Hearing on Reasonable Contracts or Arrangements Under Section 408(b)(2)—Welfare Plan Fee Disclosure

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Summary

- The FTC has concluded on many occasions that the pharmacy benefit manager (PBM) market is highly competitive.
- The PBM market is operating efficiently.
- Plan sponsors have many options, and already receive a wide range of disclosures.
- The Department should not mandate a disclosure regime that could result in the very anti-competitive consequences about which the FTC has repeatedly warned.

PCMA Background

- The PCMA is the national association representing America's PBMs.
- PBMs administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program.

PBMs and Drug Cost Reduction

- PBMs typically reduce drug benefit costs by 30 percent for public and private payers by encouraging the use of generic drug alternatives, negotiating discounts from manufacturers and retail pharmacies, saving money with home delivery through mail order pharmacies, and using health information technology like e-prescribing to reduce administrative expenses and improve patient safety.
- These tools allow for a system-wide approach to address the dangers and costs of misuse, overuse, and underuse of prescription drugs.

PBM Networks

- PBMs typically organize retail pharmacies into networks and bargain with the network pharmacies to set a rate at which the PBM will pay the pharmacy for each prescription that the pharmacy fills as a network provider.
- Some PBMs also operate, directly or through affiliates, their own mail-order, specialty drug and retail pharmacies, and negotiate directly with pharmaceutical manufacturers to purchase prescription drugs, which they use to fill prescriptions. In many (but not all) cases, those PBM-owned pharmacies are included in the pharmacy network pursuant to the client's agreement with the PBM.

Role of PBMs

- Through the PBM’s contract with its client (the plan sponsor), the individuals covered by the client‘s prescription drug program obtain access to the retail pharmacy networks and mail-order and specialty drug pharmacies established by the PBM.
- When plan participants fill their prescriptions with a retail pharmacy in the PBM's network, the plan and the participants each pay a set amount determined under the PBM contract for the prescription that almost always will be less than what the total cost would be if the prescriptions were filled out of network.

Structuring Prescription Drug Plans

- Plan sponsors decide the kind of overall prescription drug benefit that will be offered to plan participants. The sponsor makes all decisions regarding the cost and access of the plan.
- Sponsors choose the specific designs of their prescription drug plans, including member cost sharing and any other limitations or restrictions.
- Legal and business consultants work with plan sponsors to develop written contracts that protect the sponsor's financial and business interests.

Competition and Accreditation

- Marketplace competition among PBMs allows plan sponsors to safeguard their interests.
- Plan sponsors regularly conduct detailed audits to ensure PBM performance and contract compliance.
- Many PBMs voluntarily participate in third-party accreditation or certification programs, such as the URAC Pharmacy Benefit Management Standard and the Pharmacy Coalition of the HR Policy Association.
  - These standards are developed by organizations whose membership includes plan sponsors and other interested parties. They include transparency standards that call for the disclosure of rebate information, as well as the disclosure of pricing structure, audit arrangements, and formulary decisionmaking.
  - Thus, plans have available materials that describe industry-based transparency standards, and can use those materials to negotiate with PBMs.

Pricing of PBM Services

- PBMs currently provide plans with a wealth of information, including what they receive in the way of manufacturer rebates, both through the competitive market forces and as a result of various settlements with state attorneys general.
- Given the vigorous competition between PBMs in the marketplace, clients can choose pricing arrangements that best suits their needs.
- The pricing of PBM contracts typically is a variation of either the “spread” or the “pass-through” model or, most often, a combination of the two.
  - Clients aggressively explore these alternatives during the Request for Proposals (RFP) process. As described in more detail on slide 20, mandated disclosure might bias these alternatives and be detrimental to plans and their participants.

Clients Frequently Switch Between PBMs

- PBMs must compete for the business of plan sponsors by submitting bids through an RFP process.
- The RFP bidding process allows a plan sponsor to leverage its negotiating ability and purchasing power by creating intense competition among PBMs.
- In addition to their own expertise, plan sponsors rely on consultants knowledgeable about how PBMs operate and the economics of the PBM business to protect their interests throughout the RFP process.
- Most PBM contracts are only for a one, two, or three-year period, so plan sponsors have the opportunity to switch PBMs if they are dissatisfied with a PBM's performance or pricing.

PBMs – A Competitive Market

- FTC analyses have consistently shown that the PBM market is highly competitive.
- In 2004, the FTC and the U.S. Department of Justice ("DOJ") completed a joint two-year project examining the role of competition in the health care industry.[1] ("FTC/DOJ Report"). The findings of this study were reached after 27 days of joint hearings, including testimony from 250 panelists, which produced a transcript of almost 6,000 pages.
  - With respect to PBMs, the joint FTC/DOJ Report stated that, "[i]n general, vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation. Just as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition should also encourage disclosure of the information health plan sponsors require to decide with which PBM to contract." FTC/DOJ Report at Executive Summary, p. 28.

PBMs – A Competitive Market

- In fact, the joint report noted that "[t]o date, most empirical evidence suggests that PBMs have lowered costs for health plan sponsors," *id.* at Ch. 7, p. 1, and that "consumers with prescription drug insurance administered by a PBM save substantially on their drug costs as compared to cash-paying customers." *Id.* at Ch. 7, p. 11.
- Panelists consulted during the course of the FTC/DOJ investigation advised that "rebate transparency can be handled through private contracts, because there is no barrier to a plan sponsor negotiating an arrangement providing it with access to the PBM's rebate information." *Id.* at Ch. 7, p. 16.

PBMs – A Competitive Market

- While collecting information with respect to the joint FTC/DOJ Report, the FTC was also conducting a separate study of the PBM industry pursuant to a congressional request that it investigate allegations of PBM conflicts of interest.[2] ("FTC Report").
- The FTC examined "differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers."
- According to the FTC, in 2004 there were 40 to 50 PBMs operating in the United States (there now are more than 60). In addition, the FTC stated that one-third to one-half of each regional market is serviced by smaller PBMs.
- The resulting report, released in 2005, concluded that there was no merit in the charge that PBMs were engaging in self-dealing by both administering a health plan's pharmacy benefits program and directly selling prescription drugs to plan participants via the PBM's own mail-order pharmacy. FTC Report at vi. ("The actual data from study participants on the business practices Congress requested the FTC to study revealed that these allegations are without merit.").

PBMs – A Competitive Market

- The FTC's conclusions are solidly backed by other governmental and private sector studies that have also concluded that mandatory disclosures are not necessary and that market forces are working efficiently.
  - For example, the Congressional Budget Office, when examining a potential PBM disclosure requirement as part of the Prescription Drug and Medicare Improvement Act of 2003, concluded that such a requirement would cost taxpayers $40 billion over 10 years.[3]
  - Similarly, a 2007 PricewaterhouseCoopers study determined that legislation requiring disclosure of private PBM terms would increase drug spending by $127 billion over the next decade.[4]

FTC Responses to Proposed State Regulation of PBMs

- The FTC has objected to numerous state statutes that would more closely regulate PBMs:
  - For example, the FTC in September 2004 objected to a proposed California law that would have required PBMs to make specific disclosures to their health plan clients regarding revenues (including rebates from drug manufacturers), administrative fees, and arrangements to encourage formulary compliance or manage benefits.[5]
  - Among other things, the FTC observed that the proposed legislation might well have an anticompetitive effect:

    > [F]inancial information disclosed by PBMs to [health plans] may become public and a knowledgeable pharmaceutical manufacturer might well be able to use this information to calculate the rebate a competitor was offering. If pharmaceutical manufacturers learn the exact amount of the rebates offered by competitors . . . then tacit collusion among manufacturers is more feasible. Consequently, the required disclosures may lead to higher prices for PBM services and pharmaceuticals.

FTC Responses to Proposed State Regulation of PBMs

- California legislation (cont'd)
  - The FTC also found that "[t]here do not appear to be any significant barriers to negotiation between health plan sponsors and PBMs over all the terms of their agreement, including how PBMs are to be paid for their services and the disposition of any rebates." Indeed, the FTC observed that:

> [V]igorous competition in the marketplace for PBMs is more likely to arrive at an economically efficient level of transparency than regulation of those terms. Just as competitive forces encourage PBMs to offer their best price and service combinations to health plan sponsors in order to gain access to subscribers, competition also encourages disclosure of the information group health plan sponsors require to decide which PBM to contract with. . . .

FTC Responses to Proposed State Regulation of PBMs

- The FTC has reached similar conclusions on several other occasions:
  - North Carolina (Letter from Maureen K. Ohlhausen, Director, Office of Policy Planning, Michael A. Salinger, Director, Bureau of Economics, and Susan A. Creighton, Director, Bureau of Competition, U.S. Federal Trade Commission, to Patrick T. McHenry, U.S. House of Representatives (July 15, 2005)).
  - Virginia (Letter from Maureen K. Ohlhausen, Director, Office of Policy Planning, Michael A. Salinger, Director, Bureau of Economics, and Jeffrey Schmidt, Director, Bureau of Competition, U.S. Federal Trade Commission, to Terry G. Kilgore, Member, Commonwealth of Virginia House of Delegates (Oct. 2, 2006)).
  - New Jersey (Letter from Maureen K. Ohlhausen, Director, Office of Policy Planning, Michael A. Salinger, Director, Bureau of Economics, and Jeffrey Schmidt, Director, Bureau of Competition, U.S. Federal Trade Commission, to Nellie Pou, Assemblywoman, New Jersey General Assembly (Apr. 17, 2007)).

FTC Responses to Proposed State Regulation of PBMs

- Proposed New York Statute
  - Most recently, in 2009, a proposed New York statute (SB 58) would have required PBMs to make substantial disclosures to health plans during contract negotiations and annually thereafter. Disclosures would have included extensive details of the PBM's cost structure and business strategies, and the bill also would have required PBMs to provide physicians with financial and clinical information upon request.
  - The FTC strongly objected to the proposed bill.[6]
    - The FTC noted an undemonstrated need for the bill's disclosure requirements, stating that "health plans appear able to protect themselves . . . through arms-length contracts." The FTC concluded: "Allowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than contract terms regulated by government regulation."

The Market is Working Effectively

- As described above, many studies establish that the marketplace for PBM services is functioning well, and that plans have sufficient information to judge the reasonableness of the fees charged and the quality of the services that PBMs provide.
- Mandated disclosure of drug manufacturers rebates can diminish competition and result in tacit collusion by manufacturers that would push drug prices higher. The same concern applies to large retail pharmacy chains.
  - In addition to the direct costs of a disclosure regime, mandatory disclosures would limit a plan sponsor's ability to bargain over various disclosure terms in the interest of other contract terms that may be more important to its particular interests.
- The FTC believes that competition, not regulation, should encourage disclosure of the information sufficient to allow plans to select the PBM that best meets its needs.

The Market is Working Effectively

- Most PBM clients are large and hire sophisticated consultants. Smaller plans usually retain third party administrators or insurance companies that service many other plans and that have the financial wherewithal to retain their own expert consultants.
- Most complaints against PBMs come from independent pharmacies, including the members of the National Community Pharmacists Association. Those pharmacies are advancing their own economic interests, which are not necessarily aligned with the interests of consumers of prescription drugs, like ERISA health benefit plans.
- Mandated disclosure requirements are likely to drive more plan sponsors to a variation of the "pass-through" model. Currently, plan sponsors have the choice between the two models (and variations/combinations of the basic models). Variations of the "spread" model often are more cost-effective for plan sponsors, in large part because that model strongly incentivizes PBMs to negotiate lower costs with pharmacists and other parts of the supply chain. This is one key reason why the NCPA is pushing for mandatory disclosure: its members believe that they will do better under the pass-through model because PBMs will have less incentive to negotiate reduced drug prices with the pharmacy members of their distribution networks. However, there is no empirical or theoretical reason to believe that ERISA plans and their participants would benefit from this outcome.

Current Disclosure Regimes

- The Patient Protection and Affordable Care Act requires PBMs to disclose a variety of information to state exchanges starting in 2014; importantly, the statue includes very strong confidentiality protections. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 includes similar disclosure rules for Medicare Part D.
- A number of state laws regulate PBMs. Perhaps recognizing the anti-competitive concerns raised by the FTC, most of these laws do not impose additional disclosure obligations, but typically are limited to PBM registration and licensure.

The Justifications for Pension Plan Disclosures Do Not Apply to PBMs

- The fundamental justification for the new rules applicable to service providers to pension benefit plans, and the data relied upon by the Department in formulating those rules, was to address a demonstrated need for greater transparency in the contracting for investment services to defined contribution plans, specifically the providers of pooled investment vehicles. In that context, amounts received or retained by service providers reduce dollar-for-dollar the funds that could provide retirement benefits to plan participants.
- These concerns do not apply to PBMs or other service providers to welfare benefit plans, as the Department recognized when issuing the Form 5500, Schedule C FAQs relating to PBMs.

Exclusions for Specific Types of Payments

- To date, the Department has not required PBMs to treat as indirect compensation rebates, discounts and other payments that PBMs receive or earn in connection with providing health care benefits to ERISA plan participants.
- The Form 5500, Schedule C instructions, as clarified by the FAQs issued by the Department in 2009, exclude from “indirect” compensation rebates and discounts received by PBMs, unless the plan and the PBM agree that such rebates or discounts (or earnings on rebates and discounts held by the PBM) would be used to compensate the PBM for managing the plan’s prescription drug coverage, dispensing prescriptions or other administrative and ancillary services.
- The Department’s current position on these issues is the right one.

Conclusion

- All of this strongly indicates that, as the FTC has repeatedly pointed out, mandated disclosure could well have profound anti-competitive effects. The PBM marketplace is highly competitive, and direct contract negotiations between PBMs and plans have resulted in disclosures more than sufficient to allow plans to make reasonable contract arrangements with regard to fees and quality of service.

Endnotes

1 U.S. Federal Trade Commission and the U.S. Department of Justice, *Improving Health Care: A Dose of Competition* (July 2004).

2 U.S. Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Aug. 2005).

3 Congressional Budget Office, *Cost Estimate: S1, Prescription Drug and Medicare Improvement Act of 2003*, at 15 (July 22, 2003).

4 PricewaterhouseCoopers, *Pharmacy Benefit Management Savings and the Commercial Marketplace & the Cost of Proposed PBM Legislation 2008-2017* (Mar. 2007).

5 Letter from Susan A. Creighton, Director, Bureau of Competition, Luke M. Froeb, Director, Bureau of Economics, Maureen K. Ohlhausen, Acting Director, Office of Policy Planning, and David A. Hyman, Special Counsel, U.S. Federal Trade Commission, to Greg Aghazarian, Assemblyman, California Legislature (Sept. 3, 2004).

6 Letter from James Cooper, Acting Director, Office of Policy Planning, Pauline M. Ippolito, Acting Director, Bureau of Economics, and David P. Wales, Acting Director, Bureau of Competition, U.S. Federal Trade Commission, to James L. Seward, New York Senate (March 31, 2009).