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.”

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. 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, 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, research, and advocacy. 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. 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.

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.” 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.” These proposed regulations generally mirror those found in some state-level any willing provider and FOC laws.

FTC staff have previously expressed concerns about potential anticompetitive effects and consumer harm associated with any willing provider and FOC laws. 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. 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.

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. The second study, released in December 2013, performed a similar analysis focused on comparing negotiated prices at retail pharmacies and mail order pharmacies. The impetus for this research was “individual complaints about some drug costs being higher in preferred pharmacies.”

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
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. 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, 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. 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. 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.” 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. Another analysis found that Massachusetts health plans willing to be more selective in forming their hospital networks obtained deeper discounts. 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. 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. 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.

We recognize that limited networks do not “per se [lead] to significantly lower costs.” Yet the theoretical and empirical economic literature indicates that they can and do, on average, yield lower costs and prices. 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, and do not mean to suggest that such plan design options should be restricted. 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.” 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,

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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.


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).


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.”).


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.

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.

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].


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

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).

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.

FTC PBM STUDY, supra note 9, at 71-76.

Id. at 62-71 (discussing observed generic substitution rates and generic dispensing rates).


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.