Executive Order 25-23

Report 2025

Prepared for the Governor and the Legislative Council

By Indiana Department Of Insurance

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Overview

On January 21, 2025, Indiana Governor Mike Braun issued Executive Order 25-23, which states, in relevant part, that the Indiana Department of Insurance (“Department”):

> “shall conduct a review of potentially harmful practices of pharmacy benefit managers ("PBMs") operating in the State of Indiana, including the charging of retroactive fees and use of anticompetitive steering practices. As part of the review, IDOI shall develop proposed legislative and regulatory recommendations to prohibit any harmful practices. The review shall be completed by October 31, 2025, with a written report provided to the Governor and the Legislative Council by November 31, 2025.”

To meet the requirements of this Executive Order, the Department issued a survey in the Spring of 2025 to the forty-eight (48) PBMs then licensed in Indiana. The survey was developed to better understand current business practices and procedures of PBMs, including prior authorization, generics, administrative fees and rebating, and vertical integration. This report aggregates and summarizes individual responses. It also includes proposed legislative and regulatory recommendations to address several potentially harmful practices.

Executive Summary

The Department’s review revealed several practices that could potentially impact consumers, healthcare providers, and pharmacies. Out of the forty-eight (48) then-licensed PBMs surveyed, several stated that they do not do business in the State of Indiana or operate solely in areas preempted by federal legislation. This report breaks down the responses from the PBMs that conduct business in the State of Indiana.

Prior authorization
All PBMs surveyed use some sort of prior authorization process to control drug costs. Most PBMs impose step therapy requirements, which set out the order in which a patient must use different prescription drugs to treat a given condition, in conjunction with their prior authorization process for certain types of drugs. When reviewing prior authorization denial appeals, most PBMs use pharmacists or trained technicians on first review. Licensed physicians or contracted review boards provide reviews for additional appeals.

Vertical integration
While specialty pharmacy products made up about twenty-five percent (25%) of products dispensed, PBM ownership of specialty pharmacies ranged from one percent (1%) to eighty percent (80%). Prescriptions dispensed through mail-order at a PBM-owned pharmacy ranged from four percent (4%) to one hundred percent (100%). Not every PBM licensed in Indiana owns or contracts with mail-order pharmacies.

Rebates
Although a few PBMs still provide health plans with spread pricing as an option, the majority of PBMs do not use spread pricing. Spread pricing is where the PBM charges the health plan a higher price for a drug than it pays the pharmacy. The PBM then keeps the difference which is referred to as the “spread.” Instead, those PBMs pass through rebates to the health

plans. Rebates are price concessions from drug manufacturers negotiated by a PBM. Those that retain rebates do so based upon contracted agreements with the specific health plan. Some PBMs use group purchasing organizations, called rebate aggregators, to combine the purchasing power of multiple PBMs in an effort to secure higher rebates from manufacturers. Several PBMs retroactively adjust fees.

Confidentiality

The individual company responses are confidential pursuant to Ind. Code § 27-1-3.1-15. The Department has taken the responses and aggregated this information in the preparation of this report.

Methodology

To understand current practices in the market, the Department developed a list of questions and surveyed PBMs licensed in Indiana pursuant to Ind. Code § 27-1-3.1-9(a). The responses were then collated and summarized for this report.

Summary By Question

The Department developed questions focused on different types of practices seen as emerging trends or that could have negative impacts on Hoosiers.

Prior Authorization

Prior authorization ("PA") is defined generally for health care services under Ind. Code § 27-1-37.5-7[1] and specifically for prescription drugs under Ind. Code § 27-1-37.4-3.[2]

According to the American Medical Association, PA can be a cost control process that requires a healthcare provider to receive advanced approval for payment of a specific healthcare product or service before administering that product or service to a patient. Health plans may contract with a PBM to perform these PA reviews for prescription drug products, where a PBM would approve or deny the prescription based on the terms of coverage under the contract. Some reasons a prescription drug might be subject to PA processes include: (1) the drug not being on formulary; (2) the drug posing a health risk for a patient; and (3) the drug being high cost.

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[1] "The process by which a utilization review entity determines the medical necessity of an otherwise covered health care service before the health care service is rendered. The term includes a utilization review entity's requirement that a covered individual or health care provider notify the utilization review entity prior to providing a health care service."

[2] "[I]ncludes a health plan requirement that a prescription drug be authorized for payment by the health plan before the prescription drug is provided to the particular covered individual."

The Department requested responses to the following questions to better understand how the PBMs implemented their PA processes and how the processes might impact health plan participants.

Please explain the PBM's PA processes.

All forty-eight (48) PBMs use some sort of PA process. The PA processes vary across PBMs based on their contracts. Some PBMs, based on the health plan, will "PA to label," meaning the PBM will automatically deny use of a product unless it is aligned specifically to the FDA-approved label. Health care providers can prescribe prescriptions for off-label use of products, which are uses for which the product is not approved by the FDA. When a PBM "PAs to label," the PBM will initially deny the claim and require the prescriber to fill out a form to defend the use of the specific drug for their patient. This PA practice often delays insureds from receiving medically justified treatment and increases administrative burdens on health care providers, particularly when the off-label use is common and backed by substantial evidence and experience.

Some PBMs do not prior authorize certain off-label uses of prescription drugs if the use fits within recognized treatment guidelines. More restrictive PA practices include PA requirements for generic drug products depending upon the drug's net price and average rebates. Additionally, some PBMs program software to proactively place PAs on drug products before a patient begins treatment or goes to the pharmacy.

Communication regarding PA outcomes is either provided directly to the patient by the PBM or provided to the patient by a pharmacist or health care provider. There are times when a healthcare provider will appeal an initial PA denial. When reviewing prior authorization appeals, seventy-five percent (75%) of the time PBMs use licensed pharmacists and twenty-five percent (25%) of the time PBMs use pharmacy technicians to review the initial PA appeal. Second level appeals or reviews were most often completed by physicians or in-house pharmacists. If a PBM requires additional reviews after the appeal, some PBMs will utilize outside Independent Review Organizations. During the multiple review steps, the patient must wait for approval for their prescription, delaying treatment and increasing administrative burdens on providers.

Does the PBM have step-therapy processes, and if so, how are they implemented?

Most PBMs impose step therapy requirements in conjunction with their PA process. Step therapy protocol is defined under Ind. Code § 27-1-37.4-8(a).[3] Much of the focus of step therapy is on the cost of therapies and contracted drug formularies.

Some PBMs apply a formulary that is designed via Pharmacy & Therapeutics (P&T) Committee review. In these cases, step 1 drugs are usually generics and preferred brands according to formulary, while step 2 drugs are non-preferred brands. When a

[3] "[A] protocol that specifies, as a condition of coverage under a health plan, the order in which certain prescription drugs must be used to treat a covered individual's condition."

health care provider prescribes a drug that is step 2 and sends it to the pharmacy, PA often will be required. In many cases the patient will have to first try a step 1 medication. Once the step one drug proves to be ineffective , the prescriber is given the opportunity to submit a prior authorization appeal and provide documentation that a step 2 drug is necessary for the patient because the step 1 drug is not effective.

Other PBMs apply step therapy broadly to specific classes of drugs, such as expensive or high-demand medications. Still, other PBMs have more intricate step therapy processes, including rules for therapeutic equivalents in the drug class, clinical recommendations by P&T committees, as well as net cost of the product. These rules are applied to formulary models for the plans to determine cost and clinical effectiveness of products.

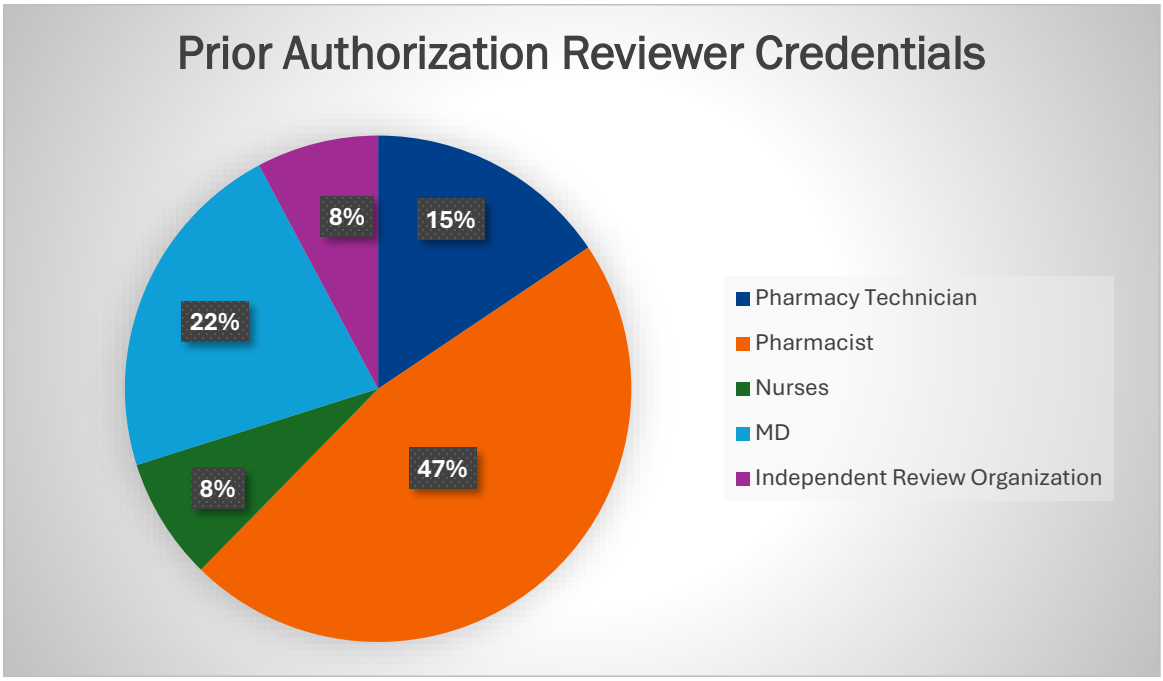
A study was conducted by Health Affairs on ten (10) diseases where step therapy was implemented.[4] Of the protocols for the ten (10) diseases, "thirty-four percent (34%) were consistent with corresponding clinical guidelines, fifty five percent (55.6%) were more stringent, and six percent (6.1%) were less stringent." Trials of alternatives that were not included in the clinical guidelines were required in four percent (4.2%) of protocols, and the consistency of protocols varied within and across health plans. These findings raise questions about overly restrictive step therapy protocols, as well as concerns that variability across health plans makes navigation of step therapy protocols onerous for patients and practitioners. The findings from this study suggest the need for state and federal legislative initiatives to ensure appropriate and timely prescription drug treatment.

Who reviews PA requests on behalf of the PBM? What are their qualifications?

When reviewing PA denial appeals, most PBMs use a pharmacist or trained technician for the initial denial review, while some PBMs use internally trained employees to do these initial reviews. If there are additional appeals, the PBM may use licensed physicians or contracted review boards to review those specific appeals. This process can help save costs, but it can also delay prescriptive care which could have a negative impact on patient outcomes. Figure 1, below, breaks down the credentials of PA reviewers the PBMs surveyed use.

[4] Kelly L. Lenahan et al., *Variation in Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans*, 40 HEALTHAFFAIRS 1749 (2021). https://doi.org/10.1377/hlthaff.2021.00822

Figure 1: Prior Authorization Reviewer Credentials



Generics

Generic drugs are defined under Ind. Code 27-1-24.5-4.[5] Under the Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, generic drugs are allowed to be manufactured once the brand patents have expired. Generic drugs often provide a cost savings to plan participants. The Department asked the following questions to better determine the impact of generic drugs on PBMs; specifically, the amount of usage of generic drugs by the PBMs as well as any instances where a brand product might be used instead of a generic for cost control measures.

Does the PBM exclude any generics on its formulary?

In an effort to understand drug formularies, the Department sought information regarding generic exclusion in this survey. Manufacturers negotiate with PBMs for placement of products on their formularies. There are different levels or tiers on most PBM formularies, and the highest tier on a formulary is the preferred level.

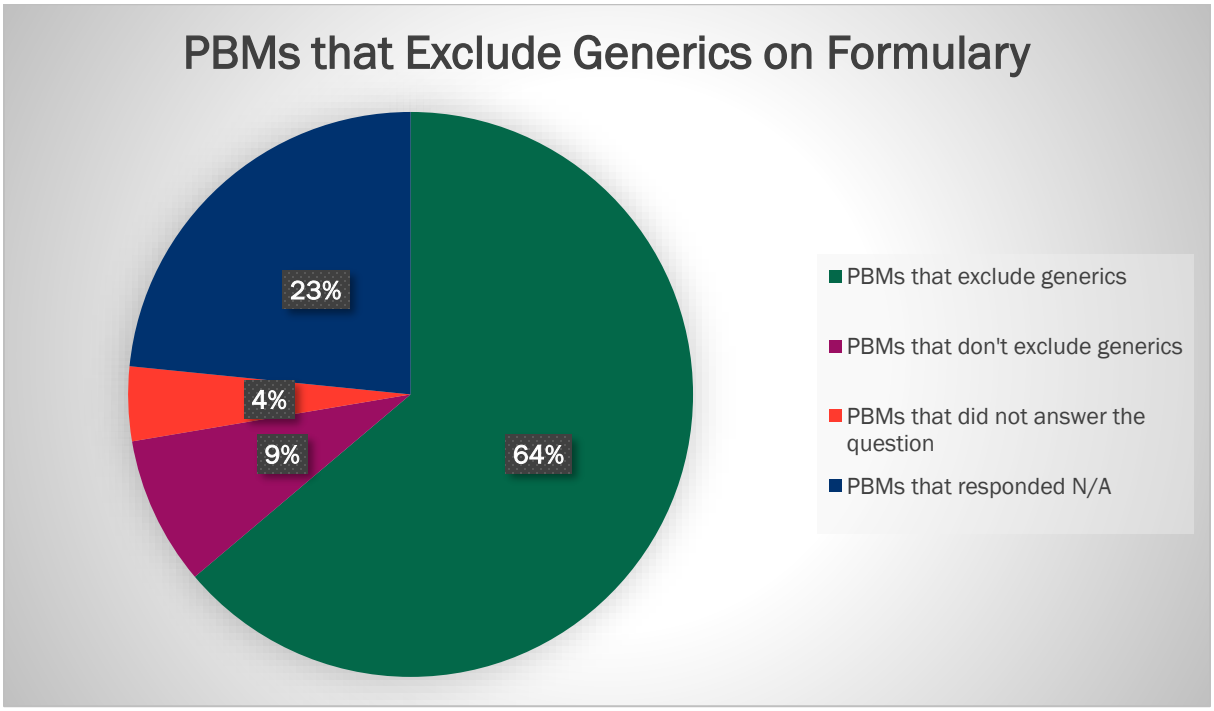
It is a common practice for PBMs to exclude generic drugs from their formularies for various reasons. Of the PBMs that responded to the survey, thirty (30) stated they exclude generics in some capacity. The most common reason provided is that the drug is not the most cost-effective option for the PBM, followed by the brand name drug being preferred or that a particular generic is not currently available. PBMs may offer a health plan benefit sponsor the choice between a standard formulary that does not exclude

[5] "[A] drug product that is identified by the drug's chemical name that is: (1) accepted by the federal Food and Drug Administration; (2) available from at least three (3) sources; and (3) therapeutically equivalent to an originating brand name drug."

generics and one that does. In some cases, PBMs will allow a provider to submit PA request for a generic drug that is excluded from the formulary. Many PBMs cited cost savings without reference to whether those benefits flow to health plans or are retained by the PBM.

Thirteen (13) PBMs responded that the survey question pertaining to the exclusion of generics within a formulary did not apply to their PBM or did not directly answer the survey question. Figure 2, below, breaks down the PBMs' responses pertaining to exclusion of generics on formulary.

Figure 2: PBMs that Exclude Generics on Formulary



The data in the following table was gleaned from the responses regarding generic drugs. The responses indicated several possible reasons for exclusion of generic drugs from preferred drug lists. Since each PBM serves multiple health plans, differences in health plan design led to multiple answers from many PBMs.

Generic drug exclusion explanations:	Number	Percentage
Lower cost generic alternatives	22	46%
Lower net cost for brand after rebates	5	10%
Lack of favorable pricing agreements	5	10%
Safety and efficacy	5	10%
Brand preferred	5	10%
Federal plan limitations	5	10%
Availability	4	8%
Clinical appropriateness based on their own Pharmacy and Therapeutic Committees	4	8%
A generic product appears to be generic by name but is classified as a brand or trade name product or single-source generic.	4	8%
Variations in approved indications differing from brand	2	4%

Is the PBM using a Generic Product Identifier (GPI) to identify drugs on a Maximum Allowable Cost (MAC) list?

A maximum allowable cost (MAC) drug list is a guide used to list the highest amount reimbursed to a pharmacy for a generic or multi-sourced brand pharmaceutical product. Typically, MAC lists include the drug name along with the National Drug Code (NDC) that contains information on the manufacturer, dosage, and pack size of the drug. A Generic Product Identifier (GPI) is a list that includes a drug therapeutic class, active ingredient, strength and dosage. MAC is defined under Ind. Code § 27-1-24.5-7[6], while the MAC list is defined under Ind. Code § 27-1-24.5-8.[7] PBMs are required to disclose their list of sources for MAC pricing to pharmacies within ten (10) days of a request and must update their MAC lists every seven (7) days and ensure the drugs are currently available from wholesalers licensed in Indiana, not obsolete or temporarily unavailable, and not on a drug shortage list, pursuant to Ind. Code § 27-1-24.5-22. PBMs or their contracted entities may create a MAC list from commonly used drugs, often generics, that are generally on their formulary or available through a prior authorization.

Some PBMs are moving away from the MAC pricing model. Many PBMs list the drugs on their MAC list with an NDC, but some have started listing by GPI. There are no current regulations in Indiana law regarding GPI. The various pricing references provided by PBMs can create confusion for pharmacies and pharmacists.

[6] "[T]he maximum amount that a [PBM] will reimburse a pharmacy for the cost of a generic drug . . . [and] does not include a dispensing fee or professional fee."
[7] "[A] list of drugs that is used: (1) by a [PBM]; and (2) to set the maximum amount that may be reimbursed to a pharmacy or pharmacist for a drug."

Administrative Fees and Retained Rebates

PBMs receive payment for their services through administrative fees and retained rebates. Rebate is defined under Ind. Code § 27-1-24.5-16.[8] In practice, a rebate is a discount or payment from a pharmaceutical manufacturer that lowers the net price of a prescription drug while administrative fees are fees charged by an entity to perform a specific function in the supply chain before a product reaches the end user.

Various factors impacting administrative fees have created a more complex structure and led to increased fees. The average drug rebate varies widely based on the product, product class, and contracting agreements between the PBM and health plan. A majority of PBMs pass through rebates to the health plans. The PBMs who retain rebates do so in accordance with the specific health plan contract. Some PBMs adjust administrative fees and rebates over a period of time, called “true up,” generally over a six (6) month to one (1) year period or as stated in the plan contracts. These can go back as far as three (3) years. Some PBMs use rebate aggregators, also known as group purchasing organizations (GPOs), to combine the purchase power of multiple PBMs in an effort to secure higher rebates from manufacturers. Both practices impact administrative fees and rebates timelines, and the delay in payment or payment adjustments in arrears can cause financial issues for independent pharmacies. Additionally, PBMs stated that administrative fees have increased due to inflation and vendor costs.

The Department asked the following questions to better understand how the PBMs used different fee structures.

What is the PBM’s average rebate per product?

The average rebate for specialty products can range between $750 to $1900 depending on the cost of products and contract terms. Specialty drugs are medicines that require specialized handling, distribution and monitoring. These requirements include drugs with refrigerated supply chains, scheduled drugs which have a high propensity for abuse, or drugs with special handling requirements.

For other non-specialty products, rebates can range between less than $25 to $800 depending on product, product classes, contracts, and product utilization. Some PBMs will only reimburse products that are on their negotiated preferred drug list for the specific plan. Preferred Drug lists periodically change based upon contract negotiations with plans and product manufacturers. Additionally, mail-order pharmacies may have a different rebate level from brick-and-mortar pharmacies, which also impacts average rebates.

[8] “[A] discount or other price concession that is: (1) based on use of a prescription drug; and (2) paid by a manufacturer or third party to a PBM, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at the pharmacy.”

How often does the PBM adjust or "true up" administrative fees and rebate amounts?

Some PBMs only charge an administrative fee, so they do not do any adjustments or "true ups". Others "true up" on a weekly, quarterly, yearly, or ad hoc basis based on contracted agreements.

Some PBMs will initially withhold a portion of rebates when they pay health plans until the final data is received from the rebate aggregator. Once data is received from the rebate aggregator showing the full amount due, then the PBM will "true up" the remainder of the payment based on the data received. Any "true up" payments are then sent the following month. Additionally, some contracts allow for rebates and administrative fees to be paid up to six (6) months in arrears, after the close of the contract year. Others may have a rebate life cycle of up to three (3) years before final settlement. Some PBMs also change the rebate amounts every six (6) months to one (1) year as agreed upon in their contracts. These changes can make prescription costs to patients or providers fluctuate depending on the timing of the PBM rebate life cycle and contracts.

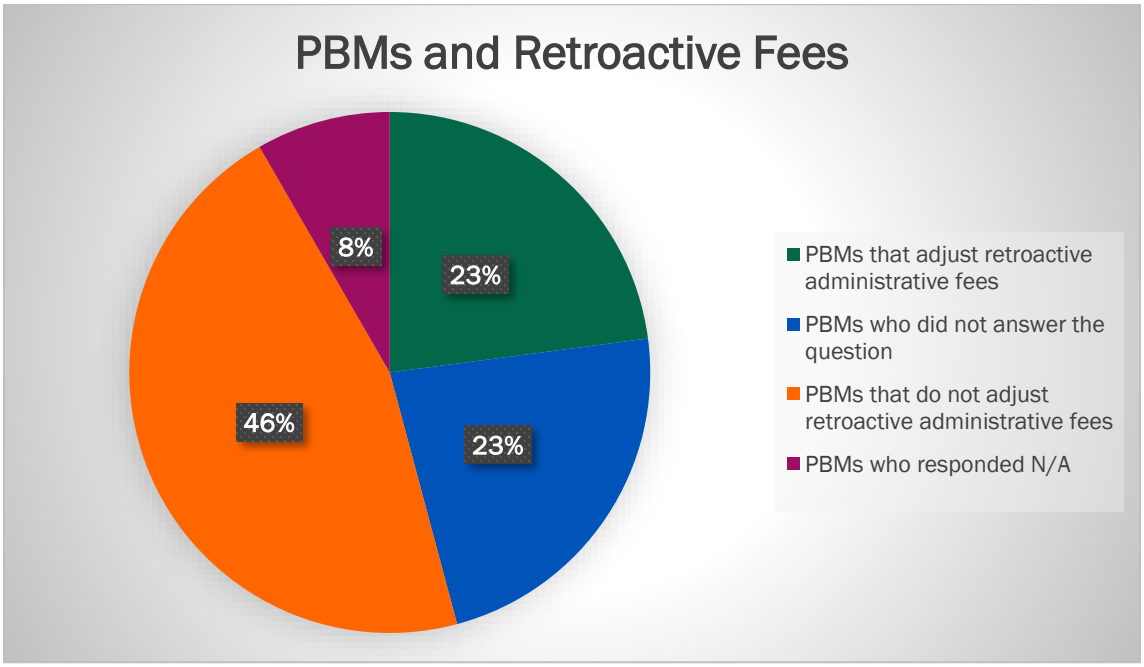
What factors make up the retained rebates, and how have those factors changed since January 1, 2024?

The majority of PBMs responded that they pass through one hundred percent (100%) of rebates directly to health plans, although some charge a health plan a service fee which is paid out of those rebates based on the contract terms. However, twelve percent (12%) of PBMs still offer what they refer to as a traditional pricing method, where the PBM retains a portion of the rebates in exchange for the PBM's service offerings. These PBMs also offer what they refer to as a fully transparent rebate model, where they charge the plan administrative fees instead of retaining rebates. The PBMs argue that the health plan can make the choice they feel is best for them. Since January 1, 2024, PBMs reported there were no changes to factors making up retained rebates or they have changed their practices to align with any new laws and regulations focused on retained rebates.

Does the PBM make retroactive adjustments to administrative fees, retained rebates, or other fees charged to pharmacies and under what circumstances?

Of the PBMs surveyed, twenty-two (22) indicated they do not retroactively adjust fees to pharmacies. The eleven (11) PBMs who reported they adjust fees retroactively do so for various reasons, including the result of an audit, an accounting error, or mutual agreements with clients. For example, a claim may be reversed and resubmitted; in this case, retroactive payments may be made to account for the plan's payment liability. Figure 3, below, breaks down the PBMs' responses pertaining to retroactive adjustments to administrative fees.

Figure 3: PBMs and Retroactive Fees



Does the PBM reimburse in-network and out-of-network pharmacies at different rates? What is the relative difference?

Several PBMs responded that they reimburse at the same rates for in-network and out-of-network pharmacies. Some PBMs negotiate reimbursement rates with each pharmacy which can lead to different reimbursement rates. Further, a plan contract can determine in-network pharmacies and whether out-of-network pharmacies would be reimbursed for filling plan member prescriptions. Some PBMs do not maintain a pharmacy network. Other PBMs only allow patients to fill prescriptions at pharmacies within their network or the network of another PBM they have contracted with.

With all of these factors, patient costs and discounts can vary widely when comparing in-network to out-of-network pharmacies. Patients are often encouraged to use in-network pharmacies as they typically offer the lowest costs to the patient and provide a better reimbursement rate for the PBM.

Does the PBM employ spread pricing?

Spread pricing is a practice where the PBM negotiates a higher price with the health plan than what it reimburses the pharmacy. This creates a “spread” in the price which the PBM would then keep. Pursuant to Ind. Code § 27-1-50-8, an insurer is required to pass through to a plan sponsor one hundred percent (100%) of all rebates concerning the dispensing or administration of prescription drugs to the covered individuals of the plan sponsor.

The majority of PBMs that responded do not use spread pricing but rather employ a pass-through pricing model. Several PBMs allow plans to select a spread pricing model where it is allowed by law. PBMs reasoned that spread pricing resulted in more stable pricing arrangements for their clients. There are also situations where differential spread pricing arrangements are an option for plans for specific products or product categories as opposed to the whole book of business. Under a spread pricing model, consumers and health plans may be unable to take advantage of lower prices negotiated by PBMs, while the PBM retains the pricing differential.

Vertical Integration

Vertical integration is where a company expands to control multiple parts of their supply chain either through acquisitions, business development or contracting. In this context, PBMs engaging in vertical integration might control the pharmacies and the distribution of medicines. Some PBMs are even expanding into insurance and generic drug manufacturing. This can be via direct ownership or contractual arrangements. The Department asked the following questions to better understand how vertical integration within PBMs can impact the healthcare system.

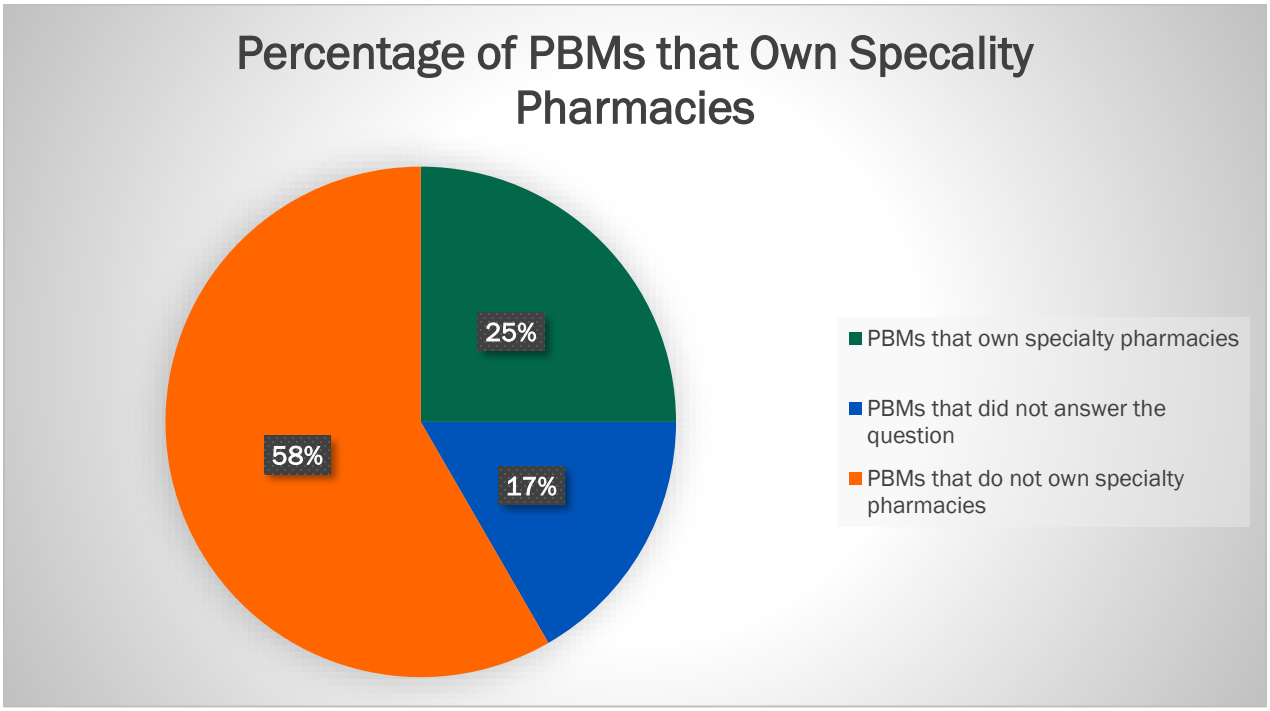
What percentage of the PBM's prescriptions are specialty pharmacy?

The percentage of PBM specialty pharmacy business varied from one percent (1%) to sixty-three percent (63%), but the overall average amount of specialty prescription business is two and a half percent (2.5%). While most PBMs reported that specialty drug products are a small portion of their overall prescription claims, a few PBMs have a larger focus on the specialty market, which accounts for the wide percentage range of PBM specialty pharmacy business.

What percentage of the PBM's specialty pharmacy business is dispensed by pharmacies the PBM owns?

Out of the forty-eight (48) PBMs surveyed, twelve (12) indicated they own specialty pharmacies. For those PBMs which owned specialty pharmacies, between thirty percent (30%) to one hundred percent (100%) of the PBM's specialty pharmacy business was dispensed by the specialty pharmacies owned by the PBM. Twenty-eight (28) PBMs indicated that they do not own specialty pharmacies. Figure 4, below, breaks down the percentage of PBMs that own specialty pharmacies.

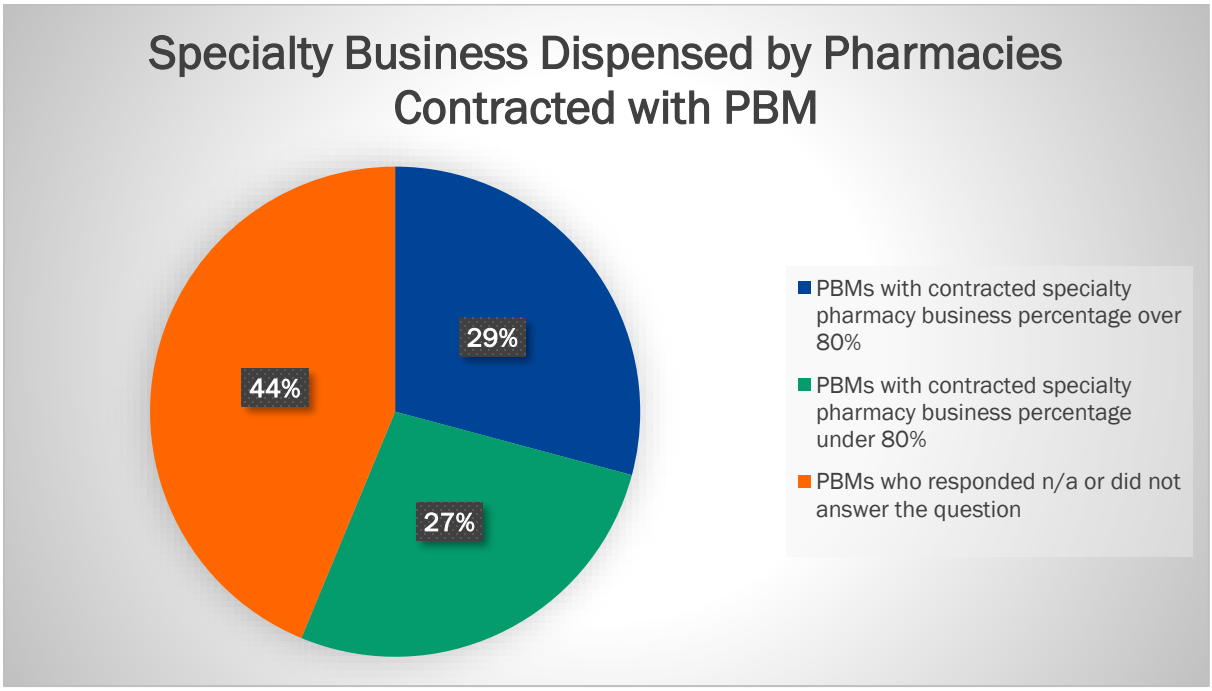
Figure 4: Percentage of PBMs that Own Specialty Pharmacies



What percentage of the PBM's specialty pharmacy business is dispensed by pharmacies the PBM has contracts with?

Not every PBM has contracts with specialty pharmacies, but for the PBMs that do contract directly with pharmacies for their specialty business, an average of seventy-two percent (72%) of the business is dispensed at those contracted pharmacies. Figure 5, below, breaks down the among of a PBMs' specialty pharmacy business dispensed by pharmacies with which the PBM has contracts.

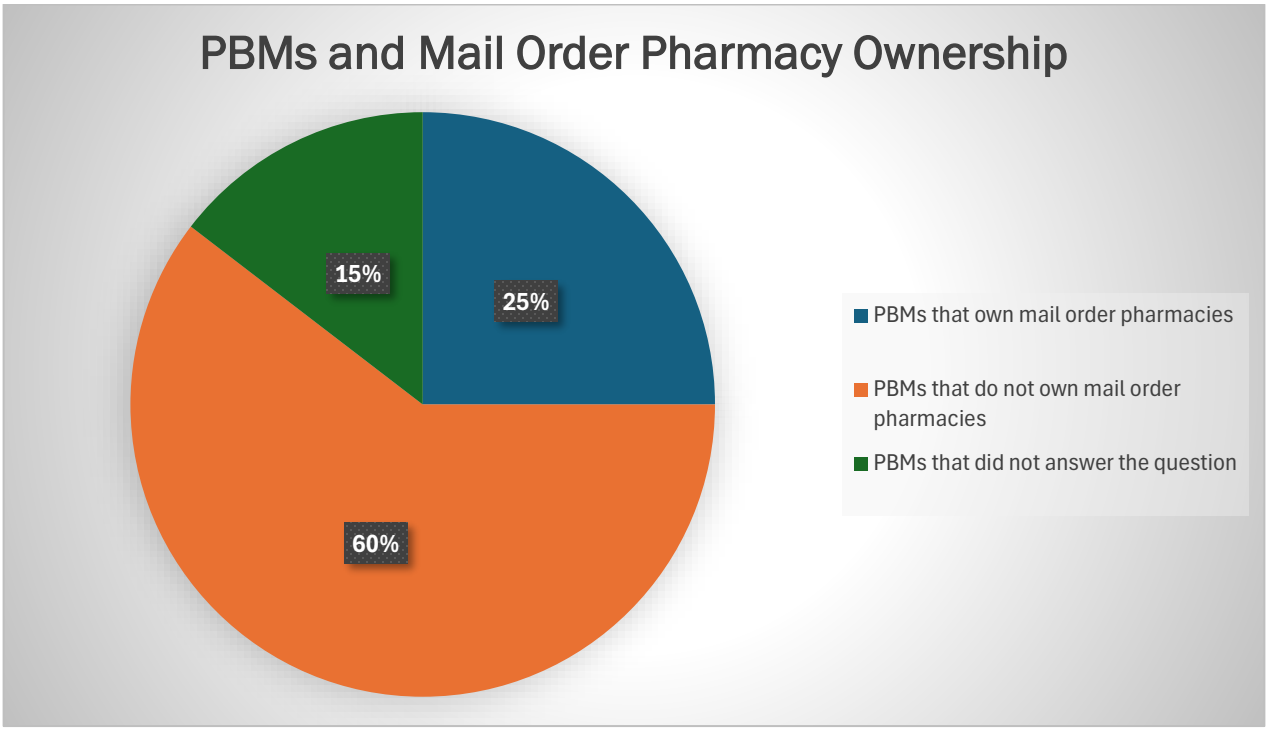
Figure 5: Specialty Business Dispensed by Pharmacies Contracted with PBM



What percentage of the PBM's mail order pharmacy business is dispensed by pharmacies owned by the PBM?

Twelve (12) PBMs responded they owned mail order pharmacies. The percentage of mail order business sent to PBM-owned mail order pharmacies ranged from four and a half percent (4.5%) to one hundred percent (100%). For PBMs that own mail order pharmacies, an average of eighty percent (80%) of mail order business was filled by their own pharmacies. Not every PBM is affiliated with a pharmacy and the majority of PBMs operating in Indiana do not own mail order pharmacies. Figure 6, below, breaks down PBM ownership of mail order pharmacies.

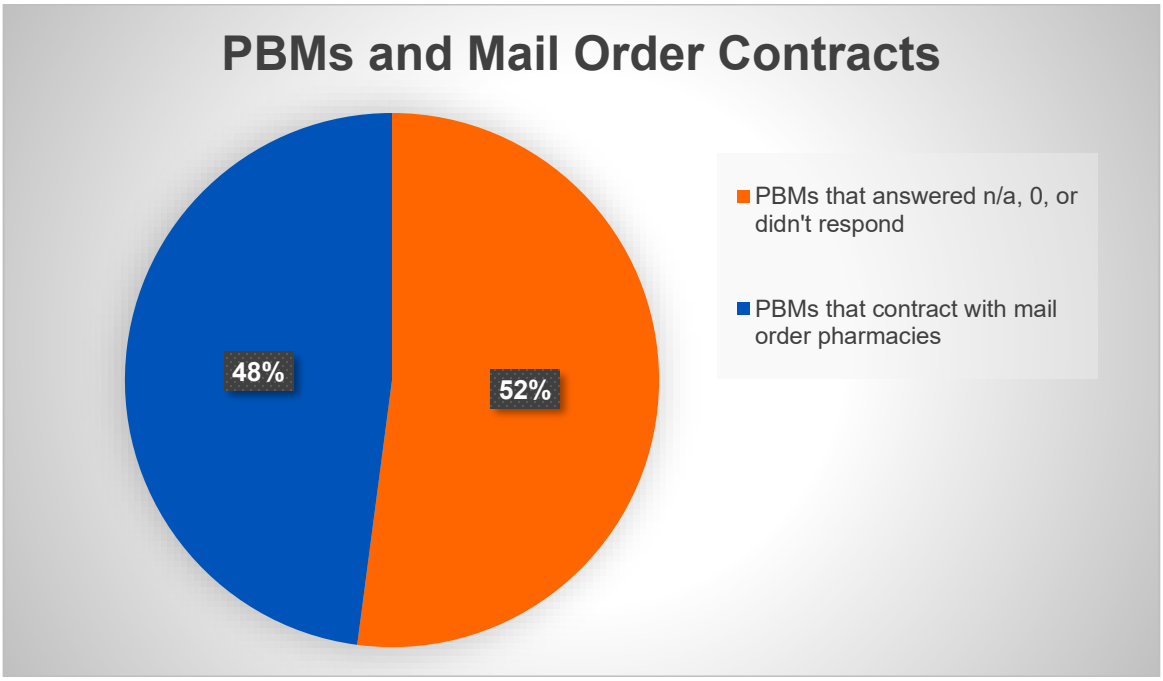
Figure 6: PBMs and Mail Order Pharmacy Ownership



What percentage of the PBM's mail order pharmacy business is dispensed by pharmacies the PBM has contracts with?

Not every PBM has a contract with mail order pharmacies. According to the survey, the range for PBMs contracted with mail-order pharmacies was about zero percent (0.3%) to one hundred percent (100%) depending upon the contract terms. Of the twenty-three (23) PBMs that contract with pharmacies for mail-order business, about seventy-eight percent (78%) of their mail order business was dispensed by contracted pharmacies. PBMs that do not contract with pharmacies for mail-order business cited contracts with third parties or other PBMs for their specialty network, owning their own specialty pharmacies, or the PBM did not have mail-order business as reasoning. Figure 7, below, breaks down the percentage of PBMs that contract with mail order pharmacies.

Figure 7: PBMs and Mail Order Contracts



Please provide organizational charts for the PBM including all subsidiaries, parent companies, partnerships, affiliates, etc.

The majority of PBMs have multiple business units and affiliates. Additionally, some PBMs have partial ownership of other business units and some contract with other PBMs to perform services for health plans and other lines of business, such as insurance products or prescription drug distribution chains on their behalf. This demonstrates PBMs implement both vertical and horizontal integration in this space.

Does the PBM provide incentives to use in-network or PBM owned pharmacies?

In general, PBMs reported they do not incentivize patients to use a specific pharmacy. The majority of PBMs follow the health plans' member cost-sharing agreement with pharmacies which are incentives to use in-network or PBM-owned pharmacies. This includes charging lower costs for patients to use an in-network pharmacy in accordance with Indiana law. However, some PBMs reject claims from out-of-network pharmacies altogether.

Legislative and Regulatory Recommendations

The Department noted several potentially harmful practices in reviewing responses to the survey which could be addressed through legislative or regulatory changes.

Spread pricing

Currently, fifteen (15) states have regulations restricting or banning the practice of spread pricing. The Department recommends that Indiana adopt direct language regarding the prohibition against spread pricing, and the Department recommends consideration of the language of Florida (Fla. Stat. § 626.8825) and Delaware's (Del. Code Ann. § 3372A) prohibitions on spread pricing.

Retroactive Adjustments and "True ups"

Ind. Code § 27-1-24.2 prohibits retroactive adjustments except under specific circumstances. However, those specific circumstances are not time limited in the statue and the survey responses indicated that PBMs sometimes go back as much as three years to retroactively adjust fees. The Department suggests limiting the amount of time for a PBM to "true up" any fees or retroactive adjustments. The Department also recommends consideration of Florida's prohibition on financial clawbacks and adding a prohibition against withholding any financial remuneration or any portion of rebates from adjudicated claims, found in Fla. Stat. § 626.8825.

Steering

Currently, sixteen (16) states have regulations prohibiting patient steering. While Ind. Code § 27-1-24.2-16(a)(4) attempts to address steering practices, Ind. Code § 27-1-24.2-16(b)(1) exempts mail order pharmacies from steering regulations. The Department's review showed that steering toward mail order pharmacies is a common practice with potential impact on consumers. To address this practice, the Department recommends consideration of the language of Louisiana (La. Stat. Ann. § 40:2870), Minnesota (Minn. Stat. § 62W.07), and West Virginia (W. Va. Code § 33-51-9), which specifically include mail order pharmacies in their anti-steering legislation.

Subcontracting PBM services

Indiana requires disclosure of contracting agreements pursuant to Ind. Code § 27-1-24.5-26. However, when a PBM contracts out specific services, such as claims processing or call center support, a pharmacy, patient or health plan may not realize they are dealing with a subcontracted entity. In the Department's review a number of PBM's reported that they subcontracted significant portions of their operations. To provide more transparency, the Department recommends legislation to further define the disclosure process for subcontracted PBMs and to consider whether yearly updates to health plans and pharmacies should be required.

Step therapy

Indiana sets out requirements for step therapy protocols pursuant to Ind. Code § 27-8-5-30. As discussed in the report, step therapy can negatively impact patients and providers when required to repeatedly submit documentation for a step therapy protocol exception. This is especially true for a patient who has gone through the step therapy process but must start over if they change health plans. The Department recommends including a grandfather provision to Indiana Code that allows a patient who (1) is on a medically necessary medication; (2) is stable on that medication; and (3) switches health plans; be allowed to continue with this medically necessary medication without being subject to step therapy.

Rebate aggregators

A rebate aggregator or group purchasing organization combines the purchasing power of multiple PBMs in an effort to secure higher rebates from manufacturers. Rebate aggregators can impact drug prices by keeping a percentage of the negotiated rebates as payments for their services. Indiana law addresses prescription drug rebates but not specifically rebate aggregators. The Department recommends amending Ind. Code § 27-1-50-8 and Ind. Code § 27-1-49 to specify when a rebate aggregator is used, the rebate aggregator must be paid via defined fees for service and not as a percentage of the negotiated rebates from manufacturers.

MAC v GPI

In its review of survey responses, the Department noted a trend of PBMs moving from using MAC lists to GPI. This creates confusion for pharmacies when they attempt to use the PBM's MAC list. Additionally, GPI falls outside the definition of maximum allowable cost list under Ind. Code § 27-1-24.5-8. This creates a regulatory gap, and the Department recommends including GPI in the definition of MAC list to be more inclusive of other PBM generic drug pricing practices.

Generic Drug Price Transparency

The Department's review revealed that generic drug pricing can vary significantly based on a variety of factors including contracting terms. In some cases, patients may now need PA approval for a generic drug they have been historically prescribed based on new pricing agreements. The Department recommends that PBMs be required to provide information on the real cost to the patient of a given prescription.

Conclusion

PBMs play a significant role in delivering pharmacy services to Hoosiers. The survey issued by the Department provided insight into the current business practices and procedures of PBMs operating in Indiana, including PA, generics, administrative fees and rebating, and vertical integration. In its review of the survey responses, the Department noted several PBM business practices that could potentially harm patients and providers, such as delay in care or increased administrative burdens. Based on the Department's review, the Department proposed legislative and regulatory recommendations to address spread pricing, retroactive adjustments, mail-order pharmacy anti-steering, transparency in subcontracting, step therapy procedures, rebate aggregators, generic product identifiers, and generic drug price transparency.