PCMA

September 6, 2018

The Honorable Edmund G. Brown, Jr.
Governor of California
State Capitol, Suite 1173
Sacramento, CA 95814

Re: Veto Request – AB 315

Dear Governor Brown:

On behalf of the Pharmaceutical Care Management Association (PCMA), we respectfully request that you veto Assembly Bill 315 (Wood) relating to Pharmacy Benefit Management.

PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans and operate mail-order and specialty pharmacies for more than 266 million Americans with health coverage through employers, health insurers, labor unions, Medicare, Medicaid, and other programs. Despite ever-increasing prescription drug costs, PBMs will save plan sponsors and consumers almost $2 trillion from 2012 through 2021, or about 35%, compared with drug expenditures made without pharmacy benefit management.[1] These savings allow employers, government-sponsored plans, and health care services plans to lower co-pays and premiums for beneficiaries and/or mitigate increases.

AB 315:
(1) Will result in higher prescription drug costs for patients by forcing PBMs to disclose proprietary financial data, including rebates to clients, who include, competing drug manufacturers;
(2) Will put patients at risk by mandating a delay in terminating contracts with fraudulent or unsafe pharmacies; and
(3) Is likely pre-empted under the federal Employee Retirement Income Security Act (ERISA) of 1974.[2]

Our specific issues and concerns are outlined below.

Disclosure requirements will increase the cost of prescription drugs

PBMs compete for clients through the negotiation of contract terms, including pharmacy network and access levels, pharmacy performance requirements and metrics, benefit design, mail-order benefit design, and formulary development. Section 2 of AB 315 requires PBMs to disclose extensive proprietary and competitive financial information, including rebates and fees received

[1] *PBMs: Generating Savings for Plan Sponsors and Consumers*, Visante, September 2011. Average PBM savings represents current practice and is reflected in the government's baseline projections for national health expenditures and Medicare Part D.
[2] 29 U.S.C. §1001 *et seq.*

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by the PBM through their contracts with all drug manufacturers. These mandated disclosures risk leaking into the public domain and reducing competition in the marketplace, thereby increasing overall healthcare costs. PBMs have thousands of clients, and while we try to protect such data through confidentiality agreements, there are no guarantees. The detailed disclosure requirements of AB 315 will increase the risk of anti-competitive behavior among manufacturers if the data is inadvertently made public. Once data is publically disclosed, there's no way to re-secure it.

Additionally, the contracting requirements will result in higher prescription drug prices by forcing PBMs to provide aggregate rebate data, fees, and other proprietary financial information to their self-insured clients, who include drug manufacturers (directly or through Third Party Administrators). The bill tries to limit disclosure by applying only to therapeutic categories in which there are a minimum of three drugs, but this is irrelevant. Even if a class of drugs has 3 or more products, it is important to note that: (1) a formulary may only cover one or two drugs in a therapeutic category, so the disclosure is still specific to a single drug; (2) if a PBM client is a drug manufacturer, they will get direct access to their competitor's pricing; and (3) drug manufacturers often have multiple drugs in a class, which inflates the number of drugs but not unique competitors, and they will take full advantage of this situation. For example, Gilead manufacturers Sovaldi, Harvoni, Epclusa, and Vosevi to treat Hepatitis-C. Additionally, Novo Nordisk manufacturers Novolog, Novolin, Victoza, Ozempic, and NovoRapid to treat Diabetes.

Drug manufacturers will learn what their competitors have paid in rebates, fees, exclusivity contracts and other proprietary financial information. This will lead to the "tacit collusion" the U.S. Federal Trade Commission (FTC) expressly cautioned against. Since 2005, the FTC has analyzed several state legislative proposals involving mandatory transparency requirements and concluded that "[i]f 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." [3]

In opposing AB 315, the Department of Finance (DOF) analyzed these same provisions and concluded they "could increase health care costs due to lower drug rebates being secured by PBMs when they have to disclose sensitive price and rebate information used in negotiations with pharmaceutical companies."[4]

Mandating that every PBM contract contain the same information reduces competition in the marketplace, inhibiting the ability of PBMs to differentiate themselves among potential clients. Contracting restrictions such as the ones in AB 315 will reduce competition and, by definition, increase costs for patients and health plans.

PBM clients are sophisticated purchasers of health care and often hire consultants to advise them during their process of creating their pharmacy benefit and seeking a PBM to administer the benefit. Each PBM can design different products that reach clients of varying sizes, enrollee/employee population, and g0eographic reach. Each client determines which services it

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[3] Joint letter from the FTC's Office of Policy Planning, Bureau of Economics, and Bureau of Competition to Larry Good, Executive Secretary, ERISA Advisory Council, Department of Labor, March 14, 2014.
4 California Department of Finance, AB 315 Bill Analysis, Amendment Date: 7/11/2017

wants a PBM to perform on its behalf and contracts with a PBM accordingly. This can include assisting with managing the health plan's list of covered drugs (a "formulary"), contracting with pharmacies for participation in the plan's provider network, using a mail service pharmacy, and managing pharmacy claims payment, to name a few. The client also indicates how it wants the PBM to deal with rebate payments—whether it wants a 100% pass through of rebates or an alternative arrangement. AB 315 is contrary to the options plan sponsors currently have to obtain the services and information they want from the PBM they select to administer their prescription drug benefits. The PBM marketplace is highly competitive and PBMs compete for business by creating robust pharmacy benefits that also provide cost savings.

Pharmacy notice requirements will put patients at risk

Under section 4441(i) of AB 315, PBMs must provide a pharmacy notice of any material change that affects, among other things, "contract termination," but does not include any exceptions for instances of fraud, patient safety, or serious contract breaches such as exclusion from a federal or state health care program, or failure to maintain proper insurance. This, in turn, would require plans to include pharmacies in their network for up to 30 additional days to comply with the notice provisions, exposing patients to potentially unsafe pharmacies and/or health plans to fraudulent pharmacy claims.

A recent example is a pharmacy in the East Bay under investigation by the federal Drug Enforcement Agency (DEA) for dispensing large quantities of opioids under suspicious circumstances. The DEA revoked the pharmacy's DEA registration. Under AB 315, a PBM contracting with this pharmacy would be required to provide the pharmacy a 30 day notice of termination and continue to allow patients to fill prescriptions at this store.[5]

Further, section 4441(j) would prohibit a PBM from notifying plan enrollees when a pharmacy has been terminated from the network until notice has been provided to the pharmacy. Like section 4444(i) above, this provision could result in patients filling prescriptions at fraudulent and/or potentially unsafe pharmacies for up to 30 additional days, putting them at risk. Unfortunately, there have been numerous cases of "pharmacy shopping" for people addicted to opioids. In some instances, pharmacies have been caught illegally dispensing thousands of controlled substances before being shut down. Once exposed, these pharmacies should not be dispensing for one additional day, let alone 30 days.

Under continuity of care, PBMs typically provide plan beneficiaries impacted by a pharmacy termination with 30-day notice, except in cases of immediate termination based on fraud when 30-day notice is impractical. This is done so the enrollee may transition their prescriptions to a new pharmacy. Notifying beneficiaries and pharmacies at the same time provides adequate notice to pharmacies while keeping focus on the needs of beneficiaries.

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[5] https://www.nbcbayarea.com/news/local/DEA-Seizes-Records-and-Drugs-from-East-Bay-Pharmacy-with-Troubled-Past-482212961.html

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AB 315 is at odds with federal law

In addition to the increase in prescription drug costs and risk to patient safety, the bill raises several potential conflicts with federal law. Specifically, the bill appears to violate ERISA.

ERISA prohibits states from imposing laws that deal with the administration of health plans. The United States Supreme Court has interpreted this to mean any state law that has a "reference to" or "connection with" ERISA-governed plans.[6] Section 4441(a)(3) defines "purchaser" as a "health benefit plan sponsor or other third-party payer", the vast majority of which are governed under ERISA. The contract requirements in section 2 of the bill "refer to" and/or create a "connection with" ERISA plans and, therefore, appear on their face to be preempted under federal law.

The DOF also raised this concern in its analysis of AB 315 last year, stating that "This bill could also create ambiguity between state and federal law and result in costly litigation to resolve federal preemption issues."

A detailed legal analysis of potential ERISA preemption concerns with AB 315 is attached.

For the reasons stated, we respectfully urge you to veto AB 315.

Sincerely,

Bill Head
Sr. Director, State Affairs

[6] Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 943 (2016).

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