

Competitive Concerns and Price Transparency in the PBM Market

by David A. Balto

As Congress struggles with providing a prescription drug benefit under Medicare, many proposals include the use of pharmaceutical benefit managers (PBMs). PBMs are fiscal intermediaries that specialize in the administration and management of prescription benefit programs. PBMs provide these services for insurers, unions, and employers (plan sponsors). PBMs help control and manage pharmaceutical spending and provide services for over 180 million Americans.

Although PBMs can provide a valuable service, consumers and plan sponsors often do not receive their full benefits due to certain market characteristics and a lack of transparency in the process. Substantial entry barriers and significant switching costs dampen the degree of competition in PBM markets. A lack of transparency about the compensation PBMs receive from pharmaceutical manufacturers prevents plan sponsors from effectively securing the lowest pharmaceutical prices. Before Congress extends the use of PBMs in a Medicare pharmaceutical benefit, it must reform PBM markets to provide substantially greater transparency.

PBM Markets and Competitive Concerns

PBMs are intermediaries in the complex pharmaceutical distribution chain; they negotiate contracts with pharmaceutical manufacturers and pharmacies. PBMs steer healthcare consumers and physicians by placing certain drugs in a preferential status on formularies—lists of approved drugs used to manage drug spending. Manufacturers pay a variety of fees for preferential placement on a formulary, including 1) access rebates, 2) market share rebates for meeting certain market share goals, and 3) administrative and other fees. Some PBMs also have their own mail order operations.

In theory, a PBM serves as a middleman attempting to secure favorable pharmaceutical prices. But unlike a true group purchasing operation that may be efficient, PBMs do not actually purchase the drugs. Rather, they receive rebates from manufacturers for placement of drugs on a formulary, a list of approved drugs. Generally these rebates can benefit

consumers where they are transparent. Secret rebates, however, can lead to discrimination that ultimately may harm buyers and the ultimate consumer. Secret rebates may encourage a PBM to choose a higher priced drug with a higher rebate, instead of a lower priced drug, resulting in higher costs to consumers. Consumers do not necessarily receive the benefit of these middleman rebates.

Competitive concerns have arisen in the PBM market—a highly concentrated industry in which the four largest firms hold about a combined 80% market share. The market for full-service PBM providers capable of bidding on Medicare contracts is even more concentrated. Moreover, concentration in the market has increased substantially over the past decade. Substantial costs have prevented any successful entry into the PBM market for quite some time, and substantial switching costs create obstacles for plan sponsors to change PBMs.

This situation is one in which PBMs can act opportunistically—easily increasing prices or decreasing service. Indeed, the Federal Trade Commission (FTC) placed the two largest PBMs—Merck and PCS—under regulatory consent orders to prevent opportunistic conduct that would harm consumers.¹ The FTC found that 1) there was a national market for PBMs with very few competitors; 2) PBMs had the ability and incentive to engage in exclusionary conduct; 3) there was the potential for collusion among PBMs; and 4) PBMs could disadvantage rivals by establishing closed formularies.² To address these potential competitive concerns, the FTC required PBMs to establish independent and open formularies to provide plan sponsors with greater choice and transparency.

The competitive practices of PBMs are the subject of several investigations and regulatory enforcement actions.



A group of 21 state attorneys general is investigating anticompetitive conduct by the major PBMs.³ The Attorney General of New York recently subpoenaed Express Scripts for information “regarding the company’s compliance with certain state and federal antitrust and consumer protection statutes.”⁴ The Department of Health and Human Services (DHHS) Office of Inspector General has warned that rebates collected by PBMs under state Medicaid programs might violate federal anti-kickback laws. The Department of Justice recently joined a *qui tam* lawsuit filed by a former employee against Merck/Medco.⁵ The complaint alleges that as a result of long-standing fraudulent business practices, Merck/Medco’s services to plan sponsors resulted in price increases and a threat to the prescription users’ health.

Much of the concern over PBMs focuses on whether the rebates and other payments received from pharmaceutical manufacturers are passed on to plan sponsors in lower prices; PBMs consistently decline to provide systematic and complete payment information to their plan sponsors. The American Federation of State, County, and Municipal Employees (AFSCME) sued the nation’s four largest PBMs,⁶ alleging that they violated California’s Unfair Competition Law.⁷ The complaint charges, *inter alia*, that the four PBMs have negotiated rebates from drug manufacturers and discounts from retail pharmacies, yet have not passed those savings on to healthcare plans and consumers. In addition, the complaint also alleges that the PBMs developed a pricing system based on the average wholesale price (AWP), which is widely considered an inflated “sticker” price set by drug manufacturers.

The Need for Transparency and the Proposed Reforms

PBM market reforms are major components in the Medicare reform packages currently before both houses of Congress.⁸ The bills would require reforms to current Medicare prescription drug provisions, including expanded governmental audit rights of prescription providers, financial statements and records, and competitive bidding rules for Medicare contracts. Disclosures and price transparency enable buyers to determine whether they are receiving the full benefit of the price concessions received by PBMs from manufacturers. Armed with information about rebates, buyers such as Medicare can more effectively encourage PBMs to compete.

In addition, these reforms will transform PBMs into more traditional insurers by giving them fixed premiums from plan beneficiaries, rather than allowing them to earn their profits

from a complex set of fees, discounts, and rebates produced from their dealings with pharmaceutical companies.⁹

Mandated price transparency, as called for in the proposed legislation, will help solve the competitive issues in the national PBM market, and will play an essential role in securing for consumers the benefits of a competitive marketplace. Arguments to the contrary, are inconsistent with common sense, economic learning, and decades of antitrust law.

“Secret” rebates may encourage a PBM to choose a higher priced drug with a higher rebate instead of a lower priced drug, resulting in higher costs to consumers and higher rebates to the PBMs. By disclosing rebates, buyers can monitor and prevent this potential discrimination. Congress enacted legislation to prevent such conflicts of interest and possible discrimination.¹⁰ Under the Medicare/Medicaid anti-kickback law, criminal penalties attach to any person who knowingly solicits, receives, offers, or pays remuneration (including rebates) in exchange for a payment or service under a federal healthcare program. A U.S. attorney’s office in Pennsylvania currently is investigating whether the rebates that PBMs receive from manufacturers constitute illegal kickbacks. Congress and the DHHS require full disclosure of any rebates or price concessions as a prerequisite to application of the discount safe harbor to the anti-kickback law.¹¹

Transparency Is Essential to Competitive Markets and Consumer Choice

Price and service transparency is a cornerstone to competition because when it exists, purchasers can make fully informed choices. Transparency in the process forces firms to compete more aggressively because they know that purchasers can and will make such choices. Price transparency invariably leads to lower prices, not higher prices. As economists observe, “Firms obtain market power from consumer lack of knowledge about prices and quality Limited information can lead to a monopolistic price in what would otherwise be a competitive market.”¹²

Antitrust litigation reflects the fact that transparency is vital to the effective functioning of markets. For example, in *Bates v. State Bar of Arizona*,¹³ the U.S. Supreme Court struck down a ban on lawyer advertising. Petitioners, members of the Arizona Bar, offered low-cost legal services to low-income clients in need of routine legal services. The attorneys’ financial success depended on high case volume

from unsophisticated legal consumers, and advertising was one of the best avenues to achieve that success. Although the state bar expressly forbade the activity, petitioners nevertheless placed a newspaper advertisement for their practice. In declaring the rule illegal, the Court noted that advertising can help the bar better serve the general community: “Advertising is the traditional mechanism in a free-market economy for a supplier to inform a potential purchaser of the availability and terms of exchange. The disciplinary rule at issue likely has served to burden access to legal services.”¹⁴

Transparency also plays an important role in efforts by managed care to control healthcare costs. In *FTC v. Indiana Federation of Dentists*,¹⁵ the FTC challenged an effort by a group of dentists to collectively refuse to provide x-rays to managed care providers. The insurers needed this information to make coverage decisions. The FTC deemed the boycott violative of antitrust laws, and the Supreme Court agreed, finding the conspiracy had the actual effect of suppressing competition.¹⁶ The Court noted, “While this is not price fixing as such, no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement.”¹⁷

A lack of transparency invariably leads to less competition and higher prices. As the Supreme Court has observed, restrictions on price transparency “increase the difficulty of discovering the lowest cost seller of acceptable ability[,] . . . [reduce] the incentive to price competitively,” and “serv[e] to perpetuate the market position of established [market participants].”¹⁸ As a result, “where consumers have the benefit of price advertising, retail prices often are dramatically lower than they would be without advertising.”¹⁹ The importance of transparency, however, attaches not only to price information, but also to all material aspects of the transaction. In *United States v. National Society of Professional Engineers*, the Court indicated that “all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers.”²⁰

Regulation Often Is Necessary to Protect Transparency

Markets often work well to provide the type of transparency consumers need; in some cases, however, it is necessary for the government to intervene. This is especially true in complex markets like pharmaceutical distribution and in concentrated markets with high entry barriers.

Federal antitrust enforcement agencies have brought several enforcement actions and adopted regulations to protect the vital role of price transparency in many markets.²¹ In

several cases the FTC has required disclosure of the underlying terms of transactions to help consumers make fully informed choices. For example, in the funeral industry—an industry that resisted disclosing price information to consumers—the FTC enacted regulations requiring price disclosure. Among the numerous goods and services listed by the regulations for disclosure, the regulations designate certain core components of the total funeral package as mandatory disclosure items.²² Sections of those regulations include mandatory posting of notices regarding prices, and items required to be included on billing statements.

The FTC instituted similar rules concerning telemarketing companies. To ensure complete disclosure to customers purchasing goods and services over the telephone, the regulations require disclosure of certain information before customers pay for the good or service, and prohibit nondisclosure of such information as a deceptive telemarketing act or practice.²³ A company must disclose, among other information, the price of shipping, any restrictions or conditions on the sales offer, the refund policy, and the total cost of the transaction in a clear and conspicuous manner. Offers of consumer credit products are subject to the additional requirements of the Truth in Lending Act (TILA).²⁴ Misrepresenting any of the information required for disclosure also is considered deceptive, as is causing billing information to be submitted to the company in violation of TILA or the Electronic Fund Transfer Act.²⁵ The FTC rule also classifies any false or misleading statement to induce a person to make a charitable contribution as a violation.²⁶

That a “middleman” such as a PBM may face a conflict of interest and that disclosure may alleviate the potential for such conflicts has been recognized in other contexts. For example, Internet search engines often receive payments from companies that place advertising on websites. By letter, the FTC informed Internet search engine companies that they must disclose the existence of these payments on the website.²⁷ Although the Commission elected not to commence actions against the search engine companies, it noted that disclosure of payments made by companies to them in exchange for preferential placement in search results “would put consumers in a better position to determine the importance of these practices in their choice of search engines to use.”²⁸ The FTC specifically recommended that any paid-for search result rankings be distinguished from nonpaid-for results; that paid-for inclusion be clearly and conspicuously disclosed; and that no affirmative statement be made that might mislead consumers about the basis of search results.

Conclusion

Providing pharmaceutical benefits under Medicare is a laudable goal and intermediaries such as PBMs can play an important role in delivering those benefits. Like all markets, however, PBM markets work most effectively where there is real transparency so consumers can make fully informed choices. Congress should make sure that transparency is an essential element in providing comprehensive pharmaceutical benefits. ▲

¹ Eli Lilly, 61 Fed. Reg. 31,117 (FTC July 31, 1996); Merck & Co., 63 Fed. Reg. 46,451 (FTC Sept. 1, 1998).

² See Elizabeth L. Mitchell, *The Potential for Self-Interested Behavior by Pharmaceutical Manufacturers Through Vertical Integration With PBMs: The Need for a New Regulatory Approach*, 54 FOOD & DRUG L.J. 151 (1999); David A. Balto, *A Whole New World?: Pharmaceutical Responses to the Managed Care Revolutions*, 52 FOOD & DRUG L.J. 83 (1997) (detailing the competitive problems posed by PBMs and FTC enforcement actions).

³ *More Disclosure for Drug Plans*, N.Y. TIMES, July 19, 2003, at <http://www.nytimes.com/2003/07/19/business/19CARE.html> (last visited Aug. 8, 2003); *Express Scripts Gets Subpoena from NY Attorney General*, available at <http://uk.biz.yahoo.com/030620/80/e2we6.html> (last visited Aug. 8, 2003) ("[I]n several states including North Carolina and West Virginia have launched queries into PBM practice").

⁴ *Express Scripts Subpoenaed by NY Attorney General*, St. Louis Bus. J., June 20, 2003, at <http://sanfrancisco.bizjournals.com/stlouis/stories/2003/06/16/daily76.html> (last visited Aug. 8, 2003).

⁵ United States ex. rel. Hunt v. Merck & Co. Inc., Mo. 00-737, notice of intervention (E.D. Pa. Jun. 23, 2003).

⁶ The largest PBMs are PCS, Express Scripts, Medco, and Caremark.

⁷ See First Amended Representative Action and Complaint for Violations of the Unfair Competition Law, available at <http://www.hagens-berman.com/files/>

PBM%20Complaint%20-%20Amended%20-%20NP1049738021600.pdf (last visited July 3, 2003).

⁸ See Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Cong. (2003); Medicare Prescription Drug and Modernization Act of 2003, H.R. 1, 108th Cong. (2003).

⁹ See http://www.kaisernetwork.org/daily_reports/print_report.cfm?DR_ID=18741 (last visited Aug. 8, 2003).

¹⁰ See Medicare-Medicaid Anti-Fraud and Abuse Amendments, 42 U.S.C. § 1320a-7b(b) (2003).

¹¹ *Id.*

¹² DENNIS W. CARLTON & JEFFREY M. PERLOFF, *MODERN INDUSTRIAL ORGANIZATION* 431 (2000).

¹³ *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977).

¹⁴ *Id.* at 376.

¹⁵ *FTC v. Indiana Federation of Dentists*, 476 U.S. 447 (1986).

¹⁶ *Id.* at 454-55.

¹⁷ *Id.* at 459 (quoting *United States v. National Society of Professional Engineers*, 435 U.S. 679, 692 (1978)).

¹⁸ *Bates*, 433 U.S. at 377-78.

¹⁹ *Id.* at 377.

²⁰ *National Soc'y of Professional Engineers*, 435 U.S. at 695.

²¹ See, e.g., *In re Detroit Auto Dealers Ass'n*, 955 F.2d 457 (6th Cir. 1992), cert. denied, 506 U.S. 973 (1992).

²² 16 C.F.R. § 453.2(a), (b)(2)(B)(4) (2003).

²³ 16 C.F.R. § 310.3(a).

²⁴ *Id.*; Truth in Lending Act, 15 U.S.C. §§ 1601 et seq.

²⁵ 16 C.F.R. § 310.3(a)(3); see also Electronic Fund Transfer Act, 15 U.S.C. § 1693(b).

²⁶ 16 C.F.R. § 310.4(a)(4).

²⁷ See Letter to Gary Ruskin, Exec. Dir., Consumer Alert (June 27, 2002), available at <http://www.ftc.gov/os/closings/staff/commercialalertletter.htm> (last visited Aug. 8, 2003).

²⁸ *Id.*

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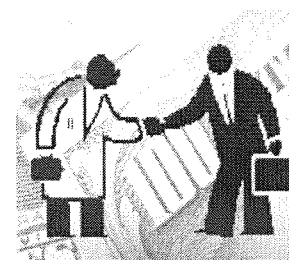
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