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ALERT

Proposed State and Federal PBM Legislation: Is There Reason for Action Now?

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Legislation aiming to reform the regulation of pharmacy benefit managers (PBMs) remains on the horizon on both the federal and state levels. In particular, 2023 was a fertile year for PBM legislative initiatives. Some of these initiatives include, for example: (i) Lower Costs, More Transparency Act (H.R. 5378); (ii) Pharmacy Benefit Manager Reform Act (S. 1339); (iii) Modernizing and Ensuring PBM Accountability Act (S.2973); (iv) Pharmacy Benefit Manager Transparency Act (S. 127); (v) Delinking Revenue from Unfair Gouging (DRUG) Act (H.R. 6283); (vi) Missouri's Senate Bill 843 (S.B. 843); and (vii) Wisconsin's Assembly Bill 773 (W.I. AB773).

Of the many proposed legislative initiatives introduced in 2023, several attempt to regulate PBMs by increasing transparency of PBMs' pricing and practices and by curtailing and realigning certain PBM relationships. Common themes found across the proposed legislation include: (i) eliminating spread pricing; (ii) expanding reporting obligations; (iii) reshaping the relationship between PBMs and their affiliated pharmacies; and (iv) redefining and constricting PBMs' outlets for remuneration. While it is not clear whether any of these bills will pass, it does seem clear that exposing PBMs' opaque business practices and imposing regulatory constraints will remain a top priority for regulators. Evaluating various legislative proposals provides insight into regulators' current priorities and offers potential opportunities for action vis-à-vis your current (as well as future) PBM contract.

These opportunities for "action" might encompass different activities, such as: (i) examining how your current PBM contract addresses, if at all, the various regulatory principles; (ii) determining whether there are benefits to your health plan and/or your group health plans to

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integrate some of these principles now into your current PBM contract (and the potential impact on current pricing); and/or (iii) determining how these regulatory principles could shape the contours of your next-generation pharmacy program. We summarize below some of these proposed legislative changes, the questions they provoke, and the actions you might want to consider.

What to Consider About Your PBM Contract Now

Eliminating Spread Pricing

Spread pricing is one of the main PBM practices being targeted in ongoing federal and state legislation. At least seven legislative bills introduced in 2023 are seeking to eliminate spread pricing including, for example, the Pharmacy Benefit Manager Reform Act (S. 1339), which proposes 100% pass-through of all drug rebates and requires a series of disclosures regarding the cost, price and reimbursement of drugs and PBM fees, markups, and discounts.

Spread pricing is a practice in which a PBM earns a profit or "spread" by keeping the difference between the price the PBM pays for drugs and the higher drug price the PBM charges to its payors, such as a health plan. Through this spread pricing model, the opaque drug pricing channel – rather than the more transparent administrative fees channel – becomes a PBM's major source of profit. While this practice has historically been common among PBMs, the chorus of criticism against this pricing model is reaching a crescendo for its lack of transparency and fairness that results in increased drug costs to health plans (and their members) and decreased reimbursements to pharmacies.

Even before a statutory or regulatory elimination of spread pricing, health plans should begin to consider now how this change could impact current and future PBM contracts by asking:

- If your current PBM contract includes both spread and pass-through pricing models, which model predominates among your group health plans?
- Who/what is the current driver of traditional/spread pricing in your service area (general market forces; tradition; group health plan preferences; group health plan administrative ease)?
- If the majority/many of your group health plans have adopted the traditional or spread pricing model, what is your plan of action (financial, operational, cultural) to prepare these group health plans for the transition to pass-through pricing (and the impact of significant administrative fees, notwithstanding transparent drug costs)?

Expanding Reporting Requirements

Various ongoing federal and state legislative efforts that aim to increase oversight and transparency in the PBM industry are resulting in increased disclosure and reporting requirements for both health plans and PBMs. At least 15 legislative bills introduced in 2023 require increased disclosures and reporting related to PBM drug pricing and rebates. The Lower Costs, More Transparency Act (H.R. 5378), for example, which is a

consolidation of numerous former bills aimed at PBM cost transparency, proposes that health plans and/or PBMs semi-annually report to plan sponsors (as defined by ERISA) certain drug pricing information through machine-readable files.

The information to be reported would include, but is not limited to: (i) drug pricing information such as total amount of out-of-pocket spending by members, total net spending by the health plan, and total amount received by the health plan from any remuneration including drug manufacturer rebates; (ii) a breakdown of the total gross spending by drug category or class before remuneration from drug manufacturers, and the net spending after such remuneration; (iii) amounts paid directly or indirectly in rebates, fees, or any other type of compensation to entities referring health insurance business to the PBM; (iv) explanation of benefit disclosing affiliate pharmacies; and (v) dispensing percentage from affiliated pharmacies and the amount charged.

Given this move toward more mandated reporting and disclosures, you might want to begin to consider the following questions:

- Do these various increased reporting and disclosure requirements identify categories of data/information that would be useful to your health plan now?
- Can any of the existing reporting requirements in your PBM contract be restructured to align more closely to the proposed reporting and disclosure requirements?
- What impact, if any, could there be on your administrative fees if the proposed legislation strengthens/changes existing reporting and disclosure requirements?

Reshaping the Relationship Between PBMs and Affiliated Pharmacies

Some proposed legislation also attempts to further regulate the relationship between a PBM and its affiliated pharmacies. Affiliated pharmacies are perceived to receive more favorable treatment from their organizationally aligned PBMs (e.g., increased reimbursements and member steering that results in higher utilization). To address this issue, some legislation attempts to limit transactions between a PBM and pharmacies it owns, controls, or is otherwise affiliated with. One such piece of proposed legislation, the Delinking Revenue from Unfair Gouging (DRUG) Act (H.R. 6283), would prohibit PBMs' ability to reimburse affiliated pharmacies more than non-affiliated pharmacies for dispensing the same drug or providing the same pharmacist services. The same legislation also would prohibit PBMs from steering members to pharmacies the PBM owns, controls, or is otherwise affiliated with.

Health plans typically do not have direct contracts with their network pharmacies (whether such pharmacies are affiliated with the PBM or non-affiliated) and rely upon the PBM to build pharmacy networks. Therefore, your PBM contract should (and likely does) set forth terms that the PBM is required to include in its contracts with pharmacies supporting your health plan. In anticipation of additional controls being established on the relationship between the PBM and its affiliated pharmacies, you might want to consider whether opportunities exist now to better ensure a level playing field among your network pharmacies by asking:

- How does your current PBM contract define "affiliate"? Are retail pharmacies included in/excluded from that definition? Should the definition be refined to encompass retail pharmacies and/or affiliated retail pharmacies in certain circumstances?
- Is there reporting you should require now that would allow you to better understand the member utilization patterns between affiliated and non-affiliated pharmacies?
- To what extent, if at all, does creating a more precise distinction between affiliated and non-affiliated pharmacies impact the pricing under your PBM contract and/or future PBM contract?

Redefining and Constricting PBMs' Outlets for Remuneration

Ultimately, we can expect that any legislation regulating PBMs will attempt to limit the amount of remuneration available to a PBM.

The Delinking Revenue from Unfair Gouging (DRUG) Act (H.R. 6283) (discussed above), specifically proposes to limit PBM remuneration obtained in connection with Part D covered drugs to only "bona fide service fees." At a high level, "bona fide service fees" are defined as fees that represent fair market value for a bona fide, itemized service. Therefore, under the proposed legislation, a PBM's remuneration for Part D covered drugs would exclude fees based on drug pricing, discounts, rebates, and other fees. It is difficult not to speculate that the scope of this limitation could expand to the commercial sector – if not by legislative fiat, by market demands created by health plans or group health plans.

Thus, it may be worthwhile to consider now the various channels for PBM profit available under your PBM contract, and whether you can begin to limit/narrow (or consider limiting/narrowing) those avenues for PBM remuneration that exceed the scope of "bona fide service fees." This may include questions like the following:

- Does your definition of "rebates" that are to be paid to the health plan include *all* forms of revenue from the manufacturer that are attributable to your pharmacy program claims (e.g., inflation protection payments, educational payments, data payments, etc.)?
- Does your current PBM contract directly address any fees the manufacturer pays the PBM for services performed by the PBM (e.g., does it already include a definition of "bona fide service fees")?
- What reporting mechanisms are needed in your PBM contract to obtain the necessary data/information to ensure the PBM's remuneration does not exceed the scope of "bona fide service fees"?

Ultimately, any proposed legislation attempting to regulate the transparency of PBMs' pricing and practices is a signal for health plans to take the necessary action to evaluate potential relevancy and impacts to your PBM contract as well as the future state of your pharmacy program. These questions provide a starting point for determining what action you can take now, and what action you may want to consider in the future as legislation regulating PBMs continues to emerge.

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Wiley's PBM Contracting team of experienced attorneys and advisors is closely monitoring these legislative developments and is available to assist with any questions.