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

Office of Policy Planning
Bureau of Economics
Bureau of Competition

March 22, 2011

The Honorable Mark Formby
Representative, District 108
Mississippi House of Representatives
New Capitol, P.O. Box 1018
Jackson, MS 39215-1018

Dear Representative Formby:

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 the pharmacy benefit manager ("PBM") related provisions of Mississippi Senate Bill 2445 ("SB-2445" or "the Bill"). The Bill, among other things, would "shift regulatory authority over PBMs from the Insurance Commissioner to the Board of Pharmacy." You asked the FTC to examine the Bill to determine "whether the proposed legislation is anti-competitive and will likely result in the increased cost of pharmaceutical care for consumers."[2]

We are concerned that SB-2445, if enacted as passed by the Mississippi State Senate, may increase pharmaceutical prices and reduce competition. First, allowing the Pharmacy Board to regulate PBMs will likely undermine the PBM's ability to negotiate lower prices for prescription drugs, which in turn, will raise those prices for both insurers and consumers covered by insurance. Second, the Bill appears to allow the Pharmacy Board to obtain from PBMs financial and any other business information it desires and to provide that information to third parties.[3] If pharmaceutical manufacturers, pharmacists, and pharmacies gain access to whatever information the Pharmacy Board requires the

[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. Mark Formby to Jon Leibowitz, Chairman, Federal Trade Commission (March 1, 2011). This comment addresses SB-2445, as requested, but staff notes that similar legislation was passed by the Mississippi House of Representatives on March 3, 2011. It is our understanding that the two bills will be considered and reconciled by a conference committee and that these comments are being requested for the purpose of informing those discussions.

[3] SB-2445, Section 73-21-157 (2)(a-b).

PBMs to produce, they could have access to competitively sensitive information, potentially facilitate collusion, and increase prescription drug prices. Third, SB-2445 would change current law to require nonresident pharmacies that deliver prescription drugs to Mississippi residents to have a Mississippi-licensed pharmacist-in-charge.[4] This requirement would add to out-of-state pharmacies' expenses the fees and other costs associated with licensure, continuing education, and registration of a pharmacist in Mississippi, in addition to the costs imposed by requirements for pharmacists in the state in which the nonresident pharmacies operate.[5] These additional costs would likely be passed on to Mississippi consumers and health plans.

Interest and Experience of the Federal Trade Commission

Congress has charged the Federal Trade Commission ("FTC" or "Commission") with preventing 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 regulations that impede competition without offering countervailing benefits to consumers. For several decades, the FTC and its staff have investigated the competitive effects of restrictions on the business practices of health care providers,[7] issued reports and studies regarding various aspects of the pharmaceutical industry,[8] and brought numerous enforcement actions in the pharmaceutical industry.[9]

The Commission has significant expertise in the competitive issues surrounding PBMs. Of particular relevance to SB-2445 is the Commission's "Conflict of Interest Study" regarding PBM practices. In response to a Congressional directive in 2003, the FTC analyzed data on PBM pricing, generic substitution, therapeutic interchange, and repackaging practices. The study examined whether PBM ownership of mail-order pharmacies served to maximize competition and lower prescription drug prices for plan sponsors. In its 2005 report based on the study ("PBM Study"), the FTC found, among other things, that the prices for a common basket of prescription drugs dispensed by PBM-owned mail order pharmacies were typically lower than the prices charged by retail pharmacies.[10] The study also found competition affords health plans substantial tools with which to safeguard their interests. Consumers benefit as a result.

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[4] SB-2445, Section 73-21-106.

[5] The current law requires, among other things, registration of the non-resident pharmacy, which is generally a less-restrictive alternative to duplicative professional licensure.

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

[7] *See* Federal Trade Commission, *FTC Antitrust Actions in Health Care Services and Products* (Oct. 2003), *available at* http://www ftc.gov/bc/hcupdate031024.pdf.

[8] *See* Federal Trade Commission, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION (July 2002); DAVID REIFFEN AND MICHAEL R. WARD, GENERIC DRUG INDUSTRY DYNAMICS, Federal Trade Commission Bureau of Economics Working Paper No. 248 (Feb. 2002), *available at* http://www ftc.gov/be/econwork htm.

[9] *See* Federal Trade Commission, *FTC Antitrust Actions in Pharmaceutical Services and Products* (Oct. 2005), *available at* http://www ftc.gov/bc/0310rxupdate.pdf.

[10] *See* Federal Trade Commission, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER

This 2005 PBM study continued the FTC's ongoing experience with PBMs. PBM practices were a particular focus of hearings on health care markets jointly conducted by the FTC and the Department of Justice Antitrust Division ("DOJ") in 2003 ("Health Care Hearings").[11] In 2004, the FTC and DOJ issued a report based on the hearings, a Commission-sponsored workshop, and independent research.[12] In addition, FTC staff have analyzed and commented on proposed PBM legislation in several states.[13]

Background on PBMs

PBMs contract with health plans to manage the cost and quality of the plans' drug benefits. They act as clearinghouses for health plans, covered individuals, and retail pharmacies, and may provide a variety of related services. These include: 1) developing networks of local pharmacies; 2) providing access to mail order pharmacies; 3) developing drug formularies and negotiating discounts and rebates from drug companies in exchange for preferential placement in the formulary;[14] 4) providing analysis of physician prescribing patterns; and 5) providing treatment information and monitoring of covered individuals with certain chronic diseases.

Of particular relevance to SB-2445, PBMs negotiate drug prices with pharmacies participating in the PBMs' networks and payments for prescription drugs and services with health plan sponsors. In addition, contracts with health plan sponsors specify how the plan will share in any rebates or discounts the PBM obtains from pharmaceutical manufacturers.[15]

PHARMACIES, 23 (Aug. 2005) ("PBM STUDY"), *available at* http://www ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

[11] *See* Hearings on Health Care and Competition Law and Policy, June 26, 2003, *available at* http://www ftc.gov/ogc/healthcarehearings/030626ftctrans.pdf. ("Health Care Hearings") Subsequent references to the hearings will identify a panelist, affiliation (as of hearing date), and transcript page.

[12] *See* FEDERAL TRADE COMMISSION AND DEPARTMENT OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

[13] *See, e.g.*, Letter from FTC staff to New York Senator James L. Seward (March 31, 2009), *available at* http://www ftc.gov/os/2009/04/V090006newyorkpbm.pdf; Letter from FTC staff to New Jersey Assemblywoman Nellie Pou (Apr. 17, 2007), *available at* http://www ftc.gov/be/V060019.pdf; Letter from FTC staff to Virginia Delegate Terry G. Kilgore (Oct. 2, 2006), *available at* http://www ftc.gov/be/V060018.pdf.

[14] A formulary is a list of approved or preferred drugs for the plan.

[15] These payments are paid to the plan sponsor, retained by the PBM, or shared between them depending on the specifics of the contract between these parties. *See* PBM STUDY, *supra* note 10, at 59-60; John Richardson, Health Strategies Consultancy, Health Care Hearings, *supra* note 11, at 23-24 (PBMs "can be paid through administrative fees, share of rebates, or some combination."); Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 11, at 124. Typically, contracts also specify a plan's audit rights with respect to formulary and payment sharing. *See* PBM STUDY, *supra* note 10, at 58.

PBMs negotiate lower pharmacy costs by forming a preferred or exclusive network of retail pharmacies.[16] Retail pharmacies offer discounts to PBMs depending on the type and number of health plans covered by the PBM and the exclusivity of the network — the more exclusive the network, the higher the discount. This mechanism can make customer volume respond very strongly to prices, creating an incentive for pharmacies to bid aggressively on prescription drug prices and potentially reducing the prices that public and private health plans and consumers pay for pharmaceuticals.[17]

PBMs also use mail-order pharmacies to manage prescription drug costs. Many PBMs own mail-order pharmacies. Plan sponsors sometimes encourage patients with chronic conditions who require repeated refills to seek the discounts that 90-day prescriptions and high-volume mail-order pharmacies can offer. Mail-order pharmacies, including those owned by PBMs, compete directly with retail pharmacies.[18]

PBMs also establish relationships with pharmaceutical manufacturers, who compete to have their drugs placed on a PBM's formulary by offering discounts or rebates.

Likely Effects of SB-2445

Several provisions of the Bill could harm competition and consumers. First, the bill empowers the Pharmacy Board to regulate PBMs and may impede PBMs' ability to negotiate effectively contracts with pharmacies that save money for Mississippi health plans and consumers. Second, the Pharmacy Board would have vague and potentially unlimited authority to demand disclosures of sensitive PBM business information, without any confidentiality protections, which could restrict PBMs' ability to negotiate contracts with pharmaceutical manufacturers and pharmacies to provide the best prescription drug programs and prices for Mississippi consumers. Third, changing the law to require an out-of-state pharmacy to have a Mississippi licensed pharmacist-in-charge if it wants to sell prescription drugs to Mississippi consumers could raise the costs of doing business without any countervailing benefits. Collectively, these requirements may increase the prices that both public and private health plans, and ultimately Mississippi consumers, pay for prescription drugs.

(a) Shifting Regulatory Authority of PBMs from the Insurance Commissioner to the Pharmacy Board

[16] A PBM may have several networks that differ in degree or scope of exclusivity.

[17] *See* PBM STUDY, *supra* note 10, at 3; General Accounting Office, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* at 11 (Jan. 2003) ("GAO Report"), *available at* http://www.gao.gov/cgi-bin/getrpt?GAO-03-196 (noting when Blue Cross Blue Shield introduced a plan with a smaller network of retail pharmacies, it included deeper discounts in its retail pharmacy payments); Letter from FTC staff to Patrick C. Lynch, Rhode Island Attorney General and Juan M. Pichardo, Rhode Island Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations (Apr. 8, 2004), *available at* http://www ftc.gov/os/2004/04/ribills.pdf (discussing these issues more extensively).

[18] *See* PBM STUDY, *supra* note 10, at i, 18-19.

The current law places regulatory authority over PBMs with the Insurance Commissioner, who has discretion over what information PBMs must provide on their annual financial statements and reports. The Pharmacy Board currently receives copies of those annual reports. SB-2445 would shift the regulatory authority and power to the Pharmacy Board, which consists of seven members, all of whom must be pharmacists. Thus, pharmacists, who negotiate retail prescription drug prices with PBMs and compete against PBM-owned mail-order pharmacies, would now be regulating PBMs.

Although we offer no specific recommendations on the ideal structure for regulating PBMs,[19] it is our understanding that no other state has placed PBMs under the regulatory control of its pharmacy board.[20] Because pharmacists and PBMs have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulatory power over PBMs may create tensions and conflicts of interest for the pharmacy board.[21] Indeed, the antitrust laws recognize that there is a real danger that regulatory boards composed of market participants may pursue their own interests rather than those of the state.[22] We urge the Mississippi legislature to consider

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[19] We note that most professions, including medical professions, have self-regulatory boards whose principal function is to regulate the activities of their own profession. In many cases, the membership of these boards also includes members from outside the profession to represent the public interest, including consumers' interests. *See, e.g.*, HHS, BUREAU OF HEALTH PROFESSIONS, HEALTH RESOURCES AND SERVICES ADMINISTRATION THE PROFESSIONAL PRACTICE ENVIRONMENT OF DENTAL HYGIENISTS IN THE FIFTY STATES AND THE DISTRICT OF COLUMBIA, 2001 at 80-81 (2004), *available at* ftp://ftp.hrsa.gov/bhpr/workforce/dentalhygen.pdf ("Dental hygiene is idiosyncratic in that most health professions are self-regulated. Dental hygiene is largely under the purview of dentistry. This is not true for similarly situated medical professionals who are principally self-regulated. Only the physician assistant (PA) profession is, to some extent, governed by Boards of Medicine."). [Hereinafter HHS Dental Hygienists Report].

[20] *See generally* Richard Cauchi, National Conference of State Legislatures, Background Brief - 2007 State Legislation Affecting Pharmaceutical Benefit Managers (PBMs) (Feb. 5, 2007) (summarizing PBM legislation); National Conference of State Legislatures, Prescription Drug 2009 Enacted State Laws (Jan. 4, 2010), *available at*: http://www ncsl.org/default.aspx?tabid=18909 (same); National Community Pharmacists Association, LAWS THAT PROVIDE REGULATION OF THE BUSINESS PRACTICES OF PHARMACY BENEFIT MANAGERS, *available at:*
http://www ncpanet.org/pdf/leg/leg_pbm_business_practice_regulation.pdf (same).

[21] *See* Drug Topics: The Newsmagazine for Pharmacists, "Independent pharmacies must unify to fight PBM industry", Drug Topics E-News, Feb. 22, 2011, at
http://drugtopics.modernmedicine.com/drugtopics/Modern+Medicine+News/Independent-pharmacies-must-unify-to-fight-PBM-ind/ArticleStandard/Article/detail/708606 (discussing what pharmacists must do to fight PBM industry and citing the Mississippi bill, which "proposes to move the regulatory authority (over PBMs) from the Department of Insurance to the State Board of Pharmacy, which will be responsible for overseeing and issuing permits to every PBM. Fortunately, the State Board of Pharmacy understands the industry and some of its members are friends of independent pharmacy"). *See generally* HHS Dental Hygienists Report at 73,165 (HHS noted that "[t]he dental hygiene profession has progressed less quickly than most other health professions. This is largely due to the regulation of the profession of dentistry, a condition that is unusual in health regulation since most other professions are provided with autonomy in governing their constituents." HHS further noted "There is a demonstrated, adversarial relationship in organized professional circles between dental professionals and hygiene professionals.").

[22] *See* Patrick v. Burget, 486 U.S. 94, 100 (1988); Opinion of the Commission, North Carolina State Board of Dental Examiners at 9 (Feb. 8, 2011), *available at:*

this concern.

(b) Information Disclosures to the Pharmacy Board and Others

SB-2445 gives the Pharmacy Board complete discretion over what information PBMs must provide and allows the board to share that information with pharmacies and health plans. Moreover, there are no confidentiality provisions for sensitive financial or business information.[23] The bill requires each PBM to file an annual statement with the Pharmacy Board. This statement "shall be on forms prescribed by the board and shall include: (a) A financial statement of the organization, including its balance sheet and income statement for the preceding year; and (b) Any other information relating to the operations of the pharmacy benefit manager required by the board under this section."[24] Moreover, the bill authorizes the Board to "provide a copy of the financial examination to the person or entity who provides or operates the health insurance plan or to a pharmacist or pharmacy."[25]

These provisions could result in sharing competitively sensitive cost information among competing pharmacies and pharmaceutical manufacturers. In particular, such information sharing could undermine competition between pharmacies to be included in PBM networks and between pharmaceutical manufacturers to offer discounts to PBMs. Both outcomes could raise prescription drug prices for consumers. We note, however, that if there are appropriate confidentiality safeguards in place, health plan sponsors (and their consultants) may find specific cost information helpful as they seek to select among PBMs, understand their enrollees' prescription drug use, and ensure that they are receiving appropriate rebates from PBMs.

In some circumstances, sharing information among competitors may increase the likelihood of collusion or coordination on matters such as price or output.[26] The antitrust agencies have explained how coordinated interaction harms consumers: coordinated

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http://www ftc.gov/os/adjpro/d9343/110208commopinion.pdf.

[23] *But see* SB-2445 at § 73-21-107 (4) (unlike the provisions related to PBMs, this Section prevents the pharmacy board, without written consent, from inspecting drug wholesalers' "(a) Financial data; (b) Sales data other than shipment data; or (c) Pricing data").

[24] SB-2445 at § 73-21-157.

[25] SB-2445 at § 73-21-159 (3).

[26] FTC/DOJ GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS §3.31(b) (discussing potential harms to competition when competitors exchange or disclose sensitive business information). *See also* DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE, Statement 6 (Aug. 1996) (same); *available at* http://www.ftc.gov/bc/healthcare/industryguide/policy/hlth3s.pdf; Letter from FTC Staff to Sen. James L. Seward, New York Senate (Mar. 31, 2009) (disclosure of sensitive business data in one market segment may chill competition in multiple market segments); *available at* http://www ftc.gov/os/2009/04/V090006newyorkpbm.pdf; U.S. DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION, HORIZONTAL MERGER GUIDELINES §7 (2010) (describing anticompetitive effects of coordination among rivals), *available at* http://ftc.gov/os/2010/08/100819hmg.pdf [hereinafter FTC/DOJ HORIZONTAL MERGER GUIDELINES].

interaction "can blunt a firm's incentive to offer customers better deals by undercutting the extent to which such a move would win business away from rivals" and "also can enhance a firm's incentive to raise prices by assuaging the fear that such a move would lose customers to rivals."[27]

For example, pharmacies may compete with one another by offering deeper discounts or lower dispensing fees in order to be included in a PBM's limited network or to become a preferred provider. Knowing that rivals will see, and can respond to, one's prices can dilute incentives to bid aggressively. Thus, depending on the information the Board requires, the disclosure provisions may undercut the most efficient pharmacy network contracts, leading to higher prescription drug prices.

Similarly, if the Pharmacy Board requires PBMs to provide detailed information about their rebate arrangements with pharmaceutical manufacturers, then tacit collusion among the manufacturers may be more feasible.[28] Absent such knowledge, manufacturers have powerful incentives to bid aggressively for formulary position, because preferential formulary treatment offers the prospect of substantially increased sales. Disclosure of such confidential financial and business information thus may raise the price that Mississippi consumers pay for pharmaceutical coverage by harming competition among pharmaceutical companies for preferred formulary treatment.

In sum, allowing the Pharmacy Board to demand confidential business information from PBMs and to disclose it presents a significant threat to competition that could lead to higher prescription drug prices for Mississippi consumers.

(c) Requirement that Nonresident Pharmacies have a Mississippi-licensed Pharmacist-in-Charge

Section 73-21-106 of the Mississippi Code currently requires a nonresident pharmacy to register with the board. In addition, the nonresident pharmacy, among other things, must "[c]omply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed . . . [and] maintain at all times a valid unexpired license, permit or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident." SB-2445 would amend this section to add the requirement that the pharmacist-in-charge of a nonresident pharmacy "hold a Mississippi pharmacist license, be licensed to practice pharmacy in the state of residence of the nonresident pharmacy, and be current and in good standing with the licensing boards of both states."[29]

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[27] FTC/DOJ HORIZONTAL MERGER GUIDELINES §7.

[28] *See, e.g.*, Svend Albaek *et al.*, *Government Assisted Oligopoly Coordination? A Concrete Case*, 45 J. INDUS. ECON. 429 (1997).

[29] A nonresident pharmacy is "Any pharmacy located outside this state that ships, mails or delivers, in any manner, controlled substances or prescription or legend drugs or devices into this state." SB-2445, Section 73-21-106.

This additional requirement could increase the costs of mail-order pharmacies that provide pharmacy services to Mississippi consumers and potentially reduce the incentives or increase the costs for health plans and PBMs to offer mail order options to beneficiaries. As noted above, in its 2005 PBM Study, the FTC found that the prices for a common basket of prescription drugs dispensed by PBM-owned mail order pharmacies were typically lower than the prices charged by retail pharmacies.[30] Similarly, a Maryland study found that statutory impediments to the use of mail-order pharmacies for maintenance drugs can be costly for a State and its citizens.[31] In the absence of countervailing health and safety rationales for the new licensure requirement, FTC staff urges the Mississippi legislature to consider carefully whether requiring a nonresident pharmacy to employ a Mississippi-licensed pharmacist could unnecessarily hamper affordable access to pharmaceutical goods and services.

Conclusion

Our analysis of SB-2445 suggests that its passage may increase pharmaceutical prices for Mississippi consumers. FTC staff recommends that the Mississippi legislature seriously consider whether there are benefits to consumers from the additional, more restrictive regulations in SB-2445 that would outweigh the competitive harm and consumer costs identified herein. Finally, FTC staff recommends that if the Mississippi legislature concludes PBMs should be subject to additional oversight, that the legislature consider giving additional authority to the Mississippi Commissioner of Insurance rather than to the Board of Pharmacy.

We appreciate your consideration of these issues.

Respectfully submitted,

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Joseph Farrell, Director
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Richard A. Feinstein, Director
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[30] *See* PBM STUDY, *supra* note 10 at 23.

[31] *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), *available at* http://mhcc maryland.gov/legislative/mailorderrpt.pdf (noting 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%).