Spotlight on 2018 State Drug Legislation: Part 6 – Pharmacy Benefit Manager Regulation

Update: This post was written before the end of the 2018 legislative session. For the most recent count of states that passed these legislation, see the **Spotlight on 2018 State Drug Legislation Summary: The Year in Review or download our Summary Chart.*

In the 2018 legislative session, ten states passed fourteen bills to regulate pharmacy benefit mangers (PBMs). In total, 27 states considered 49 bills to regulate PBMs (see map below). This number does not include bills that relate to PBMs only as to gag-clauses in contracts with pharmacists or the state Medicaid program (e.g. KY's SB 5 and LA's SB 130). This statistic makes PBM regulation the second most popular topic in pharmaceutical legislation for state lawmakers. The only topic that got more legislative attention was the banning of gag-clauses in pharmacy contracts.

In recent years, PBMs received substantial criticism from members of the federal government. In a talk before the 2018 National Health Policy Conference of America's Health Insurance Plans (AHIP), FDA Commissioner Scott Gottlieb discussed how misaligned incentives between patients and PBMs drive prescription drug costs higher.[1] He blamed consolidation in the PBM industry, where 3 companies control 80% of the market share, and a lack of transparency in pricing that allows PBMs and others in the drug distribution chain to share monopoly rents rather than compete on pricing. In May 2018, President Trump further criticized the deceptive practices of PBMs and

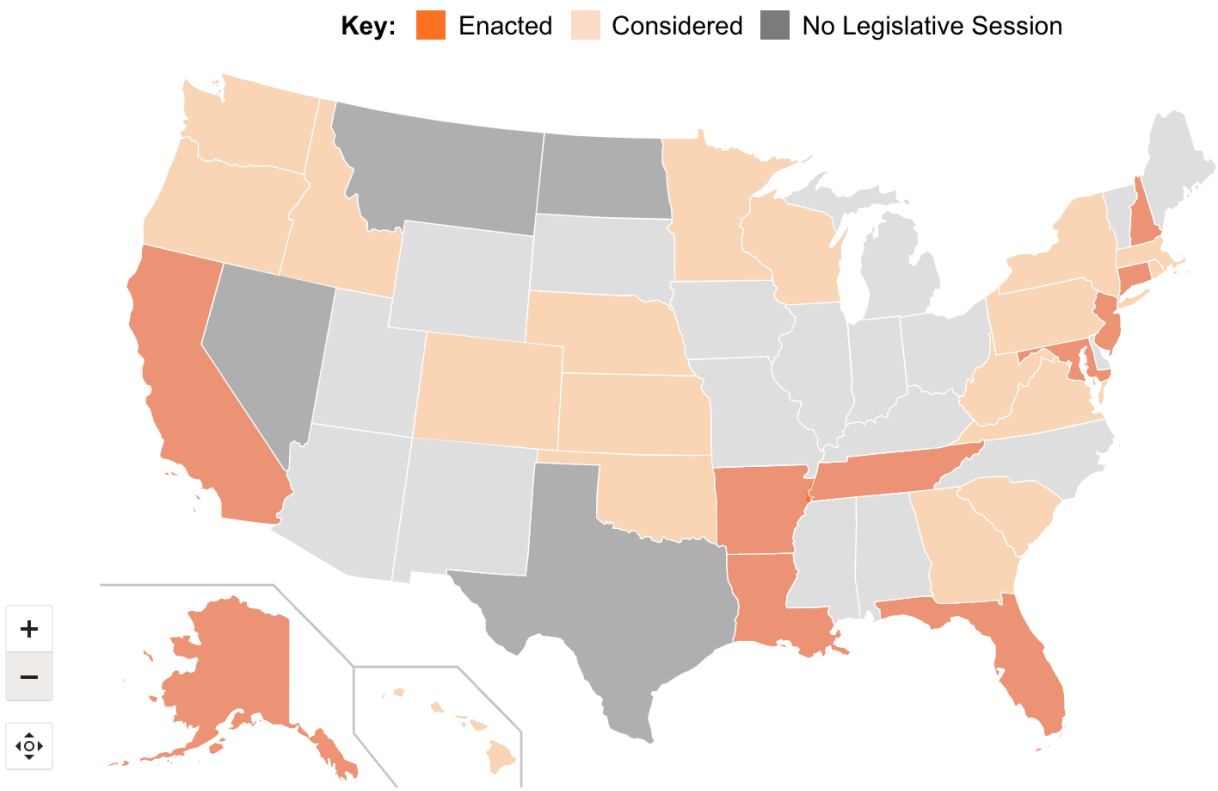
said, “We’re very much eliminating the middlemen… The middlemen became very rich. They won’t be so rich anymore.”[2] The federal government, however, has so far failed to act, so state lawmakers have taken up the mantle of the regulation of PBMs.

States’ Legislative Attempts to Regulate PBMs

Despite the growing desire among state lawmakers to address perceived concerns with PBMs’ behaviors, there was little consensus among states about the types of laws to regulate them. Many states required PBMs to be licensed in the state and to provide information the aggregate amounts of drug rebates either to the state or to payers or insurers who contract with them. Other states considered, but did not pass, provisions that would have prevented PBMs from giving patients financial incentives from using mail-order pharmacies.

Pharmacy Benefit Manager Regulation

Legislation to regulate Pharmacy Benefit Managers (PBMs) typically include provisions that 1) require PBMs to register with the state, 2) mandate disclosures by PBMs, or 3) prevent PBMs from incentivizing the use of mail-order pharmacies. See the Source’s Spotlight on 2018 State Drug Legislation Part 6 for more information. *Note: Legislation included here do not include any bills relating only to PBMs in a state Medicaid program or bills that contain only bans on pharmacist gag-clauses (see The Source’s gag-clause map or **blog post**).



State Laws Requiring PBMs to be Licensed: Seventeen states already require PBMs to be licensed.[3] This year Alaska, Arkansas, California, Florida, New Jersey and Tennessee joined those states, bringing the total number of states that require PBMs to be licensed to 23. As an example of state licensing requirements, Arkansas' SB 2/HB 1010 allows the state's insurance commissioner to establish the rules for the licensing of PBMs, including fees, application process, financial standards, and reporting requirements. The law also allows the Insurance Commissioner to approve the compensation arrangement between PBMs and pharmacies to ensure that reimbursement rates are "fair and reasonable." In California, the legislature passed AB 315, one of the most comprehensive laws passed in 2018 to regulate PBMs (see California Legislative Beat on The Source Blog). AB 315 requires PBMs to register with the Department of Managed Health Care (DMHC), disclose aggregate rebates to purchasers, and creates a task force and pilot project to assess whether the state should require PBMs to disclose more

information.

State Laws Requiring Disclosures by PBMs: In addition to AB 315 in California, Connecticut and Louisiana passed laws in 2018 to mandate additional disclosures from PBMs on top of existing laws that require PBMs to be licensed. These states join the other ten states[4] with existing disclosure laws to bring the total number of states requiring substantial PBM disclosures to thirteen. Connecticut (HB 5384) requires PBMs to file a report with the state Insurance Commissioner that discloses aggregate rebates for pharmaceuticals. The commissioner is then required to issue a report that compiles and aggregates this rebate information. HB 5384 also requires disclosures by insurers, as discussed in Part 5 of The Source's Spotlight on 2018 State Drug Legislation, to give lawmakers information about the cost of prescription drugs in the state and whether insurance carriers are using the rebates from PBMs to reduce the cost for the insured, either through premium reductions or reductions in the cost-sharing at the time the drug is sold. Louisiana (SB 283) goes even further than Connecticut's new law, as each report a PBM files will be published on the state's Department of Insurance website. While the report will not disclose the prices charged for specific drugs or classes of drugs, or the amount of any rebates provided for specific drugs or classes of drugs, it will provide the public with information about the typical size of drug rebates and give policy makers a better understanding of whether those rebates are passed on to insurers.

State Laws Prohibiting PBMs From Requiring Mail-order Pharmacies: The third category of PBM regulation prohibits PBMs from requiring patients to use mail-order pharmacies or offer them financial incentives for doing so. For more than a decade, states have debated the value of mail-order pharmacies versus retail pharmacies as they weigh the desire to preserve retail pharmacies and encourage transparency in drug pricing against

increasing operating costs for PBMs. The concern is mail-order pharmacies can drive independent and retail pharmacies out of business, causing patients to lose access to local pharmacy services (e.g. vaccinations and pharmacist counseling about medication interactions and side effects). Furthermore, PBMs with their own mail-order pharmacies (which is currently all of the large PBMs[5]) may restrict patient access to certain drugs through tighter formulary control, obscure the price of drugs, and pocket the difference between the rate they negotiate with the drug manufacturer and the amount they charge to the plan sponsor (i.e., spread pricing). Finally, the large PBMs often exclude independent mail-order pharmacies from their network and negotiate reimbursement rates with retail pharmacies that are below that of their own pharmacies, triggering antitrust concerns.[6] As a result, states like New York and Pennsylvania have existing laws that prohibit financial incentives to encourage the use of mail-order pharmacies.

In 2018, Arkansas joined New York and Pennsylvania when it passed SB 2/HB 1010. In addition to provisions requiring PBMs to be licensed, Arkansas' law requires PBMs to demonstrate "network adequacy" for pharmacy benefits so that all beneficiaries have in-network pharmacies near their homes. The law prohibits PBMs from including mail order pharmacies in the determination of network adequacy. Furthermore, the law prohibits PBMs from reimbursing a pharmacy or pharmacist in the state at an amount less than the amount that the pharmacy benefits manager reimburses a PBM-affiliate for providing the same pharmacist services. In addition to Arkansas, in 2018 five states (Colorado, Maryland, Minnesota, Nebraska, and South Carolina) considered, but did not pass, legislation to prevent PBMs from disadvantaging retail pharmacies.

Will These New Laws Regulating PBMs Affect Prescription Drug Costs?

The regulation of PBMs is another tool in the arsenal of states looking to combat rising prescription drug prices, but the effect of these laws is questionable. In theory, PBMs should *decrease* drug prices because they can negotiate on behalf of large numbers of insured patients to get discounts from pharmaceutical manufacturers who would otherwise have little incentive to offer discounts on patented drugs. A 2003 report from the General Accounting Office (GAO) found that "[t]he average price PBMs negotiated for drugs from retail pharmacies was about 18 percent below the average cash price customers would pay at retail pharmacies for 14 selected brand-name drugs and 47 percent below the average cash price for 4 selected generic drugs…PBMs provide plans even greater savings when drugs are dispensed through their mail-order pharmacies… [and] PBMs passed through to plans certain rebates they earned from drug manufacturers."[7]

If these findings are still true today, the actions by states to regulate PBMs will likely *increase* drug prices, as a result of added costs of operation for PBMs, which will likely be passed onto plan sponsors. Since the GAO report, however, the PBM industry has consolidated both horizontally and vertically. Three PBMs (CVS Caremark, OptumRx and Express Scripts) now control more than 75% of the PBM market,[8] and all of them are or will likely be vertically integrated with an insurer, leaving no standalone PBM.[9] This highly consolidated market leaves many experts questioning if PBMs have the same incentive to negotiate strongly for their beneficiaries and pass those savings on to plan sponsors. Moreover, the vertically integrated market means that prices are hidden, so payers, lawmakers, and researchers have little data to assess whether PBMs are saving payers money.

In response to this lack of transparency, in the 2018 legislative term, many states considered legislation that would provide insight into the functioning of this consolidated market, such as requiring state licensing of PBMs, mandating additional disclosures, and restricting PBMs from steering patients to in-house pharmacies. While the additional administrative requirements would likely *increase* the cost of operation for PBMs, with little power to prevent future horizontal and vertical mergers of large, national companies, the states' only effective tools in their purview may be the regulation of PBMs and a demand for more transparency. As a result, these laws, while limited in their effect, should been seen as respectable attempts by the state to exert power to protect residents in their state.

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[1] Inserro, Alison. FDA's **Gottlieb Blames Rebates, Reimbursement Issues for Holding Back Biosimilar Market**. Am. J. Managed Care. Published March 7, 2018. Available from: https://www.ajmc.com/newsroom/fdas-gottlieb-blames-rebates-reimbursement-issues-for-holding-back-biosimilar-market.

[2] O'Brien, Jack. **'Eliminating the Middlemen': Trump Takes Aim at PBMs in Drug Pricing Speech**. HealthLeaders Media. May 11, 2018. Available from: https://www.healthleadersmedia.com/finance/eliminating-middlemen-trump-takes-aim-pbms-drug-pricing-speech.

[3] 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.

[4] The nine states with existing disclosure laws are: Hawaii, Maryland, Mississippi, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Dakota, and Vermont.

[5]. ExpressScripts owns the third largest pharmacy and the largest mail-order pharmacy. CVS Caremark is the largest pharmacy chain and owns the second largest mail-order pharmacy. UnitedHealth Group, which owns the PBM, OptumRx, owns the sixth largest pharmacy and the third largest mail-order pharmacy. More details can be found at: Fein, Adam J. **The Top 15 U.S. Pharmacies of 2016**. Drug Channels Blog. Feb. 2, 2017. https://www.drugchannels.net/2017/02/the-top-15-us-pharmacies-of-2016.html.

[6] Park Irmat Drug Corp. v. Express Scripts Holding Co., 310 F. Supp. 3d 1002 (E.D. Mo. 2018). Burton's Pharmacy, Inc. v. CVS Caremark Corp., No. 1:11CV2, 2015 WL 5430354 (M.D.N.C. Sept. 15, 2015), report and recommendation adopted, No. 1:11CV2, 2015 WL 5999386 (M.D.N.C. Oct. 14, 2015)

[7] US Government General Accounting Office. Report to the Honorable Byron L. Dorgan, U.S. Senate. **Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies**. GAO-03-196. Jan. 2003. Available from: https://www.gao.gov/assets/240/236828.pdf.

[8] Rule, Michael. **Policymakers Identify PBM Consolidation as a Driver of Higher Costs and Fewer Patient Choices**. National Community Pharmacists Association Blog. Feb. 16, 2018. https://www.ncpanet.org/newsroom/ncpa's-blog–the-dose/2018/02/16/policymakers-identify-pbm-consolidation-as-a-driver-of-higher-costs-and-fewer-patient-choices.

[9] CVS Caremark is a PBM/Pharmacy group and will soon merge with the insurer Aetna (see Al-Muslim, Aisha. **CVS Lays Out Vision for Future as Aetna Merger Looms**. The Wall Street

Journal. Nov. 6, 2018. https://www.wsj.com/articles/cvs-reports-higher-revenue-profit-1541507882.). ExpressScripts and the insurer Cigna have approval from the Justice Department to merge (see Abelson, Reed. **Merger of Cigna and Express Scripts Gets Approval From Justice Dept**. The New York Times. Sept 17, 2018. https://www.nytimes.com/2018/09/17/health/cigna-express-scripts-merger.html and Federal Trade Commission. **20180982: Express Scripts Holding Company; Cigna Corporation**. Premerger Notification Granted. https://www.ftc.gov/enforcement/premerger-notification-program/early-termination-notices/20180982). OptumRx is already owned by the insurer UnitedHealth Group.