AB 315: Mandating PBM Registration and Disclosures – An Important Step to Increasing Drug Price Transparency and Competition

AB 315, considered to be a complementary bill to SB 17, which mandated prescription drug pricing transparency, is an important bill that would ensure more transparency of pharmacy benefit managers (PBMs) by regulating PBMs and gathering data on how PBMs impact the dispensing of certain prescription drugs. The intent of the bill is to allow consumers to purchase drugs at the lowest price by allowing purchasers, like health plans, to keep PBMs accountable for the savings PBMs promised.

However, this bill almost didn't come to be. AB 315 was sent to the inactive file back in September 2017, with no further movement for nearly a year. However, in the waning days of the 2017-2018 legislative session, AB 315 soared back to life. In a matter of nine days (August 20-29, 2018) and without additional hearings, AB 315 was amended, passed in the Senate, and concurred in the Assembly. As AB 315 awaits the Governor's signature, we take a look at what's at stake in this bill.

What Are the Issues Concerning PBMs?

Pharmacy benefit managers, among many duties, create drug formularies, negotiate rebates and reimbursement amounts for pharmacies, conduct drug utilization reviews, and administer pharmacy benefits for health plans.[1] As the California Assembly analysis for AB 315 noted, PBMs, as "middlemen[,] have one of the most prominent roles in determining coverage and payment for drug products, despite never taking physical possession of the drug . . . [and] are essential in the national

conversation surrounding lowering prescription drug prices."[2] Yet, the same Assembly analysis noted that "PBMs have, for the most part, escaped the scrutiny of regulation and licensure."[3]

Back in March 2018, The Source summarized two California Legislature hearings about high drug pricing. One of the hearings focused solely on PBMs. The speakers at the hearings, David Balto, a former antitrust attorney for the Department of Justice and the Federal Trade Commission, and Jon Roth of the California Pharmacists Association argued that California should adopt measures to regulate PBMs. Both of them noted that the lack of transparency and lack of regulation lead to higher drug prices and make the PBM industry "one of the least regulated sectors of the health care system."

Furthermore, in the California Assembly Standing Committee on Business and Professions Hearing on AB 315, David Dayen, author of the American Prospect article, Hidden Monopolies that Raise Drug Prices, testified that pharmacy benefits managers are "significant controllers of the drug pricing system" and were intended to "reduce the prices Americans pay for medication . . . [but] have done little but exacerbate [drug prices]."[4] Specifically, Dayen pointed out three major issues concerning PBMs: (1) "excessive sector-wide concentration" with three companies (Optum, CVS Caremark, and Express Scripts) controlling 75-80% of the market and creating "effective monopolies"; (2) "inherent conflicts of interests" where pharmacy chains like CVS merged with PBMs like Caremark or where PBMs compete with brick and mortar pharmacies through mail order pharmacies; and (3) "extreme lack of transparency," where "one obscure yet deceptively powerful player" is hoarding the information.[5] AB 315 seeks to resolve at least the second and third issue.

What's the Importance of AB 315?

The author of AB 315, Assembly member Jim Wood, stated that this bill would resolve the lack of transparency of PBMs by requiring accountability and information through a basic regulatory framework.[6] Dr. Wood explained to the full Assembly that:

"Only the PBM, the pharmacy benefit manager, knows how much each component in this multi-sided market makes each prescription drug purchase. They use this information to their advantage, and to their profit. I believe the lack of transparency in PBM operations is an issue requiring greater information and accountability to purchasers, and ultimately to consumers."[7]

AB 315's basic regulatory framework would result in: (1) **pharmacy point-of-sale notification**, where pharmacies must notify the customer when the retail price of a prescription drug is lower than the applicable cost-sharing amount; (2) **mandated duties of PBMs**, such as requiring PBMs to exercise good faith and fair dealing, to notify any conflicts of interests, to disclose to purchasers aggregate amounts like total rebates received, and to disclose to pharmacy network providers any material changes in reimbursement or other specified contract provisions; (3) **a pilot project** to assess how health plan and PBM prohibitions affect the dispensing of certain prescription drugs; (4) **registration of PBMs** with the Department of Managed Healthcare (DMHC); and (5) creation of a **Task Force on Pharmacy Benefit Management Reporting** to determine what information health plans or their contracted PBMs should report to DMHC.

Proponents of AB 315 argue that the mandated disclosure under the bill would ensure that purchasers of drugs would know that PBMs are doing their job.[8] They point out that although "secrecy around PBM transactions has a ripple affect across various areas for consumers, not the least of which is health insurance premiums," somehow, "PBMs and prescription drug companies are some of the last few health care actors that have escaped state requirements for regulation, disclosure, and transparency" and the "sole exception" to "increased scrutiny of all providers, insurers, and manufacturers" has been the PBM industry.[9] Senator Ed Hernandez, the author of SB 17, agrees that AB 315 would allow "pharmacists and consumers [to] have the best information and can get the best product at the lowest price" by requiring transparency from "an industry that has never been regulated."[10]

On the other hand, the national trade organization for PBMs, Pharmaceutical Care Management Association (PCMA), oppose AB 315 arguing that the Federal Trade Commission found PBM competition to be "robust" and that the amount of disclosure desired differ for each purchaser. Furthermore, opponents argue that too

much transparency will lead to lower rebates and lower discounts because manufacturers, which PBMs negotiate with to lower drug pricing, would gain insights on the PBMs' negotiating tactics.[11] As such, that knowledge would produce a "chilling effect" and take away a "critical tool to lower drug costs."[12]

Mandated Disclosures By PBMs is Not New for Almost Half of U.S. States (and Federal Lawmakers Take Note)

Still, mandated disclosures of PBMs are not new. A cursory review of state laws reveal that at least twenty-six states require disclosure of drug pricing methodology or pricing sources, adjudication of complaints between PBMs and pharmacies, and/or require consistent MAC[13] pricing information update. Ten states require more extensive disclosures of PBMs, and seventeen states require licensure of PBMs.[14] So, what California is seeking to do with AB 315 is nothing new. Instead, California would be joining other states in tackling high drug pricing by regulating all parts of the drug pricing system including PBMs.

Regulation of PBMs has also attracted the attention of federal lawmakers. For example, in 2017, U.S. Representative Doug Collins (R-GA) introduced H.R. 1316, the Prescription Drug Price Transparency Act, to require transparency from PBMs. He noted that:

"PBMs engage in predatory practices designed to boost their own profit margins at the expense of insurers, contracting pharmacies, patients, and—in their relationships with federal programs—taxpayers. The lack of transparency in their operations has allowed them to control the market unjustly, with the result that these companies withhold savings that they have promised to pass on."[15]

Additionally, also in 2017, U.S. Senator Ron Wyden (D-OR) introduced S. 637, the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act, to require PBMs to disclose their aggregate rebates provided by drug manufacturers. Sen. Wyden pointed out that "there is little information about why these drugs are so expensive. . . [and that disclosure would] promote competition to bring down the cost of prescription drugs."[16]

Most recently, U.S. Senator Chuck Grassley (R-IA) wrote to the Federal Trade Commission, raising concerns that the pending mergers between Cigna and Express Scripts, a PBM, as well as CVS Health and Aetna would result in the "three largest pharmacy benefit managers (PBMs) all vertically integrated with insurance companies."[17] Such integration may lead to more anticompetitive practices such as collusion to increase prices. As such, increased transparency and regulation of PBMs would ensure that the negative effects of such integration are tempered. Disclosure and regulation would make all purchasers aware of how PBMs conduct business and whether the savings secured by PBMs are actually passed down to the purchasers and consumers, thereby preventing unjustified increase in prices.

It's clear that PBMs have increasingly come under scrutiny and that the push for increased transparency is forthcoming at both the state and federal level. While it's still unclear how these new laws impact PBMs or drug prices specifically, what's agreed upon is that data on how PBMs conduct business is useful and provides important information and insight. As such, the passage of AB 315, pending the Governor's signature, is a small but important step towards better understanding how drug prices are formulated and consequently decelerating the rise of drug prices.

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[1] Senate Committee on Business, Professions and Economic Development, Background Paper for Oversight Hearing, Pharmacy Benefit Managers 101 at 2 (Mar. 20, 2017), http://sbp.senate.ca.gov/sites/sbp.senate.ca.gov/files/PBM%20Background%20paper.pdf.

[2] Concurrence in Senate Amendments of Assem. Bill No. 315 (2017-2018 Reg. Sess.) as amended August 24, 2018, pg. 9.

[3] *Id.*

[4] Hearing before the Assem. Standing Com. on Bus. and Prof. (Apr. 18, 2017), testimony of David Dayen.

[5] *Id.*

[6] *Id.*, testimony of Assemblymember Jim Wood.

[7] Assembly Floor Hearing (June 1, 2017), testimony of Assemblymember Jim Wood.

[8] *See* Hearing before the Assem. Standing Com. Health (May 9, 2017), testimony of Sara Flocks, policy coordinator for the California Labor Federation.

[9] Sen. Comm. On Health, Analysis of Assem. Bill No. 315 (2017-2018 Reg. Sess.) as amended May 30, 2017, pg. 8.

[10] Senate Floor Hearing (Aug. 28, 2018), testimony of Senator Ed Hernandez.

[11] *See* Hearing before the Assem. Standing Com. Health (May 9, 2017), testimony of John Caldwell, senior lobbyist for Public Policy Advocates.

[12] Sen. Comm. On Health, Analysis of Assem. Bill No. 315 (2017-2018 Reg. Sess.) as amended May 30, 2017, pg. 8.

[13] MAC stands for Maximum Allowable Cost. MAC pricing means the maximum amount a purchaser will pay for a specific drug. MAC pricing is up to each PBM, and there is no standardized process on how to determine MAC pricing.

[14] The ten states that would require extensive disclosures are Hawaii, Maryland, Mississippi, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Dakota, and Vermont. The seventeen states requiring licensure for PBMs are Connecticut, Georgia, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Mississippi, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Washington, and Wyoming.

For more on state efforts to prevent gag clauses where PBMs can contractually prevent pharmacists from helping consumers pay less for a drug, see the Source's blog post, Spotlight on 2018 State Drug Legislation: Part 3 – Pharmacist Gag Clauses.

[15] *Collins Introduces Legislation to Increase Drug Pricing Transparency* (Mar. 2, 2017), https://dougcollins.house.gov/media-center/press-releases/collins-introduces-legislation-increase-drug-pricing-transparency.

[16] *Wyden Calls for Increased Drug Pricing Transparency to Lower Costs* (Mar. 15, 2017), https://www.finance.senate.gov/ranking-members-news/wyden-calls-for-increased-drug-pricing-transparency-to-lower-costs.

[17] *Grassley Requests Robust Antitrust Review of Pharmaceutical Supply Chain Mergers* (Aug. 14, 2018), https://www.grassley.senate.gov/news/news-releases/grassley-requests-robust-antitrust-review-pharmaceutical-supply-chain-mergers.