March 2, 2017

The Honorable Jim Wood
California State Assembly
California State Capitol
Sacramento CA 95814

Re: Oppose AB 315 (Wood)

Dear Assembly Member Wood:

On behalf of the Pharmaceutical Care Management Association (PCMA) we must respectfully oppose AB 315. PCMA is the national trade association for America's Pharmacy Benefit Managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage through large employers, health insurers, labor unions, and federal and state-sponsored health programs.

AB 315 would require PBMs to be regulated by the California Board of Pharmacy, and would grant broad rulemaking authority to the board. The bill would also require the public disclosure of competitively sensitive business information. While we understand that it is not the intent of this bill, we are concerned that both policies would undercut competition in the drug marketplace and raise prescription drug prices for consumers.

Board of Pharmacy Regulation of PBMs is Anticompetitive and Will Likely Raise Health Care Costs.

PCMA has significant concerns with the proposal to have the California Board of Pharmacy regulate PBMs because of the potential for conflicts of interest to arise as board members exercise regulatory authority. Though board members may have the best intentions in exercising regulatory authority, "[s]tate agencies controlled by market participants, who possess singularly strong private interests, pose the…risk of self-dealing…This conclusion does not question the good faith of the state officers but rather is an assessment of the structural risk of market participants' confusing their own interests with the State's policy goals."[1]

Pharmacies and PBMs work together, as partners, to deliver and pay for pharmaceuticals dispensed to patients. PBMs and pharmacies also sit across the negotiating table from each other as contracts are developed, and for pharmacy services, are direct market competitors. There are pharmacists that serve on the Board of Pharmacy that work for, or own and operate pharmacies that are market competitors to PBMs.

The U.S. Federal Trade Commission (FTC), charged with preventing business practices that are anticompetitve and encouraging a U.S. economy characterized by vigorous competition,[2] has opined on the issue of pharmacy board regulation of PBMs. In a letter to Mississippi

[1] NC Board of Dental Examiners v. FTC, 135 S. Ct. 1101 (2015) p. 13.
[2] www.ftc.gov/about-ftc.

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Representative Mark Formby regarding a legislative proposal to regulate PBMs under the Mississippi Board of Pharmacy, the FTC stated, "pharmacists and PBMs have a competitive, and at times, adversarial relationship," and that they are "concerned that giving the pharmacy board regulatory power over PBMs may create tensions and conflicts of interest for the pharmacy board."[3] The FTC goes on to say, "[i]ndeed, 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."[4] Mississippi is the only state in the country that has enacted Board of Pharmacy regulation of PBMs. The first and only board regulatory action directed at PBMs was withdrawn shortly after introduction because the attempt to regulate exceeded the board's statutory authority.

The Northwestern Journal and Social Policy study of the subject summarized the issue: "The power to regulate a market adversary gives pharmacists unprecedented power and will undercut competition in the prescription drug market." Professor Shepherd adds that "this regulatory scheme will not only hurt the PBM industry, but will also increase the prices that consumers and third parties pay for prescription drugs."[5]

Further complicating board regulation of PBMs is the risk that any actions the board would take against PBMs in a regulatory role would be held to legal scrutiny under the long line of antitrust cases that warn against the dangers of board members acting in self-interested ways and questioning whether state immunity would be extended to board members.[6] Actions anticompetitive to PBMs by board members who are market participants could run the risk of stripping those board members of state immunity if they have not been appropriately supervised by an independent entity.

Even within the text of AB 315, anticompetitive intent seems to appear. Proposed Bus. & Prof. Code Section 4428(a) would require disclosure to the board of a PBM's reliance on its affiliated pharmacies to dispense outpatient drugs, as compared to its retail pharmacies. The value of this information to the board or the public is unclear, but it would allow pharmacist members of the board—many of whom work in retail settings—to have insight into how much business their mail-service or PBM-affiliated retail competitors are receiving.

Finally, Board of Pharmacy regulation is inappropriate because the board is not qualified to oversee benefits management. The board's expertise is in licensing pharmacy professionals and ensuring the safety pharmaceuticals dispensed, or in the board's terms, "pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals,"[7] not health

[3] FTC Staff Letter to The Honorable Mark Formby Re: SB 2445, March 21, 2011, available at: https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-mark-formby-mississippi-house-representatives-concerning-mississippi/110322mississippipbm.pdf.
[4] Id.
[5] "The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary," by Professor Joanna Shepherd, Emory University School of Law, Northwestern Journal and Social Policy, 2013, available at https://www.ftc.gov/system/files/documents/public_comments/2014/02/00005-88683.pdf.
[6] *See* NC State Board of Dental Examiners v. Federal Trade Commission, 135 S. Ct. 1101 (2015); California Retail Liquor Dealers Assn. v. Midcal Aluminum, Inc., 445 U.S. 97; Goldfarb v. Virginia State Bar, 421 U.S. 773; Columbia v. Omni Outdoor Advertising, Inc. 499 U.S. 365.
[7] California State Board of Pharmacy Statement, www.pharmacy.ca.gov.

benefit and plan design or the administration thereof, which is the purview of the Departments of Managed Health Care and Insurance.

For these reasons, Board of Pharmacy regulation of PBMs is inappropriate.

The Purpose of AB 315's Disclosure Provisions is Unclear and Disclosure May Result in Higher Drug Costs.

Though PCMA is still examining the disclosure provisions in AB 315, we are concerned that the purpose of these provisions is unclear, the information gleaned will have no value to the public, and at worst, disclosure of pharmaceutical rebates could raise costs for consumers. If the purpose of the pharmaceutical rebate disclosure provisions is to understand the marketplace, expressly exempting a major health plan in California from reporting obligations will prevent obtaining a clear picture. In addition, federal ERISA law will prohibit enforcement of the disclosure provisions for ERISA plans, which includes not only self-funded employer plans but also fully-insured employer plans. Ultimately, the information gleaned will be a sliver of the California marketplace.

In addition, information about pharmaceutical rebates is already being reported to the appropriate interested parties. PBMs negotiate and collect rebates *on behalf of their clients*, such as large employers, labor unions, and health plans. The rebates themselves are passed along to the clients according to the terms of their contracts, and clients can and do exercise their rights to audit PBM compliance with those terms.

To the extent that aggregate rebate data could be analyzed to determine specific drug rebates, there is a significant risk that pharmaceutical prices would increase because competitive forces among pharmaceutical manufacturers would be severely damaged. The FTC and the Congressional Budget Office have both indicated that various types of disclosure of sensitive pricing information would likely raise prices for prescription drugs:

- In analyzing the potential effect of stricter transparency rules in Medicare, the Congressional Budget Office said, "The disclosure of drug rebates could affect Medicare spending through two principal mechanisms. First, disclosure would probably make rebates less varied among purchasers, with large rebates and small rebates tending to converge toward some average rebate. Such compression…would tend to reduce the rebates that [plan sponsors] received and thus would raise Medicare costs. Second, for a range of medical conditions, drugs appropriate for treatment are available from only a few manufacturers; [and thus] disclosure of drug-by-drug rebate data in those cases would facilitate tacit collusion among those manufacturers, which would tend to raise drug prices."[8]

[8] Letter from Congressional Budget Office to Honorable Joe Barton and The Honorable Jim McCrery, p. 2, available at: https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/03-12-drug%20rebates.pdf, (emphasis added).

- In a letter to the New York Legislature in 2009, the FTC cautioned that mandatory disclosure of pricing information to plan sponsors may excessively restrict the abilities of PBMs and health plans to negotiate efficient, mutually advantageous contracts. To the extent that mandatory disclosures may increase the risk that sensitive business information becomes public, they may also facilitate collusion among third parties.[9] In 2014, the FTC reiterated its point to the ERISA Advisory Council that "if such disclosures publicly reveal previously proprietary and private information about discounts negotiated with PBMs, disclosure may result in less aggressive pricing by, or even collusion among, pharmaceutical manufacturers."[10]

- Additionally, the Department of Justice and the FTC issued a report noting that "states should consider the potential costs and benefits of regulating pharmacy benefit transparency" while pointing out that "vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms."[11]

- Finally, the FTC has also warned several states that legislation requiring PBM disclosure of negotiated terms could increase costs and "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[12]

PCMA is interested in further discussing the underlying goals of the reporting obligations to find solutions that may achieve those goals without risking damaging the competitive forces that allow health care payers to put downward pressure on pharmaceutical costs.

AB 315 Mischaracterizes the Role that PBMs Play in the Health Care System.

Proposed Bus. & Prof. Code Section 4053.2 requires designation and licensing of a PBM representative to be responsible for "supervising" the PBM in the "handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices for each of the pharmacy benefit manager's premises." PBMs do not handle or store drugs. Some PBMs do have affiliated mail-service pharmacies or affiliated retail pharmacies, but those entities do not serve the PBM administrative functions that are the subject of this bill. Mail-service and retail pharmacies are already regulated by the California Board of Pharmacy under nonresident or resident retail licensure regulations, respectively. Additionally, as a nonresident licensee or resident retail licensee, the requirement to have a "pharmacist in charge" already exists. Not all PBMs have affiliated retail or mail-service pharmacies. Therefore, it is unclear what this section

[9] Letter from FTC staff to the Honorable James Seward Concerning NY Senate Bill 58 on Pharmacy Benefit Managers (PBMs), 2009, available at: https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf, (emphasis added).
[10] U.S. Federal Trade Commission, Letter to Larry Good, ERISA Advisory Council, 2014, available at: https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-erisa-advisory-council-u.s.department-labor-regarding-pharmacy-benefit-manager-compensation-fee-disclosure/140819erisaadvisory.pdf.
[11] U.S. Federal Trade Commission & US Department of Justice Antitrust Division, "Improving Health Care: A Dose of Competition," July 2004.
[12] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004).

of the bill is attempting to achieve. To the extent it is attempting to require a PBM representative to oversee *pharmacy practice* in affiliated pharmacies, it is duplicative and unnecessary. To the extent it is attempting to require a PBM representative to oversee the *administrative* functions of a PBM, it is inappropriate under the purview of the Board of Pharmacy because it does not relate to the practice of pharmacy.

AB 315's Reporting Requirements are Preempted by Federal ERISA.

Most PBMs are serving as third-party administrators to welfare benefit plans covered by the Employee Retirement Income Security Act of 1974 (ERISA), a federal law that sets consumer protection standards for most voluntarily established private health plans.[13] These plans are regulated by the U.S. Department of Labor. States are generally pre-empted from regulating those plans covered under federal ERISA. AB 315 would require PBMs to make detailed reports to the Board of Pharmacy, including information relating to benefits managed for the PBMs' California clients that would show the percentage of drugs dispensed through different pharmacy channels, as well as detailed information regarding discounts and price concessions received from drug manufacturers and how those are shared with California clients.

In keeping with a long line of ERISA preemption case law, the U.S. Supreme Court recently held in Gobeille v. Liberty Mutual, that the U.S. Department of Labor has the sole and extensive authority to require reporting, disclosure, and record keeping for welfare benefit plans.[14] Under *Gobeille*, the Supreme Court stressed that ERISA "certainly contemplated the preemption of substantial areas of traditional state regulation." It held that a Vermont all payer claims database reporting law that required third-party administrators (TPAs) serving ERISA plans was pre-empted because it regulated "a key facet of plan administration," and rejected Vermont's contention that it had a traditional power to regulate "in the area of public health." Compliance with the law in *Gobeille* fell on Liberty Mutual's TPA, just as compliance with the terms of AB 315 would fall on PBMs acting as administrators of benefit plans. Like Vermont's reporting law, AB 315 would both (a) intrude on a central matter of plan administration by requiring reporting from plan TPAs, and in addition (b) interfere with nationally uniform plan administration. States simply cannot impose "novel, inconsistent, and burdensome reporting requirements on plans" or on their TPAs,[15] which include PBMs. The Department of Labor, the Court noted, has the sole and "extensive" authority to require reporting, disclosure, and record keeping for welfare benefit plans.

AB 315's Legislative Intent Language is Inaccurate and Does Not Reflect how PBMs Operate in the Health Care Marketplace.

AB 315's legislative intent language alleges that pharmaceutical rebate money causes PBMs to prefer brand name drugs over generic or cheaper brands. This is simply inaccurate. PBMs implement a variety of tools and techniques to promote generics and more affordable brands. These tools include formularies, tiered copays, prior authorization, step-therapy programs,

[13] U.S. Department of Labor, https://www.dol.gov/general/topic/health-plans/erisa.
[14] Gobeille v. Liberty Mutual Insurance Company, 577 U.S. ___ (2016), available at: https://www.supremecourt.gov/opinions/15pdf/14-181_5426.pdf.
[15] Id., at 10.

generic incentives, and consumer education. The GAO reported that plan savings for these PBM intervention techniques ranged from 1% to 9% of total spending on prescription drug benefits.[16]

Additionally, most plans now require generic substitution whenever possible. A survey of health plans indicates that generic substitution rates (i.e., how often a generic product is dispensed when available as a brand alternative) are more than 96% for commercial plans.[17] This number will never be 100% because some prescribers note "Dispense as Written" on the prescription, and in these cases, substitution is not authorized. Also, as drug mandates or restrictions on tools such as step therapy are enacted by state legislatures, the opportunity to substitute brands for generics becomes more limited.

AB 315's legislative intent also alleges that mergers between PBMs, manufacturers, and large pharmacy chains have caused concern about inhibiting competition, conflicts of interest, increased out-of-pocket costs, denying consumer choice, and questions about whether plan sponsors are getting the benefit of rebates. However, the FTC has looked at the issues of mergers in the pharmacy benefit management industry comprehensively and determined that there are not conflicts of interest between PBMs and mail/retail pharmacies and that despite consolidation, competition still exists.[18] PBMs work with all network pharmacies to make sure they offer the best deals possible for consumers and payers. PBMs are evaluated by plan sponsor clients based on savings for their payers and consumers, among other items, and if clients want to make a change at the end of their contract period, they can, and at times, do, because there is healthy competition in the PBM marketplace.

Additionally, PBMs disclose their ownership interests, if any, in mail and retail pharmacies to their clients and government programs. Plan designs and pharmacy networks developed by PBMs are reviewed by plan sponsors, and must meet access standards imposed by plan sponsors and in some cases, law and regulation. Such disclosures manage and avoid potential conflicts of interest regarding pharmacy ownership.

On the issue of rebates, PBMs pass along an average of 90% of drug rebates to their plan sponsor clients.[19] These terms are spelled out in PBM-client contracts and plan sponsors can audit these contracts regularly to ensure that PBMs are complying with the contract terms.

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[16] Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies, U.S. General Accounting Office, p. 4, (2003) available at: http://www.gao.gov/new.items/d03196.pdf.

[17] Pharmacy Benefit Report, 2010/2011, Facts, Figures & Forecasts, 2011, 18th Ed., Novartis Pharmaceutical Corporation, as cited in Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, Visante, Report Prepared for PCMA, 2016, available at: https://www.pcmanet.org/pbms-generating-savings-for-plan-sponsors-and-consumers/.

[18] See, U.S. Federal Trade Commission, PBM Ownership of Mail-Order Pharmacies, August 2005, available at: https://www.ftc.gov/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report, and FTC Letter to Larry Good, ERISA Advisory Council, 2014, available at: https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-erisa-advisory-council-u.s.department-labor-regarding-pharmacy-benefit-manager-compensation-fee-disclosure/140819erisaadvisory.pdf.

[19] Solving the Mystery of Employer-PBM Rebates, Adam Fein, Drug Channels, http://www.drugchannels.net/2016/01/solving-mystery-of-employer-pbm-rebate.html

Finally, AB 315's legislative intent alleges that PBMs are unregulated. PBMs are, in fact, heavily regulated both under federal and state law. In many cases those PBMs are providing services to ERISA plans that operate in California. Those ERISA plans are regulated by the U.S. Department of Labor, and in aspects of insurance, are regulated by the Department of Managed Health Care or the Department of Insurance. PBMs cannot take actions that cause plan sponsors to fall out of compliance with their regulators on insurance matters.

In addition, there are many California statutes that directly regulate PBM activities. Most deal with patient safety and consumer access to prescription drugs—everything from regulation of formularies, Pharmacy and Therapeutic (P&T) Committees, step therapy, prior authorization, capping consumer cost-sharing on high priced dugs, and regulation of mail-service pharmacies operated by PBMs.[20] Supporters argue that there is not a single regulator enforcing those laws. In fact, PBMs are regulated in this state by many entities. The Board of Pharmacy regulates mail-service pharmacies, and the Department of Managed Health Care and the Department of Insurance regulate plan design issues as well as consumer protection and all aspects of the law relating administering outpatient prescription drug benefits.

[20] *See* Cal. B&P Code Secs 4112, 4120, 4124, 4127.2, 4149, 4303, 4340 – Regulation of non-resident pharmacies which includes PBM mail-service pharmacies.
B&P Code Sec 4433 – PBM Audits of Pharmacies.
B&P Code Sec 4440 – PBM/Pharmacy contracts re: maximum allowable costs (MAC).
H&S Code Sec 1342.7 – Standard for approval of copayment, deductible, limitation or exclusion to plan drug benefits.
H&S Code Sec1342.71 (c), Ins Code Sec 10123.193 (c) – Coverage for medically necessary prescription drugs, including non-formulary drugs determined to be medically necessary.
H&S Code Sec1342.71 (d) (1), Ins Code Sec 10123.193 (e)(1) – Formularies "shall not discourage the enrollment of individuals with health conditions."
H&S Code Sec1342.71 (e) (1), Ins Code Sec 10123.193 (f)(1) – Limits the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days to $250.
H&S Code Sec1342.71 (e) (2), Ins Code Sec 10123.193 (f)(2) – Limits bronze level cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days to $500.
H&S Code 1342.71 (f) (1), Ins Code Sec 10123.193 (g)(1) – Defines tiers in formulary.
H&S Code 1342.71 (g), Ins Code Sec 10123.193 (i) – Requires placement of prescription drugs on formulary tiers be based on clinically indicated, reasonable medical management practices.
H&S Code Sec 1363.01 – Notice and explanation of formulary.
H&S Code Sec 1367.01 – Decisions/Appeals re medical necessity.
H&S Code Sec 1367.22 – Prohibits limitation or exclusion of coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug.
H&S Code Sec 1367.24 – Expeditious process by which prescribing providers may obtain authorization for a medically necessary non-formulary prescription drug.
H&S Code Sec 1367.241 – Prior authorization.
H&S Code Sec 1367.244 – Step Therapy.
H&S Code Sec 1367.41 (b), Ins Code Sec 10123.201 (b) – Specifies membership, qualifications for pharmacy and therapeutics committee (P&T) board membership.
H&S Code Sec 1367.41 (f), Ins Code Sec 10123.201 (b)(6) – Specifies pharmacy and therapeutics (P&T) committee duties including "base clinical decisions on the strength of the scientific evidence and standards of practice…"

Although the pharmacy supply chain can seem complicated, PBMs serve an important role. PBMs save 40-50% on drug costs, through unit cost savings, placing incentives for plan sponsors to achieve an affordable drug mix, and managing utilization. Researchers have found that PBMs help patients and payers save $941 per enrollee per year in prescription drug costs, equaling $654 billion over the next 10 years.[21] Plan sponsors use these savings to benefit patients by lowering premiums, deductibles, and cost sharing. California should not be considering barriers to these tools, but AB 315 does just that. For these reasons, PCMA respectfully must oppose AB 315.

If you have any questions, please contact me at 202-756-5743 or our Sacramento advocate, John Caldwell, at 916-441-0702. Thank you.

Sincerely,

April C. Alexander
Senior Director, State Affairs

[21] Visante, "The Return on Investment (ROI) on PBM Services," prepared for PCMA, Nov. 2016, and "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers," prepared for PCMA, Feb. 2016.

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