See* Westlaw KeyCite attached as Exhibit B. While the *Miller* case may have been "illuminating" to the 5th Circuit, it clearly did not "unequivocally direct" the 5th Circuit to overrule its finding in the *Texas Pharmacy Assn.* case. The proponents of the requestors' arguments have two remedies: another judicial challenge or an ERISA compliant legislative solution.

The requestors also cite the Texas Senate State Affairs Committee interim report to the 79th Legislature in December 2004 wherein the committee concluded that the decision in the *Miller* case "effectively reversed" the 5th Circuit's decision in the *Texas Pharmacy Assn.* case. As you

[1] *See* 29 U.S.C. §1144(b)(2)(A)

know, the opinions expressed in a legislative committee's interim report have no legal weight in the analysis of the vitality or enforceability of a Texas statute or court case. The legislature may certainly act to address the statute in question, and the legislature did look at the "any willing pharmacy provider" question during the last two legislative sessions, but took no action[2]. The legislature has had no less than six legislative sessions to address this question after the *Miller* decision, and five legislative sessions since the referenced 2004 interim report, but has declined to do so.

The requestors cite Tex. Op. Att'y Gen. No. JM-1116 (1989) for the premise that when a judicial ruling that had rendered a statute invalid is reversed, the statute becomes effective once again. But, JM-1116 also states that "an opinion of the attorney general cannot overrule a judicial decision, and therefore cannot validate the… statute." Once again, the proponents of the Texas AWP law should seek legislative or judicial action to pursue their goals.

Conclusion:

While it is clear that the case law does not allow a reinvigoration of the Texas AWP statute, we also submit that there are good reasons why the legislature has chosen not to perform that task. There are numerous economic studies and Federal Trade Commission statements about the negative impact of enforcing any willing provider mandates, including restricting private market negotiation, eliminating competition, reducing consumer choice, and increasing the cost of premiums for individuals and employers[3]. The legislature has repeatedly chosen not to reenact this mandate because of the severe and far reaching negative impact on the private health insurance market in Texas.

The Texas Association of Health Plans and the members it represents respectfully submit the forgoing arguments in support of the position that the Texas "AWP" statute remains preempted based on the 5th Circuit's 1997 decision in the *Texas Pharmacy Assn.* case.

Respectfully submitted,

Jamie Dudensing

Jamie Dudensing

cc: The Honorable Charles Schwertner
The Honorable Todd Hunter

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[2] *See* HB 778 by Bell, 84th Legislative Session; HB 1770 by Hunter, 84th Legislative Session; SB 322 by Schwertner, 84th Legislative Session; HB 3455 by Eiland, 83rd Legislative Session.

[3] *See* attached as Exhibit C: April 24, 2015 correspondence from the United States Federal Trade Commission to Rep. Kenneth Sheets (TX); March 7, 2014 correspondence from the United States Federal Trade Commission to Centers for Medicare & Medicaid Services; August 8, 2011 correspondence from the United States Federal Trade Commission to Sen. James Seward (NY).

EXHBIT A

Negative Treatment

Negative Citing References (8)

The KeyCited document has been negatively referenced by the following events or decisions in other litigation or proceedings:

Treatment	Title	Date	Type	Depth	Headnote(s)
Declined to Follow by	1. Express Scripts, Inc. v. Wenzel 102 F.Supp.2d 1135 , W.D.Mo. LABOR AND EMPLOYMENT - Benefit Plans. Statute forbidding HMOs from requiring enrollees to fill prescriptions by mail was not preempted by ERISA.	June 12, 2000	Case		1 F.3d
Declined to Follow by	2. Kentucky Ass'n of Health Plans, Inc. v. Nichols ❞ MOST NEGATIVE 227 F.3d 352 , 6th Cir.(Ky.) HEALTH - HMOs. "Any Willing Provider" provisions in Kentucky Health Care Reform Act were not preempted by ERISA.	Sep. 07, 2000	Case		1 2 4 F.3d
Called into Doubt by	3. Witt v. Aetna U.S. Healthcare, Inc. ❞ 2000 WL 1336491 , D.Me. Defendants move pursuant to Fed.R.Civ.P. 12(b)(6) to dismiss all counts of Plaintiffs' First Amended Complaint for failure to state claims upon which relief can be granted....	Sep. 14, 2000	Case		1 2 F.3d
Called into Doubt by	4. Quality Infusion Care, Inc. v. Unicare Health Plans of Texas ❞ 2007 WL 1887734 , S.D.Tex. Pending before the Court is a Motion to Dismiss [Doc. # 9] (the "Motion") filed by Defendant UniCare Health Plans of Texas ("UHPT"). Plaintiff Quality Infusion Care, Inc....	June 29, 2007	Case		2 4 F.3d
Called into Doubt by	5. Quality Infusion Care Inc. v. Humana Health Plan of Texas Inc. 290 Fed.Appx. 671 , 5th Cir.(Tex.) INSURANCE - Health. Claims under Texas any willing provider (AWP) statute were preempted by ERISA.	Aug. 13, 2008	Case		1 F.3d
Distinguished by	6. Washington Physicians Service Ass'n v. Gregoire 147 F.3d 1039 , 9th Cir.(Wash.) Group of health maintenance organizations (HMOs) and health care service contractors (HCSCs) sought a declaration that the Employee Retirement Income Security Act (ERISA) preempts...	June 18, 1998	Case		1 F.3d
Distinguished by	7. Corporate Health Ins., Inc. v. Texas Dept. of Ins. ❞ 12 F.Supp.2d 597 , S.D.Tex. Health plans and insurers sought a declaration that federal law preempts the Texas Health Care Liability Act. On motions for summary judgment, the District Court, Gilmore, J., held...	Sep. 18, 1998	Case		1 2 4 F.3d

List of 8 Negative Treatment for Texas Pharmacy Ass'n v. Prudential Ins. Co. of America

Treatment	Title	Date	Type	Depth	Headnote(s)
Distinguished by	8. Quality Infusion Care Inc. v. Aetna Health Inc. ❞ 2006 WL 3813774 , S.D.Tex. Plaintiff Quality Infusion Care, Inc. sued Aetna Health, Inc. in Texas state court, alleging damages from Aetna's refusal to pay for at-home chemotherapy infusion services provided...	Dec. 26, 2006	Case	[redacted]	1 2 4 F.3d

EXHIBIT B

Negative Treatment

Negative Citing References (13)

The KeyCited document has been negatively referenced by the following events or decisions in other litigation or proceedings:

Treatment	Title	Date	Type	Depth	Headnote(s)
Abrogation Recognized by	1. Rogers v. Rogers and Partners, Architects, Inc. ,, MOST NEGATIVE 2009 WL 5124652 , D.Mass. LABOR AND EMPLOYMENT - Benefit Plans. A beneficiary's state law claim for negligent misrepresentation against an employer was preempted under ERISA.	July 27, 2009	Case		1 2 5 S.Ct.
Declined to Extend by	2. Sgro v. Danone Waters of North America, Inc. ,, 532 F.3d 940 , 9th Cir.(Cal.) LABOR AND EMPLOYMENT - Benefit Plans. ERISA preempted state insurance regulation requiring reimbursement of claimant's copying costs for relevant records.	July 02, 2008	Case		1 2 5 S.Ct.
Distinguished by	3. Nguyen v. Healthguard of Lancaster, Inc. ,, 282 F.Supp.2d 296 , E.D.Pa. LABOR AND EMPLOYMENT - Benefit Plans. Pennsylvania Bad Faith Insurance statute does not "regulate insurance" under ERISA savings clause.	Aug. 14, 2003	Case		1 2 5 S.Ct.
Distinguished by	4. Bonnell v. Bank of America ,, 284 F.Supp.2d 1284 , D.Kan. LABOR AND EMPLOYMENT - Benefit Plans. Claim against benefit plan insurer under state unfair claims practices statute was preempted by ERISA.	Sep. 30, 2003	Case		1 2 5 S.Ct.
Distinguished by	5. Eubanks v. Prudential Ins. Co. of America 336 F.Supp.2d 521 , M.D.N.C. LABOR AND EMPLOYMENT - Benefit Plans. Plan administrator could setoff previously made unintentional overpayments.	Sep. 02, 2004	Case		2 5 S.Ct.
Distinguished by	6. Levine v. United Healthcare Corp. ,, 402 F.3d 156 , 3rd Cir.(N.J.) LABOR AND EMPLOYMENT - Benefit Plans. New Jersey's anti-subrogation statute did not fall within scope of savings clause in ERISA preemption provision.	Mar. 16, 2005	Case		1 2 5 S.Ct.
Distinguished by	7. Prudential Ins. Co. of America v. National Park Medical Center, Inc. 413 F.3d 897 , 8th Cir.(Ark.) LABOR AND EMPLOYMENT - Benefit Plans. Self-funded ERISA plan was exempt from direct or indirect regulation by "any willing provider" law.	June 29, 2005	Case		2 3 5 S.Ct.
Distinguished by	8. Daley v. Marriott Intern., Inc. ,, 415 F.3d 889 , 8th Cir.(Neb.)	July 25, 2005	Case		2 4 5

List of 13 Negative Treatment for Kentucky Ass'n of Health Plans, Inc. v. Miller

Treatment	Title	Date	Type	Depth	Headnote(s)
	LABOR AND EMPLOYMENT - Benefit Plans. ERISA "deemer clause" exempted employer-funded benefit plan from application of state mental-health parity law.				S.Ct.
Distinguished by	9. Hester v. Union Cent. Life Ins. Co. 2006 WL 2927252 , S.D.Ohio This matter is before the court upon Magistrate Judge's Report and Recommendation ("R & R") granting Defendant's Motion to Enforce Decision of the ERISA Administrator (Doc. 15);...	Oct. 11, 2006	Case		—
Distinguished by	10. Quality Infusion Care Inc. v. Humana Health Plan of Texas Inc. ❞ 290 Fed.Appx. 671 , 5th Cir.(Tex.) INSURANCE - Health. Claims under Texas any willing provider (AWP) statute were preempted by ERISA.	Aug. 13, 2008	Case		1 2 3 S.Ct.
Distinguished by	11. Flowers v. Life Ins. Co. of North America ❞ 781 F.Supp.2d 1127 , D.Colo. INSURANCE - Bad Faith and Unfair Practices. Beneficiaries' action against life insurer for unreasonably delayed payment in violation of Colorado law, was preempted by ERISA.	Mar. 15, 2011	Case		2 4 5 S.Ct.
Distinguished by	12. North Cypress Medical Center Operating Co., Ltd. v. Cigna Healthcare ❞ 781 F.3d 182 , 5th Cir.(Tex.) HEALTH - Hospitals. Hospital, as assignee of patients, had Article III standing to bring Employee Retirement Income Security Act underpayment claims.	Mar. 10, 2015	Case		2 4 5 S.Ct.
Distinguished by	13. Mission Specialty Pharmacy, LLC v. OptumRx, Inc. 2015 WL 9581866 , W.D.Tex. Background: Retail pharmacy brought Texas state action against pharmacy benefits management company, alleging breach of contract and violation of the Texas Insurance Code....	Dec. 30, 2015	Case		2 S.Ct.

EXHIBIT C

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

Office of Policy Planning
Marina Lao, Director

April 24, 2015

The Honorable Kenneth Sheets
Representative, District 107
Texas House of Representatives
P.O. Box 2910
Austin, TX 78768-2910

Dear Representative Sheets:

The Federal Trade Commission's (Commission or FTC) Office of Policy Planning appreciates your request for comments on Texas House Bill 778 (HB 778). As you noted in your letter, the bill, if enacted, would provide

> that a health plan in Texas may not deny a pharmacist or pharmacy the right to participate as a provider or preferred provider if the pharmacist or pharmacy agrees to provide prescription drugs in accordance with the terms of the health plan and accept the conditions that apply to pharmacists and pharmacies that have been designated as providers or preferred providers under the health plan. This type of legislation is typically referred to as "any willing provider" or "any willing pharmacist" legislation.[1]

FTC staff are familiar with the evidence and arguments concerning "any willing provider" or "any willing pharmacist" provisions. Notably, the Commission authorized its staff to issue a March 7, 2014 public comment to the Centers for Medicare and Medicaid Services (CMS) concerning proposed changes to Medicare prescription drug benefit programs.[2] The FTC staff comment expressed concerns that "any willing pharmacy provisions . . . may impair, rather than enhance, the ability of plan sponsors to negotiate lower prices." The comment concluded that

> [b]ased on FTC staff's experience in this area, as well as [their] review of empirical studies of preferred provider contracting and any willing provider and [freedom of choice] (FOC) laws, there are two clear and consistent conclusions in the literature:

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1 Letter from the Honorable Kenneth Sheets to Marina Lao, Director, Office of Policy Planning, at 1.

2 The March 7, 2014 staff comment to CMS is available at https://www.ftc.gov/policy/policy-actions/advocacy-filings/2014/03/federal-trade-commission-staff-comment-centers.

- Selective contracting with pharmacies and other health care providers can lower prices paid by plans and their beneficiaries; and

- Any willing provider and FOC laws tend to raise prices or spending because they impair the ability of . . . plan[s] to engage in selective contracting.[3]

The CMS comment also cited several prior FTC staff comments expressing similar concerns about proposed any willing pharmacy laws that were under consideration in several states.[4]

We hope the attached staff comment to CMS will be useful to your deliberations on HB 778.[5]

Respectfully submitted,

Marina Lao

Marina Lao, Director
Office of Policy Planning

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3 FTC staff comment to CMS at 6.

4 FTC staff comment to CMS at 8, note 16.

5 This staff letter expresses the views of the FTC's Office of Policy Planning. This letter, as well as the March 2014 FTC staff comment to CMS, do not necessarily represent the views of the Commission or of any individual Commissioner. The Commission did vote to authorize staff to issue the CMS comment, which discusses issues pertinent to the proposed bill in Texas.

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

Office of Policy Planning
Bureau of Economics
Bureau of Competition

March 7, 2014

Via Electronic Submission

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4159-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition (collectively, "FTC staff" or "staff"),[1] are pleased to respond to your January 10, 2014 request for comments on "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" ("Proposed Rule").[2] In its request, CMS observes that, in establishing the Medicare prescription drug program, Congress sought "to promote competition in the private market for Part D drugs."[3] We write to share our perspective on the "any willing pharmacy" provisions in the Proposed Rule,[4] in light of FTC staff experience examining competition issues and the workings of private markets for prescription drugs.

The issue CMS has raised in proposing these provisions is an important one. The ability of health plans to construct networks that include some, but not all, providers (so-called "selective contracting") has long been seen as an important tool to enhance competition and lower costs in markets for health care goods and services. Both economic principles and empirical evidence support that view.

The proposed any willing pharmacy provisions threaten the effectiveness of selective contracting with pharmacies as a tool for lowering costs. Requiring prescription drug plans to contract with any willing pharmacy would reduce the ability of plans to obtain price discounts based on the prospect of increased patient volume and thus impair the ability of prescription drug plans to negotiate the best prices with pharmacies. Evidence suggests that prescription drug prices are likely to rise if Prescription Drug Plans ("PDPs") are less able to assemble selective pharmacy networks. The proposed provisions may also hinder the ability of plans to steer beneficiaries to lower-cost, preferred pharmacies and preferred mail order

vendors through financial incentives or other terms. Finally, Medicare beneficiaries may also have fewer choices if the any willing pharmacy provisions change the incentives of PDPs and result in fewer plans competing in the Part D marketplace. Specifically, beneficiaries who are willing to accept coverage under a plan with a narrow network of preferred pharmacies in exchange for lower costs may be deprived of that option. We are therefore concerned that the proposed any willing pharmacy provisions may threaten to harm competition and Medicare beneficiaries.

CMS has suggested that the proposed any willing pharmacy provisions are needed in part because its data show that limited networks of pharmacies do not consistently achieve greater savings than broad networks. We support the goal of ensuring that selective contracting by Medicare Part D plans does not misalign incentives and contribute to higher costs. In addition, we recognize there are constraints on CMS rulemaking. However, we urge CMS to proceed cautiously before concluding that an any willing pharmacy rule is the way to address its concerns. We share this concern with the Medicare Payment Advisory Commission, which has advised CMS of "several programmatic changes" other than any willing provider provisions to "ensure that the use of tiered pharmacy networks do not increase Medicare costs and do not harm beneficiaries."[5]

CMS studies have found substantial savings associated with preferred pharmacies and mail order pharmacies on average, which is generally consistent with independent research on selective contracting. If some subset of plans are not achieving the expected costs savings, that does not mean that the basic premise of selective contracting is unsound or that an any willing pharmacy rule is the solution. In the view of FTC staff, an any willing pharmacy rule likewise may not serve to address other important objectives that CMS identifies in its request for comment.

If the proposed any willing pharmacy provisions are implemented and result in higher Medicare costs, all American consumers – not just Medicare beneficiaries – may feel the effects of diminished Part D competition, given the substantial impact of Medicare spending on the federal budget.

I. Interest and Experience of the Federal Trade Commission

The Federal Trade Commission ("FTC" or "Commission") is an independent agency responsible for maintaining competition and safeguarding the interests of consumers. Congress has charged the FTC with enforcing the FTC Act, which prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[6] 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,[7] and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products, and greater innovation.

Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct in health care markets, including pharmaceutical markets,

has long been a focal point of FTC law enforcement,[8] research,[9] and advocacy.[10] FTC staff continue to monitor economic research on issues regarding, for example, selective contracting, pharmacy benefit managers ("PBMs"), mail order and "brick and mortar" retail pharmacies, and related issues.[11] Based on the FTC's study and research (including reviews of pertinent economic literature), FTC staff also have analyzed certain state-level statutory and regulatory any willing provider and "freedom of choice" ("FOC") policy proposals, many of which have mirrored the any willing pharmacy provisions in the Proposed Rule.[12]

II. Background: "Any Willing Provider" and "Freedom of Choice" Laws

CMS proposes to require that PDPs offering preferred cost sharing permit "any willing pharmacy the opportunity to offer preferred cost sharing if the pharmacy can offer the requisite level of negotiated prices."[13] CMS also proposes publication of preferred and non-preferred prices, terms, and conditions. The rules require that variation of these terms or tiers be restricted such that, "[f]or prescriptions not subject to Long Term Care, specialty pharmacy, or home infusion pricing, … [there will be] three authorized levels of cost sharing: Standard, preferred, and extended days' supplies for retail and mail order pharmacies."[14] These proposed regulations generally mirror those found in some state-level any willing provider and FOC laws.[15]

FTC staff have previously expressed concerns about potential anticompetitive effects and consumer harm associated with any willing provider and FOC laws.[16] Although more limited networks may sometimes limit patient choice, any willing provider and FOC laws can make it more difficult for health insurers, plans, or PBMs to negotiate discounts from providers, resulting in higher costs. 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 – by offering better rates – is undermined.[17] At the same time, any willing provider and FOC provisions may also reduce incentives for plans to invest in plan designs and complex negotiations with pharmacies and manufacturers. Any willing provider and FOC provisions can therefore undermine the ability of plans to reduce costs. This is likely to result in higher negotiated prices, ultimately harming consumers. Any willing provider and FOC laws can also limit competition by restricting the ability of insurance companies to offer consumers different plans, with varying levels of coverage, cost, and choice. These restrictions on competition may result in insurance companies paying higher fees to providers, which generally lead to higher premiums, and may increase the number of people without coverage.

Both economic theory and empirical evidence suggest that any willing provider and FOC provisions are likely to have these negative effects.[18]

III. Research Demonstrates that There Are Savings Associated with Preferred Pharmacies and Mail-order Pharmacies, and that Any Willing Provider Regulations Tend to Increase Costs

Basic economic principles suggest that a buyer can obtain a negotiating advantage by contracting selectively with a subset of providers. Empirical studies regarding the contracting

and pricing practices of pharmacies and other health care providers support the theory, as providers are willing to offer lower prices in exchange for increased volume.

a. CMS Studies of Medicare Part D Plans

CMS has released two studies analyzing prescription drug data from March 2012 for Medicare Part D plans. Both studies concluded that selective contracting has resulted in lower prices on average. These studies sought to compare the prices negotiated by plan sponsors with pharmacies under varying contractual arrangements. The first study, released in April 2013, focused on plans with pharmacy networks that included preferred and non-preferred pharmacies. The purpose of the study was to determine whether the increased cost sharing offered at preferred pharmacies – *i.e.*, lower copayments for beneficiaries – resulted in increased payments to the plans from the program.[19] The second study, released in December 2013, performed a similar analysis focused on comparing negotiated prices at retail pharmacies and mail order pharmacies.[20] The impetus for this research was "individual complaints about some drug costs being higher in preferred pharmacies."[21]

The CMS studies considered whether Part D plans encourage beneficiaries to fill their prescriptions at higher-priced pharmacies, raising costs for the program. In the first study, CMS compared various measures of unit cost for the top 25 brand and top 25 generic drugs for prescriptions filled at preferred pharmacies and prescriptions filled at non-preferred pharmacies under 13 PDP contracts. CMS found that, on average, branded drugs cost 3.3 percent less at preferred pharmacies and generic drugs, on average, cost 11 percent less at preferred pharmacies. However, CMS also found that average drug costs were higher in preferred pharmacies for five of the 13 PDP contracts it examined. Although these five contracts accounted for more than one-third of the contracts studied, they only accounted for about four percent of the claims in the CMS sample. CMS's second study considered costs for the same 50 drugs under 57 PDP contracts with mail order benefits. Taking the average across all 57 contracts, CMS found that the weighted average unit cost was 16.4 percent lower in mail order pharmacies than retail pharmacies for brands and generics combined, and 11 percent lower for generics. Despite the lower average costs, costs were higher for drugs purchased through mail order pharmacies for 21 contracts.

In both studies, CMS found substantial savings on average associated with preferred pharmacies and mail order pharmacies. This finding is generally consistent with the independent research on selective contracting discussed below. Despite these findings, CMS appears to conclude that selective contracting is of limited value because costs appear to be higher in either preferred or mail-order pharmacies under certain plans. FTC staff agrees that these studies may signal a problem that merits further investigation and appropriate intervention. However, we caution against using the finding that not all preferred or mail-order pharmacies have offered lower prices as a basis to adopt a broad rule that undermines the use of selective contracting and may threaten the lower costs that result overall.

In addition, we note that in both of these CMS studies, none of the unit cost measures used controlled for the mix of drugs dispensed at different types of pharmacies. The types of drugs dispensed via mail order can be significantly different than those dispensed at "brick

and mortar" retail pharmacies.[22] Generally, mail order pharmacies dispense a greater relative proportion of "maintenance drugs" used to treat chronic or recurring ailments while retail pharmacies dispense a greater relative proportion of drugs for acute or short-term ailments. For example, it would be unusual to use a mail order pharmacy to fill a prescription for antibiotics to treat an emergent infection. On the other hand, maintenance drugs, such as cholesterol-lowering statins, might be obtained via mail order relatively often.[23] It may also be the case that consumers are more responsive to enhanced cost-sharing for relatively expensive drugs. Therefore, beneficiaries may be more likely to fill more expensive prescriptions at preferred pharmacies. Average cost measures that do not account for the product mix may be misleading precisely because they do not disentangle differences in prices from differences in dispensing patterns. Without controlling for the product mix,[24] it is difficult to reach broad conclusions regarding the relative cost differences between different pharmacies.

We appreciate the importance of examining whether plan designs distort incentives for consumers to make cost-effective choices. The FTC considered these issues in its 2005 pharmacy benefit manager ("PBM") study, which examined whether pharmacy benefit designs properly align incentives between PBMs, plan sponsors, and enrollees. For example, the FTC study considered whether pharmacies owned by a PBM have the incentive to dispense more costly branded drugs, instead of low-cost generics. The data analysis in that study showed not only that beneficiaries and plan sponsors save money with generics, but that the PBM also earned higher profits when generic drugs were dispensed instead of branded ones.[25] The data showed that pharmacies owned by PBMs typically dispensed generics at rates comparable to pharmacies not owned by PBMs because their incentives to do so were similar.[26] The FTC study also found that, for example, "[a]fter controlling for prescription size and drug mix differences, mail prices are typically lower than retail prices."[27] The data used for the FTC study is now more than ten years old and predates the Part D benefit rollout, but it does support the need for continued analysis of potential misalignment of incentives or conflicts of interest in pharmacy benefit plan design.

b. Research on Selective Contracting and the Costs of Any Willing Provider Regulations

One related area in which selective contracting has been examined in the health care industry is in connection with hospital markets. Health plans build networks of hospitals to serve their beneficiaries, much as PDP sponsors assemble networks of preferred pharmacies. One study concluded that Connecticut health plans' ability to negotiate discounts with hospitals increased with the plan's willingness and/or ability to channel patients to selected hospitals, consistent with the predictions of a theoretical model introduced in the same study.[28] Another analysis found that Massachusetts health plans willing to be more selective in forming their hospital networks obtained deeper discounts.[29] These studies demonstrate that buyers in health care markets have effectively used selective contracting to negotiate lower prices.

In addition, two peer-reviewed studies analyzing state-by-state policy variation to measure the effects of any willing provider laws have confirmed that any willing provider

requirements undercut negotiating strategies. Research performed and published by an FTC economist has found, for example, that any willing provider laws generally undermine the ability of managed care organizations to lower health care spending. Specifically, the study found that per capita total health care expenditures are higher in states with any willing provider laws.[30] A 2009 study similarly examined variations in state any willing provider laws applicable to drug purchases to measure their effects. It found that states with any willing provider laws have higher prescription drug spending than those without them. The conclusion was the same, even when using different econometric techniques to account for variations across the states, such as differences in demographics, market structure, and regulatory environment.[31] Finally, a more recent working paper examined state-level per capita health expenditure data from CMS and found that any willing provider and FOC laws are associated with four percent higher per-capita drug expenditures.[32]

We recognize that limited networks do not "*per se* [lead] to significantly lower costs."[33] Yet the theoretical and empirical economic literature indicates that they can and do, on average, yield lower costs and prices.[34] At the same time, we understand that some PDPs elect, for various business reasons, to implement something akin to an any willing provider provision as part of their voluntary contracting,[35] and do not mean to suggest that such plan design options should be restricted.[36] As a policy matter, however, we hope that CMS will recognize the tendency of limited networks to yield lower costs and prices. We therefore urge CMS to preserve consumer choice by recognizing the potential advantages of selective contracting and limited networks where they work to the advantage of competition and consumers, and to be wary of any willing provider requirements, which can foreclose business models that aim to compete based on selected contracting and limited networks.

IV. Conclusion

FTC staff appreciates the important task faced by CMS in implementing the laws regarding Medicare Part D plans. We appreciate, too, CMS's interest in striking "an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs."[37] As we have noted, however, we are concerned that the any willing pharmacy provisions in the Proposed Rule may impair, rather than enhance, the ability of plan sponsors to negotiate lower prices. Based on FTC staff's experience in this area, as well as our review of empirical studies of preferred provider contracting and any willing provider and FOC laws, there are two clear and consistent conclusions in the literature:

- Selective contracting with pharmacies and other health care providers can lower prices paid by plans and their beneficiaries; and

- Any willing provider and FOC laws tend to raise prices or spending because they impair the ability of Part D plan providers to engage in selective contracting.

For this reason, we urge CMS to consider the issues raised in this letter to reassess whether its proposed any willing pharmacy provisions are likely to benefit Part D beneficiaries and the Part D program. Before proceeding with a full rollout of this any willing

provider pharmacy provision, CMS might consider whether further data analysis or new policy experiments might provide valuable information on the effects of these provisions on plans and beneficiaries.

Respectfully submitted,

Andrew I. Gavil, Director
Office of Policy Planning

Martin S. Gaynor, Director
Bureau of Economics

Deborah Feinstein, Director
Bureau of Competition

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[1] This comment expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics. It does not necessarily represent the views of the Federal Trade Commission or of any individual Commissioner. Commissioner Brill is dissenting from the filing of this comment.

[2] 79 Fed. Reg. 1918 (Jan. 10, 2014) [hereinafter Proposed Rule].

[3] Proposed Rule 79 Fed. Reg. at 1969 (Jan. 10, 2014) (discussing the non-interference provision); *see also id.* at 1979, 1982 (noting CMS's desire to "maximize opportunities for price competition" and "improve market competition" through proposals on any willing pharmacy standards).

[4] We focus here on the "Any Willing Pharmacy Standard Terms & Conditions (§423.100(a)(8))" discussed in Part 29 of the Proposed Rule, 79 Fed. Reg. 1978-82, and their likely competitive consequences.

[5] MedPac Public Comment on Contract Year 2015 Policy and
Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, Proposed Rule (Feb. 28, 2014), *available at* http://www.medpac.gov/documents/02282014_partD_COMMENT.pdf.

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

[7] *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.").

[8] *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.

[9] *See, e.g.*, FTC & U.S. DEP'T OF JUSTICE, 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. Of particular relevance to our discussion of the Proposed Rule and any willing provider provisions is the Commission's 2005 "Conflict of Interest Study" regarding pharmacy benefit managers, and the Commission's subsequent report on pricing and contracting practices for mail-order and brick-and-mortar pharmacies. *See* FEDERAL TRADE COMMISSION, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (Aug. 2005) [hereinafter FTC PBM STUDY] at 25, 31-36, *available at* http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

[10] 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* 9.

[11] FTC PBM STUDY, *supra* note 7; *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.

[12] *See, e.g.*, FTC Staff Comment to the Honorable James L. Seward, Concerning New York Assembly Bill 5502-B to Regulate the Use of Mail Order Pharmacies by Health Plans Offering Prescription Drug Coverage (Aug. 2011), *available at* http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-assembly-bill-5502-b-regulate-use-mail-order-pharmacies-health-plans/110808healthcarecomment.pdf.

[13] Proposed Rule, 79 Fed. Reg. at 1978.

[14] *Id.* at 1981.

[15] Generally, any willing provider laws require health plans to include in their networks any provider that is willing to participate in accordance with the plan's terms. *See, e.g.*, Michael Vita, *Regulatory Restrictions on Selective Contracting: An Empirical Analysis of 'Any Willing Provider' Regulations*, 20 J. HEALTH ECON. 955, 956 (2001). FOC laws are similar, but are directed at health plan reimbursements 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. *Id.* Some states have adopted such laws for pharmacy services, although the laws vary substantially. *See, e.g.*, Anne Carroll and Jan M. Ambrose, *Any-Willing-Provider Laws: Their Financial Effect on HMOs*, 27 J. Health Pol., Pol'y & L. 928 (2002). Other states have adopted similar laws for other types of health care benefits. Due to limitations of the available data, the literature tends to look at the effect of any willing provider laws on total spending, instead of prices. Because the quantity of health care is generally measured to have a negative, though small, relationship with health care prices, these studies likely understate the effect of any willing provider laws on prices.

[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* 9, at Ch. 1.

[18] For example, one study found that expenditures rise when any willing provider or FOC laws are enacted, and tend to rise more with stronger laws. Vita, *supra* note 15, at 966 (panel data showing, e.g., that states with highly restrictive any willing provider/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, for example, 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].

[19] Part D Claims Analysis: Negotiated Pricing Between Preferred and Non-Preferred Pharmacy Networks (April 30, 2013), *available at* http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf (last checked Feb. 24, 2014).

[20] Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies, *available at* https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf (last checked Feb. 24, 2014).

[21] Part D Claims Analysis: Negotiated Pricing Between Preferred and Non-Preferred Pharmacy Networks, *supra note 19*, at 1.

[22] *See, e.g.*, FTC PBM STUDY, *supra note* 9, at 25-26, 31-32.

[23] In fact, this is exactly what the FTC found in 2004 when analyzing dispensing patterns across therapeutic classes in the PBM study. Nearly 100% of prescriptions for certain classes of antibiotics and for cold/cough medicines were dispensed via retail pharmacies whereas almost 50% of osteoporosis drugs and statins were dispensed via mail. *See* FTC PBM STUDY, *supra note* 9, at 32, Figure II-5. Also a quick look at the drug level claims data reported in Table 2 of the first CMS study shows that there can be considerable variation in dispensing patterns between preferred and non-preferred pharmacies as well. For instance, the total branded claims in preferred pharmacies are approximately 500,000 and the non-preferred total is around 300,000, so non-preferred claims are about 40% lower across all branded drugs. However, the 7th largest branded drug, ProAir HFA, has nearly an equal number of claims in preferred and non-preferred pharmacies (27,820 versus 27,522).

[24] A more informative way to perform this analysis would be to construct a price index based on a common market basket so that the mix of products is kept constant across the comparison groups, and differences in the price index reflect actual price differences. For a discussion of different methods to calculate a market basket, see "Alternative Weighting of the Hospital Market Basket Input Price Index", Office of the Actuary, CMS, November 13, 2008, available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/alternativeindexweights.pdf.

[25] FTC PBM STUDY, *supra note* 9, at 71-76.

[26] *Id.* at 62-71 (discussing observed generic substitution rates and generic dispensing rates).

[27] *Id.* at 25. For a general overview of retail and mail-order pharmacy pricing, see Chapter II of the report, *id.* at 23-39.

[28] Alan T. Sorensen, *Insurer-Hospital Bargaining: Negotiated Discounts in Post-Deregulation Connecticut*, 51 J. INDUS. ECON. 469 (2003) (building a simple theoretical model describing the dynamics of the bargaining effects and testing it with data on negotiated Connecticut hospital discounts).

[29] Vivian Y. Wu, *Managed Care's Price Bargaining with Hospitals*, 28 J. HEALTH ECON. 350 (2009).

[30] Michael G. Vita, *Regulatory Restrictions on Selective Contracting: An Empirical Analysis of 'Any-Willing-Provider' Regulations*, 20 J. HEALTH ECON. 955 (2001).

[31] Christine Piette Durrance, *The Impact of Pharmacy-Specific Any-Willing-Provider Legislation on Prescription Drug Expenditures*, 37 ATLANTIC ECON. J. 409 (2009).

[32] Jonathan Klick & Joshua D. Wright, *The Effect of Any Willing Provider and Freedom of Choice Laws on Health Care Expenditures*, U. Penn. Inst. for Law & Econ. Res. Paper No. 12-39 (Feb. 24, 2014), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2183279.

[33] Proposed Rule, 79 Fed. Reg. at 1979.

[34] A literature review was conducted by FTC staff in preparing this comment has revealed no countervailing evidence. Our concerns about a failure to control for composition notwithstanding, CMS's own studies are generally consistent with the empirical literature, to the extent that CMS observes significant average savings associated with preferred pharmacies for 49/50 of the drugs they studied.

[35] *Id.* at 1979-80.

[36] Like CMS, we seek to avoid "policies that would be expected to interfere with competitive market negotiations," *id.* at 1969, and, absent anticompetitive conduct, the contract terms that are its result. In that regard, we also suggest that CMS might carefully study the potential costs of its proposed "T&C" disclosure terms. 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 consumers and has opposed government regulation that restricts advertising to consumers. Regarding attempts to suppress price information, *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). Regarding over restrictive regulations, *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* http://www.ftc.gov/os/2004/05/040512dtcdrugscomment.pdf. At the same time, there is no theoretical or empirical reason to assume that consumers require sellers' underlying cost information for markets to achieve competitive outcomes, and mandatory disclosures of such information can be costly, and can sometimes have the unintended consequence of publicizing proprietary business information in a way that could foster collusion among third parties.

[37] Proposed Rule, 79 Fed. Reg. at 1978.

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 Economics[1] 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 members[9]

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.[10] 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.[11] 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.[12]

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.[16] 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.[17] 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.[25] 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.[26] 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."[29]

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."[30]

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

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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 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.

[8] 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).

[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.*

[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.,

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.