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BY HAND AND ELECTRONIC DELIVERY
Malcolm J. Broussard
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3388 Brentwood Drive
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Re: Notice of Intent re Regulatory Project 2018 – Pharmacy Benefit Managers
The Louisiana Register, Vol. 44, No. 05 (May 20, 2018)
Louisiana Board of Pharmacy

Dear Mr. Broussard:

On behalf of the Pharmaceutical Care Management Association ("PCMA"),[1] we thank you for the opportunity to submit data, views, and arguments at the June 25, 2018, public hearing of the Louisiana Board of Pharmacy ("the Board") in regards to the referenced matter. Our law firm has been retained by PCMA to respond on its behalf to the Board's publication of its Notice of Intent ("the Notice of Intent") in the *Louisiana Register*, Vol. 44, No. 05 (May 20, 2018) regarding the Board's proposed promulgation of a set of new rules ("the Proposed Rule") for the licensing and regulation of pharmacy benefit managers ("PBMs"). For the following reasons, PCMA respectfully opposes the promulgation of the Proposed Rule and asserts that the regulation of PBMs by the Board is neither warranted nor permitted under Louisiana or federal law. Accordingly, the Board should terminate this rulemaking proceeding.

I. Introduction

Since the enactment of Act No. 386 of the 2008 Regular Session of the Louisiana Legislature, PBMs have been regulated by the Louisiana Department of Insurance ("DOI")

[1] PCMA is a national trade association representing PBMs. Its mission is to lead the effort in promoting PBMs and the proven tools they utilize, which are recognized by consumers, employers, policymakers, and others as key drivers in lowering prescription drug costs and increasing access. PCMA monitors and advocates on a range of important health care issues that allow PBMs to continue:

1) Lowering pharmacy costs for America's employers and consumers;
2) Protecting affordability and choice in Medicare Part D;
3) Lowering pharmacy costs for Medicare seniors; and
4) Improving safety with specialty pharmacies.

https://www.pcmanet.org/our-industry/ (Last visited June 20, 2018).

pursuant to La. R.S. 22:1657, which provides that PBMs shall be deemed to be third-party administrators for purposes of the Insurance Code, La. R.S. 22:1, *et seq.*

On August 3, 2017, the Office of the Attorney General of the State of Louisiana issued an Opinion in response to an inquiry by Representative Robert Johnson regarding whether PBMs are subject to regulation by the Louisiana (sometimes "State") Board of Pharmacy.[2] In its Opinion, the Attorney General advised that PBMs may be subject to regulation by the Board depending on the specific facts of the situation.[3]

Thereafter, on May 20, 2018, the Board published a Notice of Intent in the *Louisiana Register*, indicating that it intends to promulgate new rules for the licensing and regulation of PBMs.[4] Pursuant to La. R.S. 37:1172(A), the Board is comprised of seventeen (17) members appointed by the governor, including sixteen (16) licensed pharmacists and one consumer representative.

In addition to delineating the activities that constitute a PBM service, and thus, subject a PBM to the jurisdiction of the Board,[5] the Proposed Rule also provides other regulations setting forth licensing procedures and providing for sanctions for non-compliance with the Rule.[6] In addition, the Notice of Intent states that the Proposed Rule (1) will have no effect on family earnings and budgets;[7] (2) will have no effect on health care;[8] (3) will not affect the ability of PBMs to provide the same level of service to individuals with developmental disabilities;[9] (4) will increase aggregate expenditures for PBMs conducting business in Louisiana by an estimated $6,000 in FY 19 and by $5,000 in subsequent fiscal years;[10] and (5) will not affect competition.[11]

II. Summary of the Argument

PCMA opposes the Board's promulgation of the Proposed Rule for several reasons. First, the Board does not have the statutory authority under La. R.S. 37:1162, or elsewhere in its practice act, to regulate PBMs because PBMs, for the most part, do not engage in pharmacy

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[2] Att'y Gen. Opinion No. 2017-0076.

[3] *Id.* at 22-23.

[4] *Louisiana Register*, Vol. 44, No. 05 (May 20, 2018), available at http://www.doa.la.gov/osr/REG/1805/1805.pdf.

[5] Proposed regulation LAC 46:LIII.2473.

[6] Proposed regulation LAC 46:LIII.2475.

[7] *Louisiana Register*, *supra* note 4, at 969.

[8] *Id.*

[9] *Id.* at 970.

[10] *Id.*

[11] *Id.*

operations affecting the public health, safety, and welfare of consumers. While PCMA acknowledges that the operation of mail-order services and specialized pharmacies by PBMs are subject to regulation by the Board because those activities fall within the scope of the statutory definition of the "practice of pharmacy", no other actions performed by PBMs fit within that definition. Significantly, the Board's history of not attempting to regulate PBMs, combined with DOI's consistent statutorily-authorized regulation of PBMs, suggests that the legislature never intended for PBMs to be regulated by the Board.

Second, the Notice of Intent published by the Board is deficient for several reasons. For example, the Notice does not contain a statement indicating whether the agency has prepared a preamble explaining the basis and rationale for the intended action, summarizing the information and data supporting the intended action, and providing information concerning how the preamble may be obtained. In addition, the Notice misstates the effects the Proposed Rule would have on family earnings and budgets. Furthermore, the Notice does not accurately depict the effects the Proposed Rule would have on health care. Moreover, the Notice mistakenly states that the Proposed Rule will not affect the ability of PBMs to provide the same level of service to individuals with developmental disabilities. Additionally, the Notice does not accurately represent the estimated costs to directly affected persons or nongovernmental groups. Also, the Notice erroneously states that the Proposed Rule will not affect competition.

Third, the Board and its market competitor members are not entitled to state-action antitrust immunity under *Parker v. Brown.* The State has not articulated a clear policy to allow the anticompetitive conduct that will result from the enactment of the Proposed Rule. In addition, the Board's actions taken by Board Member actors, who contract with and/or compete with PBMs, are not actively supervised by the State. Because the Board members are composed of market participants, state regulation is required in order for the Board to be entitled to state-action immunity. The Board has not indicated that the State of Louisiana, through its governor or some other elected official, intends to actively supervise the proposed rulemaking instead of merely rubberstamping the Proposed Rule.

Fourth, the Board members are prohibited by the Louisiana Code of Governmental Ethics from regulating PBMs due to conflicts of interests that such regulation would necessarily entail. The Board members stand to personally benefit from regulation of PBMs regardless of whether the regulation is favorable to the PBMs. Therefore, the Board is ethically prohibited from exercising regulatory control over PBMs.

Fifth, the Board's Proposed Rule is preempted by ERISA and the Medicare Part D statutes in regards to certain benefits administered by PBMs. Thus, the Board is prohibited from regulating PBMs to the extent the PBMs offer benefits that are covered by ERISA or Medicare Part D.

Finally, PBMs are already sufficiently regulated by DOI, headed by a popularly-elected commissioner of insurance, and thus, there is no need for additional, duplicative regulation by the Board. The Louisiana Legislature has consistently acknowledged DOI's regulatory authority over PBMs by amending the Insurance Code statutes that apply to PBMs. On the other hand, the

legislature has not taken *any* action suggesting that it believes the Board should be regulating PBMs in place of or in tandem with DOI.

Accordingly, PCMA respectfully submits that the Board should terminate this rulemaking proceeding as the Board's proposed regulation of PBMs is neither warranted nor authorized by law.

III. Factual and Procedural Background

A. The Role of Pharmacy Benefit Managers

A PBM is defined in the Insurance Code as "a person, business, or other entity and any wholly or partially owned or controlled subsidiary of such entity that administers the prescription drug or device portion of one or more health benefit plans on behalf of a third party, including plan sponsors, insurance companies, unions, and health maintenance organizations, in accordance with a pharmacy benefit management plan."[12] By contrast, the Proposed Rule defines a PBM as "any person or other entity who administers the prescription drug or device program of one or more health insurance plans on behalf of a third party in accordance with a pharmacy benefit program."[13] In turn, a "pharmacy benefit program" is defined as "a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services or drugs or devices to individuals who reside in or are employed in Louisiana."[14] In addition, the Federal Trade Commission ("the FTC") has explained,

> 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;[15] 4) providing analysis of physician prescribing patterns; and 5) providing treatment information and monitoring of covered individuals with certain chronic diseases.[16]

The FTC has explained the business model implemented by PBMs as follows:

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[12] La. R.S. 22:1641.

[13] Proposed regulation LAC 46:LIII.2471.

[14] *Id.*

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

[16] Letter from FTC Office of Planning, Susan S. Desanti, Director, Bureau of Economics; Joseph Farrell, Director, Bureau of Competition; and Richard A. Feinstein, Director to Mark Formby, Representative, District 108, Mississippi House of Representatives (March 22, 2011).

- PBMs negotiate lower pharmacy costs by forming a preferred or exclusive network of retail pharmacies. 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.

- 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.

- PBMs also establish relationships with pharmaceutical manufacturers, who compete to have their drugs placed on a PBM's formulary by offering discounts or rebates.[17]

While some pharmacies contract directly with PBMs, most pharmacies contract with pharmacy services administrative organizations ("PSAOs") to manage negotiations with PBMs.[18] As explained by the United States Government Accountability Office ("GAO"), "When a PSAO enters into a contract with a...PBM, the pharmacies in its network gain access to the... PBM contract – and the individuals it covers – by virtue of belonging to the PSAO's network."[19] Thus, "by providing access to multiple independent pharmacies, PSAOs enable...PBMs to expand and maintain networks in certain geographic areas – such as rural and underserved areas – where independent pharmacies are more likely to be located. Thus, PSAOs help...PBMs build networks of pharmacies to meet the needs of health plans and their enrollees and, in some cases, to satisfy federal requirements."[20] Although some pharmacies may not contract directly with PBMs, PSAOs – which do contract directly with PBMs – are often owned by pharmacy cooperatives.[21]

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[17] *Id.* (internal citations omitted).

[18] U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-176, PRESCRIPTION DRUGS: THE NUMBER, ROLE, AND OWNERSHIP OF PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS (January 2013), available at https://www.gao.gov/assets/660/651631.pdf.

[19] *Id.* at 9.

[20] *Id.* at 3.

[21] *Id.* at 24-25.

PBMs reduce prescription drug costs and improve convenience and safety for consumers, employers, unions, and government programs.[22] PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program ("FEHBP"), state government employee plans, managed Medicaid plans, and other health plans.[23] Notably, PBMs are projected to save employers, unions, government programs, and consumers $654 billion – up to 30 percent – on drug benefit costs over the next decade.[24]

As summarized by PCMA, PBMs reduce drug costs by:

1) offering Amazon-style home delivery of medications and creating select networks of more affordable pharmacies;
2) interacting electronically with pharmacists that are filling prescriptions to encourage the use of generics and more affordable brand medications;
3) negotiating discounts, payments, and rebates from drug manufacturers in exchange for the manufacturers' drugs placement on the preferred list of medication for various illnesses;
4) negotiating discounts from pharmacies in exchange for the pharmacy's placement on the preferred network for plan participants;
5) managing high-cost specialty medications; and
6) reducing waste and improving adherence.[25]

Notably, consumers with prescription drug coverage administered by a PBM pay between 15% and 50% less for drugs than do customers without insurance buying the exact same medications.[26]

In addition, several federal government agencies, including the FTC, the GAO, and the Congressional Budget Office, have analyzed the PBM industry to ascertain its effect on consumers and plan sponsors. All such studies have concluded that PBMs are beneficial to consumers and plan sponsors because they reduce the prices paid by consumers for prescription drugs.[27] For example, a 2005 study conducted by the FTC found that the prices for prescription

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[22] https://www.pcmanet.org/our-industry/ (Last visited June 20, 2018).

[23] *Id.*

[24] *Id.*

[25] *Id.*; Joanna Shepherd, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary*, 9 Nw. J. L. & Soc. Pol'y (2013).

[26] Shepherd, *supra* note 25, at 3, citing FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 36 (2005), available at http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

[27] Shepherd, *supra* note 25, at 10, citing FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 36 (2005), available at http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf; U.S. GOV'T ACCOUNTABILITY OFF., GAO-

medication dispensed by PBM-owned mail-order pharmacies were typically lower than the prices for the same medications charged by retail pharmacies.[28] The study also determined that the competition resulting from the efforts undertaken by PBMs affords health plans substantial tools that safeguard their interests, and that consumers benefit as a result.[29]

B. The Regulatory History of Pharmacy Benefit Managers

The federal government has not taken upon itself to regulate PBMs to the degree states have done so.[30] Beyond regulating PBMs to ensure that they do not violate antitrust laws, the FTC has found it unnecessary and, in fact, has written numerous papers opposing additional regulation of the PBM industry.[31] Likewise, the Federal Department of Labor, which is charged with regulating employee benefit plans, has refrained from exercising any regulatory authority over PBMs.[32] The hesitancy of these agencies to regulate the PBM industry is not surprising, as some regulatory scholars have opined that it would not be possible for preexisting administrative agencies to regulate the nuanced actions undertaken by PBMs that result in lower health care costs, and some of these scholars are even concerned that misguided actions by regulatory agencies who do not fully comprehend the complex business model utilized by the PBM industry could negatively impact the integrity of the health care system.[33]

All states that have chosen to regulate PBMs have done so through their respective insurance departments or commissions.[34] In fact, as more thoroughly discussed below, in Louisiana, PBMs are regulated by the Louisiana Department of Insurance ("DOI"), as a PBM is deemed to be a third-party administrator pursuant to La. R.S. 22:1657. However, in 2011, Mississippi became the first state to propose regulation of PBMs by its Board of Pharmacy.[35] In response to a letter sent to the FTC by a member of the Mississippi House of Representatives

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10-11, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES, available at http://www.gao.gov/cgi-bin/getrpt?GAO-03-196; CONG. BUDGET OFFICE, ISSUES IN DESIGNING A PRESCRIPTION DRUG BENEFIT FOR MEDICARE, 14, 40 tbl. 6 (2002), available at http://www.cbo.gov/ftpdocs/39xx/doc3960/10-30-PrescriptionDrug.pdf.

[28] Letter from FTC Office of Planning, *supra* note 16, at 2.

[29] *Id.*

[30] Shepherd, *supra* note 25, at 11, citing KEVIN C. GREEN, REGULATION OF PHARMACY BENEFIT MANAGERS: AN ECONOMIC ANALYSIS OF REGULATION AND LITIGATION AS AGENTS OF HEALTH CARE CHANGE 9 (January 2008), http://works.bepress.com/kevin_green/1.

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] *Id.*, at 12, citing EDWARD C. LAWRENCE, ET AL., AN OVERVIEW OF PHARMACY BENEFIT MANAGERS: FOCUS ON THE CONSUMER 15 (2012), available at http://www.rxobserver.com/wpcontent/uploads/2012/05/lawrencestudy.pdf.

[35] Letter from FTC Office of Planning, *supra* note 16, at 5.

asking whether the proposed regulation was anti-competitive and whether it would likely result in increased drug costs for consumers, the FTC expressed the following concerns:

- 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 [proposed regulation] 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. If pharmaceutical manufacturers, pharmacists, and pharmacies gain access to whatever information the Pharmacy Board requires the PBMs to produce, they could have access to competitively sensitive information, potentially facilitate collusion, and increase prescription drug prices.

- Third, [the proposed regulation] would change current law to require nonresident pharmacies that deliver prescription drugs to Mississippi residents to have a Mississippi-licensed pharmacist-in-charge. 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. These additional costs would likely be passed on to Mississippi consumers and health plans.[36]

The FTC also expressed concern over the fact that seven members of the Mississippi Board of Pharmacy are pharmacists, who negotiate retail prescription drug prices with PBMs and compete against mail-order pharmacies owned by PBMs.[37] These seven pharmacists would be regulating PBMs, which often have competitive and sometimes adversarial relationships.[38] This arrangement could create conflicts of interests for the members of the Pharmacy Board as "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."[39]

Despite the concerns raised by the FTC, the Mississippi Legislature amended its Pharmacy Practice Act in 2011 to provide regulatory authority to the Board of Pharmacy.[40]

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[36] *Id.* at 4.

[37] *Id.* at 5.

[38] *Id.*

[39] *Id.*

[40] *See*, Mississippi Pharmacy Practice Act, Miss. Code Ann. § 73-21-71, et seq. and Mississippi Pharmacy Benefit Prompt Pay Act, Miss. Code Ann. § 73-21-151 et seq.; *see specifically*, Miss. Code Ann. § 73-21-73, 83, 91, 106, 153, 157, 159.

However, that board has not elected to embark on a regulatory project, such as proposed in this Notice of Intent.

C. Louisiana Attorney General Opinion 2017-0076

On August 3, 2017, the Office of the Attorney General of the State of Louisiana ("the AG") issued an Opinion ("the AG Opinion") in response to an inquiry by Representative Robert Johnson regarding whether PBMs are subject to regulation by the Board.[41] In the AG Opinion, the AG notes that PBMs are regulated by DOI as third-party administrators under the Insurance Code, La. R.S. 22:1, *et seq.*, and that the Insurance Code defines "pharmacy benefits plan" or "pharmacy benefits program" to mean "a plan or program that pays for, reimburses, covers the cost of, *or otherwise provides for pharmacist services to individuals who reside in or are employed in Louisiana.*"[42] However, these terms are not defined in the Louisiana Pharmacy Practice Act, La. R.S. 37:1161, *et seq.*[43]

The AG states that pursuant to La. R.S. 37:1162, the legislative purpose behind the Louisiana Pharmacy Practice Act is "to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy; the licensure of pharmacists; and the licensure, permitting, certification, registration, control, and regulation of all persons or sites in or out of this state that sell drugs or devices to consumers and/or patients or assist in the practice of pharmacy within the state."[44] In turn, it is the responsibility of the Board to control and regulate the practice of pharmacy,[45] which is defined as "the compounding, filling, dispensing, exchanging, giving, offering for sale, or selling, drugs, medicines, or poisons, pursuant to prescriptions or orders of physicians, dentists, veterinarians, or other licensed practitioners, or any other act, service operation or transaction incidental to or forming a part of any of the foregoing acts, requiring, involving or employing the science or art of any branch of the pharmacy profession, study or training."[46]

Citing, though not fully analyzing, the United States Supreme Court's decision in *North Carolina State Board of Dental Examiners v. Federal Trade Commission* ("*N.C. State Bd. of Dental Exam'rs*"), the AG states that "[w]hether particular services or acts of a PBM constitute the Practice of Pharmacy is a determination to be made according to existing state law and by the

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[41] Att'y Gen. Opinion No. 2017-0076, *supra* note 2.

[42] *Id.* at 6, citing La. R.S. 22:1863(7) (emphasis in original).

[43] *Id.* at 10.

[44] *Id.* at 8.

[45] *Id.*, citing La. R.S. 37:1182.

[46] *Id.* at 9-10, citing La. R.S. 37:1164(43) (emphasis in original).

judiciary."[47] Therefore, "Consistent with the existing law provided in the Louisiana Pharmacy Practice Act, the Board has an obligation to regulate the practice of pharmacy and prevent the unauthorized Practice of Pharmacy, even if it is a PBM that is engaging in the Practice of Pharmacy."[48]

Noting PCMA's acknowledgement that a PBM is subject to regulation by the Board to the extent it operates mail-order services and special pharmacies,[49] the AG states that certain other activities performed by PBMs may, depending on the facts of each circumstance, constitute "dispensing" under the Pharmacy Practice Act,[50] which is defined as "the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient."[51] Critically, the term "dispense"... "necessarily includes a transfer of possession of a drug or device to the patient or the patient's agent."[52] The AG explains that certain "utilization review services" may involve "dispensing", and thus, comprise a pharmacy practice that is subject to regulation by the Board.[53] "Utilization review" type services are services PBMs provide in administering and implementing formularies for its clients and which may involve the interpretation, evaluation, and implementation of a prescription drug order.[54] Included within the ambit of "utilization review services" are the following:

- "Quality care dosing", which likely is encompassed by the definition of "drug regimen review", and whereby a PBM checks prescription drug before they are filled to ensure that the quantity and dosage is consistent with the recommendations of the Federal Food and Drug Administration.

- "Step therapy", which likely is encompassed by the definition of "drug regimen review", and whereby a PBM requires a patient to first try a certain drug to treat his or her health condition before using another drug for that condition.[55]

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[47] *Id.* at 17, citing *N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101, 191 L. Ed. 2d 35 (2015). As explained below, the Supreme Court's ruling in *N.C. State Bd. of Dental Exam'rs* actually supports PCMA's position that the Board is prohibited by federal antitrust law from regulating PBMs.

[48] *Id.* at 17-18.

[49] *Id.* at 18-19.

[50] *Id.* at 20-21.

[51] *Id.* at 11, citing La. R.S. 37:1164(11).

[52] *Id.*

[53] *Id.* at 20-21.

[54] *Id.*

[55] *Id.* at 20.

Alternatively, the AG states that even if "utilization review" services do not meet the definition of "dispensing", the services may still be subject to regulation by the Board if, depending upon the facts, the services are comprised of an "act, service operation or transaction incidental to or forming a part of any of the forgoing acts, requiring, involving or employing the science or art of any branch of the pharmacy profession, study or training."[56] The AG concludes the Opinion by again stating that such determinations are questions of fact and that such factual determinations are within the province of the judiciary, not the Attorney General's Office.[57]

D. Notice of Intent Issued By the Louisiana Board of Pharmacy

In its Notice of Intent published on May 20, 2018 in the *Louisiana Register*, the Board indicates that it intends to promulgate new rules for the licensing and regulation of PBMs. In the Notice of Intent, the following activities are identified by the Board as pharmacy benefit management services ("PBM services"), the performance of which would require a PBM to obtain a permit from the Board *prior* to rendering services:

1) development, maintenance, and/or administration of drug formularies;
2) development, maintenance, and/or administration of step therapy procedures;
3) development, maintenance, and/or administration of utilization management and utilization reviews;
4) development, maintenance, and/or administration of drug regimen reviews;
5) development, maintenance, and/or administration of quality care dosing services;
6) development, maintenance, and/or administration of prescription drug management programs and the contracting with pharmacies for same;
7) development, maintenance, and/or administration of disease management programs;
8) administration, processing, and/or payment of claims for prescription drugs;
9) processing of prior authorization requests;
10) adjudication of appeals and/or grievances related to prescription drug coverage; and
11) any other act, service, operation, or transaction incidental to or forming a part of the compounding, filling, dispensing, exchanging, giving, offering for sale, or selling drugs, medicines, poisons or devices in this state by pharmacists or pharmacies, pursuant to a prescription or an order of physicians, dentists, veterinarians, or other licensed practitioners, requiring, involving, or employing the science or art of any branch of the pharmacy profession, study, or training.[58]

In addition to delineating those activities that constitute PBM services, and thus, subject a PBM to the jurisdiction of the Board,[59] the Proposed Rule also provides regulations setting forth

[56] *Id.* at 22, citing La. R.S. 37:1164(43).

[57] *Id.* at 22-23.

[58] Proposed regulation LAC 46:LIII.2473.

[59] Proposed regulation LAC 46:LIII.2473.

licensing procedures;[60] sanctions for adversely affecting or impairing the health, safety, and welfare of consumers and other beneficiaries of the pharmacy benefit program administered by PBMs;[61] and sanctions for directly impairing the ability of a pharmacist or pharmacy to compound, fill, dispense, exchange, give, offer for sale, or sell drugs, medicines, poisons or devices to consumers and other beneficiaries of the pharmacy benefit program administered by PBMs.[62] Furthermore, the Proposed Rule states that "Louisiana pharmacy laws shall be applicable to regulation of the practice of pharmacy for that portion of the permitted pharmacy benefit manager's Louisiana pharmacy practice or operation."[63]

Finally, the Notice of Intent states that the Proposed Rule (1) will have no effect on family earnings and budgets;[64] (2) will have no effect on health care;[65] (3) will not affect the ability of PBMs to provide the same level of service to individuals with developmental disabilities;[66] (4) will increase aggregate expenditures for PBMs conducting business in Louisiana by an estimated $6,000 in FY 19 and by $5,000 in subsequent fiscal years;[67] and (5) will not affect competition.[68]

IV. Law and Argument

A. The Louisiana Board of Pharmacy Does Not Have the Statutory Authority to Regulate Pharmacy Benefit Managers.

The legislative declaration set forth in La. R.S. 37:1162 provides,

> The practice of pharmacy in the state of Louisiana is declared a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. Therefore, any rule or regulation adopted relative to pharmacists and the operations of pharmacies, including any amendment, modification, or repeal thereof, shall be adopted as provided by the Administrative Procedure Act and shall be effective only upon approval by the respective oversight committees having jurisdiction over matters relative to pharmacists and

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[60] Proposed regulation LAC 46:LIII.2475.

[61] Proposed regulation LAC 46:LIII.2477.

[62] *Id.*

[63] *Id.*

[64] *Louisiana Register*, *supra* note 4, at 969.

[65] *Id.*

[66] *Id.* at 970.

[67] *Id.*

[68] *Id.*

> the operation of pharmacies. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this Chapter, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy. This Chapter shall be liberally construed to carry out these objectives and purposes.

i. For the Most Part, Pharmacy Benefit Managers Do Not Engage in the Practice of Pharmacy.

La. R.S. 37:1164(43) defines the "practice of pharmacy" or the "practice of the profession of pharmacy" as "the compounding, filling, dispensing, exchanging, giving, offering for sale, or selling, drugs, medicines, or poisons, pursuant to prescriptions or orders of physicians, dentists, veterinarians, or other licensed practitioners, or any other act, service operation or transaction incidental to or forming a part of any of the foregoing acts, requiring, involving or employing the science or art of any branch of the pharmacy profession, study or training."

While PCMA acknowledges that the operation of mail-order services and specialized pharmacies by PBMs are subject to regulation by the Board because those activities fall within the scope of the statutory definition of the "practice of pharmacy", no other actions performed by PBMs fit within that definition. [69]As explained above, aside from operating mail-order services and special pharmacies, PBMs reduce drug costs by creating select networks of more affordable pharmacies; interacting electronically with pharmacists that are filling prescriptions to encourage the use of generics and more affordable brand medications; negotiating discounts, payments, and rebates from drug manufacturers in exchange for the manufacturers' drugs placement on the preferred list of medications for various illnesses; negotiating discounts from pharmacies in exchange for the pharmacy's placement on the preferred network for plan participants; managing high-cost specialty medications; and reducing waste and improving adherence.[70] These acts do not effortlessly fit within the definition of "practice of pharmacy" set forth by the legislature.

Despite the AG's tortured attempts to include "utilization review" services within the ambit of the practice of pharmacy, the AG admits that it is not in possession of the facts required in order for the AG to determine whether such services do, in fact, constitute pharmacy practices.[71] The AG correctly notes that the AG's Office is not a trier of fact and that factual determinations are reserved for the judiciary.[72] Therefore, the AG admittedly rendered conclusory advice without being in possession of the facts required to formulate an educated opinion. Accordingly, no deference should be shown to the AG Opinion. A literal application of

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[69] Indeed, all PBMs conducting these activities have long had employees apply for and hold BOP-issued pharmacist licenses.

[70] https://www.pcmanet.org/our-industry/ (Last visited June 20, 2018).

[71] Att'y Gen. Opinion No. 2017-0076, *supra* note 2, at 22-23.

[72] *Id.*

La. R.S. 37:1164(43) to the additional activities undertaken by PBMs reveals that PBMs, without question, do not engage in the practice of pharmacy outside of operating mail-order services and special pharmacies. Accordingly, the Board of Pharmacy does not have the statutory authority to regulate PBMs.

ii. In Accordance With the Contemporaneous Construction Principle, Pharmacy Benefit Managers Were Never Intended to Be Subjected to Regulation By the Louisiana Board of Pharmacy, nor has the Board attempted to regulate them under the existing statutory regime.

As noted by the Louisiana Supreme Court, the contemporaneous construction principle gives "substantial and often decisive weight" to an agency's long-standing interpretation.[73] The Supreme Court in *Coastal Drilling Co., LLC v. Dufrene* affirmed a "time-endured construction" by the Department of Revenue, which had been in existence since 1987, and determined that the Department's construction of the regulation "may reasonably be presumed to be in accord with the legislative intent."[74] As explained by the Supreme Court in *Traigle v. PPG Industries, Inc.*,

> [A]n administrative construction cannot have weight where it is contrary to or inconsistent with the statute. However, where the statute is ambiguous…a long settled contemporaneous construction by those charged with administering the statute is given substantial and often decisive weight in its interpretation.
>
> This is especially so where, as here, the administrative construction has consistently been followed since adoption of the statute over twenty years ago. In the absence of legislative amendment during that long period, the administrative construction may reasonably be presumed to be in accord with the legislative intent; it also being a reasonable meaning of the legislative language in the light of the legislative purpose evidenced by the statute as a whole.[75]

In addition, in *Southern Message Service, Inc. v. Louisiana Public Service Commission*, the Supreme Court stated, "The interpretation placed upon an ambiguous statute by the agency charged with its enforcement, when adopted soon after the enactment of the statute and adhered

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[73] *Coastal Drilling Co., LLC v. Dufrene*, 2015-1793 (La. 3/15/16); 198 So.3d 108, 116, citing *Traigle v. PPG Industries, Inc.*, 332 So.2d 777, 782 (La. 1976).

[74] *Id.*, citing *Traigle*, 332 So.2d at 782.

[75] *Traigle*, 332 So.2d at 782, citing *Roberts v. City of Baton Rouge*, 236 La. 521, 108 So. 2d 111 (1958); *Esso Standard Oil Co. v. Crescent River Port P. Assn.*, 235 La. 937, 106 So. 2d 316 (1958); *Tennessee Gas Transmission Co. v. Violet Trapping Co.*, 248 La. 49, 176 So. 2d 425 (1965); 3 SUTHERLAND, STATUTORY CONSTRUCTION, § 66.04 (4th (Sands) ed., 1974).

to over a long period of time, can be persuasive as to the proper interpretation of the statute."[76] Furthermore, "The legislature is presumed to know of the construction adopted, and the long continuance of the interpretation without any sign of legislative disapproval warrants the adoption of that construction by the courts."[77]

In line with the cases cited above, the definition of "practice of pharmacy" set forth in La. R.S. 37:1164(43) has long been interpreted to ***not*** include activities performed by PBMs. In 2008, with the enactment of Act No. 386, PBMs were regulated for the first time by the DOI pursuant to the provisions of the Insurance Code. Not only did the Board not attempt to regulate PBMs at that point, it expressly recognized DOI's authority to regulate PBMs in a Bulletin it published on August 15, 2008.[78] Ten years have elapsed since PBMs have been regulated in the State of Louisiana, and the Board has not taken any action to indicate that it believes the activities undertaken by PBMs are subject to the Board's regulation. Likewise, DOI, pursuant to the unambiguous authority granted to it by La. R.S. 22:1657, has consistently regulated PBMs since the date the statute became effective.

As explained by the Louisiana Supreme Court in *Coastal Drilling Co., LLC*, such "time-endured construction[s]" of the respective statutes rendered by the Board and DOI "may reasonably be presumed to be in accord with the legislative intent."[79] After all, "the long continuance of the interpretation" of the two statutes "without any sign of legislative disapproval warrants the adoption of that construction by the courts."[80] The Board's history of not attempting to regulate PBMs, combined with DOI's consistent statutorily-authorized regulation of PBMs, suggests that the legislature ***never*** intended for PBMs to be regulated by the Board.

Indeed, the BOP and DOI have existed quite nicely in their respective statutory spheres of authority. The Board's attempt to regulate outside of its existing "swim lane" clearly violates the regulatory deference this Board historically afforded to DOI, without meaningful or legal articulation of why such monumental change of position is in the public interest.

B. The Notice of Intent Published by the Board Is Deficient.

La. R.S. 953 provides, in pertinent part,

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[76] *Southern Message Service, Inc. v. Louisiana Public Service Com.*, 554 So.2d 47, 54 (La. 1989), citing *Traigle*, 332 So. 2d 777; *Roberts*, 108 So. 2d 111 ; 2A N. SINGER, SUTHERLAND STATUTORY CONSTRUCTION § 49.03 (4th ed. 1984).

[77] *Id.* at 54, citing *Washington v. St. Charles Par. Sch. Bd.*, 288 So. 2d 321 (La.1974); *Dominion Land Co. v. Stark*, 156 La. 124, 100 So. 244 (1924).

[78] *Louisiana Board of Pharmacy Bulletin*, No. 08-03 (August 15, 2008), available at http://www.pharmacy.la.gov/assets/docs/Bulletins/Bulletin_08-03.pdf.

[79] *Coastal Drilling Co., LLC*, 198 So.3d at 116, citing *Traigle*, 332 So.2d at 782.

[80] *Southern Message Service, Inc.*, 554 So.2d at 54 (internal citations omitted).

A. Prior to the adoption, amendment, or repeal of any rule, the agency shall:

(1)(a) Give notice of its intended action and a copy of the proposed rules at least ninety days prior to taking action on the rule. The notice shall include:

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(iii) A statement, approved by the legislative fiscal office, of the economic impact of the intended action, if any; or a statement, approved by the legislative fiscal office, that no economic impact will result from such proposed action;

***

(vii) A statement indicating whether the agency has prepared a preamble which explains the basis and rationale for the intended action, summarizes the information and data supporting the intended action, and provides information concerning how the preamble may be obtained.
***

(viii) A statement concerning the impact on family formation, stability, and autonomy as set forth in R.S. 49:972.[81]

(ix) A statement concerning the impact on child, individual, or family poverty in relation to individual or community asset development as set forth in R.S. 49:973.[82]

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[81] La. R.S. 49:972 provides, in pertinent part,

A. Prior to the adoption and implementation of rules, each state agency shall consider and state in writing the impact of such rules on family formation, stability, and autonomy. This written consideration shall be known as the "family impact statement".

B. The family impact statement will consider and respond in writing to the following regarding the proposed rule:

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(4) The effect on family earnings and family budget.

[82] La. R.S. 49:973 provides, in pertinent part,

A. In the formation of rules, each state agency shall consider and state in writing the impact of such rules on child, individual, or family poverty in relation to individual or community asset development prior to the adoption and implementation of such rules. This written consideration shall be known as the "poverty impact statement".
B. The poverty impact statement shall consider and respond in writing to the following regarding the proposed rule:

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> (3)(a) For the purposes of this Subsection, the statement of fiscal impact shall be prepared by the proposing agency and submitted to the Legislative Fiscal Office for its approval. Such fiscal impact statement shall include a statement of the receipt, expenditure, or allocation of state funds or funds of any political subdivision of the state.
>
> (b) For the purposes of this Subsection, the statement of economic impact shall be prepared by the proposing agency and submitted to the Legislative Fiscal Office for its approval. Such economic impact statements shall include an estimate of the cost to the agency to implement the proposed action, including the estimated amount of paperwork; an estimate of the cost or economic benefit to all persons directly affected by the proposed action; an estimate of the impact of the proposed action on competition and the open market for employment, if applicable; and a detailed statement of the data, assumptions, and methods used in making each of the above estimates.

In addition, the Notice of Intent contains a "Provider Impact Statement", which states, in pertinent part,

> In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities.
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> ***
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> 3. The overall effect on the ability of the provider to provide the same level of service. The proposed Rule will have no effect on the ability of the provider to provide the same level of service.[83]

i. The Notice Does Not Contain a Statement Indicating Whether the Agency Has Prepared a Preamble Explaining the Basis and Rationale for the Intended Action, Summarizing the Information and Data Supporting the Intended Action, and Providing Information Concerning How the Preamble May Be Obtained.

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(5) The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

[83] *Louisiana Register*, *supra* note 4, at 970.

At the outset, PCMA notes that the Notice of Intent published by the Board does not comply with La. R.S. 49:953(A)(1)(a)(vii) because it does not contain a statement that (1) indicates whether the agency has prepared a preamble which explains the basis and rationale for the intended action; (2) summarizes the information and data supporting the intended action; and (3) provides information concerning how the preamble may be obtained. Even if no such preamble is available, the Board is still obligated pursuant to the plain language of the statute to notify the public that no preamble exists. Without this information, the Board's Notice of Intent is facially deficient.

ii. The Notice of Intent Misstates the Effects the Proposed Rule Would Have on Family Earnings and Budgets.

In its Notice of Intent, the Board includes a Family Impact Statement in accordance with La. R.S. 49:953(A)(1)(a)(viii), in which it states, "The proposed Rule will have no effect on family earnings or family budget."[84] This statement is woefully inaccurate. As explained by one scholar,

> [W]hen PBMs negotiate price discounts for prescription drugs at network pharmacies, they put direct pressure on the profits of both network and non-network pharmacies. In addition, when PBMs attract customers to mail-order pharmacies with lower drug costs, they reduce the number of prescriptions filled at retail pharmacies. Granting Boards of Pharmacy regulatory control over PBMs creates an inherent conflict of interest by giving pharmacists regulatory control over their natural competitors in the marketplace. Under this new regulatory scheme, a Board has both the incentive and the power to exercise its regulatory power in ways that weaken PBMs' competitive positions, and in turn, benefit pharmacies. The power to regulate a market adversary gives pharmacists unprecedented power and will severely undercut competition in the prescription drug market. Moreover, ***this regulatory scheme will increase the prices of prescription drugs for*** both ***consumers*** and health plan sponsors.[85]

Furthermore, as explained by the Federal Trade Commission, "***[A]llowing 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***." [86] In addition, regulation of PBMs by the Board 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

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[84] *Id.* at 969.

[85] Shepherd, *supra* note 25, at 3 (emphases added).

[86] Letter from FTC Office of Planning, *supra* note 16, at 4 (emphases added).

requirements for pharmacists in the state in which the nonresident pharmacies operate. ***These additional costs would likely be passed on to*** Mississippi ***consumers*** and health plans."[87]

Thus, there can be no question that the implementation of the Proposed Rule by the Board will, in fact, affect family earnings and budgets. As shown in the preceding paragraphs, the Board's regulation of PBMs will ultimately result in families having to pay higher prices for medications, which will reduce their earnings and provide greater strain on their budgets. Therefore, the Board's Family Impact Statement is simply inaccurate.

iii. The Notice of Intent Does Not Accurately Depict the Effects the Proposed Rule Would Have on Health care.

In the Poverty Impact Statement included in its Notice of Intent pursuant to La. R.S. 49:973(A)(1)(a)(ix), the Board states, "The proposed Rule will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance."[88]

For all the reasons discussed above, the cost of health care will ultimately rise should the Proposed Rule be adopted and the Board be permitted to regulate PBMs. Regulation of PBMs by the Board will also result in increased costs on health plans,[89] thus resulting in higher health care costs for individuals. Consumers can expect to see significant increases in drug prices due to the chilling effect the Proposed Rule has on the ability of PBMs to negotiate lower prices, thus also impacting purchasers who buy prescriptions without insurance thus pay cash. For this reason, cash customers will see an increase in the costs of their medications should the Proposed Rule be adopted. Accordingly, the Board's Poverty Impact Statement is also inaccurate because the enactment of the Proposed Rule will most certainly cause health care costs to rise.

iv. The Notice of Intent Mistakenly States That the Proposed Rule Will Not Affect the Ability of PBMs to Provide the Same Level of Service to Individuals with Developmental Disabilities.

In its Provider Impact Statement, the Board states, "The proposed Rule will have no effect on the ability of the provider to provide the same level of service" to individuals with developmental disabilities[90] For the reasons discussed above, the ability of PBMs to provide services (such as drug cost-lowering mechanisms) to all individuals, including those with disabilities, will be diminished should PBMs be subjected to regulation by the Board.

v. The Notice of Intent Does Not Accurately Represent the Estimated Costs to Directly Affected Persons or Nongovernmental Groups.

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[87] *Id.* (emphases added).

[88] *Louisiana Register*, *supra* note 4, at 969.

[89] Shepherd, *supra* note 25, at 3; Letter from FTC Office of Planning, *supra* note 16, at 4.

[90] *Louisiana Register*, *supra* note 4, at 970.

In its Fiscal and Economic Impact Statement for Administrative Rules, the Board explains, "The proposed rules will increase aggregate expenditures for PBMs conducting business in Louisiana by an estimated $6,000 in FY 19 and by $5,000 in subsequent fiscal years. PBMs operating in Louisiana will be subject to an initial $150 permit fee in FY 19 and a $125 permit renewal fee in subsequent fiscal years. With an assumption of 40 such entities seeking a credential, the Board anticipates PBMs' costs to be $6,000 in FY 19 (40 permits at $150 initial permit fee) and $5,000 per year thereafter (40 permits at $125 permit renewal fee).[91]

The Board has underestimated the negative cost effects that the enactment of the Proposed Rule would have on affected persons or nongovernmental groups. As stated above, the FTC has expressly noted that regulation of PBMs by a Board of Pharmacy would "add to out-of-state pharmacies' expenses the fees and other costs associated with licensure, continuing education, and registration of a pharmacist…in addition to the costs imposed by requirements for pharmacists in the state in which the nonresident pharmacies operate."[92] While these additional costs may be passed on to consumers and health plans, they do comprise "estimated costs to directly-affected persons or nongovernmental groups."

vi. The Notice of Intent Erroneously States That the Proposed Rule Will Not Affect Competition.

Also in its Fiscal and Economic Impact Statement for Administrative Rules, the Board explains, "The proposed rule will not affect competition or employment."[93] This statement is perhaps the Board's most erroneous assertion. As more thoroughly discussed in the following section, there can be no question that the enactment of the Proposed Rule would result in an impermissible restraint on competition in violation of federal antitrust law.

C. The Louisiana Board of Pharmacy Is Not Entitled to State-Action Antitrust Immunity under *Parker v. Brown*.

In the seminal case of *Parker v. Brown*, the United States Supreme Court held that the Sherman Act[94] does not apply to anticompetitive conduct undertaken by states in their sovereign capacity.[95] This principle, known as the "state action doctrine", has also been applied on antitrust cases brought by the FTC pursuant to Section 5 of the FTC Act, 15 U.S.C. § 45.[96]

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[91] *Id.*

[92] Letter from FTC Office of Planning, *supra* note 16, at 4.

[93] *Louisiana Register*, *supra* note 4, at 970.

[94] As stated by the United States Supreme Court in *N.C. State Bd. of Dental Exam'rs*, "The Sherman Act, 26 Stat. 209, as amended, 15 U.S.C. §1 *et seq.*, services to promote robust competition, which in turn empowers the States and provides their citizens with opportunities to pursue their own and the public's welfare." 135 S. Ct. at 1104, citing *FTC v. Ticor Title Ins. Co.*, 504 U.S. 621, 632, 112 S. Ct. 2169, 119 L. Ed. 2d 410 (1992).

[95] *Parker v. Brown*, 317 U.S. 341, 350-51 (1943).

[96] *In re Louisiana Real Estate Appraisers Board*, Opinion of the Commission, FTC Docket No. 9374 (April 10, 2018).

However, in order for a private party to avail itself of the state action doctrine, two conditions must be met.[97] First, the challenged restraint must be clearly articulated and affirmatively expressed as state policy.[98] This requirement is satisfied "where the displacement of competition [is] the inherent, logical, or ordinary result of the exercise of authority delegated by the state legislature. In that scenario, the State must have foreseen and implicitly endorsed the anticompetitive effects as consistent with its policy goals."[99] Second, the policy must be actively supervised by the State itself.[100] The requirement demands, *inter alia*, "that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy."[101]

The Supreme Court in *N.C. State Bd. of Dental Exam'rs* explained that the first requirement – clear articulation – rarely will be sufficient to establish whether an anticompetitive policy is indeed the policy of a state, "for a policy may satisfy this test yet still be defined at so high a level of generality as to leave open critical questions about how and to what extent the market should be regulated."[102] After all, "Entities purporting to act under state authority might diverge from the State's considered definition of the public good," and "[t]he resulting asymmetry between a state policy and its implementation can invite private self-dealing."[103]

The second requirement – active supervision – "seeks to avoid [private self-dealing] by requiring the State to review and prove interstitial policies made by the entity claiming immunity."[104] This requirement "stems from the recognition that '[w]here a private party is engaging in anticompetitive activity, there is a real danger that he is acting to further his own interest, rather than the governmental interests of the State.'"[105] Moreover, the requirement "does not question the good faith of state officers but rather is an assessment of the structural risk of market participants' confusing their own interests with the State's policy goals."[106] The Court then explained that although the adequacy of supervision is dependent on all the circumstances

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[97] *N.C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1111-12, citing *California Retail Liquor Dealers Assn. v. Midcal Aluminum, Inc.*, 445 U.S. 97, 100 S. Ct. 937, 63 L. Ed 2d 233.

[98] *N.C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1112, citing *Ticor*, 504 U.S. at 631, *Midcal*, 445 U.S. at 105.

[99] *Id.* at 1112, citing *FTC v. Phoebe Putney Health Sys.*, 133 S. Ct. 1003, 1013 (2013).

[100] *Id.*, citing *Ticor*, 504 U.S. at 631, *Midcal*, 445 U.S. at 105.

[101] *Id.*, citing *Patrick v. Burget*, 486 U.S. 944, 100 (1988).

[102] *Id.*, citing *Ticor*, 504 U.S. at 636-37.

[103] *Id.*

[104] *Id.*

[105] *Id*, citing *Patrick*, 486 U.S. at 101.

[106] *Id.* at 1114, citing *Patrick*, 486 U.S. at 100-01.

of a case, the Court has "identified only a few constant requirements of active supervision," which are as follows:[107]

1) The supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it;[108]
2) The supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy;[109]
3) The "mere potential for state supervision is not an adequate substitute for a decision by the State;"[110] and
4) The state supervisor may not itself be an active market participant.[111]

In *N.C. State Bd. of Dental Exam'rs*, which was referenced but not adequately analyzed in the AG Opinion,[112] the United States Supreme Court held that because a controlling number of the North Carolina State Board of Dental Examiners' decision-makers are active market participants in the occupation the Board regulates, the Board can invoke state-action antitrust immunity only if it was subject to active supervision by the State.[113] The FTC had filed an administrative complaint accusing the Board of Dental Examiners of violating federal antitrust law as the Board had issued cease-and-desist letters to non-dentists who provided teeth-whitening and manufacturers of whitening products and taken other actions with the intention of deterring non-dentists from offering teeth-whitening services.[114] While North Carolina law authorized the Board to regulate dentistry, it did not address whether teeth-whitening constitutes the practice of dentistry.[115] The Board moved to dismiss on the grounds of state-action immunity.[116]

An Administrative Law Judge ("ALJ") denied the Board's motion to dismiss, and the FTC on appeal sustained the ALJ's ruling, finding that in order to claim immunity, the Board must be actively supervised by the State.[117] The ALJ then conducted a hearing on the merits and

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[107] *Id.* at 1116-17.

[108] *Id.* at 1116, citing *Patrick*, 486 U.S. at 102-03.

[109] *Id.*

[110] *Id.*, citing *Ticor*, 504 U.S. at 638.

[111] *Id.* at 1117.

[112] Att'y Gen. Opinion No. 2017-0076, *supra* note 2, at 17, citing *N.C. State Bd. of Dental Exam'rs*, 135 S. Ct. 1101.

[113] *N.C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1104.

[114] *Id.* at 1108.

[115] *Id.* at 1104.

[116] *Id.* at 1109.

[117] *Id.*

determined that the Board had violated antitrust law by unreasonably restraining trade.[118] The FTC once again affirmed the ALJ's ruling, thus rejecting the Board's public safety justification in light of the "wealth of evidence suggesting that non-dentist provided teeth-whitening is a safe cosmetic procedure."[119] The United States Court of Appeals for the Fourth Circuit affirmed the FTC in all respects, and the Supreme Court granted certiorari.[120]

The Supreme Court held that the Board did not qualify for state-action immunity because it was controlled by active market participants due to the fact that six of the eight Board members were dentists.[121] Therefore, the State was required to actively supervise the Board – which it did not do – when the Board determined that teeth-whitening constituted the practice of dentistry and implemented anticompetitive measures to deter non-dentists from offering such services.[122] The Court explained,

> The Board does not contend in this Court that its anticompetitive conduct was actively supervised by the State or that it should receive Parker immunity on that basis.
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> By statute, North Carolina delegates control over the practice of dentistry to the Board. ***The Act, however, says nothing about teeth-whitening, a practice that did not exist when it was passed***. After receiving complaints from other dentists about the non-dentists' cheaper services, the Board's dentist members – some of whom offered whitening services – acted to expel the dentists' competitors from the market. In so doing the Board relied upon cease-and-desist letters threatening criminal liability, rather than any of the powers at its disposal that would invoke oversight by a politically accountable official. ***With no active supervision by the State, North Carolina officials may well have been unaware that the Board had decided teeth-whitening constitutes "the practice of dentistry" and sought to prohibit those who competed against dentists from participating in the teeth-whitening market.*** Whether or not the Board exceeded its powers under North Carolina law…***there is no evidence here of any decision by the State to initiate or concur with the Board's actions against the non-dentists.***[123]

In a recent FTC enforcement case involving a Louisiana agency, the Louisiana Real Estate Appraisers Board ("the LREAB"), the FTC opined that the LREAB did not qualify for

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[118] *Id.*

[119] *Id.* (internal citation omitted).

[120] *Id.* (internal citation omitted).

[121] *Id.* at 1108, 1110.

[122] *Id.* at 1110.

[123] *Id.* at 1116 (emphases added) (internal citation omitted).

state-action antitrust immunity under *Parker v. Brown* because the agency's anticompetitive actions were not actively supervised by the State of Louisiana.[124] FTC complaint counsel has alleged and proven that such regulation has displaced competition and caused prices Louisiana customers paid for appraisal services to *rise*. In that matter, the LREAB – which consists of ten members, eight of which were required by statute to be licensed appraisers – adopted and subsequently enforced a regulation that had the effect of restraining price competition for appraisal services provided to appraisal management companies ("AMCs").[125] After the FTC filed its Complaint alleging that the regulation violated antitrust law because the State of Louisiana did not supervise the LREAB's anticompetitive conduct, Louisiana officials and the LREAB engaged in certain actions with the goal of increasing state supervision over the LREAB's conduct.[126] Specifically, the Governor issued an executive order directing changes both in the way the LREAB promulgates rules relating to the fees charged by AMCs and in the way the LREAB enforces those rules.[127] Notably, the executive order directed the LREAB to submit any proposed rule, along with the rulemaking record, to the Louisiana Commissioner of Administration ("Commissioner") for approval, rejection, or modification.[128]

In granting a Motion for Partial Summary Decision and thereby disposing of the merits of the case, the FTC determined that the LREAB still had not proven that its anticompetitive actions were supervised by the State.[129] The FTC found, *inter alia*, that the Commissioner failed to exercise sufficient judgment and control in order to show that the reissuance of the regulation was a "product of deliberate state intervention" and not "simply [an] agreement among private parties."[130] In addition, the FTC noted that the LREAB had produced no evidence that the Governor actively supervised the reissuance of the regulation.[131] The FTC's ruling has been appealed by the LREAB to the United States Court of Appeals for the Fifth Circuit.[132]

i. The State Has Not Articulated a Clear Policy to Allow the Anticompetitive Conduct.

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[124] *In re Louisiana Real Estate Appraisers Board*, Opinion of the Commission, FTC Docket No. 9374, *supra* note 96.

[125] *Id.* at 2.

[126] *Id.*

[127] *Id.* at 5.

[128] *Id.*

[129] *Id.* at 10.

[130] *Id.*, citing *Ticor*, 504 U.S. at 634-35.

[131] *In re Louisiana Real Estate Appraisers Board*, Opinion of the Commission, FTC Docket No. 9374, *supra* note 96, at 12.

[132] On June 22, 2018, Louisiana State Representative Edmond Jordan sent the FTC a letter, a copy of which is enclosed herewith, in which he requested that the FTC provide its views on the anticipated anticompetitive effects that would result from the enactment of the Proposed Rule by the Board.

In the instant matter, the State of Louisiana has not articulated any policy to allow the regulation of PBMs by market competitors, an anticompetitive conduct. Again, the requirement is satisfied "where the displacement of competition [is] the inherent, logical, or ordinary result of the exercise of authority delegated by the state legislature. In that scenario, the State must have foreseen and implicitly endorsed the anticompetitive effects as consistent with its policy goals."[133] As stated above, the Notice of Intent does not contain any preamble explaining the basis and rationale for the Proposed Rule or summarizing the information and data supporting the intended action. Therefore, while the intent to allow the Board to regulate PBMs is clear, one cannot be certain of the purpose of the regulation, as there is no indication that the State of Louisiana must have foreseen and implicitly endorsed the anticompetitive nature of the Proposed Rule. Therefore, the Board is not entitled to state-action immunity because it has not articulated a clear policy to allow the anticompetitive conduct that would result from the enactment of the Proposed Rule. In any event, as noted by the United States Supreme Court in *N.C. State Bd. of Dental Exam'rs*, the clear articulation requirement rarely will be sufficient to establish whether an anticompetitive policy is indeed the policy of a state.[134]

ii. The Anticompetitive Conduct Is Not Actively Supervised by the State.

Even if it were determined that the Board has articulated a clear policy for the enactment of the Proposed Rule, the Board still is not entitled to state-action immunity because it cannot show that its conduct is actively supervised by the State, which it is required to do because a controlling number of its decision makers (16 out of 17[135]) are active market participants in the occupation the Board regulates.[136] In fact, as discussed in the following section, the conflict of interests among the Board, its pharmacist members, and the PBMs is two-fold. On one hand, a member of the Board of Pharmacy may be tempted to interfere with a PBM's operation from a competitive point of view. On the other hand, the Board member may be tempted to favorably regulate a PBM in exchange for being placed on the PBM's preferred or exclusive network of retail pharmacies. Thus, because the United States Supreme Court in *N.C. State Bd. of Dental Exam'rs* determined that supervision by the State was required in that scenario due to the relationship between the Board of Dental Examiners and the non-dentist market participants,[137] an argument can be made *a fortiori* that the Board of Pharmacy is not entitled to state-action immunity in the absence of supervision by the State.

This Board is unable to establish that the State has supervised its conduct, let alone met the federal *active* supervision requirements, because the State has never given any indication that it desires the regulation of PBMs by the Board. Just as teeth-whitening was not yet in existence

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[133] *N.C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1112, citing *FTC v. Phoebe Putney Health Sys.*, 133 S. Ct. 1003, 1013 (2013).

[134] *Id.*, citing *Ticor*, 504 U.S. at 636-37.

[135] See La. R.S. 1172(A).

[136] *N.C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1104.

[137] *Id.*

when the Dental Practice Act was passed in *N.C. State Bd. of Dental Exam'rs*,[138] PBMs were clearly not contemplated by the Louisiana Legislature when it passed the Pharmacy Practice Act, as evidenced by the fact that in 2008 the legislature authorized DOI – ***not*** the Board – to regulate PBMs. Also, just as the Supreme Court in *N.C. State Bd. of Dental Exam'rs* determined that there was no evidence of any decision by the State of North Carolina to initiate or concur with the Board's actions against the non-dentists, the State of Louisiana has given no indication that it supports the Proposed Rule. When considering that the State of Louisiana provides no supervision of the Board's efforts to regulate PBMs, and in light of the FTC's recent ruling against the LREAB, it is evident that the Board's anticompetitive conduct is not entitled to state-action immunity.

Finally, during the 2018 Regular Session of the Louisiana Legislature, the legislature passed Act 623, tiled "The Occupational Board Compliance Act" ("the OBC Act"). The OBC Act, which became effective May 30, 2018, expressly states that its purpose is to "ensure that occupational licensing boards and board members will avoid liability under federal antitrust laws."[139] To that end, the OBC Act creates the Occupational Licensing Review Commission ("Commission") that is charged with providing active supervision of occupational licensing boards.[140] This Commission is composed of the governor or his designee, the secretary of state or his designee, the commissioner of agriculture or his designee, the commissioner of insurance or his designee, and the state treasurer or his designee.[141] "Active participation" is defined in the OBC Act as "the Occupational Licensing Review Commission's responsibilities to do both of the following: (a) review the substance of an occupational regulation proposed by any occupational licensing board; (b) approve or disapprove with suggested amendments, or allow an occupational licensing board to withdraw for revision an occupational regulation to ensure compliance with state policy."[142]

The OBC Act appears to be little more than a codification of the actions undertaken by certain state officials in the FTC's lawsuit against the LREAB. As explained by the FTC in its ruling, "The ultimate question is always simply 'whether the State's review mechanisms provide 'realistic assurance' that a nonsovereign actor's anticompetitive conduct 'promotes state policy, rather than merely the party's individual interests.'"[143] As stated above, the Board had not articulated a state policy that justifies the anticompetitive conduct that will result from the implementation of the Proposed Rule. The Commission must "exercise[] sufficient judgment and control" to show that the approval of the proposed regulation is "a product of deliberate state

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[138] *Id.* at 1116.

[139] La. R.S. 37:42.

[140] La. R.S. 37:45

[141] *Id.*

[142] La. R.S. 37:43

[143] *In re Louisiana Real Estate Appraisers Board*, Opinion of the Commission, FTC Docket No. 9374, *supra* note 96, at 9-10, citing *N.C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1116 (internal citation omitted).

intervention, not simply [an] agreement among private parties."[144] After all, "[A] program for state supervision that appears adequate on paper is not, by itself, sufficient to establish active supervision; state officials must actually exercise their supervision authority in a meaningful way."[145] Accordingly, the Commission's simple rubberstamping of a proposed regulation, which appears to be what the OBC Act contemplates, will not suffice, as "[a]ctual state involvement, not deference to private price-fixing arrangements under the general auspices of state law, is the precondition for immunity from federal law."[146] As noted by the FTC, "Application of such deferential review is insufficient to make the Board's remedial determination 'the State's own,' or to ensure that the State has accepted 'political accountability' for any anticompetitive conduct attributable to the Board."[147]

D. The Pharmacist Members of the Board of Pharmacy are Prohibited by the Louisiana Code of Governmental Ethics from Regulating Pharmacy Benefit Managers.

La. R.S. 42:1112, a statute contained in the Louisiana Code of Governmental Ethics, provides, in pertinent part,

> A. No public servant, except as provided in R.S. 42:1120, shall participate in a transaction in which he has a personal substantial economic interest of which he may be reasonably expected to know involving the governmental entity.
>
> B. No public servant, except as provided in R.S. 42:1120, shall participate in a transaction involving the governmental entity in which, to his actual knowledge, any of the following persons has a substantial economic interest:
> (1) Any member of his immediate family.
> (2) Any person in which he has a substantial economic interest of which he may reasonably be expected to know.
> (3) Any person of which he is an officer, director, trustee, partner, or employee.
> (4) Any person with whom he is negotiating or has an arrangement concerning prospective employment.
> (5) Any person who is a party to an existing contract with such public servant, or with any legal entity in which the public servant exercises control or owns an interest in excess of twenty-five percent, or who owes any thing of economic value to such public servant, or to any legal entity in which the public servant exercises control or owns an interest in excess

[144] *Id.* at 10, citing *Ticor*, 504 U.S. at 634-35.

[145] *Id.* at 13, citing *Ticor*, 504 U.S. at 637-38.

[146] *Id.* at 14, citing *Ticor*, 504 U.S. at 633.

[147] *Id.*, citing *N.C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1111.

of twenty-five percent, and who by reason thereof is in a position to affect directly the economic interests of such public servant.

C. Every public employee, excluding an appointed member of any board or commission, shall disqualify himself from participating in a transaction involving the governmental entity when a violation of this Part would result. The procedures for such disqualification shall be established by regulations issued pursuant to R.S. 42:1134(A)(1).

D. No appointed member of any board or commission, except as otherwise provided in R.S. 42:1120.1 or 1120.4, shall participate or be interested in any transaction involving the agency when a violation of this Part would result.

La. R.S. 42:1102 provides definitions for the following terms:

(2)(a) "Agency" means a department, office, division, agency, commission, board, committee, or other organizational unit of a governmental entity. For purposes of this Chapter, "agency of the public servant" and "his agency" when used in reference to the agency of a public servant shall mean:
(i) For public servants in the twenty principal departments of the executive branch of state government, the office in which such public servant carries out his primary responsibilities; except that in the case of the secretary, deputy secretary, or undersecretary of any such department and officials carrying out the responsibilities of such department officers it shall mean the department in which he serves; and except that in the case of public servants who are members or employees of a board or commission or who provide staff assistance to a board or commission, it shall mean the board or commission.
(ii) For the governor and lieutenant governor, it shall mean the executive branch of state government.
(iii) For public servants in the office of the governor or the lieutenant governor it shall mean their respective offices.
(iv) For public servants in the legislative branch of state government, it shall mean the agency or house of the legislature by which a public employee is employed and the legislative branch in the case of legislators.
(v) For public employees, except judges, of the supreme court, courts of appeal, district courts, and other courts authorized by Article V of the Constitution of 1974, it shall mean the court in which the public employee serves and any other court in which decisions of that court may be reviewed.
(vi) For public servants of political subdivisions, it shall mean the agency in which the public servant serves, except that for members of any governing authority and for the elected or appointed chief executive of a governmental entity, it shall mean the governmental entity. Public

servants of political subdivisions shall include, but shall not be limited to, elected officials and public employees of municipalities, parishes, and other political subdivisions; sheriffs and their employees; district attorneys and their employees; coroners and their employees; and clerks of court and their employees.
***

(9) "Elected official" means any person holding an office in a governmental entity which is filled by the vote of the appropriate electorate. It shall also include any person appointed to fill a vacancy in such offices.

***

(12) "Governmental entity" means the state or any political subdivision which employs the public employee or employed the former public employee or to which the elected official is elected, as the case may be.

***

(15) "Participate" means to take part in or to have or share responsibility for action of a governmental entity or a proceeding, personally, as a public servant of the governmental entity, through approval, disapproval, decision, recommendation, the rendering of advice, investigation, or the failure to act or perform a duty.

(16) "Person" means an individual or legal entity other than a governmental entity, or an agency thereof.

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(18)(a) "Public employee" means anyone, whether compensated or not, who is:
(i) An administrative officer or official of a governmental entity who is not filling an elective office.
(ii) Appointed by any elected official when acting in an official capacity, and the appointment is to a post or position wherein the appointee is to serve the governmental entity or an agency thereof, either as a member of an agency, or as an employee thereof.
(iii) Engaged in the performance of a governmental function.
(iv) Under the supervision or authority of an elected official or another employee of the governmental entity.

(19) "Public servant" means a public employee or an elected official.

***

(21) "Substantial economic interest" means an economic interest which is of greater benefit to the public servant or other person than to a general class or group of persons, except:
(a) The interest that the public servant has in his position, office, rank, salary, per diem, or other matter arising solely from his public employment or office.
(b) The interest that an elected official who is elected to a house, body, or authority has in a position or office of such house, body, or authority which is required to be filled by a member of such house, body, or authority by law, legislative rule, or home rule charter.
(c) The interest that a person has as a member of the general public.

***

(23) "Transaction involving the governmental entity" means any proceeding, application, submission, request for a ruling or other determination, contract, claim, case, or other such particular matter which the public servant or former public servant of the governmental entity in question knows or should know:
(a) Is, or will be, the subject of action by the governmental entity.
(b) Is one to which the governmental entity is or will be a party.
(c) Is one in which the governmental entity has a direct interest. A transaction involving the agency of a governmental entity shall have the same meaning with respect to the agency.

As explained above, this Board of Pharmacy is comprised of 17 members, 16 of whom are licensed pharmacists.[148] The United States Supreme Court in *N.C. State Bd. of Dental Exam'rs* noted that "[w]here a private party is engaging in anticompetitive activity, there is a real danger that he is acting to further his own interests, rather than the governmental interest of the State."[149] As one scholar explains it, "Granting Boards of Pharmacy regulatory control over PBMs creates an inherent conflict of interest by giving pharmacists regulatory control over their natural competitors in the marketplace. Under this new regulatory scheme, a Board has both the incentive and the power to exercise its regulatory power in ways that weaken PBMs' competitive positions, and in turn, benefit pharmacies. The power to regulate a market adversary gives pharmacists unprecedented power and will severely undercut competition in the prescription drug market."[150]

However, the Board and the PBMs are not always competitors and, in fact, have long-established business relationships. While the Board in *N.C. State Bd. of Dental Exam'rs* did not

[148] La. R.S. 42:1172(A).

[149] *N.C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1112, citing *Patrick*, 486 U.S. at 101.

[150] Shepherd, *supra* note 25, at 3 (emphases added).

have any working relationship with its non-dentist market competitors, the Board of Pharmacy and the PBMs in the instant matter frequently negotiate pharmacy costs, thus resulting in (1) higher customer volume for retail pharmacies; (2) reduced drug prices paid by health plans; and (3) most importantly, lower drug prices paid by consumers.[151] As explained by the FTC,

> PBMs negotiate lower pharmacy costs by forming a preferred or exclusive network of retail pharmacies. 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.[152]

Notably, as explained above, most pharmacies contract directly PSAOs to manage negotiations with PBMs instead of negotiating directly with PBMs.[153] Nevertheless, while some pharmacies may not contract directly with PBMs, PSAOs – which do contract directly with PBMs – are often owned by pharmacy cooperatives.[154] Therefore, the conflict of interest remains to the extent a Board member is associated with a pharmacy cooperative-owned PSAO that has entered into a contractual relationship with a PBM.

Thus, the working arrangement between PBMs and the Board of Pharmacy makes their relationship even more susceptible to impairment by the enactment of the Proposed Rule than the relationship between the Board of Dental Examiners and its non-dentist competitors in *N.C. State Bd. of Dental Exam'rs*.[155] For example, not only may a member of the Board of Pharmacy be tempted to interfere with a PBM's operation from a competitive point of view, the Board member may also be tempted to favorably regulate a PBM in exchange for being placed on the PBM's preferred or exclusive network of retail pharmacies. Therefore, the conflict of interests is two-fold.

As set forth above, La. R.S. 42:1112(A), a "public servant" is prohibited from "participating" in a "transaction involving the governmental entity" in which he has a personal "substantial economic interest" of which he may be reasonably expected to know. The Board members qualify as "public servants" because they are appointed to serve the Board by the governor, an "elected official", to serve an "agency" (the Board). Therefore, the Board members

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[151] Letter from FTC Office of Planning, *supra* note 16, at 2.

[152] *Id.*

[153] U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-176, PRESCRIPTION DRUGS: THE NUMBER, ROLE, AND OWNERSHIP OF PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS (January 2013), available at https://www.gao.gov/assets/660/651631.pdf.

[154] *Id.* at 24-25.

[155] *N.C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1112.

are not allowed to "participate" (take part in or to have or share responsibility for action of the Board, through approval, disapproval, decision, or recommendation of the Proposed Rule) in a "transaction" involving the Board (this rulemaking proceeding, which the Board members show know they have a direct interest for the reasons set forth above).

In addition, La. R.S. 42:1112(B) prohibits a "public servant" from "participating" in a "transaction involving the governmental entity which, to his actual knowledge, certain persons have a "substantial economic interest", including any "person" in which he has a "substantial economic interest" of which he may reasonably be expected to know; any "person" of which he is an officer, director, trustee, partner, or employee any "person" who is a party to an existing contract with such public servant; any legal entity in which the "public servant" exercises control or owns an interest in excess of twenty-five percent; any legal entity who owes any thing of economic value to such "public servant"; and to any legal entity in which the "public servant" exercises control or owns an interest in excess of twenty-five percent, and who by reason thereof is in a position to affect directly the economic interests of such "public servant". For all the reasons discussed above, Board members, who are "public servants", have significant economic interests (interests which are of greater benefit to the Board members or other persons affiliated with Board members than to a general class or group of persons) in the regulation of PBMs. Sixteen out of seventeen of the members of the Board are pharmacist who will benefit from the Board's regulation of PBMs, whether through favorable or unfavorable regulatory actions taken against PBMs.

Aside from the Board being prohibited from regulating PBMs due to the foregoing statutory provisions, the Board members are expressly prohibited from doing so pursuant to the plain language of La. R.S. 42:1112(D), which states that no member of a board shall "participate" or be interested in any "transaction involving the agency" when a violation of this Part would result. For the reasons discussed above, the Board's regulation of PBMs would result in inherent conflict of interests, and thus, violate the provisions of La. R.S. 42:1112. Accordingly, La. R.S. 42:1112(D) clearly prohibits the Board from engaging in the instant rulemaking proceeding.

For these reasons, a Board member is likely to have a personal substantial economic interest that would impair his partiality in regards to regulating PBMs. Because 16 of the 17 members of the Board are prohibited by La. R.S. 42:1112 from participating in a discussion or vote pertaining to the Proposed Rule, the Board is unable to achieve a quorum to conduct business and facilitate the enactment of the Proposed Rule. La. R.S. 42:1112(C) requires every Board member to disqualify himself or herself from this rulemaking proceeding due to the inherent conflicts of interests that would arise from this Board's regulation of PBMs. Accordingly, the ethical constraints governing the Board members prohibits them from being able to take further action in this matter, and thus, the Board should terminate this rulemaking proceeding.

E. ERISA and the Medicare Part D Preempt the Proposed Rule Insofar as It Regulates PBMs Servicing ERISA and Part D Plans.

In structurally similar express preemption provisions, ERISA[156] and Medicare Part D[157] preempt state law that "relates to" ERISA and Part D plans. In *Pharm. Care Mgmt. Ass'n v. Rutledge*,[158] the United States Court of Appeals for the Eighth Circuit very recently held that both of these federal statutes preempted an Arkansas law that regulated prices negotiated between PBMs and pharmacies and allowed pharmacies to decline to dispense covered prescription drugs, notwithstanding the terms of PBM-pharmacy contracts.

The Eighth Circuit affirmed the district court's determination that the Arkansas statute was preempted by ERISA, citing a previous case in which the court held that an Iowa statute was preempted by ERISA because it "both explicitly and implicitly referred to ERISA by regulating the conduct of PBMs administering or managing pharmacy benefits, and also had a connection with ERISA."[159]

In addition, the Eighth Circuit reversed the district court's determination that the Arkansas statute was not preempted by Medicare Part D. Federal law sets a standard governing "negotiated prices" between plans and pharmacies, *see* 42 U.S.C. § 1395w-102, and the Arkansas statute's "efforts to change the pricing model" between PBMs and pharmacies acted with respect to that standard.[160] In addition, the Eighth Circuit concluded that that the decline-to-dispense provisions in the statute acted "with respect to" federal standards governing pharmacy access because pharmacies that decline to dispense, in effect, become "out of network."[161] The court stressed that while the Arkansas statute "actually interfere[d]" with the federal standard, that is "more than is required for preemption."[162] If state law "merely acts 'with respect to' the standard, it is preempted."[163]

Applying *Rutledge*, Supreme Court decisions relied upon by *Rutledge*, and Center for Medicare ("CMS") guidance, is clear that both ERISA and Medicare Part D would preempt the Proposed Rule in regards to qualifying plans should the Proposed Rule be adopted by the Board. First, the Proposed Rule has an impermissible "reference to" both ERISA and Medicare Part D

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[156] ERISA's preemption provision provides: "[T]he *provisions of this subchapter* and subchapter III *shall supersede any and all State laws* insofar as they may now or hereafter *relate to any employee benefit plan* described in section 1003(a) of this title and not exempt under section 1003(b) of this title." 29 U.S.C. § 1144(a) (emphasis added).

[157] Medicare's preemption provision provides: "The *standards established under this part* shall *supersede any State law or regulation* (other than State licensing laws or State laws relating to plan solvency) *with respect to [Part D] plans* which are offered by [Part D] organizations under this part." 42 U.S.C. §§ 1395w-26(b)(3), 1395w-112(g) (emphasis added).

[158] *Pharm. Care Mgmt. Ass'n v. Rutledge*, 2018 U.S. App. LEXIS 15487 (8th Cir. June 8, 2018).

[159] *Id.* at *6, citing *Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017).

[160] *Id.* at *9.

[161] *Id.* at *11.

[162] *Id.*

[163] *Id.*

plans because it refers to "health benefit plan sponsor" and "other third-party payer" (terms which necessarily include ERISA and Part D benefit plans) in § 2473(A).

Second, the Proposed Rule also has an impermissible "connection with" with both ERISA and Part D plans because it purports to allow the Board to regulate activities that involve the structure and administration of plans far removed from *pharmacy* practices, including developing plan formularies, utilization management, administration of prescription drug management programs, processing authorization requests, processing claims, and adjudicating appeals of reimbursement decisions. In other words, the Proposed Rule seeks to regulate PBMs (and by extension, the ERISA and Medicare Plans they service), not pharmacies.

The Proposed Rule is not saved from Medicare Part D express preemption by that provision's exception for "State licensing laws." That exception only applies to state law that licenses Medicare *plans*. *See* 42 U.S.C. §§ 1395w-26(b)(3), 1395w-112(g). The Proposed Rule licenses PBMs. Moreover, CMS has recognized that the licensing law exception is "limited to State requirements for *becoming State licensed*, and do not extend to any requirement that the State might impose on licensed health plans[.]" CMS, Medicare Managed Care Manual, ch. 10, § 30.1. The exception does not allow states to impose substantive requirements on PBMs that service Medicare plans.

Finally, we note that DOI has recognized that because of express preemption, it lacks authority to regulate PBMs servicing Medicare Part D plans.[164] If DOI lacks such authority because of preemption, then surely the Board does as well.

In sum, any regulations that are enacted pursuant to the adoption of the Proposed Rule would have no authority over qualifying ERISA and Medicare Part D health plans. Accordingly, the Board should refrain from adopting the Proposed Rule given that the Board will be significantly limited in its ability to enforce the provisions of the Proposed Rule.

F. Pharmacy Benefit Managers Are Already Sufficiently Regulated By the Louisiana Department of Insurance.

As explained above, for ten (10) years now PBMs have been regulated by DOI pursuant to La. R.S. 22:1657. DOI's regulatory authority over PBMs has been consistently recognized by the legislature, even as recently as the 2018 Regular Session, through various legislative amendments that have been made to the Insurance Code statutes that apply to PBMs.[165] There has never been ***any*** indication that DOI's regulatory authority over PBMs is insufficient, nor has there ever been ***any*** indication that the legislature, DOI, or any other state agency has determined that regulation of PBMs by the Board of Pharmacy is warranted. Again, the AG Opinion, which admittedly was formed without knowledge of the pertinent facts, does not suffice as a valid

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[164] *See* DOI Advisory Letter 2016-01 (July 1, 2016), available at https://www.ldi.la.gov/docs/default-source/documents/legaldocs/advisoryletters/al2016-01-cur-applicabilityproviderfee.

[165] Acts 2008, No. 386, § 1; Acts 2009, No. 99, §§ 1, 2; Acts 2011, No. 94, § 1; Acts 2018, No. 317, § 1; Acts 2018, No. 423, § 1.

authoritative endorsement of Board regulation over PBMs. Accordingly, there is no need for the Board to regulate PBMs as they are already sufficiently regulated by DOI.

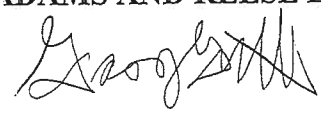
V. Conclusion

The public health, safety, and welfare of consumers are best served when PBMs are not subjected to a regulatory landscape that discourages competitive pricing and creates a scenario wherein Board members regulate market competitors. This is especially true in the instant matter, whereby Board members stand to derive benefits regardless of whether they take favorable or unfavorable regulatory actions against PBMs. For all the reasons set forth herein, PCMA respectfully opposes the Board's promulgation of the Proposed Rule and requests that this rulemaking proceeding be terminated.

We remain,

Sincerely yours,

ADAMS AND REESE LLP



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Attorneys for the Pharmaceutical Care Management Association

RLR/gjg

Cc: The Honorable Jeff Landry
The Honorable James J. Donelon
The Honorable Frank A. Hoffmann
The Honorable Fred H. Mills, Jr.
The Honorable John R. Smith
The Honorable Kirk Talbot
Matthew F. Block
Korey Harvey

LOUISIANA HOUSE OF REPRESENTATIVES

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Commerce
Insurance
Agriculture, Forestry, Aquaculture and Rural Development
Select Committee on Homeland Security

Louisiana Legislative Black Caucus, Secretary
Capital Region Legislative Delegation
Louisiana Rural Caucus
Democratic Caucus

Edmond Jordan
State Representative ~ District 29

June 22, 2018

Sent Via email: tkoslov@ftc.gov

Ms. Tara Isa Koslov
Acting Director, Office of Policy Planning
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

Re: Louisiana Board of Pharmacy Regulatory Project 2018-1 – Pharmacy Benefit Managers
Notice of Proposed Rulemaking (LAC 46:LIII.2471 through 2477)

Dear Ms. Koslov:

I am writing to request that the Federal Trade Commission ("FTC"), or its staff, provide its views on the anticipated anticompetitive effects of a proposed rulemaking by the Louisiana Board of Pharmacy ("BOP") that would – among other things – assert regulatory authority over Pharmacy Benefit Managers ("PBMs"). A Notice of Intent – published in Vol. 44, No. 5 of the May 20, 2018 edition of the Louisiana Register, (enclosed) – would grant the BOP regulatory authority over PBMs.

The proposed rules would require PBMs to: (1) obtain BOP issued licenses before conducting operations; and (2) disclose information that constitutes confidential information and/or trade secrets upon demand from the BOP.

Concerns have been raised that this new regulatory regime – complete with investigative and enforcement powers – would duplicate a regulatory regime currently enforced by the Louisiana Department of Insurance. Additionally, this new regulatory regime appears to pose a conflict of interest and could negatively impact the competitive nature of the pharmacy sector; leading to an increase in the cost of pharmaceutical benefits for employers, insurers, and; ultimately, the citizens of Louisiana.

I understand that the FTC has noted in the past that similar legislative and proposed rulemaking provisions in Mississippi would have the unintended consequence of decreasing competition and raising drug prices for consumers. Therefore, I am requesting that the FTC examine the Louisiana BOP rulemaking to determine whether the proposed administrative action is anti-competitive and will likely result in the increased cost of pharmaceutical care for Louisiana consumers.

Thank you for your attention to this matter. If you have any additional questions, please feel free to contact my office via email at jordane@legis.la.gov.

Sincerely,

Edmond Jordan
Louisiana State Representative
District 29, Baton Rouge
Enclosure: Notice of Intent

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

May 11, 2018

Senator John A. Alario, Jr, President
Louisiana Senate
PO Box 94183
Baton Rouge, LA 70804-9183

Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2018-1 ~ Pharmacy Benefit Managers

Dear Senator Alario:

The Board has initiated the rulemaking process to adopt a new subchapter of rules relative to the licensure and regulation of pharmacy benefit managers. The proposed rule will require pharmacy benefit managers operating within the state of Louisiana to obtain a pharmacy permit from the Board of Pharmacy and comply with the Board's rules relative to certain of their activities construed to be within the practice of pharmacy. In connection with this regulatory project, you should find the following documents in this packet:

- Notice of Intent
- Proposed Rule
- Family Impact Statement
- Poverty Impact Statement
- Provider Impact Statement
- Regulatory Flexibility Analysis
- Solicitation of Comments
- Fiscal & Economic Impact Statement

As indicated in the solicitation, we will convene a public hearing on June 25, 2018 to receive public comments and testimony on this proposed rule. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

cc: Chair, Senate Health & Welfare Committee
Via Email: APA.S-H&W@legis.la.gov
Speaker, House of Representatives
Via Email: APA.HouseSpeaker@legis.la.gov
Chair, House Health & Welfare Committee
Via Email: APA.H-HW@legis.la.gov
Director, Community Outreach Services, La. Economic Development
Via Email: Pat.Witty@la.gov
Editor, *Louisiana Register*
Via Email: Reg.Submission@la.gov
Reference File

Notice of Intent

Department of Health
Board of Pharmacy

Pharmacy Benefit Managers (LAC 46:LIII.2471 through 2477)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to promulgate new rules for the licensing and regulation of pharmacy benefit managers, more specifically *Subchapter F – Pharmacy Benefit Managers* of *Chapter 24 – Limited Service Providers.*

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 24. Limited Service Providers

...

Subchapter F. Pharmacy Benefit Managers

§2471. Definitions

A. The following terms shall have the meaning ascribed to them in this Section:

1. *"Health insurance plan"* means an individual or group plan or program, whether commercial, self-insured, or mandated or sponsored by any federal, state, or local government, which is established by contract, certificate, law, plan, policy, subscriber agreement, or by any other method and which is entered into, issued, or offered for the purpose of arranging for, delivering, paying for, providing, or reimbursing any of the costs of health or medical care, including pharmacy services, drugs, or devices.
2. *"Pharmacy benefit management plan"* or *"pharmacy benefits program"* means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services or drugs or devices to individuals who reside in or are employed in Louisiana.
3. *"Pharmacy benefit manager"* or *"PBM"* means any person or other entity who administers the prescription drug or device program of one or more health insurance plans on behalf of a third party in accordance with a pharmacy benefit program. This term includes any agent or representative of a pharmacy benefit manager, hired or contracted by the pharmacy benefit manager to assist in the administering of the drug program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

§2473. Pharmacy Benefit Manager Permit; Activities; Prohibitions

A. Any pharmacy benefit manager who, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer, either directly or through an intermediary, manages the drug or device coverage or other pharmacy benefits provided by the carrier, plan sponsor, or other third-party payer, shall be permitted by the board.

B. A pharmacy benefit manager permit shall authorize the permit holder to administer pharmacy benefit management services.

C. Pharmacy benefit management services include, but are not limited to:

1. Development, maintenance, and/or administration of drug formularies;
2. Development, maintenance, and/or administration of step therapy procedures;
3. Development, maintenance, and/or administration of utilization management and utilization reviews;
4. Development, maintenance, and/or administration of drug regimen reviews;
5. Development, maintenance, and/or administration of quality care dosing services;
6. Development, maintenance, and/or administration of prescription drug management programs and the contracting with pharmacies for same;
7. Development, maintenance, and/or administration of disease management programs;
8. Administration, processing, and/or payment of claims for prescription drugs;
9. Processing of prior authorization requests;
10. Adjudication of appeals and/or grievances related to prescription drug coverage; and
11. Any other act, service, operation, or transaction incidental to or forming a part of the compounding, filling, dispensing, exchanging, giving, offering for sale, or selling drugs, medicines, poisons or devices in this state by pharmacists or pharmacies, pursuant to a prescription or an order of physicians, dentists, veterinarians, or other licensed practitioners, requiring, involving, or employing the science or art of any branch of the pharmacy profession, study, or training.

D. The provisions of R.S. 37:1232(A) and Section 2303 of this Part notwithstanding, the pharmacy benefit manager need not hold a resident pharmacy permit in the state in which it is located prior to applying for a pharmacy benefit manager permit. However, should the pharmacy benefit manager not hold a resident pharmacy permit in the state in which it is located, the pharmacy benefit manager shall be subject to an inspection by the board or its designated agent, in compliance with the provisions of R.S. 37:1232(C).

E. The board shall not issue a pharmacy benefit manager permit to any person or other entity which has not yet registered with the Louisiana Secretary of State to conduct business within the state.

F. When the pharmacy benefit manager permit is issued, it shall be valid only for the owner and specific location noted on the application and recorded on the permit, and the permit shall not be valid for any premises other than the physical location to which it was issued.

G. A pharmacy benefit manager permit is not transferable from the original owner. The permit shall not be subject to sale, assignment or other transfer, voluntary or involuntary. Moreover, in the event the ownership of the pharmacy benefit manager changes by 50 percent or more after the initial issuance of the permit, the ownership will be deemed sufficiently different as to require a new pharmacy benefit manager permit. The continued operation of a pharmacy benefit manager permit after its ownership has changed by more than 50 percent shall constitute sufficient basis for the board to issue a finding for the operation of a pharmacy benefit manager without a valid permit, in violation of R.S. 37:1241 (A)(12).

H. Any pharmacy benefit manager may request an exemption from the requirement of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

§2475. Licensing Procedures

A. Application for Initial Issuance of Permit

1. The board shall develop an application form suitable for the pharmacy benefit manager permit. The board may revise that application form on its own initiative in order to collect the information it deems necessary to properly evaluate an applicant.
2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
3. Once received by the board, an application for the permit shall expire one year thereafter. Fees attached to an expired application shall be forfeited by the applicant and deposited by the board.
4. In the event any information contained in the application or accompanying documents changes after being submitted to the board and before the issuance of the permit, the applicant shall immediately notify the board in writing and provide corrected information.
5. The applicant may be required to personally appear before the board or one of its committees prior to any decision on the permit application.
6. Upon approval of the application, the board shall issue the pharmacy benefit manager permit to the applicant.

B. Application for Renewal of Permit

1. All pharmacy benefit manager permits shall expire at midnight on August 31 of every year, regardless of the date of its initial issuance.
2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
3. In the event the pharmacy benefit manager does not submit a properly completed renewal application and fee to the board prior to the expiration of the permit, the permit shall be rendered null and void. A pharmacy benefit manager shall not operate with an expired permit. The continued operation of a pharmacy benefit manager with an expired permit shall constitute sufficient basis for the board to issue a finding for the operation of a pharmacy benefit manager without a valid permit, in violation of R.S. 37:1241(A)(12).
4. An application for the late renewal of an expired pharmacy benefit manager permit that is received in the board office no later than 30 days after the expiration date of the permit may be processed by the board office provided the appropriate delinquent fee authorized in R.S. 37:1184 is included with the application.
5. A pharmacy benefit manager permit not renewed by 30 days after the expiration date shall be automatically terminated by the board.
6. An application for the reinstatement of a terminated pharmacy benefit manager permit shall be referred to the board's reinstatement committee for its consideration.

C. Application for Reinstatement of Lapsed, Suspended, or Revoked Permit
   1. The applicant shall complete the application form for this specific purpose supplied by the board
   2. The application shall be accompanied by the payment of the permit fee, delinquent renewal fee, and reinstatement fees authorized in R.S. 37:1184.
   3. Upon the receipt of a properly completed application form and fee, the board staff shall refer the application to the board's reinstatement committee for its consideration and shall notify the applicant of the time and place for the committee meeting.

D. Maintenance of Permit
   1. A pharmacy benefit manager permit shall be valid for the entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the business location recorded on the permit.
   2. Upon receipt of a written request and payment of the fee authorized in R.S. 37:1184, the board shall issue a duplicate or replacement permit to the applicant; however, such duplicate or replacement permit shall not serve or be used as an additional or second permit.
   3. Prior to any change in the location of a pharmacy benefit manager, the owner of the permit shall submit an application form for that purpose supplied by the board and pay the appropriate fee authorized in R.S. 37:1184. The board may require an inspection of the new location prior to the issuance of the permit for the new location. The operation of a pharmacy benefit manager in a new location not approved by the board shall constitute sufficient basis for the board to issue a finding for the operation of a pharmacy benefit manager without a valid permit, in violation of R.S. 37:1241(A)(12).
   4. In the event the pharmacy benefit manager contemplates permanent closure of the pharmacy benefit manager business, the owner of the permit shall notify the board, in writing, 10 days prior to the anticipated date of closure and surrender its permit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

§2477. Applicable Laws and Regulations; Sanctions

A. Any pharmacy benefit management service of a pharmacy benefit manager that adversely affects or impairs the health, safety, and welfare of a person who is a beneficiary of the pharmacy benefit program administered by the pharmacy benefit manager and who resides or works in this state or directly impairs the ability of a pharmacist or pharmacy to compound, fill, dispense, exchange, give, offer for sale, or sell drugs, medicines, poisons or devices to any such person shall be deemed a violation of R.S. 37:1241(A)(1), as well as a violation of any other applicable provisions of R.S. 37:1241(A), providing cause for the board to take any of the actions permitted in R.S. 37:1241. Further, Louisiana pharmacy laws shall be applicable to regulation of the practice of pharmacy for that portion of the permitted pharmacy benefit manager's Louisiana pharmacy practice or operation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

FAMILY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on the stability of the family.

The proposed rule will have no effect on the stability of the family.

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

The proposed rule will have no effect on the authority and rights of parents regarding the education and supervision of their children.

III. The effect on the functioning of the family.

The proposed rule will have no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

The proposed rule will have no effect on family earnings or family budget.

V. The effect on the behavior and personal responsibility of children.

The proposed rule will have no effect on the behavior and personal responsibility of children.

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

The proposed rule will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.

POVERTY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the rule proposed for adoption, repeal, or amendment.

I. The effect on household income, assets, and financial security.

The proposed rule will have no effect on household income, assets, or financial security.

II. The effect on early childhood development and preschool through postsecondary education development.

The proposed rule will have no effect on early childhood development or preschool through postsecondary education development.

III. The effect on employment and workforce development.

The proposed rule will have no effect on employment or workforce development.

IV. The effect on taxes and tax credits.

The proposed rule will have no effect on taxes or tax credits.

V. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

The proposed rule will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

PROVIDER IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

I. The effect on the staffing level requirements or qualifications required to provide the same level of service.

The proposed rule will have no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.

II. The total direct and indirect effect on the cost to the provider to provide the same level of service.

The proposed rule will have no effect on the total direct or indirect costs to the provider to provide the same level of service.

III. The overall effect on the ability of the provider to provide the same level of service.

The proposed rule will have no effect on the ability of the provider to provide the same level of service.

REGULATORY FLEXIBILITY ANALYSIS
FOR ADMINISTRATIVE RULES

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

The proposed rule requires pharmacy benefit managers to obtain a pharmacy permit from the Board. There are not specific reporting requirements. However, the proposed rule does provide that any pharmacy benefit manager that adversely affects or impairs the health, safety, and welfare of a person who is a beneficiary of the pharmacy benefit program administered by the pharmacy benefit manager, or directly impairs the ability of a pharmacist or pharmacy to compound, fill, dispense, exchange, give, offer for sale, or sell drugs, medicines, poisons, or devices to any such person shall be deemed to have violated the Louisiana Pharmacy Practice Act and shall be subject to the disciplinary sanctions authorized by that same act.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no specific reporting requirements in the proposed rule.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

There are no specific reporting requirements in the proposed rule.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

There are no design or operational standards required in the proposed rule.

V. The exemption of small businesses from all or any part of the requirements contained in the proposed rule.

There are no exemptions for small businesses.

SOLICITATION OF COMMENTS

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative, by personal delivery, to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding this proposed rule. A public hearing on this proposed rule is scheduled for Monday, June 25, 2018 at 9:00 a.m. in the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Malcolm J. Broussard, Executive Director

Dept.: Health

Office: Board of Pharmacy

Phone: (225) 925-6481

Title: Pharmacy Benefit Managers

Return Address: 3388 Brentwood Drive, Baton Rouge, LA 70809

Effective Date of Rule: Upon promulgation, Oct. 20, 2018 (est.)

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)

The proposed rules will increase self-generated expenditures for the Louisiana Board of Pharmacy (LBP) by an estimated $214,500 beginning in FY 19 and in subsequent fiscal years. The proposed rules establish a new type of pharmacy permit for pharmacy benefit managers (PBMs) in order to regulate the activities of PBMs that are construed as the practice of pharmacy.

The Board anticipates inspecting PBMs annually. To accomplish annual inspections of PBMs, LBP anticipates hiring one additional pharmacist compliance officer at a cost of $166,500 annually ($111,000 salary and $55,500 related benefits) to supplement the six current compliance officers and carry out the annual inspections. LBP anticipates licensing and inspecting 40 PBMs annually, with inspection costs totaling an estimated $48,000. Anticipated costs for an individual inspection total $1,200 and include expenditures for travel ($500), lodging ($400), and meals and ground transportation for three days ($300). LBP anticipates the aforementioned inspection costs because all PBMs conducting business in Louisiana are located out-of-state. Furthermore, LBP may incur additional expenditures to conduct complaint-related investigations of PBMs. The expenditures associated with complaint-related investigations of PBMs is indeterminable and dependent upon he number of complaints received in a given year.

In addition, LBP has anticipated printing expenditures of $1,000, including $500 for the Notice of Intent in FY 18 and $500 for the Final Rule in FY 19.

The proposed rules will not result in any additional expenditures or savings for local governmental units.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)

The proposed rules will result in an initial self-generated revenue increase of $6,000 in FY 19 that will reduce to a $5,000 self-generated revenue increase beginning in FY 20 and in subsequent years. The LBP anticipates licensing 40 PBMs beginning in FY 19. The existing fee for an initial pharmacy permit is $150 and the annual renewals have an associated fee of $125. With an assumption of 40 such entities seeking a permit, the Board anticipates up to $6,000 in FY 19 (40 permits at $150 initial permit fee) and $5,000 per year thereafter (40 permits at $125 permit renewal fee).

Furthermore, the LBP may realize additional self-generated revenue collections as a result of PBMs being subject to fines up to $5,000 per offense to the extent they are found to be in violation of the Board's laws and regulations. Any revenue from this source is currently

indeterminable and dependent upon PBMs committing violations and being fined as a result.

LBP does not anticipate any revenue collections for other state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rules will increase aggregate expenditures for PBMs conducting business in Louisiana by an estimated $6,000 in FY 19 and by $5,000 in subsequent fiscal years. PBMs operating in Louisiana will be subject to an initial $150 permit fee in FY 19 and a $125 permit renewal fee in subsequent fiscal years. With an assumption of 40 such entities seeking a credential, the Board anticipates PBMs' costs to be $6,000 in FY 19 (40 permits at $150 initial permit fee) and $5,000 per year thereafter (40 permits at $125 permit renewal fee).

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will not affect competition or employment.

Malcolm Broussard
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

May 10, 2018
Date of Signature

Evan Brasseaux, Staff Director
Legislative Fiscal Officer or Designee

5/10/18
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The Board proposes to establish a new type of pharmacy permit for pharmacy benefit managers (PBMs) and to regulate that portion of their activities which are construed as the practice of pharmacy.

B. Summarize the circumstances that require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

The Board determined that some of the practices of PBMs are construed as the practice of pharmacy. The Pharmacy Practice Act authorizes the Board to license and regulate the practice of pharmacy within, or for the benefit of residents within, the state.

C. Compliance with Act 11 of the 1986 First Extraordinary Session:

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

The Board has allocated $00 each for printing the Notice of Intent and the Final Rule. The Mississippi Board of Pharmacy, which has a registration requirement for pharmacy benefit managers operating in that state, recently reported 44 such entities have registered with that agency. The Louisiana Board estimates approximately 40 pharmacy benefit managers would be eligible for and seek the required pharmacy permit and that none of them are located within the state of Louisiana. LBP estimates the need for one additional pharmacist compliance officer, at a cost of $166,500 per year. LBP estimates the cost of an inspection to be $1,200, for a total of $48,000 per year for 40 permits. Additional site visits may be required in connection with complaints against the pharmacy benefit manager. Since LBP has no basis to estimate the number of complaints, the Board has no way to estimate the expenditures resulting from such additional site visits. The Board operates on self-generated funds.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) ____ Yes. If yes, attach documentation.
(b) __X__ No. If no, provide justification as to why this rule change should be published at this time.

The Board has determined it necessary to license and regulate pharmacy benefit managers using its self-generated funds.

D. Compliance with Act 820 of the 2008 Regular Session

(1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of "small businesses", LBP is unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data. However, the Board does not believe that any PBM would qualify as a small business.

(2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

The proposed rule does not specify any recordkeeping or reporting requirements. However, to the extent the PBM engages in any activities construed as the practice of pharmacy, some or all of those pharmacy practice activities may have recordkeeping or reporting requirements delineated elsewhere in the Board's rules.

(3) A statement of the probable effect on impacted small businesses.

Since the Board does not believe any PBM would qualify as a small business, LBP does not anticipate the proposed rule will have any impact on small businesses.

(4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

There are no alternative methods for achieving the purpose of the proposed rule.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 17-18	FY 18-19	FY 19-20
PERSONAL SERVICES	$ 0	$166,500	$166,500
OPERATING EXPENSES	$ 500	$ 48,500	$ 48,000
PROFESSIONAL SERVICES	$ 0	$ 0	$ 0
OTHER CHARGES	$ 0	$ 0	$ 0
EQUIPMENT	$ 0	$ 0	$ 0
MAJOR REPAIR & CONSTR.	$ 0	$ 0	$ 0
TOTAL	$ 500	$215,000	$214,500
POSITIONS (#)	0	1	1

2. Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The proposed rules will increase self-generated expenditures for LBP by an estimated $214,500 beginning in FY 19 and in subsequent fiscal years. The proposed rules establish a new type of pharmacy permit for pharmacy benefit managers (PBMs) in order to regulate the activities of PBMs that are construed as the practice of pharmacy.

The Board anticipates inspecting PBMs annually. To accomplish annual inspections of PBMs, LBP anticipates hiring one additional pharmacist compliance officer at a cost of $166,500 annually ($111,000 salary plus $55,500 related benefits) to supplement the six current compliance staff and carry out the annual inspections. LBP anticipates licensing and inspecting 40 PBMs annually, with inspection costs totaling an estimated $48,000. Anticipated costs for an individual inspection total $1,200 and include expenditures for travel ($500), lodging ($400), and meals and ground transportation for three days ($300). The Board anticipates the aforementioned inspection costs because a majority of PBMs doing business in Louisiana are located out-of-state. Furthermore, LBP may incur additional expenditures to conduct complaint-related investigations of PBMs. The expenditures associated with complaint-related investigations is indeterminable and dependent upon the number of complaints received in a given year.

In addition, the Board has anticipated expenditures of $1,000 for the printing of each document; the Notice of Intent for $500 in FY 18 and the Final Rule for $500 in FY 19.

The proposed rules will not result in any additional expenditures or savings for local governmental units.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 17-18	FY 18-19	FY 19-20
STATE GENERAL FUND	$ 0	$166,500	$166,500
AGENCY SELF-GENERATED	$ 500	$ 48,500	$ 48,000
DEDICATED	$ 0	$ 0	$ 0
FEDERAL FUNDS	$ 0	$ 0	$ 0
OTHER (Specify)	$ 0	$ 0	$ 0
TOTAL	$ 500	$215,000	$214,500

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

The Board has sufficient funds available to implement the proposed rule.

B. COST SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

There will be no impact or cost savings for local governmental units resulting from the proposed rule.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

SOURCE	FY 17-18	FY 18-19	FY 19-20
STATE GENERAL FUND	$ 0	$ 0	$ 0
AGENCY SELF-GENERATED	$ 0	$ 6,000	$ 5,000
DEDICATED FUNDS	$ 0	$ 0	$ 0
FEDERAL FUNDS	$ 0	$ 0	$ 0
LOCAL FUNDS	$ 0	$ 0	$ 0
TOTAL	$ 0	$ 6,000	$ 5,000

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

The proposed rules will result in an initial self-generated revenue increase of $6,000 in FY 19 that will reduce to a $5,000 self-generated revenue increase beginning in FY 20 and in subsequent fiscal years. The LBP anticipates licensing 40 PBMs beginning in FY 19. The existing fee for an initial pharmacy permit is $150 and annual renewals have an associated fee of $125. With an assumption of 40 such entities seeking a permit, the Board anticipates up to $6,000 in FY 19 (40 permits at $150 initial permit fee), and $5,000 per year thereafter (40 permits at $125 permit renewal fee).

Furthermore, the LBP may realize additional self-generated revenue collections as a result of PBMS being subject to fines up to $5,000 per offense to the extent they are found to be in violations of the Board's laws and regulations. Any revenue from this source is indeterminable and dependent upon PBMs committing violations and being fined as a result.

LBP does not anticipate any revenue collections for other state or local governmental units.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rules will increase aggregate expenditures for PBMs by an estimated $6,000 in FY 19 and by $5,000 in subsequent fiscal years. PBMs operating in Louisiana will be subject to an initial $150 permit fee in FY 19 and a $125 permit renewal fee in subsequent fiscal years. With an assumption of 40 such entities seeking a credential, the Board anticipates up to $6,000 in FY 19 (40 permits at $150 initial permit fee), and $5,000 per year thereafter (40 permits at $125 permit renewal fee).

Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

The proposed rule will have no effect on receipts or revenue.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

The proposed rule will not affect competition or employment.

Malcolm Broussard
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

May 10, 2018
Date of Signature