WASHINGTON HEALTH ALLIANCE

A Buyer's Guide to Negotiating, Executing and Implementing a Pharmacy Benefit Program

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Letter from the Washington Health Alliance

To our members:

It has never been more imperative for self-funded insurers and plan sponsors such as employers and union trustsx to examine the prescription drug marketplace. Core to their duty to their members is a firm understanding of how they can save them money.

More than half of the adults in this country take some form of prescription medication (CDC) and the costs for many drugs are fluctuate in price based on their individual prescription drug programs. Those costs can cause hardships, and nearly 10 percent of individuals who took a prescription drug at one point had stopped because of the cost.

In the face of these often-rising drug costs, strongly controlled by a few Pharmacy Benefit Managers, health care purchasers have asked how they can better respond to the marketplace to better serve their members and adhere to the fiduciary responsibility.

With clearly outlined steps, our partner Susan Hayes AHFI, CPhT, has compiled this educational guide to improve informed decision making and ensure pharmacy benefit programs meet the needs of the members.

It can be used as a step-by-step approach to managing prescription drug programs. Step One initiatives are designed to be the most basic and immediate actions plan sponsors should take when managing a prescription drug program to ensure basic fiduciary responsibilities are met. These include audits, monitoring of costs and reporting, contract review and how to conduct a Request for Proposal to obtain PBM services.

Step Two initiatives describe decisions plan sponsors need to make about basic and more advanced pricing considerations. These initiatives include pricing alternatives, network configuration, whether to implement PBM owned or independent partnerships and the overall impact of rebates on prescription drug programs.

Step Three Initiatives include the various plan design and clinical management programs available to plan sponsors. In this section, copays, exclusions, limitations and formularies are discussed. Additional clinical management vendors outside the PBM are also discussed.

This guide is intended to be a neutral guide to allow plan sponsors to exercise as much or as little control as each situation presents. In other words, the guide is not intended to endorse any one program or ideology. It is intended to be educational and allow plan sponsors to make informed decisions based on each plan sponsors' unique characteristics.

We encourage our plan sponsor members to read through this guide and continue to engage with the Washington Health Alliance as we work together to ensure high-quality, affordable care, including prescription medications, are available to all Washingtonians.

Step One Initiatives

Conducting thorough audits and maintaining ongoing monitoring are essential for a plan sponsor to manage pharmacy benefit programs effectively, ensuring both financial accountability and alignment with plan goals. In addition, plan sponsors should regularly conduct Request for Proposal (RFP) projects because the market in pharmacy benefits administration changes rapidly with the advancement of new drugs and technology. At a minimum, plan sponsors should perform market checks to ensure financial terms remain competitive.

Audits

Here's a detailed look at why each type of audit is important and the role of ongoing monitoring:

Claims Audits

PBM claims audits are a critical tool for plan sponsors to ensure that Pharmacy Benefit Managers (PBMs) are administering their pharmacy benefit programs as intended, adhering to contract terms, and managing costs effectively. Audits typically focus on three main areas: accuracy in claims processing, contract compliance, and cost controls. Here's an overview of these purposes and the issues that often arise:

Accuracy in Claims Processing

Auditing for accuracy helps ensure that PBMs process claims correctly according to the plan's design. This includes verifying that correct copayments, coinsurance, and deductibles are applied, appropriate drug pricing is used, and discounts and rebates are accurately reflected.

PBMs often use complicated pricing methodologies, which can lead to discrepancies in drug pricing and difficulty in verifying claims accuracy. Issues such as incorrect copayment amounts, applying the wrong formulary or tier structure, and administrative errors can lead to consistent inaccuracies. PBMs may limit access to certain data, citing proprietary pricing information or trade secrets, making it difficult to perform a thorough review.

Contract Compliance

Auditing for contract compliance ensures that the PBM is adhering to all contractual obligations, including pricing guarantees, rebate pass-through requirements, and administrative fees. It also verifies that any exclusions or limits (e.g., specialty drug restrictions) are enforced as agreed.

PBM contracts are often complex and include ambiguous language, which makes it challenging to interpret and enforce contract terms. PBMs sometimes withhold rebate and discount data, making it difficult to verify if the correct amount has been passed through to the plan. Ensuring the PBM meets service-level agreements and performance guarantees (such as processing time and accuracy rates) can be challenging to measure and track consistently.

Cost Controls

Auditing for cost controls helps the plan sponsor ensure that the PBM is taking appropriate steps to manage costs, including offering competitive pricing, utilizing generic drugs when available, and implementing cost-effective formulary management practices.

PBMs often charge the plan sponsor more for a drug than they pay the pharmacy, pocketing the difference (known as spread pricing). This practice is sometimes hidden in contract language, making it hard to audit effectively.

PBMs might retain a portion of manufacturer rebates, which reduces cost savings for the plan sponsor. Determining if the PBM is passing through the full rebate amount can be difficult due to opaque rebate arrangements. PBMs may favor higher-cost drugs that offer more significant rebates rather than lower-cost options, inflating costs for the plan and members. Audits can reveal whether PBMs are enforcing utilization controls (e.g., prior authorizations, step therapy), but these controls may be inconsistently applied, impacting cost-effectiveness.

There are challenges that occur with claims audits. PBMs often claim proprietary rights over data, making it hard to access the granular claims information needed for a thorough audit. This can limit the auditor's ability to verify pricing, rebate amounts, and other key cost components. PBM contracts are highly complex, often involving layers of rebates, spread pricing, and hidden fees. This complexity can hinder a clear understanding of the true cost of drugs and the amount passed on to the plan sponsor. Terminologies such as "rebate" or "discount" can vary between PBMs, and differences in contract language can lead to misunderstandings. This lack of standardization makes it challenging to compare or enforce terms consistently across different PBM arrangements. Unlike other industries, there are few standardized practices for auditing PBM claims. This means each audit can vary significantly, depending on the PBM's contract terms, the plan's specific benefit structure, and the auditing firm's methodology. PBMs may resist audits or attempt to limit their scope, especially when contract clauses are vague or give the PBM control over what data can be audited. This can lead to a limited or incomplete audit that does not capture the full picture of compliance and accuracy. With new pricing models, specialty drugs, and biosimilars entering the market, PBM pricing structures and rebate practices are continually evolving. This dynamism can complicate audits, as it requires auditors to stay updated on current market practices and anticipate future changes. Privacy laws, such as HIPAA in the U.S., require that member data is handled securely and responsibly, which adds complexity to the audit process and necessitates rigorous security protocols.

To address these challenges, plan sponsors should employ best practices for conducting effective PBM claims audits. Contracts should include clear audit rights, allowing the plan sponsor or an independent auditor full access to claims data, rebate information, and pricing structures. Engage auditors with a deep understanding of PBM practices and pharmacy pricing to ensure they can effectively interpret and analyze complex PBM data. Regular audits (annually or biennially) can help detect issues early and hold PBMs accountable over time. Comparing PBM practices and costs with industry benchmarks can help identify potential savings and expose unusual pricing patterns. Requiring PBMs to provide periodic reports on claims accuracy, rebate pass-through, and compliance with performance guarantees can improve transparency and simplify audits.

In summary, while PBM claims audits are essential for ensuring PBM accountability and optimizing costs, the process is fraught with potential challenges. A structured approach and the right expertise are essential to navigate these issues and derive meaningful insights from PBM audits.

Rebate Audits

A rebate audit of a Pharmacy Benefit Manager (PBM) is conducted to ensure that the PBM is accurately passing through manufacturer rebates and other financial concessions that reduce drug costs to the plan sponsor. Rebates are a critical component of controlling prescription drug spending, especially as drug costs rise. However, due to the complexity and opacity of rebate arrangements, rebate audits are essential for verifying rebate pass-through, transparency, and financial optimization.

There are several purposes of a PBM rebate audit. One is to ensure a full rebate pass-through of rebate terms. Plan sponsors typically contract with PBMs under an agreement that includes a "full pass-through" or percentage-based pass-through of rebates from drug manufacturers. A rebate audit verifies that all rebates promised in the contract are actually credited to the plan, ensuring that sponsors receive the full financial benefits to which they are entitled.

Secondly**,** PBMs often negotiate rebates with manufacturers and manage how much of those rebates are disclosed or passed along to plan sponsors. A rebate audit seeks to bring transparency to these arrangements by confirming the amounts, terms, and timing of rebates received and remitted. Rebates can have a significant financial impact, so accurate rebate collection and reporting are critical for optimizing a plan's overall prescription drug costs. Audits ensure that all potential rebate revenue is recognized, which can reduce overall plan costs.

Lastly, rebate audit should evaluate contract compliance. Rebates can come with various terms, such as performance metrics or formulary placement requirements. A rebate audit ensures that the PBM complies with these terms and doesn't misinterpret contract provisions to its own advantage.

Plan sponsors should adhere to the following steps to ensure full rebate data collection, transparency, and financial optimization. To maximize the effectiveness of a rebate audit, include clear rebate audit rights in the contract. Contracts should include specific terms allowing the plan sponsor or an independent auditor to review all rebate data and records. This may include definitions of rebates, administrative fees, and other concessions to eliminate ambiguities and ensure full access to necessary data. Regular, itemized rebate reports are essential. These reports should detail rebate amounts by drug, therapeutic class, and manufacturer, as well as any fees or offsets that reduce rebate payments. Clear reporting requirements enhance transparency and simplify the auditing process.

Given the complexity of rebate arrangements, it's essential to work with auditors who specialize in PBM and pharmacy rebate structures. Experienced auditors can identify potential discrepancies, interpret contract language accurately, and address any issues of non-compliance. Experienced auditors are not necessarily ones that are "mutually agreeable" to a plan sponsor's PBM. In fact, be cautious of auditors that a PBM "goes out on a limb" to endorsed. These auditors or consultants may have side deals with PBM to return an auditor that shows the PBM in the best light possible. Ambiguities in the contract (e.g., "rebate," "administrative fee," "other discounts") can allow PBMs to manipulate rebate pass-through calculations. Sponsors should specify clear definitions of all financial terms in the contract to prevent misinterpretation.

Setting rebate targets and comparing PBM performance to industry benchmarks can help the plan sponsor understand if the rebate amounts, they're receiving are in line with market standards. These benchmarks also provide context for negotiating improved rebate terms in future contracts.

There are common issues that arise during a rebate audit. PBMs may resist providing full access to rebate data, citing proprietary information or confidentiality agreements with manufacturers. This can prevent auditors from obtaining a complete picture of rebate collections and pass-throughs. PBMs and manufacturers often have complex rebate structures, including volume-based incentives, market-share thresholds, and other performance-based terms that aren't disclosed to plan sponsors. These complexities can obscure the actual rebate amount due and lead to under-reporting. The term "rebate" can vary widely in definition. Some contracts allow PBMs to deduct "administrative fees" or other costs from rebates before passing them through, reducing the net rebate the plan sponsor receives. Clear definitions in the contract help reduce this ambiguity, but it's a common challenge when these details aren't defined.

Rebate payments often occur months after the drug claims are processed, creating a delay in revenue for the plan sponsor. This lag can make it challenging to reconcile rebate payments with corresponding drug claims, and the timing may affect the plan sponsor's financial planning. Because PBMs don't have standardized rebate reporting practices, it's challenging for plan sponsors to compare performance or assess the accuracy of reported rebates across different PBMs. Audits must account for these variations, which can complicate analysis.

In addition to rebates, PBMs may negotiate other discounts or "rebate-like" payments from manufacturers (e.g., administrative fees, data sales) that aren't necessarily passed through to the plan sponsor. A lack of transparency around these financial arrangements can result in missed savings. PBMs may prioritize higher-rebate drugs on

formularies over equally effective lower-cost alternatives. This practice, known as “rebate chasing,” maximizes PBM revenue but can result in higher overall costs for the plan sponsor. Audits should review formulary decisions and rebate policies to assess if rebate chasing is impacting costs. Some PBMs retain a portion of the rebates as per contract terms, which may not always be clear to the plan sponsor. Audit findings sometimes reveal undisclosed rebate retention practices that reduce the savings passed on to the sponsor.

In summary, plan sponsors should adhere to the following best practices for conducting a thorough a rebate audit:

- Use an Independent Auditor with PBM Expertise - Working with an independent auditor who specializes in PBM rebate structures can improve audit accuracy and ensure all rebate discrepancies are identified and rectified.
- Request Full Transparency in Rebate Categories - Specify that all rebate types, including volume rebates, performance-based rebates, and other financial concessions, be disclosed and reported in detail. This can reduce the risk of undisclosed rebates.
- Structure Audits for Regular Review: - Conduct rebate audits annually or biannually to regularly monitor PBM compliance with rebate terms and ensure that any issues are caught and addressed early.
- Leverage Benchmarking for Negotiation - After identifying discrepancies or potential savings, use these insights to negotiate improved rebate terms, pass-through requirements, or rebate administration terms in future PBM contracts.

Rebate audits are essential for ensuring that plan sponsors receive full value from their PBM contracts. However, they are complex and require diligence, expertise, and well-defined contract terms to overcome the issues that arise during the auditing process. By focusing on transparency, well-defined contractual terms, and regular audits, plan sponsors can improve their financial outcomes and ensure PBMs are fully accountable for rebate revenue.

Plan Design Audits

A Pharmacy Benefit Manager (PBM) plan design audit is conducted to ensure that the PBM administers the pharmacy benefit plan in a way that aligns with the plan sponsor’s goals, meets regulatory requirements, and optimizes the experience for members. A plan design audit assesses whether the PBM has implemented the agreed-upon benefits structure, cost-sharing, and coverage limitations according to contract terms, plan documents, and regulatory standards.

To conduct a plan design audit, the audit should align with plan goals. These goals are typically to ensure that the benefit structure reflects the plan sponsor’s cost-sharing strategy, formulary goals, and drug utilization priorities. This includes verifying copayment and coinsurance amounts, formulary placement, step therapy, and utilization management requirements. If the plan sponsor aims to manage costs by encouraging generic drug utilization or leveraging mail-order options, the audit checks that these strategies are effectively implemented. The audit can confirm that members with chronic conditions have adequate access to necessary medications, such as by ensuring that drugs for common chronic diseases (e.g., diabetes, hypertension) are appropriately tiered to encourage adherence.

Plan design audits should also improve the member experience. The audit examines formulary design to ensure essential medications are covered and that the formulary promotes therapeutic alternatives without excessive exclusions. This helps members access affordable, effective treatment options without frustration.

Further, a well-executed plan design should minimize out-of-pocket costs where possible. Audits identify any discrepancies in copayment or coinsurance application, which could reduce members' financial burden and improve satisfaction with the benefit. Complex prior authorization or step therapy requirements can be burdensome for members. An audit can reveal if these requirements are excessive or misaligned with plan goals, suggesting areas where adjustments might reduce member inconvenience and improve overall experience.

Lastly, the audit should ensure regulatory compliance. For employer-sponsored plans, the audit checks that ACA-mandated preventive medications are covered without cost-sharing, as required by law. For plans covering Medicare or Medicaid populations, the audit verifies compliance with the specific formulary, cost-sharing, and coverage requirements mandated by these programs. This includes ensuring that protected drug classes are adequately covered. Many states have specific requirements for pharmacy benefits, such as restrictions on formulary exclusions or regulations on copay accumulator programs. The audit ensures that the PBM's administration aligns with state-specific regulations. The audit may also verify that the PBM's processes for handling member information comply with data privacy standards, particularly in relation to any member health information gathered during claims processing or prior authorization.

There are some common issues and opportunities Identified in PBM Plan Design Audits. There can be a misalignment with plan goals. Audits may reveal instances where the PBM's administration deviates from the agreed-upon cost-sharing arrangements, resulting in members paying more than intended. Some audits find that PBMs fail to promote generics or preferred alternatives effectively, which can lead to higher costs for both the sponsor and members. Members may face barriers such as frequent prior authorization or limited formulary options that discourage adherence. The audit can identify these issues and suggest simplifications. Audits often identify errors in copayment or deductible application, which can lead to member dissatisfaction. Correcting these issues helps improve the affordability of the benefit.

PBM plan design audits often uncover compliance gaps and errors in applying cost-sharing for preventive drugs required by the ACA to be covered at no cost to members. If out-of-pocket costs are not capped as required by the ACA or other regulations, members may pay more than allowed, putting the plan at risk of non-compliance. For multi-state plans, compliance with varying state laws is complex, and audits often uncover areas where the PBM's administration doesn't fully align with all relevant state mandates.

Plan sponsors should adhere to the best practices to enhance the value of PBM plan design audits. Sponsors should articulate specific goals for the audit, such as cost containment, accessibility, or compliance, to ensure the audit focuses on areas with the most potential for improvement. Audits should be conducted periodically (e.g., annually or biennially) to maintain ongoing alignment with plan goals, evolving member needs, and regulatory requirements. Working with an auditor who understands PBM contracts, formulary structures, and the regulatory landscape can help uncover subtle but impactful issues. Audit findings can inform plan design adjustments that enhance value, simplify member experience, and strengthen compliance.

By conducting regular PBM plan design audits, plan sponsors can make sure their PBM-administered benefits align with their strategic goals, improve the experience for plan members, and meet regulatory obligations. This, in turn, can lead to more cost-effective, compliant, and member-friendly pharmacy benefits.

Ongoing Monitoring and Reporting

Ongoing monitoring involves continuous oversight of PBM activities to detect any deviations, maintain compliance, and ensure transparency. It includes regular reporting on key performance metrics and is crucial for plan sponsors to manage costs, fulfill fiduciary responsibilities, adapt to industry changes, and use data for strategic planning. Here's a closer look at why these activities are essential:

ERISA Fiduciary Responsibilities

Under the Employee Retirement Income Security Act (ERISA), plan sponsors have a fiduciary duty to act in the best interests of plan participants and beneficiaries. For ERISA-covered health plans, this includes ensuring that the PBM operates transparently, cost-effectively, and in alignment with plan goals. Plan sponsors must carefully select and monitor their PBM partners, ensuring that they manage pharmacy benefits prudently and deliver value to members. Regular monitoring of PBM performance helps verify that the PBM meets contractual obligations, such as rebate pass-throughs and transparent pricing practices. ERISA requires plan sponsors to avoid conflicts of interest. Monitoring helps identify if the PBM's formulary management or rebate practices favor its own profits over member interests, which would breach this duty.

Cost Efficiency and Budget Control

Prescription drug costs are a major expenditure, and PBMs play a pivotal role in managing these costs. Continuous monitoring allows plan sponsors to evaluate whether PBM strategies, such as generic substitution, formulary design, and utilization management, effectively control costs. By regularly assessing these strategies, sponsors can adjust plan designs to better meet budgetary targets. Ongoing monitoring helps identify areas where the PBM may not be leveraging maximum discounts or negotiating optimal prices with manufacturers and pharmacies. For example, PBMs may implement spread pricing, where they charge the plan more than they pay pharmacies. Monitoring can identify these practices and prompt changes to improve cost efficiency. Cost trends and performance reports provide data that helps plan sponsors project future pharmacy costs more accurately. This is especially valuable for managing annual budgets and forecasting for long-term financial planning.

Adapting to Industry Changes

The pharmaceutical landscape evolves rapidly, with new and expensive therapies like GLP-1 drugs (e.g., for diabetes and weight management) and other specialty drugs entering the market frequently. These drugs can be costly and often require unique coverage decisions. As specialty drug costs rise, monitoring helps assess if the PBM's management approach for high-cost therapies is appropriate, whether through prior authorizations, step therapy, or clinical guidelines. Adjusting strategies for new drug categories based on monitored data allows plan sponsors to better control costs and manage the impact of these drugs on their budget. Some newer drugs offer significant clinical benefits but come with high price tags. Plan sponsors may work with PBMs to explore value-based contracts, outcomes-based pricing, or other innovative pricing models that manage the cost of new therapies. Monitoring PBM performance helps ensure these models are implemented effectively.

Strategic Data Utilization and Planning

By regularly analyzing PBM performance data, plan sponsors can make informed adjustments to plan design. For example, if data shows an increase in high-cost drug utilization, the plan sponsor might choose to adjust cost-sharing or formulary exclusions to better manage this trend. Monitoring data on drug utilization, member adherence, and prescription patterns can reveal trends that affect plan costs. For instance, if a significant percentage of members are using brand-name drugs when generics are available, plan sponsors might adjust formulary or copayment structures to promote cost-effective alternatives. Data insights can help identify

member pain points, such as frequent prior authorization requirements or high out-of-pocket costs. Addressing these areas can improve member satisfaction and adherence to treatment plans, potentially reducing overall healthcare costs. Using data to ensure compliance with regulations (e.g., ACA preventive drug coverage, Medicare Part D requirements) helps plan sponsors avoid penalties and protect members' interests.

Plan sponsors can use data points to evaluate PBM performance and support decision-making. Tracking the amount and timing of rebates received from PBMs helps verify pass-through and identify savings opportunities. Monitoring utilization patterns, especially for specialty and high-cost drugs, provides insight into cost drivers. Regular claims audits ensure that claims are processed correctly, with accurate cost-sharing and adherence to the plan's formulary.

Further, plan analytics and key performance metrics are important. Analyzing the average cost per claim helps plan sponsors understand where costs are concentrated and whether there are opportunities for savings. Reviewing data on member out-of-pocket costs helps identify if members are facing financial barriers to medication access, which could impact adherence. Monitoring the cost and quality of care across different pharmacies helps verify that network choices are delivering cost savings without compromising access.

There are benefits of a proactive monitoring approach. By proactively monitoring PBM performance, plan sponsors can negotiate more favorable contract terms. Insights gained from monitoring empower plan sponsors to negotiate improved terms, such as better rebate pass-throughs, lower administrative fees, or performance guarantees. Regular monitoring helps plan sponsors ensure their goals around cost containment, member access, and clinical quality are met, even as market conditions and plan needs evolve. By identifying trends early, plan sponsors can make timely adjustments to avoid unexpected cost increases or adverse financial impacts from expensive therapies. Ongoing performance reviews hold PBMs accountable for their role in managing costs, enhancing transparency, and fulfilling contractual obligations.

In sum, ongoing monitoring and reporting of PBM performance enable plan sponsors to align pharmacy benefits with strategic goals, optimize costs, respond to industry changes, and maintain regulatory compliance. This approach strengthens the overall value of the pharmacy benefit, supports fiduciary responsibilities, and positions the plan for sustainable, data-driven success in managing drug spending.

Contract Review and Negotiation

PBM contract reviews are essential for ensuring that plan sponsors receive the full value of their pharmacy benefits arrangement and that the PBM operates transparently and in alignment with the sponsor's goals. However, several issues can complicate PBM contract terms, including ambiguous definitions, limited audit rights, a lack of transparency, liability gaps, insufficient fraud, waste, and abuse protections, unclear financial terms, and challenges in reconciling performance guarantees. Here's a breakdown of common issues in these areas:

Definition of Key Terms

Terms like "rebates," "discounts," "administrative fees," and "pass-through" often lack clear definitions in PBM contracts, which allows for varying interpretations that may not align with the plan sponsor's expectations. Contracts may not clearly define what constitutes a rebate versus a discount or other concessions. PBMs can leverage this ambiguity to retain a larger portion of rebates or administrative fees instead of passing them through to the plan sponsor. Terms related to "preferred drugs," "specialty drugs," or "in-network pharmacies" can have different meanings across PBMs, impacting cost and coverage. Clear definitions are needed to avoid confusion and ensure proper cost management.

Audit Rights

PBM contracts may restrict the plan sponsor's access to essential claims, rebate, and utilization data under the guise of "proprietary information." This can prevent thorough and accurate audits. Some contracts limit audit rights to once per year or restrict the scope to certain data sets, hindering the sponsor's ability to perform comprehensive audits. Some PBMs restrict the use of independent third-party auditors, making it difficult for plan sponsors to obtain unbiased, expert analysis. Plan sponsors should ensure they have the right to hire experienced, independent auditors who understand PBM practices.

Transparency

PBMs may engage in "rebate aggregating," where only a portion of rebates and other payments are passed through to the plan sponsor. Lack of transparency in these arrangements means that sponsors may miss out on substantial savings. PBMs sometimes use spread pricing—charging the plan sponsor more than they reimburse pharmacies for claims, creating an additional layer of cost. Without transparent reporting, sponsors can't easily identify or prevent this practice. Contracts may not require PBMs to disclose how much of each dollar flows back to the PBM versus the plan sponsor, obscuring the true cost of the PBM's services.

Liability

Many PBM contracts don't include clear provisions for holding the PBM liable if their actions lead to financial losses or compliance issues for the plan sponsor. This can leave the plan sponsor exposed to penalties or increased costs. Without strong indemnification clauses, plan sponsors may bear the risk if the PBM's actions lead to legal or regulatory challenges. Contracts should specify that the PBM is responsible for any compliance-related penalties that arise from its own practices. If the PBM fails to meet performance guarantees or comply with contract terms, liability clauses should specify the plan sponsor's right to seek damages or other remedies.

Fraud, Waste, and Abuse Auditing

Contracts may lack requirements for the PBM to conduct routine fraud, waste, and abuse audits, which are essential for identifying improper billing practices or fraud. PBMs may not be required to disclose findings of their FWA audits, which can prevent the sponsor from understanding the extent of potential abuse within their pharmacy benefit program. Specialty drugs are especially prone to misuse and abuse, yet some PBM contracts don't specify protections or monitoring for these high-cost items. Contracts should include regular FWA audits focused on high-cost drug categories to reduce the risk of abuse.

Financial Terms and Exclusions

Contracts may use complex pricing formulas, making it challenging for sponsors to track costs and verify that pricing aligns with contract terms. Some contracts exclude certain fees from discount calculations, reducing cost savings for the sponsor. PBMs may apply various fees (e.g., claims processing, clinical services) that are not always clearly outlined in the contract. Without a clear definition and cap on these fees, plan sponsors may face unexpected or excessive costs. Some contracts exclude certain drug categories (e.g., specialty drugs) from discount guarantees, which can significantly reduce the cost-saving potential of the plan.

Reconciliation of Financial Performance Guarantees

Performance guarantees (e.g., for rebate pass-throughs, discount rates) may be based on metrics that lack specificity, making it difficult to reconcile and verify financial outcomes. Contracts may require complex reconciliation processes that are hard to audit, leading to potential inaccuracies in financial guarantees. This complexity can benefit PBMs, as it obscures whether performance targets were truly met. Some contracts allow PBMs to delay performance reconciliation until after the contract period, limiting the sponsor's ability to hold the PBM accountable for missed guarantees or ensure timely adjustments.

To address these issues, plan sponsors can define key terms clearly. Work with legal and pharmacy benefit experts to ensure all financial and operational terms are explicitly defined, especially regarding rebates, discounts, fees, and pass-through amounts. Ensure that contracts include unrestricted audit rights, both in scope and frequency. This includes access to rebate data, claims data, and the ability to hire independent auditors.

Plan sponsors should also demand transparency. Require the PBM to provide transparent reporting on all revenue streams, including spread pricing, rebates, and administrative fees. Ideally, contracts should specify "full pass-through" on rebates and administrative fees to maximize financial benefit for the sponsor. Further, establish clear liability clauses: Include clauses holding the PBM accountable for any non-compliance or breaches of contract that lead to financial losses, as well as indemnification provisions to protect the plan sponsor from legal risks due to the PBM's actions. Do not limit liability to the administration fee which could be a very small portion of the actual liability (administration fees are generally only 5% to 10% of costs. PBM liability can, for example, be the entire cost of a drug or therapeutic category of a drug or an entire distribution channel that has been mis-programmed with an incorrect discount arrangement. Ensure FWA Audit provisions are adequate to recover on fraudulent claims and add specific requirements for the PBM to conduct regular fraud, waste, and abuse audits and report the findings to the plan sponsor. These provisions should include specialty drugs and high-cost therapies.

Best practices include simplified financial terms and plan sponsors should remove exclusions or provide pricing guarantees for drug categories that are typically excluded such as over-the counter drugs (required by the Affordable Care Act), limited distribution drugs and vaccines. Negotiate simplified and transparent pricing models, limiting exclusions for high-cost drugs and defining administrative fees. This makes it easier for the sponsor to track performance and control costs.

Lastly, require that performance guarantees be reconciled regularly, ideally quarterly or semi-annually, and that the PBM provides timely performance reports. This ensures that sponsors can adjust as needed and hold the PBM accountable for missed targets. By thoroughly reviewing and negotiating these contract elements, plan sponsors can gain greater control, ensure financial transparency, and protect their interests in the often-complex world of PBM relationships.

Request for Proposal (RFP)

Plan sponsors should conduct a Request for Proposal (RFP) from a Pharmacy Benefit Manager (PBM) when they aim to optimize pharmacy benefit costs, enhance plan performance, or address specific issues with their current PBM. A well-timed and well-structured RFP process can lead to significant financial savings, improved member experience, and a better alignment of pharmacy benefits with the sponsor's strategic goals. Here are key points on when to conduct a PBM RFP, its objectives, and important considerations.

It is difficult to pinpoint exactly when a plan sponsor should conduct an RFP project. Every three years (the typically length of a PBM contract term) may be excessive. However, some plan sponsors find value to ensuring the contract is always up to date and the market has been checked. However, the most common trigger for an RFP is the expiration of the current PBM contract. Many plan sponsors initiate the RFP process 12-18 months before the contract's end to allow ample time for selection, negotiation, and, if necessary, transition to a new PBM.

Another trigger for an RFP is performance issues with the current PBM: If a PBM is not meeting performance guarantees or has recurring issues such as high error rates in claims processing, poor member service, or suboptimal rebate management, an RFP can help identify a better-performing vendor. Significant cost increases, especially if they exceed national pharmacy trend averages, may indicate that the PBM isn't effectively managing cost drivers or negotiating competitive rebates. An RFP allows sponsors to compare vendors and potentially negotiate more favorable terms.

Changes in strategic plan goals may also necessitate an RFP. If the plan sponsor's goals evolve—such as a new focus on specialty drug cost control, chronic disease management, or improved member experience or a drastic increase in member population, say, through an acquisition or decrease in members, through layoffs—it may be time for an RFP to find a PBM that aligns more closely with these priorities.

Industry shifts, such as regulatory updates or the introduction of new high-cost therapies (e.g., gene therapies or GLP-1 medications), may prompt a plan sponsor to conduct an RFP to ensure they're obtaining competitive pricing and effective management strategies.

A desire for enhanced transparency and control may necessitate an RFP. With increased scrutiny on PBM practices, including spread pricing and rebate aggregating, plan sponsors may seek an RFP to select a PBM offering full transparency and pass-through pricing models to gain better control over pharmacy spend.

Objectives of a PBM RFP

The objectives of a PBM RFP include:

Reduce Pharmacy Benefit Costs:

Secure competitive pricing for drug claims, including discounts, rebates, and administrative fees. Ensure maximum rebate pass-through and negotiate clear terms for any rebate or fee arrangements.

Optimize Pharmacy Network and Formulary Management:

Identify a PBM with a well-structured pharmacy network, offering the right balance between cost savings and access to quality care. Ensure the PBM formulary supports the plan's goals, like promoting generic use or specialty management, and aligns with clinical efficacy.

Enhance Transparency and Reporting:

Select a PBM that provides full transparency on fees, pricing models (e.g., pass-through versus spread pricing), and rebate arrangements. Improve reporting capabilities so the plan sponsor has real-time access to claims data, utilization, and costs for better oversight and decision-making.

Ensure Compliance with Regulatory Requirements:

Verify that the PBM is well-versed in regulatory requirements (e.g., ACA, Medicare Part D for applicable plans) and has a solid compliance framework.
Ensure the PBM offers support in meeting new and evolving regulatory standards, particularly for drug pricing transparency and patient access protections.

Improve Member Experience and Satisfaction:

Ensure that members have access to medications without unnecessary barriers or high out-of-pocket costs.
Enhance the member service experience, including support for claims questions, medication adherence programs, and prior authorization processes.

Address Specific Cost Drivers, Particularly Specialty Drugs:

Specialty drugs represent a large and growing portion of pharmacy spend. The RFP should help find a PBM with robust specialty drug management programs that provide clinical oversight, cost-control mechanisms, and adherence support.

In considering whether to conduct a PBM RFP, plan sponsors should:

1. **Define Clear Goals and Priorities**:
   Before issuing the RFP, plan sponsors should clearly define what they want to achieve—whether it's cost savings, transparency, member satisfaction, or specialty management. This ensures that all vendors are evaluated based on relevant criteria and objectives.

2. **Evaluate Pricing and Financial Transparency**:
   Assess whether the PBM offers transparent pricing models, such as pass-through pricing for rebates and administrative fees. Request detailed descriptions of all financial arrangements, including spread pricing, rebate structures, and fees, to understand the true cost impact.

3. **Assess Audit Rights and Oversight Capabilities**:
   The ability to audit claims, utilization, and rebates is essential for monitoring PBM performance. Ensure that the RFP outlines expectations for robust audit rights and compliance reporting to ensure accountability.

4. **Review Network and Formulary Flexibility**:
   Evaluate each PBM's flexibility in offering tailored networks or formularies that balance cost containment with member access. Plan sponsors may prefer PBMs that provide formulary customization, step therapy, and prior authorization flexibility to align with clinical and financial goals.

5. **Consider Specialty Drug Management Expertise**:
   Specialty drug costs require specific management strategies, including utilization management, adherence programs, and outcomes-based contracts. Ensure the RFP requires PBMs to detail their specialty drug management programs, including cost-control methods and clinical support.

6. **Inquire about Technology and Data Analytics Capabilities**:
   Advanced data capabilities can greatly enhance decision-making and cost control. Consider PBMs with strong reporting and analytics platforms that allow plan sponsors to monitor utilization, costs, adherence patterns, and member satisfaction in real-time.

7. **Evaluate Member Support Services**:
   The PBM should offer quality support services, including call center capabilities, medication adherence support, and streamlined prior authorization processes. These services are critical for improving member experience and ensuring timely access to medications.

8. **Ensure Compliance with Evolving Regulations**:
   Regulatory requirements in the PBM space are evolving, with recent laws focusing on transparency and fair pricing practices. Ensure that the RFP asks PBMs to demonstrate how they comply with current laws and prepare for upcoming regulatory changes.

9. **Set Performance Guarantees and Reconciliation Requirements**:
   Include clear performance guarantees (e.g., cost savings targets, rebate pass-throughs, claims accuracy). Also, outline how financial performance should be measured and reconciled to verify that the PBM meets these guarantees and adjusts if they fall short.

There are many benefits to a thorough RFP process. These include:

- **Better Contractual Terms and Financial Outcomes**: A thorough RFP process enables plan sponsors to negotiate favorable financial terms, including lower administrative fees, transparent rebate structures, and competitive discount guarantees.
- **Increased Accountability**: Clear terms for audit rights, transparency, and performance guarantees hold the PBM accountable for its commitments, reducing the risk of unexpected costs.
- **Enhanced Member Experience**: By prioritizing vendors with strong member support and transparent pricing, plan sponsors can improve satisfaction and ensure members have affordable, timely access to needed medications.
- **Adaptability to Industry Changes**: Selecting a PBM with a flexible and data-driven approach allows the plan sponsor to adapt to emerging drug categories, new therapies, and changing regulations, keeping the plan competitive and cost-effective.

Conducting a PBM RFP is a proactive approach that allows plan sponsors to align pharmacy benefits with strategic goals, reduce costs, enhance transparency, and improve the member experience.

Consultants

Hiring a consultant to help a plan sponsor with a Pharmacy Benefit Management (PBM) Request for Proposal (RFP) can be beneficial, but it also comes with several potential challenges and issues. Here are some common concerns:

Conflict of Interest

Some consulting firms may have affiliations with PBMs, either directly or indirectly, which could bias their recommendations. If the consultant has financial or professional ties to a particular PBM, this could lead to a recommendation that isn't in the best interest of the plan sponsor.

Lack of Transparency in Fee Structures

Consultants may have complex fee structures that are not always transparent. They may charge for different phases of the RFP process, and sometimes there may be hidden fees. Additionally, if consultants receive incentives or kickbacks from PBMs for steering business their way, this could create a conflict and potentially higher overall costs.

Variability in Expertise

Not all consultants have the same level of expertise in the nuances of PBM contracting, pricing models, and rebate structures. A consultant who lacks deep experience in PBM negotiations may fail to secure optimal terms or miss opportunities for cost savings.

Incomplete Customization of RFPs

Some consultants use template-based RFPs that may not account for the unique needs of each plan sponsor. This "cookie-cutter" approach can lead to overlooking specific requirements or risks that are particular to the sponsor's plan and participants, resulting in a less effective PBM arrangement.

Inadequate Focus on Performance Guarantees and Metrics

Consultants may not prioritize securing strong performance guarantees, rebate transparency, or service-level metrics in the RFP. Without these provisions, the PBM might not be held accountable for delivering quality services or passing through savings to the plan sponsor.

Potential for Slower Decision-Making

Consultants can sometimes add layers of bureaucracy to the process. They may recommend multiple rounds of proposals or negotiations that slow down the selection process. This may also delay the implementation of cost-saving measures or enhancements to the plan design.

Cost of the Consultant

Hiring a consultant can be expensive, and the value they add isn't always clear. If the consultant's fee is substantial but the savings, they secure are minimal, it could lead to negative returns on the investment for the plan sponsor.

Limited Focus on Long-Term Value

Some consultants may focus on securing short-term savings rather than crafting a PBM contract with provisions that drive long-term value. A contract may initially seem cost-effective but may lack flexibility or transparency, leading to higher costs down the line.

Challenges with Data Security and Privacy

In the RFP process, the consultant may handle sensitive data related to plan costs, utilization, and member health information. If data security practices aren't robust, there could be risks related to data breaches or unauthorized access to private information.

Potential for Overly Complex Contract Structures

Some consultants may propose intricate contract terms and performance metrics that seem comprehensive but are hard to monitor and enforce. This can lead to difficulties in tracking compliance, measuring outcomes, or ensuring the PBM is meeting its obligations.

Mitigating These Issues

To address these challenges, plan sponsors should conduct due diligence before hiring a consultant by:

- Verifying the consultant's independence from PBMs.
- Ensuring transparency in fees and any incentives.
- Confirming their expertise and track record in PBM contracting.
- Clearly defining project goals, timelines, and expectations for consultant involvement.

A thoughtful, informed approach to selecting a consultant can help avoid these pitfalls and increase the chances of a successful PBM RFP process that delivers long-term value.

Drafting a Request for Proposal (RFP) for Pharmacy Benefit Manager (PBM) services

Drafting a Request for Proposal (RFP) for Pharmacy Benefit Manager (PBM) services is a detailed, multi-step process designed to ensure that plan sponsors can clearly articulate their needs, evaluate potential PBMs, and select a vendor that aligns with their goals. Here are the major steps plan sponsors should take to create an effective RFP for PBM services:

1. **Define Objectives and Scope**
   - **Establish Clear Goals**: Begin by outlining what the plan sponsor wants to achieve with the new PBM contract, such as reducing pharmacy benefit costs, enhancing member experience, or increasing transparency.
   - **Identify Key Priorities**: Prioritize areas like formulary management, specialty drug cost control, rebates, transparency, and compliance to focus on what matters most to the plan.
   - **Determine the Scope of Services**: Specify the range of PBM services required (e.g., claims processing, rebate management, formulary development, member support). This ensures PBMs understand the full extent of the services expected.

2. **Assemble a Cross-Functional RFP Team**
   - **Include Stakeholders**: Form a team with representatives from benefits, finance, legal, compliance, and human resources. Each department provides valuable insight into the needs and priorities of the organization.
   - **Engage Pharmacy Benefits Experts or Consultants**: If possible, work with an experienced PBM consultant who can help with the technical aspects of PBM services and contract requirements, as well as industry standards.

3. Outline RFP Requirements and Evaluation Criteria

- **Develop Clear Evaluation Criteria**: Establish criteria for evaluating PBMs based on the plan sponsor's priorities, such as cost savings, service quality, audit rights, transparency, and data capabilities.
- **Set Minimum Requirements for PBMs**: Define basic qualifications and experience requirements, such as years in the business, client size, specialty drug management, and regulatory compliance, to screen out PBMs that don't meet the minimum standards.
- **Weight Evaluation Categories**: Assign weights to each evaluation category (e.g., 30% for pricing, 20% for transparency, 15% for member experience) to ensure the RFP reflects the sponsor's priorities.

4. Draft Key Sections of the RFP in a contract form

- **Introduction and Background**: Provide an overview of the organization, the purpose of the RFP, and high-level goals for the pharmacy benefit program.
- **Scope of Services**: Detail the specific services the PBM is expected to provide, such as formulary management, rebate collection, claims processing, utilization management, and specialty drug management.
- **Performance Guarantees**: Define the performance metrics the PBM is expected to meet (e.g., cost savings targets, rebate pass-through rates, customer service standards). Specify penalties or remedies for missed guarantees.
- **Data and Reporting Requirements**: Outline expectations for data transparency, including access to real-time claims data, rebate reporting, and cost/utilization data. Specify the reporting frequency and format.
- **Audit Rights**: Define audit requirements, such as unrestricted access to claims data and the ability to conduct both internal and third-party audits to ensure accountability.
- **Financial Terms and Pricing Models**: Describe the desired pricing model (e.g., pass-through pricing, flat fees), transparency expectations, and any exclusions that are unacceptable (e.g., spread pricing). Include specific questions about administrative fees, discounts, and rebates.
- **Compliance and Regulatory Standards**: Request information on the PBM's compliance practices and how it addresses current regulatory requirements (e.g., ACA, state laws on drug pricing transparency).
- **Implementation and Transition Support**: Specify expectations for the transition process, including member communications, data transfer, and training support, to ensure a smooth transition if switching vendors.
- **Member Experience and Support Services**: Include questions about member support services, such as call center capabilities, prior authorization handling, and adherence programs, to evaluate the PBM's ability to provide a positive member experience.

5. Prepare a Contract of Terms for the PBM to redline

- Instead of developing a list of questions that may have no relevance to what the plan sponsor might want its PBM to do, a better approach is to develop a comprehensive contract of services that includes key definitions, terms, services and financial performance and annual reconciliation procedures. In each RFP contract section, the objective is to gain a full understanding of the PBM's capabilities with the PBM either agreeing to perform the services as detailed in the contract or enabling the PBM to redline the contract so that the plan sponsor can understand where the PBM might fall short of expectations. Common contract categories include:
    - **Definitions:** Provide definitions to key terms like Average Wholesale Price (AWP), National Average Drug Acquisition Cost (NADAC) pricing, Acquisition Costs, Rebates, Brand Drugs, Generic Drugs, Specialty Drugs, Pass though pricing and Claim.
    - **Services Provided:** What specific services does the plan sponsor want in terms of reporting, clinical management, eligibility, network management, audit, claims processing and member services?
    - **Cost and Pricing**: How are rebates and discounts structured? Is pricing fully transparent and pass-through?
    - **Specialty Drug Management**: How does the PBM manage specialty drug costs? What adherence support and utilization management programs are in place?
    - **Reporting and Data Transparency**: How frequently are reports provided? Is data available in real-time?
    - **Formulary Management**: What is the process for formulary development? How is clinical efficacy weighed against cost?
    - **Member Support**: What customer service resources are available to members? How does the PBM handle prior authorizations and appeals?

6. Establish a Timeline and Submission Requirements

- **Define the RFP Timeline**: Set clear dates for the RFP issuance, submission deadlines, PBM Q&A sessions, proposal review, finalist presentations, and contract award.
- **Specify Submission Guidelines**: Outline formatting requirements, submission instructions, and contact information for questions. Specify that all responses must be complete, with supporting documentation as needed.

7. Distribute the RFP and Manage Communications

- **Select Potential PBMs to Receive the RFP**: Distribute the RFP to pre-qualified PBMs that meet the sponsor's requirements. Often, this includes a mix of PBMs already on the market and niche or regional PBMs, if applicable.
- **Facilitate a Q&A Process**: Hold a Q&A session or provide a period for PBMs to submit written questions. Compile and distribute the answers to ensure all vendors have the same information.

8. Evaluate Responses and Shortlist Finalists

- **Score RFP Responses Against Criteria**: Use the weighted evaluation criteria to score each PBM's response objectively. Engage the RFP team in the review process to ensure a balanced assessment.
- **Review Pricing Proposals Carefully**: Compare financial terms, including rebates, fees, and pass-through rates. Look for hidden fees or terms that could lead to unexpected costs.
- **Assess Service and Member Experience**: Evaluate each PBM's ability to deliver a positive member experience, including their member support resources, ease of prior authorization, and response to appeals.

9. Conduct Finalist Presentations and Site Visits

- **Request Presentations from Top Candidates**: Invite the most promising PBMs to present their offerings in more detail. This is an opportunity to clarify their responses, ask additional questions, and assess their fit with the organization.
- **Conduct Site Visits or Reference Checks**: If possible, visit PBM facilities or conduct reference checks with current clients to verify service quality and alignment with the RFP promises.

10. Negotiate Terms and Finalize the Contract

- **Clarify Terms and Address Red Flags**: Before finalizing the contract, address any ambiguities in financial terms, audit rights, rebate pass-throughs, or compliance clauses to ensure clarity and accountability.
- **Negotiate Performance Guarantees**: Agree on specific performance guarantees, audit rights, and recourse options if the PBM fails to meet contractual obligations.
- **Review and Approve Final Contract**: Once all terms are negotiated, review the contract thoroughly to ensure it meets all the plan sponsor's requirements before signing.

11. Plan for Implementation and Ongoing Monitoring

- **Develop an Implementation Plan**: Work with the PBM to outline a transition plan, including timelines, member communications, and data transfers to minimize disruption.
- **Establish Ongoing Monitoring Procedures**: Set up a regular reporting and audit schedule to monitor PBM performance, ensuring they meet performance guarantees and financial targets over the life of the contract.

Each of these steps helps plan sponsors ensure that they select a PBM partner who aligns with their goals, offers competitive financial terms, and meets their members' needs. A thorough and strategic RFP process sets the foundation for a PBM contract that supports long-term cost management, transparency, compliance, and member satisfaction.

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Determining PBMs to Solicit:

Determining which Pharmacy Benefit Managers (PBMs) to send an RFP to requires a strategic approach to ensure that the plan sponsor engages only those PBMs that align with their needs, goals, and member population. Not all PBMs operate the same way; there are notable differences in their business models, pricing structures, specialty drug management, and service capabilities. Here are the steps a plan sponsor should take to determine which PBMs to consider, along with an overview of key differences among PBMs:

1. Assess Your Plan's Unique Needs and Goals

- **Cost Management Priorities**: If the primary objective is cost savings, look for PBMs with strong rebate pass-through models, aggressive discounting, and efficient cost-control strategies, particularly for high-cost drugs like specialty medications.
- **Member Experience**: If member satisfaction is a priority, consider PBMs with a strong reputation for customer service, easy access to support, and streamlined prior authorization processes.
- **Transparency Needs**: Some PBMs offer transparent pass-through pricing, while others may use spread pricing. If full financial transparency is important, seek PBMs with a pass-through pricing model that allows better insight into all costs.
- **Regulatory Compliance**: For sponsors with specific regulatory requirements (e.g., Medicare Part D or ACA compliance), choose PBMs experienced in these areas and capable of handling regulatory complexities.

2. Identify the Types of PBMs Available

PBMs can generally be grouped into three categories, each with distinct models and characteristics:

- **Traditional/Full-Service PBMs**: The largest PBMs often operate as “traditional” or “full-service” providers, handling everything from claims processing to formulary management and rebate negotiations. These PBMs may be vertically integrated with insurers and own specialty pharmacies, which can create both efficiencies and potential conflicts of interest.
- **Transparent or Pass-Through PBMs**: These PBMs focus on providing full transparency and often operate under a pass-through pricing model, where all rebates, discounts, and fees are passed back to the plan sponsor without markups. They typically charge a flat administrative fee instead of using spread pricing.
- **Specialty PBMs**: Specialty PBMs primarily manage high-cost specialty drugs, such as injectables, biologics, and gene therapies. They focus on specialty drug cost control, patient support, and clinical management for complex treatments. Some full-service PBMs also offer specialty management as part of their offerings.

3. Research PBM Reputation and Market Position

- **Evaluate Industry Reputation**: Look for PBMs with strong reputations for reliability, transparency, and customer service. Reading client testimonials, seeking recommendations, and checking for industry awards or certifications can help identify reputable PBMs.
- **Review Client Base**: Consider PBMs that serve clients similar to your organization in terms of size, industry, and geographic location. Larger PBMs may offer more comprehensive services suited for large populations, while smaller PBMs may offer more personalized service for niche or regional needs.

4. Determine Financial Model Alignment

- **Pass-Through vs. Spread Pricing**: Traditional PBMs often use a spread pricing model, where they profit by marking up the price difference between what they pay the pharmacy and what they charge the plan. Pass-through PBMs, however, offer full transparency by passing all rebates and discounts directly to the plan sponsor, usually for a flat fee.
- **Rebate Structure**: Examine how each PBM structures rebates. While traditional PBMs may retain part of the rebates, transparent PBMs typically pass 100% of rebates to the sponsor. Consider which model aligns best with your financial goals and transparency requirements.

5. Evaluate Service Capabilities

- **Formulary and Clinical Management**: Some PBMs take a more restrictive approach to formulary design, which can lower costs, while others offer more flexible formularies to accommodate specific member needs. Evaluate each PBM's formulary strategy and their ability to manage utilization effectively.
- **Specialty Drug Management**: Specialty drugs are a major cost driver, and not all PBMs have the same level of expertise in managing these. Look for PBMs that offer robust specialty drug programs, including clinical support, adherence programs, and cost-management strategies.
- **Data Analytics and Reporting**: A PBM's ability to provide detailed data and reporting can be critical for plan management. Transparent or smaller PBMs might offer more customized reporting options, while larger PBMs might provide more standardized reporting at scale.

6. Consider Technological Capabilities and Innovation

- **Data Transparency and Access**: Select PBMs with robust data-sharing capabilities that allow for real-time data access and custom reporting. This is especially important for plan sponsors wanting regular insights into drug utilization, cost trends, and member health outcomes.
- **Digital Member Tools**: Many PBMs offer digital tools for members, such as mobile apps, online portals, and telehealth services, which can improve the member experience and promote medication adherence.

7. Request Information on Audit Rights and Contractual Flexibility

- **Audit Rights**: Ensure the PBM is willing to include robust audit rights in their contract, as this is essential for verifying compliance and financial accuracy.
- **Contract Flexibility**: Look for PBMs that offer flexibility in contract terms, such as termination clauses and performance guarantees. Transparent and boutique PBMs may offer more favorable terms in this regard than larger PBMs.

In evaluating the proposals received there are key differentiators. The following areas should be considered in the evaluation:

1. **Pricing Models and Transparency**:
    - **Traditional PBMs**: May use spread pricing and retain part of the rebates, often resulting in less transparency.
    - **Transparent/Pass-Through PBMs**: Offer full pass-through of all rebates and discounts to the plan sponsor, usually charging a flat administrative fee. They prioritize transparency, often giving plan sponsors more insight into costs and savings.

2. **Specialty Drug Management Capabilities**:
    - **Traditional PBMs**: Often operate in-house specialty pharmacies and may have access to exclusive drugs or pricing, which can benefit members needing specialty medications.
    - **Specialty PBMs**: Focus solely on high-cost specialty drug management, offering tailored clinical support and cost-saving programs for these medications.

3. **Level of Control over Formulary Design**:
    - **Large, Traditional PBMs**: May have a more restrictive, one-size-fits-all formulary that maximizes rebate potential but may not be as flexible for specific plan needs.
    - **Transparent/Boutique PBMs**: May offer more flexibility with custom formularies, allowing plan sponsors to choose medications that best meet their member needs without being limited to rebate-driven preferences.

4. **Service Models and Customer Support**:
    - **Large PBMs**: Typically offer a wide range of services but may lack the personalized service that smaller PBMs can provide. Member service is often managed at scale, which can sometimes result in a less tailored experience.
    - **Smaller, Boutique PBMs**: Often offer highly personalized service and direct points of contact, which may improve responsiveness and overall member satisfaction.

5. **Data and Reporting Quality**:
    - **Traditional PBMs**: May offer standardized data analytics and reporting, which can provide high-level insights but may lack the depth or flexibility that some plan sponsors prefer.
    - **Transparent/Boutique PBMs**: Often provide more customizable data reporting, allowing for greater insights into specific cost drivers, trends, and opportunities for improvement.

6. **Regulatory Compliance Expertise**:
    - **Traditional PBMs**: Often have well-established compliance programs that can handle complex regulatory requirements, including Medicare Part D.
    - **Smaller or Specialty PBMs**: While many are fully compliant, their compliance infrastructure may vary; they may require additional due diligence to ensure they can handle complex regulatory needs if applicable to the plan.

To determine which PBMs to invite to the RFP process, plan sponsors should start by clarifying their objectives and evaluating each PBM's alignment with those goals. Differences in pricing models, transparency, specialty drug management, service quality, and reporting capabilities can heavily impact both cost outcomes and member experience. Selecting the right PBMs for the RFP process helps ensure that only the most suitable vendors are considered, leading to a better partnership and optimized pharmacy benefit management for the plan sponsor and its members.

PBM Coalitions

A PBM coalition is a group purchasing arrangement where multiple plan sponsors come together to leverage their collective buying power, typically managed by a third-party entity. By joining a coalition, plan sponsors can gain more favorable pricing, terms, and resources, which may not be achievable independently, especially for smaller plans. However, coalitions also have trade-offs, particularly in terms of control and customization. Here are the key advantages and disadvantages to consider:

Advantages of PBM Coalitions

1. **Increased Negotiating Power and Cost Savings**
    - Coalitions pool the purchasing volume of multiple employers, which often leads to lower drug pricing, deeper discounts, and better rebates due to the collective bargaining power.
    - They can often negotiate enhanced financial terms, such as higher rebate guarantees and discounts, which are passed on to each plan sponsor within the coalition.

2. **Pre-Negotiated Terms and Contract Efficiencies**
    - Coalitions often provide pre-negotiated contracts, saving time and legal costs that each individual sponsor would otherwise spend on contract reviews and negotiations.
    - For small to mid-sized employers, coalitions enable access to terms that would typically be available only to larger organizations.
3. **Administrative Support and Simplified Processes**
    - Coalition managers often handle much of the day-to-day administrative work, which can reduce the plan sponsor's administrative burden and streamline PBM management.
    - These services may include claims audits, data reporting, formulary management, and member support, which can benefit sponsors that lack internal resources for these tasks.
4. **Access to Additional Resources and Expertise**
    - Coalition members often have access to shared resources, such as data analytics, reporting tools, and consulting support, which can enhance decision-making and help optimize pharmacy benefit strategies.
    - Many coalitions also offer guidance on compliance and regulatory issues, such as ACA requirements, ERISA compliance, and state-specific drug pricing laws.
5. **Enhanced Transparency and Data Access**
    - Some PBM coalitions are structured to offer greater transparency, requiring PBMs to operate on a pass-through model with clearly disclosed rebates, fees, and costs. This can provide more control over drug spend and help identify cost-saving opportunities.
    - Coalitions often have audit rights that allow them to regularly review the PBM's adherence to contract terms, including financial guarantees.

Disadvantages of PBM Coalitions

1. **Limited Control Over Plan Design and Flexibility**
    - Coalitions typically operate with standardized plan designs, formularies, and cost-sharing structures to maintain consistency across all members, which can limit customization options.
    - Sponsors with unique requirements for their member population, such as specific formulary exclusions, specialty drug preferences, or unique utilization management programs, may find that these are not supported in a coalition environment.
2. **Less Influence on PBM Performance and Service**
    - In a coalition, individual plan sponsors have less leverage to address specific issues or demand changes from the PBM because decisions are made collectively.
    - If the PBM's performance is subpar in certain areas, such as member support or claims processing, a single sponsor may have limited ability to influence service changes.
3. **Potential for Mismatched Goals and Conflicting Interests**
    - Coalition members may have different goals and priorities, particularly regarding cost-sharing policies, member experience, and specialty drug management, which could result in compromises that don't fully meet any one sponsor's needs.
    - Larger sponsors in the coalition may have more influence over key decisions, which can sometimes lead to a one-size-fits-all approach that does not benefit smaller sponsors as much.
4. **Reduced Ability to Innovate and Implement New Programs**
    - Since coalitions rely on standardization, it may be challenging for a plan sponsor to adopt innovative programs independently, such as unique adherence initiatives, member engagement tools, or tailored wellness programs.
    - Plan sponsors with a focus on innovation may find that a coalition's slower decision-making process and administrative layers hinder their ability to quickly adapt to new industry developments.

5. **Transparency Varies by Coalition**
    - While some coalitions prioritize transparency, others may not disclose as much information to members, especially if they rely on a traditional PBM model with spread pricing.
    - Coalition-managed contracts may lack the level of transparency that certain plan sponsors require, such as full rebate pass-through and detailed financial reports on drug spend.
6. **Compliance and Fiduciary Challenges**
    - Plan sponsors under ERISA have fiduciary responsibilities, meaning they must act in the best interests of their members and ensure prudent management of plan assets. When in a coalition, sponsors may have less oversight of how PBM practices align with these fiduciary duties.
    - Sponsors should carefully evaluate the coalition's governance and monitoring practices to ensure they support ERISA compliance, as they may still be held accountable for fiduciary responsibilities even within the coalition.

Key Considerations for Joining a PBM Coalition

When considering a coalition, plan sponsors should evaluate how well the coalition's structure and goals align with their own. Some key factors to consider include:

- **Alignment with Plan Goals**: Does the coalition prioritize goals that match the sponsor's needs, such as cost savings, member experience, or regulatory compliance?
- **Transparency and Pricing Structure**: Does the coalition offer a pass-through model, and are rebate arrangements fully transparent?
- **Level of Customization Permitted**: Will the coalition allow for adjustments to plan design or cost-sharing that accommodate the sponsor's specific member needs?
- **Fiduciary Compliance Support**: Does the coalition offer reporting and auditing that align with fiduciary responsibilities under ERISA, including clear documentation and oversight processes?
- **Access to Analytics and Reporting**: Does the coalition provide robust reporting on key metrics, and is there flexibility in how data is accessed and analyzed?

Conclusion

Joining a PBM coalition can be a valuable strategy for plan sponsors looking to reduce costs and streamline contract administration, particularly for those with limited bargaining power on their own. However, it is essential to carefully assess the coalition's terms, service model, and transparency practices. Coalitions work best for plan sponsors whose goals align closely with the coalition's objectives and who are comfortable with the standardized approach coalitions typically require. For sponsors seeking high levels of customization, innovation, or direct control over their pharmacy benefit program, a coalition may not be the best fit.

Market Checks

A plan sponsor should consider conducting a market check instead of a full Request for Proposal (RFP) in specific situations where they want to assess the current market landscape without the comprehensive and often resource-intensive process that an RFP entails. Here are some scenarios where a market check might be appropriate:

1. Ongoing Relationship with Current PBM

- **Satisfactory Performance**: If the current PBM is performing well, providing adequate services, and delivering on cost savings and member satisfaction, a market check can confirm that the sponsor is getting competitive pricing without needing to initiate a full RFP process.
- **Desire for Incremental Improvements**: A market check can help identify opportunities for minor adjustments or enhancements in service, pricing, or contract terms without the need for a complete overhaul of the current relationship.

2. Budget Constraints or Resource Limitations

- **Limited Resources**: Conducting a full RFP requires significant time and resources, including the preparation of detailed specifications, coordination with multiple vendors, and comprehensive evaluations. If resources are tight, a market check can provide valuable insights with a lighter lift.
- **Cost Management**: For smaller plan sponsors or those with budget constraints, a market check can be a cost-effective way to explore options without the overhead associated with a full RFP.

3. Market Conditions and Competitive Landscape

- **Rapidly Changing Market**: If there are indications of significant changes in the PBM landscape (e.g., new entrants, regulatory changes, or shifts in pricing models), a market check can provide a snapshot of current offerings and pricing trends without the commitment of a full RFP.
- **Emerging Trends**: A market check can help identify emerging trends, such as innovative pricing models or new services that competitors might be offering, which can inform the plan sponsor's strategy moving forward.

4. Time-Sensitive Situations

- **Urgent Need for Information**: If the plan sponsor requires quick feedback on market conditions or pricing to make timely decisions (e.g., in preparation for an upcoming renewal), a market check can provide rapid insights without the lengthy RFP process.
- **Adapting to Changes**: If there are changes in the organization, such as mergers, acquisitions, or shifts in membership, a market check can quickly assess how the current PBM fits within the new context.

5. Benchmarking Performance and Costs

- **Comparative Analysis**: A market check can serve as a benchmarking exercise to compare current PBM performance and costs against market averages and best practices, helping the sponsor determine if they are in line with industry standards.
- **Identifying Competitive Advantages**: This approach can highlight areas where the current PBM may excel or fall short compared to competitors, providing data to inform future decisions.

6. Specific Focus Areas or Services

- **Niche Evaluations**: If the plan sponsor is only interested in evaluating specific aspects of PBM services (e.g., specialty drug management, clinical programs, or reporting capabilities), a targeted market check can provide relevant insights without the need for a comprehensive RFP.
- **Regulatory Compliance Review**: A market check can be useful for assessing how well the current PBM aligns with new or evolving regulatory requirements without embarking on a full RFP process.

Conclusion

Conducting a market check can be a strategic and efficient way for plan sponsors to assess their current PBM relationship and understand the market landscape without committing to the time and resource demands of a full RFP. This approach is particularly valuable when the sponsor is satisfied with current services, has budget or resource constraints, or is facing time-sensitive decisions. However, if substantial changes are needed or if the current PBM is underperforming, a full RFP may ultimately be necessary to ensure the best fit for the organization's needs.

Fraud, Waste and Abuse Programs

Fraud, waste and Abuse (FWA) programs are integral to a well-managed prescription drug program. Pharmacy Benefit Managers (PBMs) often don't mention Fraud, Waste, and Abuse (FWA) programs explicitly because PBMs take spread on all claims including FWA claims. Eliminating these claims would reduce the number of claims processed by PBMs and in turn would reduce profit and rebate payments. Further, plan sponsors perceive that PBMs do not allow fraudulent providers in the network, but FWA providers are usually included because of PSAO (Pharmacy Administrative Service Organizations, or groups of independent pharmacies) and contracting conflicts of interest.

Therefore, the reasons behind PBMs' reluctance to discuss and implement Fraud, Waste, and Abuse (FWA) programs go deeper than concerns about confidentiality, negative associations, or regulatory compliance. The real, more complex issues are tied to financial incentives and structural conflicts of interest in the pharmacy benefit management industry. Here's a more in-depth look at the reasons:

1. Incentive to Maintain High Claim Volumes (Including Fraudulent Claims)

PBMs generally make money through spread pricing, which is the difference between what they charge health plans (or plan sponsors) for medications and what they reimburse pharmacies. This model incentivizes PBMs to maintain high claim volumes, as they profit from the markup on these claims.

- FWA and the Profit Motive: Fraudulent or wasteful claims, while obviously undesirable from an ethical standpoint, are still part of the overall claim volume. By failing to aggressively target FWA, PBMs ensure that the volume of claims remains high. Reducing the number of fraudulent or wasteful claims would decrease the total claim volume, and therefore, the spread on these claims would shrink, directly reducing the PBMs' profits.
- Impact on Rebates: PBMs also negotiate rebates with pharmaceutical manufacturers based on the volume of drugs dispensed. If FWA were aggressively targeted and reduced, the volume of medications dispensed would drop, leading to smaller rebate payments from manufacturers. Therefore, PBMs may have an economic incentive to overlook or downplay FWA, as it helps maintain high claim volumes that lead to higher rebates and profit margins.

2. Provider Networks and PSAOs (Pharmacy Services Administrative Organizations)

PBMs often rely on PSAOs to manage their pharmacy networks and negotiate contracts with individual pharmacies. These PSAOs play a crucial role in expanding and maintaining the PBM's network, but there is a conflict of interest in that PSAOs also often serve the interests of the pharmacies they represent, not necessarily the PBMs or plan sponsors.

- Conflict of Interest: PBMs may hesitate to remove fraudulent or abusive providers from their networks because PSAOs may push back due to financial relationships with these providers. If PBMs cut ties with high-volume pharmacies (even those engaged in fraudulent activities), it could result in loss of revenue for the PBM and also disrupt relationships with the PSAOs, who may have significant influence over network participation. This tension can cause PBMs to turn a blind eye to some fraudulent activities or to settle for less effective monitoring practices.
- Provider Retention: If PBMs are overly aggressive in policing FWA, they may face pushback from pharmacies in their networks, particularly those that provide significant claim volumes. This is especially true if those pharmacies are part of a PSAO's network, and the PBM risks losing valuable participants in their prescription network. As a result, PBMs may prefer to quietly accept the presence of some fraudulent or wasteful claims, rather than risk alienating key network pharmacies.

3. Perception by Plan Sponsors and Lack of Accountability

Many plan sponsors believe that PBMs are already actively monitoring for and eliminating fraud in their networks, especially since PBMs often market themselves as having systems in place to prevent FWA. This perception can lead to a lack of scrutiny from plan sponsors regarding the actual effectiveness of FWA programs.

- Plan Sponsors' Trust: Plan sponsors often trust PBMs to manage the network and claims process effectively, assuming that FWA is being controlled behind the scenes. However, the true effectiveness of these programs can be diluted by the PBM's financial incentives. Plan sponsors may be unaware of the conflicts of interest that allow fraudulent providers to remain in the network or of the limitations of FWA programs in the PBM's operations.
- Minimal Public Focus on FWA: By not openly discussing FWA programs or their effectiveness, PBMs avoid drawing attention to the fact that they may not be aggressively rooting out fraud or waste. This helps maintain the illusion that the PBM is managing the situation effectively, and it prevents plan sponsors from asking uncomfortable questions about how well FWA is truly being controlled.

4. Lack of Strong Enforcement Mechanisms

The lack of effective enforcement mechanisms against FWA in many PBM models is also due to the overall structure of the pharmacy benefit landscape. For example:

- Shared Revenue from Drug Claims: PBMs, pharmacies, and PSAOs often share in the financial benefits of drug claims, including rebates, spread pricing, and dispensing fees. These financial arrangements can create a situation where PBMs are reluctant to enforce strict FWA controls that would reduce overall claims volumes or lead to the removal of certain pharmacies from the network.
- Weak Monitoring and Auditing: While PBMs often tout their FWA programs, many of these programs are not sufficiently robust to effectively identify or prevent FWA. Rather than implementing thorough auditing systems that would expose widespread abuse or fraud, PBMs often implement less aggressive monitoring processes that don't disrupt the financial flow. This approach serves the PBMs' interests by maintaining higher claim volumes and larger rebates.

5. Regulatory Oversight and the Appearance of Compliance

Finally, many PBMs design their FWA programs in a way that meets the minimum regulatory requirements without necessarily going beyond them. As long as they can show that they have a system in place to detect and manage FWA, they can satisfy regulatory bodies, even if those programs are not particularly effective in practice.

Regulatory Minimums: PBMs may not see a financial incentive to implement more stringent or proactive FWA measures unless required to do so by law or regulatory pressure. The current regulatory framework allows for a certain level of leniency, which PBMs can exploit to avoid disrupting their profitable business practices.

In essence, PBMs' reluctance to effectively address FWA issues stems from a complex set of financial incentives and structural conflicts. The spread pricing model and reliance on PSAOs to manage pharmacy networks create inherent conflicts that discourage PBMs from actively targeting fraud, waste, and abuse. By overlooking these issues, PBMs can maintain their claim volumes and rebate negotiations, which ultimately boosts their revenue. Furthermore, plan sponsors may not be fully aware of these conflicts, which allows PBMs to continue operating in ways that are not always in the best interest of the plan or its members.

Issues with Fraud, Waste, and Abuse in Prescription Drug Programs

Fraud, Waste, and Abuse (FWA) can be significant issues in prescription drug programs – as much as 10% of costs, because they lead to inflated drug costs, decreased efficiency, and poor patient outcomes. FWA in prescription drug plans can lead to significant overpayments, which ultimately result in higher premiums and out-of-pocket costs for members. Fraudulent or abusive claims may divert resources away from patients who need them, leading to inappropriate medications, harm, or treatment delays. Failure to detect and address FWA can lead to regulatory scrutiny, penalties, or other legal consequences for PBMs and plan sponsors.

Difference Between Fraud, Waste, and Abuse

Fraud: Deliberate misrepresentation or concealment of information for personal gain. Fraud typically involves an intent to deceive and usually results in direct financial gain at the expense of others. Example: A pharmacy submitting claims for medications not dispensed or for services not rendered.

Waste: The overutilization of services or the purchase of unnecessary items due to poor practices or inefficient management. Waste does not involve intentional deception, but still results in excessive costs. Example: Prescribing brand-name drugs when generic equivalents are available or dispensing larger quantities than necessary.

Abuse: Actions that are inconsistent with accepted medical practices and that result in unnecessary costs, but do not necessarily involve fraudulent intent. Abuse may involve improper billing, excessive prescribing, or diversion of drugs for non-medical use. Example: Prescribing high doses of painkillers without appropriate justification or oversight.

Types of Recoveries

1. **Monetary Recoveries**: Recouping funds that were improperly paid out due to fraudulent claims, wasteful spending, or abusive practices. These can come from providers, pharmacies, or members.

   Example: Recovering funds from a pharmacy that billed for drugs not dispensed or drugs that were dispensed improperly.

   Example Claims are adjudicated and sent to the PBM as soon as received. If the patient never picks up the drug, there is no incentive for the pharmacy to reverse the claim. Plan sponsors end up paying for medication never picked up or received by the patient. This is a particular issue for hospital pharmacies, mail order and specialty pharmacy claims.

2. **Corrective Action Recovery**: Implementing processes to prevent future occurrences of FWA, such as denying claims, requiring the repayment of overpayments, or changing policies.

   Example: A provider being required to refund payments for services that were billed incorrectly or fraudulently.

3. **Criminal or Civil Penalties**: In cases of fraud, legal actions may be taken against individuals or entities involved, potentially resulting in fines, penalties, or even criminal prosecution.

   Example: A healthcare provider or pharmacist being fined or jailed for submitting fraudulent claims.

Steps to a Thorough FWA Program

A comprehensive Fraud, Waste, and Abuse (FWA) program involves multiple steps to identify, prevent, and respond to incidents of FWA. Below are key steps for developing and maintaining an effective FWA program:

1. **Establish Clear Policies and Procedures**: Set up clear rules and processes for detecting, investigating, and preventing FWA. Ensure that all employees, contractors, and providers understand what constitutes FWA and their role in the process.
2. **Ongoing Training and Education**: Regularly educate employees, pharmacists, and healthcare providers on what constitutes FWA, how to report it, and the consequences of engaging in fraudulent or abusive activities.
3. **Fraud Detection Systems**: Implement technology tools, such as data mining and predictive analytics, to identify unusual patterns of behavior, such as prescription patterns that don't align with clinical guidelines or billing discrepancies. A full service FWA program includes data mining using manual pattern recognition and Artificial Intelligence patterns (both supervised and unsupervised learning) and on-site investigations.
4. **Monitoring and Auditing**: Regularly monitor and audit pharmacy claims, prescriptions, and medical records to identify potential instances of fraud, waste, or abuse. This can involve reviewing billing records, patient histories, and prescription drug utilization patterns.
5. **Investigation and Response**: When suspicious activity is identified, an investigation should be conducted to determine if FWA has occurred. This investigation may involve interviews, record reviews, and working with law enforcement if necessary. Investigations, including covert and overt surveillance should be performed by licensed private investigators.
6. **Corrective Actions**: Once FWA is confirmed, corrective actions should be taken. This may include recovering funds, revoking provider contracts, or taking legal action. Corrective actions should also extend to reviewing and updating internal procedures to prevent recurrence.
7. **Reporting and Compliance**: Ensure that all detected FWA incidents are reported to appropriate authorities, such as CMS, state regulatory bodies, or law enforcement. Compliance with legal and regulatory requirements is key to avoiding penalties and maintaining program integrity.
8. **Collaboration with Law Enforcement**: For cases involving significant fraud or criminal behavior, PBMs and plan sponsors may need to collaborate with law enforcement agencies (e.g., the Department of Justice or local authorities) to take action against perpetrators.
9. **Regular Program Evaluation**: Continuously evaluate the FWA program to identify areas for improvement. This involves reviewing trends in detected fraud, assessing the effectiveness of preventative measures, and adjusting the program as needed.

A robust FWA program can save significant resources, improve the integrity of prescription drug plans, and ensure that benefits are used appropriately.

Step Two Initiatives

Step Two Initiatives cover three broad areas of plan management: pricing alternatives, network configuration and carved in or out specialty providers and programs. These steps should be taken by plan sponsors after working with your existing PBM to stabilize contract terms, performance guarantees and develop an ongoing monitoring program to flag new problem areas.

Pricing Alternatives

One way to limit exposure to cost increases is to mandate prices at the drug, or National Drug Code (NDC) level. In prescription drug programs, NDC stands for National Drug Code. The NDC is a unique, standardized identifier for medications in the United States and is used primarily for tracking, billing, and identifying drugs in healthcare systems, especially in pharmacies, insurance claims, and healthcare provider records. The NDC is a 10- or 11-digit number divided into three segments, formatted as 5-4-2, 5-3-2, or 4-4-2. Each segment provides different information about the drug:

- Labeler Code (4 or 5 digits): Identifies the company or manufacturer that produces or distributes the drug. This code is assigned by the FDA.
- Product Code (3 or 4 digits): Specifies the drug formulation, including its strength, dosage form (such as tablet or liquid), and formulation specifics.
- Package Code (1 or 2 digits): Describes the package size and type, like whether it's a bottle of 30 tablets or a single-dose vial.

For example, in an NDC number like 12345-6789-01:

- 12345 identifies the manufacturer,
- 6789 identifies the specific drug and its formulation, and
- 01 identifies the package size and type.

The purpose and Use of NDCs in Prescription Drug Programs

NDCs are essential in various parts of the healthcare and insurance system. NDCs uniquely identify specific drugs, ensuring that healthcare providers, pharmacists, and insurers can accurately distinguish between different drugs, strengths, and formulations. Pharmacies use NDCs to submit claims for reimbursement to insurers and PBMs. The NDC helps ensure that the correct drug, quantity, and dose are billed. Pharmacies and healthcare providers use NDCs to manage drug inventory, track stock levels, and monitor usage. NDCs aid in assessing drug interactions, preventing duplicate therapy, and managing patient adherence, as they allow precise tracking of the exact medications dispensed.

NDCs provide a standardized way to identify and track drugs across the healthcare system. They help prevent errors, streamline processes, and ensure patients receive the correct medication. For insurance and PBMs, NDCs help with pricing, formulary management, and adherence to policies on drug coverage, making them integral to the efficient functioning of prescription drug programs.

MAC Lists and Other Pricing Lists

In prescription drug programs, Maximum Allowable Cost (MAC) and Scheduled Pricing are cost-containment strategies used to manage the expenses of drug reimbursement, especially for generic medications. Here's a breakdown of each and their respective advantages and disadvantages.

Maximum Allowable Cost (MAC)

MAC is a reimbursement limit set by insurance companies or pharmacy benefit managers (PBMs) for a group of similar or therapeutically equivalent generic drugs. This limit specifies the maximum price that the insurer will pay for a particular drug, regardless of the pharmacy's actual cost.

There are advantages of using MAC lists. MAC encourages the use of lower-cost generic drugs, which helps insurers and employers save on prescription drug costs. By setting a cap on reimbursement, pharmacies are incentivized to dispense generic versions, which are typically cheaper than brand-name drugs. For insurers and PBMs, MAC prices provide a predictable benchmark, simplifying the management of drug costs. MAC lists are publicly available to some extent, giving pharmacies an idea of what reimbursement rates to expect.

The disadvantages of MAC lists should also be considered. Each PBM or insurer may have different MAC lists and pricing, leading to inconsistencies in reimbursement rates across pharmacies. Pharmacies may lose money if their acquisition cost for a drug is higher than the MAC price. This can be a significant issue, especially for independent pharmacies with less purchasing power. Though MAC lists are sometimes public, many PBMs keep the calculation methods confidential, making it difficult for pharmacies to challenge unfair pricing.

Scheduled Pricing

Scheduled Pricing is a model where a predetermined price list is created for certain drugs, regardless of the actual cost of acquiring the drugs. This price is typically set by government agencies, insurers, or PBMs and can apply to both generic and brand-name drugs.

There are advantages of Scheduled Pricing such as Scheduled pricing allows for a standardized pricing structure, making it easier for pharmacies and insurers to anticipate reimbursement. For insurers, scheduled pricing can help cap expenses and provide greater control over overall drug costs. Like MAC, scheduled pricing incentivizes the selection of cost-effective medications, often generics, when they are available.

Likewise, there are disadvantages of Scheduled Pricing. Drug acquisition costs can fluctuate, so if the scheduled price is set too low, pharmacies may face financial losses, particularly for high-cost medications. Scheduled pricing doesn’t adjust easily for changes in the pharmaceutical market, which can disadvantage both pharmacies and patients when drug costs increase, or new generics enter the market. Some pharmacies may choose not to stock certain drugs that are unprofitable under scheduled pricing, limiting patient access to those medications.

Summary Comparison of MAC and Scheduled Pricing

Aspect	Maximum Allowable Cost (MAC)	Scheduled Pricing
Goal	**Limit reimbursement for generic drugs**	**Standardize prices for specific drugs**
Incentive	**Use generics for lower costs**	**Choose cost-effective options**
Flexibility	**Variable across PBMs; some transparency issues**	**Often rigid; based on a fixed schedule**
Impact on Pharmacies	**May lead to financial strain if prices fall below acquisition costs**	**Losses if prices exceed acquisition costs**

Both MAC and Scheduled Pricing are effective in controlling costs within prescription drug programs, but each has unique trade-offs. MAC is widely used for its effectiveness in encouraging generic drug use, but its variability and lack of transparency can challenge pharmacies. Scheduled Pricing provides standardization but can be rigid and not easily adapted to market fluctuations. Ultimately, the choice between MAC and Scheduled Pricing depends on the specific goals and structure of the healthcare plan.

Average Wholesale Price (AWP) and National Average Drug Acquisition Cost (NADAC)

Average Wholesale Price (AWP) and **National Average Drug Acquisition Cost (NADAC)** are two different drug pricing benchmarks commonly used in the United States. They serve as reference points for reimbursement and cost determination but have distinct methodologies, purposes, and implications for pharmacies, payers, and patients. Here's a detailed comparison of each, including their advantages and disadvantages.

Average Wholesale Price (AWP)

AWP is a list price, often referred to as the "sticker price," for drugs sold by wholesalers to pharmacies. Although it's called the "wholesale" price, AWP is generally higher than what pharmacies actually pay due to negotiated discounts and rebates. AWP is published by commercial pricing services (e.g., First Databank, Medi-Span) and is calculated by taking a markup (often around 20–25%) above the manufacturer's published Wholesale Acquisition Cost (WAC).

Advantages of AWP:

Widespread Use: AWP is a long-established and widely accepted benchmark in the healthcare industry. Many insurers, PBMs, and Medicaid programs use it as a baseline for calculating drug reimbursements.
Ease of Access: AWP is readily available from pricing databases, making it convenient for pharmacies, insurers, and PBMs to use as a reference.
Predictability: Because AWP is relatively stable, it allows pharmacies and payers to have a predictable pricing structure, aiding in planning and budget allocation.

Disadvantages of AWP:

Lack of Transparency: AWP often does not reflect the actual acquisition costs of drugs, as it includes markups above the real purchase price that pharmacies pay. This discrepancy can lead to inflated reimbursements.
Inaccurate Pricing: The AWP does not adjust dynamically based on actual market conditions or discounts, which can lead to overestimation of the real cost of drugs and potentially higher out-of-pocket costs for patients.
Incentive Misalignment: Because AWP is generally higher than the actual cost, it can create an incentive for some providers to favor higher-AWP drugs, which may increase healthcare costs overall.

National Average Drug Acquisition Cost (NADAC)

NADAC is a pricing benchmark developed by the Centers for Medicare & Medicaid Services (CMS) to reflect the average cost that retail pharmacies pay to acquire drugs. It's based on a survey of actual acquisition costs reported by a sample of pharmacies nationwide. NADAC is typically lower than AWP because it's based on real transaction prices, including discounts and rebates received by pharmacies.

Advantages of NADAC:

Transparency and Accuracy: NADAC is based on actual acquisition costs, providing a more accurate and realistic picture of what pharmacies pay for drugs. This can lead to fairer and more cost-effective reimbursements.

Reduced Drug Spending: For Medicaid and other payers, using NADAC helps control spending, as reimbursements are based on actual acquisition costs rather than inflated list prices.

Encourages Cost-Effectiveness: Since NADAC is more closely aligned with the true market price, it can discourage unnecessary markups and help to keep drug costs lower for both payers and patients.

Disadvantages of NADAC:

Limited Scope: NADAC does not cover all drugs, particularly specialty drugs, as the survey is largely focused on commonly dispensed drugs at retail pharmacies.

Potential Variability: Because NADAC is updated monthly based on survey data, prices can fluctuate, leading to possible variability in reimbursement rates for pharmacies. This could be challenging for pharmacies, especially small or independent ones.

Survey Participation: NADAC relies on voluntary reporting from pharmacies, which may lead to incomplete data if pharmacies don't participate consistently or provide inaccurate data.

Summary Comparison: AWP vs. NADAC

Feature	Average Wholesale Price (AWP)	National Average Drug Acquisition Cost (NADAC)
Basis	List price above wholesale acquisition cost	Average of actual pharmacy acquisition costs
Transparency	Less transparent; includes markup	More transparent; reflects real costs
Impact on Reimbursement	Generally, leads to higher reimbursements	Generally, results in lower reimbursements
Price Variability	More stable over time	Can vary monthly based on market prices
Scope of Drugs	Covers most drugs, including brand-name drugs	Primarily covers generic and commonly used retail drugs
Cost Containment	Less effective for cost containment	Effective in controlling drug spending

In summary, **AWP** is more widely used but tends to be inflated, which may benefit pharmacies but can lead to higher costs for payers and patients. On the other hand, **NADAC** is more accurate and cost-effective, as it reflects actual acquisition costs, benefiting payers and potentially lowering costs for patients, though it may be less advantageous for pharmacies with higher acquisition costs or in a fluctuating pricing environment. The choice between using AWP or NADAC largely depends on the goals of the program—whether it is to support broader access for pharmacies (AWP) or to maintain lower costs and greater transparency (NADAC).

High Cost and Specialty Drugs

High-cost specialty medications and limited distribution drugs present unique pricing and supply chain challenges due to their complex nature, high prices, and often limited access points. Specialty drugs are generally used to treat chronic, rare, or complex conditions (e.g., cancer, autoimmune diseases), while limited distribution drugs (LDDs) are distributed through a restricted network of specialty pharmacies or healthcare providers. Let's explore the pricing strategies and supply chain considerations for these types of medications.

Pricing Strategies for High-Cost Specialty Medications and Limited Distribution Drugs

Value-Based Pricing

In value-based pricing, the price of a drug is linked to the clinical outcomes it delivers. For instance, if a cancer drug improves survival rates significantly, its price might be set higher to reflect its value to patients and healthcare systems.

Advantages: This approach aligns the drug's price with its effectiveness, making it more acceptable to payers and potentially justifying high costs.

Challenges: Outcomes can be difficult to measure consistently, and there may be variations in response among patients, complicating the pricing model.

Indication-Based Pricing

For drugs approved for multiple indications, prices can vary depending on the disease or condition being treated. For example, a medication might have a higher price for a rare, life-threatening indication and a lower price for a more common one.

Advantages: This allows for better alignment between the price and the value provided in different treatment contexts.

Challenges: It can add administrative complexity, requiring robust systems to track indications and monitor pricing.

Subscription or "Netflix" Model

In this model, payers pay a flat rate for unlimited access to a particular drug over a set period. This model has been used in some states for hepatitis C treatments, allowing for broad access to high-cost medications at a fixed budget.

Advantages: Provides predictability for payers, enabling broader patient access at a manageable cost.

Challenges: This approach requires careful forecasting and risk-sharing agreements, as it may not be financially feasible for all medications or payers.

Outcomes-Based Contracts and Risk-Sharing Agreements

Drug manufacturers and payers establish contracts where reimbursement is tied to patient outcomes or clinical performance of the drug. If a drug doesn't meet agreed-upon benchmarks, the manufacturer may offer rebates or refunds.

Advantages: Reduces financial risk for payers, encourages manufacturers to focus on drug efficacy, and improves accountability.

Challenges: Requires data collection and analytics to track outcomes, which can be complex and costly.

Tiered or High-Cost Specialty Drug Pricing

Drugs are categorized into pricing tiers based on their cost and clinical necessity, often with higher copayments or coinsurance for specialty drugs.

Advantages: Helps payers manage spending on expensive medications by shifting some costs to patients.

Challenges: High out-of-pocket costs may limit patient access to necessary treatments, raising ethical concerns.

Supply Chain Considerations for Specialty Medications and Limited Distribution Drugs

Limited Distribution Networks

Many specialty and high-cost drugs are distributed through exclusive or limited networks of specialty pharmacies, which are chosen based on their ability to manage complex patient needs, provide adherence support, and handle cold chain logistics.

Advantages: Limited distribution ensures that patients receive medications from pharmacies with expertise in specialty drugs, leading to better patient outcomes and adherence.

Challenges: Limited access can restrict patient choice and availability, particularly in rural areas, and may lead to delays in treatment of patients have to work within the limited network.

Specialty Pharmacies and Patient Support Services

Specialty pharmacies play a key role in handling specialty drugs, often providing additional services such as patient education, financial assistance, and medication adherence monitoring.

Advantages: These pharmacies improve patient adherence and safety by offering dedicated support, which is crucial for complex treatments.

Challenges: These services come at a high cost, which can increase overall healthcare expenses. Coordination with providers may also be challenging due to disparate systems.

Inventory Management and Cold Chain Logistics

Many specialty drugs require strict temperature control (cold chain logistics) and careful inventory management to prevent waste and ensure product integrity.

Advantages: Proper handling prevents spoilage and waste, ensuring patients receive effective medications.

Challenges: Cold chain logistics and inventory management are expensive and require specialized handling and storage equipment, increasing operational costs across the supply chain.

Manufacturer and Payer Collaboration for Distribution

To mitigate costs and improve efficiency, manufacturers may work directly with payers to streamline the distribution and availability of high-cost drugs.

Advantages: Collaboration can improve forecasting, prevent stock shortages, and facilitate access for patients.

Challenges: Aligning interests between payers, manufacturers, and patients can be difficult, especially when considering profit margins and pricing control.

Patient Access and Affordability Programs

Manufacturers often provide copay assistance programs, financial assistance, or patient support programs to help patients afford these costly drugs. This topic is also covered below in Step Three Initiatives, Clinical Programs.

Advantages: These programs improve patient access by reducing out-of-pocket costs, particularly for those with high deductibles or limited insurance coverage.

Challenges: These programs may inadvertently shift costs to insurers or raise premiums, as they can circumvent cost-sharing mechanisms designed to manage drug spending.

Summary Comparison of Pricing Strategies and Supply Chain Considerations

Aspect	Pricing Strategies	Supply Chain Considerations
Main Focus	Aligning price with value or outcomes	Efficient distribution, handling, and patient support
Examples	Value-based, indication-based, and outcomes-based pricing	Specialty pharmacies, limited distribution networks
Advantages	Can improve cost-effectiveness, predictability, and access	Specialized support improves adherence and outcomes
Challenges	Administrative complexity, tracking outcomes, patient affordability	High costs of cold chain logistics, limited access

The combination of value-driven pricing strategies and well-managed supply chains is essential to balance the high costs of specialty and limited distribution drugs with patient access and quality care. While value-based models and limited distribution can help optimize costs, they bring challenges in tracking, distribution, and coordination that require cooperation between manufacturers, payers, pharmacies, and healthcare providers.

The Role of Specialty Drug Pricing Considerations with Plan Sponsors

In Step Three Initiatives, we discuss clinical programs that plan sponsors might want to consider in managing specialty drug costs. In this section, we discuss specific steps that plan sponsors may take regarding pricing strategies.

Preferred Provider and Exclusive Specialty Pharmacy Networks

Plan sponsors may limit specialty drug dispensing to a preferred network of specialty pharmacies that offer competitive pricing and enhanced patient support services, such as medication counseling and adherence monitoring.

Example: A plan may contract exclusively with one or more specialty pharmacies to receive better pricing and streamline drug distribution.

Advantages: Reduces costs by negotiating better rates with specialty pharmacies, improves quality of care, and enhances adherence through coordinated care.
Challenges: Limits patient choice of pharmacy, which can be a disadvantage for patients in areas without easy access to the selected pharmacies.

Outcomes-Based or Value-Based Pricing Agreements

Plan sponsors and drug manufacturers agree on pricing based on the clinical outcomes of the drug. If the drug doesn't achieve certain results, the manufacturer may provide rebates or refunds.

Example: If a costly oncology drug doesn't meet survival rate benchmarks, the manufacturer may offer a rebate to the plan.

Advantages: Aligns drug costs with actual value delivered to patients, potentially lowering plan costs for drugs that don't meet efficacy standards.

Challenges: Requires robust data collection and monitoring, which can be resource-intensive and complex to administer.

Network Configuration

From a plan sponsor's perspective, configuring a Pharmacy Benefit Manager (PBM) network requires careful consideration of different channels and distribution models to ensure effective drug access, cost management, and patient adherence. Key elements include evaluating distribution channels, considering exclusivity agreements, balancing chain versus independent pharmacy access, and exploring direct contracting options for mail order and specialty drugs. Here's how each component works and the advantages it offers to plan sponsors:

Channel Distribution: Evaluating Distribution Channels for Balanced Access

Plan sponsors must assess the different distribution channels available to members to ensure comprehensive access across retail pharmacies, mail order, and specialty pharmacies. By understanding where and how members obtain medications—whether from retail locations, home delivery, or specialty care settings—plan sponsors can configure their PBM networks to meet diverse needs.

Retail Pharmacies: Retail locations are essential for convenient access to maintenance medications and acute treatments. A broad retail network ensures members can access medications close to home, which is especially important for medications that require in-person consultations or immediate dispensing.

Mail Order: Mail order channels are ideal for chronic or maintenance medications, offering convenience and often cost savings through 90-day supplies. This channel is especially beneficial for members who prefer home delivery or may have limited mobility.

Specialty Pharmacies: Specialty drugs, often costly and complex, require additional patient support, cold-chain logistics, and close monitoring. Specialty pharmacies are designed to manage these requirements and offer personalized support to ensure adherence and safe use.

By balancing access across these channels, plan sponsors can offer members flexibility and convenience while optimizing costs. Mail order and specialty channels often provide cost efficiencies and adherence support, which can reduce long-term healthcare spending. However, ensuring seamless coordination and appropriate channel use can be difficult, as some members may have unique needs requiring flexible access points. Maintaining broad retail access without increasing costs may also be a challenge, particularly in remote areas.

Exclusivity in Channels: Considering Exclusive Partnerships to Reduce Costs and Drive Adherence

Some plan sponsors opt for exclusive partnerships with certain pharmacies or channels within the PBM network to negotiate better pricing and drive higher patient adherence. This involves designating one or a few preferred providers within a specific channel (e.g., specialty, mail order, or retail) to leverage volume for discounts.

Exclusive Mail Order: By designating an exclusive mail order provider, sponsors can secure better rates for maintenance medications and encourage members to utilize mail order, which often has lower dispensing costs.

Exclusive Specialty Pharmacy: Limiting specialty drug distribution to a single or small group of specialty pharmacies can lead to cost savings through negotiated pricing and better management of specialty drug handling and patient support.

Exclusivity can lead to significant cost savings due to volume discounts, and it can also streamline patient services, such as adherence programs, which are more consistent within a limited network. Furthermore, with exclusivity,

plan sponsors should ensure that PBMs and pharmacies may be able to offer more robust patient monitoring and support programs that reduce adverse events and improve outcomes and improved pricing/discounts. However, limiting options may restrict patient choice, which can be a drawback for members who prefer specific pharmacies. Some patients may experience logistical barriers, especially if exclusive providers are not located nearby, potentially impacting access and adherence.

Chains versus Independents: Balancing National Chain Access with Local Independent Pharmacies

Plan sponsors must decide on the right balance between including national chain pharmacies and local independent pharmacies in the PBM network. Each has distinct advantages that can influence network accessibility, cost, and member satisfaction.

National Chains: National chains offer widespread coverage and convenience, especially for members who travel or live in multiple locations. Chain pharmacies can also provide economies of scale, helping plan sponsors manage costs.

Independent Pharmacies: Local independent pharmacies often provide more personalized service, which can enhance adherence and patient satisfaction. They are also critical in rural or underserved areas where chain pharmacies may be less accessible.

Including both chains and independent pharmacies can enhance network flexibility, improving member access and satisfaction. Independent pharmacies may offer tailored services that support medication adherence, which is valuable for complex or chronic conditions. However, balancing access to both chains and independents can increase network management complexity, as independents may lack the bargaining power of large chains, potentially resulting in higher costs. Independents may also have varying service levels, which can lead to inconsistent patient experiences.

Direct Contracting with Mail Order and Specialty: Optimizing Mail Order and Specialty Drug Services

Direct contracting involves plan sponsors establishing agreements directly with mail order and specialty pharmacies to control costs, improve service quality, and tailor these services to member needs. This approach enables plan sponsors to bypass traditional PBM markups or middleman costs, potentially resulting in significant savings.

Direct Mail Order Contracting: Allows plan sponsors to negotiate prices and delivery terms directly with mail order pharmacies, improving cost efficiency for maintenance medications and offering extended supplies (e.g., 90-day supplies).

Direct Specialty Contracting: In direct specialty pharmacy agreements, sponsors can negotiate better rates for high-cost specialty drugs and ensure these pharmacies provide tailored support services, such as disease management, adherence programs, and financial assistance coordination.

Direct contracting can lead to more favorable pricing and more tailored service agreements, such as guaranteed delivery times or enhanced support programs. Specialty pharmacies in particular may provide comprehensive care management, improving outcomes and reducing unnecessary healthcare utilization. Direct contracting requires significant administrative resources to manage relationships and ensure service quality. It also may limit member access to pharmacies that fall outside the contracted network, which can be a disadvantage for members in rural or remote areas without easy access to these services.

Summary of Key Considerations

Aspect	Description	Advantages	Challenges
Channel Distribution	Balancing access across retail, mail order, and specialty	Flexibility, cost efficiency, enhanced access	Coordination complexity, possible gaps in remote areas
Exclusivity in Channels	Exclusive partnerships in mail order or specialty channels	Cost savings, improved adherence through consistency	Limits choice, potential access issues for some members
Chains vs. Independents	Combining national chains and local independents in the network	Widespread access, personalized service in local areas	Higher costs, inconsistent service levels
Direct Contracting	Direct agreements with mail order and specialty pharmacies	Lower costs, customized service for members	Resource-intensive, potentially limited access

Plan sponsors must carefully evaluate these network configuration options to balance cost, access, and patient experience. Effective PBM network configuration often involves a combination of channels, exclusive partnerships, and direct contracting, tailored to the needs and geographic distribution of plan members. By strategically managing these elements, plan sponsors can reduce costs while providing accessible, high-quality pharmacy services to their members.

PBM owned Partners versus Independent Partners in Direct Contracting

PBM-Owned Partners

PBM-owned partners are pharmacies or specialty services operated directly by the PBM or its affiliates. Examples include CVS Health's ownership of CVS pharmacies and specialty services through CVS Caremark, and Express Scripts' own network of specialty and mail-order pharmacies.

Advantages of PBM-Owned Partners are that they have built-in pricing models and rebate structures that align with the PBM's overall pricing strategy, potentially reducing costs for plan sponsors. They may be able to offer favorable pricing directly due to economies of scale. Streamlined cost control allows for better predictability and management of prescription drug spend, particularly for specialty and high-cost medications.

With PBM-owned partners, plan sponsors benefit from fully integrated data across the PBM's systems, which can lead to comprehensive reporting on drug utilization, adherence, and outcomes. Better data visibility and analytics improve the ability to make data-driven decisions, enhance patient monitoring, and identify cost-saving opportunities.

PBM-owned specialty and mail-order pharmacies often provide robust patient support services (e.g., adherence programs, financial assistance, clinical support), which help manage complex conditions. Higher adherence and better clinical outcomes can lead to reduced overall healthcare costs and improved patient satisfaction.

Since the PBM controls the full range of services, members experience seamless service continuity. For example, PBM-owned mail-order services can handle high volumes and standardize services to enhance the overall member experience. Operational efficiencies, such as faster processing times and lower administrative overhead, can contribute to both cost savings and greater patient satisfaction.

Disadvantages of PBM-Owned Partners include conflicts of Interest since PBMs directly profits from using its own network, there may be a financial incentive to prioritize PBM-owned partners over potentially more cost-effective or higher-quality independent options. This can create transparency concerns and may raise questions around whether the PBM is acting in the best interests of the plan sponsor and its members.

PBM-owned networks may restrict patient choice by directing members to use only specific pharmacies, potentially limiting access for patients who prefer other options or live in areas without the PBM-owned pharmacy. Reduced member satisfaction and potential adherence issues if patients have difficulty accessing their preferred pharmacies or if PBM-owned pharmacies are less accessible.

When a PBM controls both the pharmacy network and drug pricing, it can reduce plan sponsors' ability to negotiate prices, as there is little room to explore outside options that might offer more favorable terms. Plan sponsors may face higher costs if they cannot seek out alternative, competitive pricing.

Independent Partners

Independent partners are pharmacies and specialty providers that operate outside of the PBM's ownership. These can include independent specialty pharmacies, mail-order services, and retail chains that do not have direct ties to the PBM.

Advantages of Independent Partners are that independent partners often operate outside the PBM's internal pricing structures, which can lead to more transparent pricing and the opportunity for plan sponsors to compare prices and select cost-effective options. Increased transparency can empower plan sponsors to negotiate more favorable rates, reducing overall prescription drug costs.

Independent partners offer more choice and flexibility in the pharmacy network, allowing members to select the pharmacy that is most convenient and suitable for their needs. Better access to preferred pharmacies can lead to improved patient satisfaction, adherence, and potentially better health outcomes.

Independent pharmacies don't have the same vested financial interest in the PBM's bottom line, which can help avoid potential conflicts of interest that may occur with PBM-owned partners. Plan sponsors and members may feel more confident that their PBM is making unbiased choices that prioritize clinical needs and cost savings over profit.

Some independent specialty pharmacies offer unique expertise or highly specialized services (e.g., rare disease management, personalized medication support) that may not be available through PBM-owned networks. These specialized services can be particularly beneficial for patients with complex conditions, potentially leading to better outcomes and lower long-term costs.

Disadvantages of Independent Partners may be that the independent partners may not have fully integrated systems with the PBM, making it more challenging to collect and analyze data on utilization, adherence, and patient outcomes across different pharmacy sources. Less cohesive data tracking can hinder the PBM's ability to provide comprehensive reporting and insights for the plan sponsor.

Managing a network of independent partners often requires additional administrative effort for coordination and oversight, especially if there are variations in service standards and processes. Increased administrative costs and complexity can offset some of the financial savings gained from competitive pricing.

Service quality and patient support can vary widely among independent partners, depending on each provider's resources and expertise. Unlike PBM-owned pharmacies, independent pharmacies may not consistently offer high-touch services such as patient counseling or robust adherence programs. Variability in service quality may impact patient outcomes if certain independent pharmacies lack the resources to manage specialty medications or provide comprehensive support.

PBM-owned pharmacies can leverage scale and standardized processes for bulk purchasing, which may be more challenging for independent pharmacies with smaller operations. Reduced leverage for bulk negotiations can lead to higher drug acquisition costs or inconsistent pricing for high-cost specialty medications.

Summary Comparison

Aspect	PBM-Owned Partners	Independent Partners
Cost Control	Economies of scale, streamlined pricing	Competitive pricing with more negotiation opportunities
Data and Reporting	Integrated data, cohesive tracking	Fragmented data, potential reporting limitations
Patient Access & Choice	Limited choice, potentially restrictive	Broad choice, enhanced flexibility
Conflict of Interest	Potential conflicts, lack of transparency	Less conflict, increased transparency
Specialized Services	Robust standardization and adherence programs	Unique and specialized services
Administrative Complexity	Simplified management, fewer partners	Higher administrative costs and oversight

Plan sponsors must carefully weigh the trade-offs between PBM-owned and independent partners when designing a direct contracting strategy within their PBM networks. PBM-owned partners offer streamlined operations, cost control, and cohesive data but may restrict choice and raise conflict-of-interest concerns. Independent partners provide flexibility, transparency, and potentially lower costs through competition, but they come with added administrative complexities and data challenges. Often, a hybrid approach leveraging the strengths of both types of partners can provide optimal results for plan sponsors and their members.

Rebates

Understanding rebates is an important fiduciary duty for plan sponsors and affects almost every other consideration regarding the prescription drug plan. Rebates touch on effective audits and monitoring, how the plan will be designed, and rebates certainly impact clinical effectiveness. It is important to understand just what rebates are, how they operate and how the prescription drug program is affected by rebates.

What are rebates?

Prescription drug rebate programs are agreements between drug manufacturers and pharmacy benefit managers (PBMs) or health plans to provide financial incentives (rebates) on certain medications. These rebates are a critical part of managing pharmacy benefit costs, as they help reduce the net cost of covered drugs for the plan sponsor, often in exchange for the placement of a drug on a favorable formulary tier.

There are several types of rebates in the prescription drug landscape, each structured to achieve specific objectives:

1. Traditional (Volume-Based) Rebates

These rebates are based on the volume of a particular drug sold. Manufacturers offer discounts or rebates on a per-unit basis when a PBM or health plan achieves specific volume thresholds. The more units sold, the larger the rebate, rewarding PBMs for driving higher utilization of the drug. The objective of this kind of rebates is to encourage PBMs and health plans to promote high-use drugs by providing incentives for increased utilization. This arrangement is commonly seen with brand-name drugs that may face competition.

2. Market Share Rebates

In a market share rebate structure, manufacturers offer a rebate based on the percentage of market share that a drug achieves within its therapeutic class. If a PBM or health plan can increase the market share of a specific drug over competitors within the same class, the manufacturer provides a higher rebate. These rebates Increase the manufacturer's competitive edge by incentivizing PBMs to prioritize the drug over alternatives in the same class, often resulting in favorable formulary placement for the drug.

3. Performance or Outcome-Based Rebates

These rebates are contingent on the drug meeting specific clinical or health outcome targets, such as improvements in disease management, reduced hospitalizations, or lower overall healthcare costs. If the drug does not meet the agreed-upon outcomes, the manufacturer provides a larger rebate. These rebates programs encourage the use of drugs that have a demonstrable impact on patient health outcomes, aligning manufacturer incentives with the clinical effectiveness of the drug. This type of rebate arrangement is more common for high-cost specialty drugs.

4. Formulary Placement Rebates

Manufacturers offer rebates to secure a drug's position on a more favorable formulary tier (e.g., Tier 2 vs. Tier 3). In exchange, the PBM or health plan agrees to give preferred coverage, which reduces member cost-sharing and often leads to higher utilization. By prioritizing a drug's placement in the formulary, rebates provide increased accessibility and utilization, as lower out-of-pocket costs tend to drive patient adherence. These rebates are central to tiered formulary structures and are prevalent among brand-name drugs with close competitors.

5. Value-Based Contracting or Risk-Sharing Rebates

Similar to performance-based rebates, value-based contracts link rebates to specific metrics of value or cost savings generated by the drug. This approach might include rebates based on the total cost of care, reductions in adverse events, or cost offsets in other areas (e.g., fewer hospital visits). These rebate programs align financial incentives between the plan and the manufacturer to prioritize drugs that deliver value beyond their price tag, especially for high-cost medications or specialty drugs. These agreements are especially popular in managing complex or chronic conditions. It is rare that these types of rebates exist in commercial (employer based) programs.

6. Upfront or Administrative Fees

These fees are paid by manufacturers to PBMs in addition to rebates. They are often fixed payments and may be structured to support formulary development, administration, or specific PBM services. These rebates cover administrative costs associated with managing and implementing the formulary, ensuring the PBM has the resources to maintain the drug's position on formulary tiers. Essentially, drug manufacturers pay the PBM to prepare data to supplement an invoice that the PBM submit to the manufacturer for other types of rebate payments.

What Plan Sponsors Should Know About Rebates

Plan sponsors should ask for transparency in rebate arrangements to understand the real savings passed back to the plan versus those retained by the PBM. Many sponsors now request **100% pass-through** rebates, where all rebates are returned to the sponsor, to avoid hidden markups. Rebates heavily influence formulary design, often promoting branded medications that yield higher rebates over generics. Plan sponsors should evaluate whether rebates provide genuine cost savings or simply offset the costs of more expensive medications, which could limit access to lower-cost drugs.

Some plans may adopt **rebate optimization strategies**, allowing them to balance upfront costs with potential rebate savings. This can help sponsors determine if rebate arrangements align with plan and member needs or if they merely drive-up costs. For certain therapeutic areas (especially chronic conditions and high-cost specialty drugs), value-based or outcomes-based rebates can support better alignment between clinical outcomes and cost savings, reducing risks related to the high cost of non-effective treatments.

Summary of Rebate Types

Rebate Type	Description	Objective
Volume-Based Rebates	Rebates based on the volume of drug sales.	Drive utilization of specific high-use drugs.
Market Share Rebates	Rebates tied to increasing a drug's market share within a therapeutic class.	Promote drug over competitors in the same class.
Performance-Based Rebates	Rebates contingent on meeting clinical outcomes or performance targets.	Reward clinically effective drugs that reduce healthcare costs.
Formulary Placement Rebates	Rebates based on formulary tier placement.	Secure favorable formulary position to drive utilization.
Value-Based Rebates	Rebates linked to specific value metrics or cost savings achieved by the drug.	Encourage use of drugs that deliver measurable value beyond cost.
Administrative Fees	Upfront fees for PBM services, often related to formulary management.	Cover PBM's administrative costs in maintaining drug formulary.

What rebate programs are not shared with plan sponsors?

There are several types of rebates and revenue streams that PBMs may retain rather than passing them on to plan sponsors, resulting in hidden profits for PBMs and missed cost savings for sponsors. Here are common types of rebates and revenue sources that plan sponsors might not fully receive:

Spread Pricing Rebates

In a spread pricing model, the PBM charges the plan sponsor a higher price than what it reimburses the pharmacy for a drug. The PBM retains the difference, known as the "spread," as profit. The implication is that spread pricing can obscure the true cost of medications for the plan sponsor and inflate pharmacy benefit costs. Plan sponsors may be unaware that they are paying more than necessary for drugs due to this spread.

Rebates from Repackaging and Re-Labeling

PBMs sometimes receive additional revenue by repackaging or relabeling drugs under their own label or through specialty pharmacies owned by the PBM. These practices can lead to additional profits that are not shared with the sponsor. By using repackaged drugs, PBMs may mark up prices, increasing costs for sponsors without passing back the additional revenue generated through these practices. Audit programs should report when repackager NDCs are used. Repackagers are not only other wholesalers' products that are repackaged with a new (and inflated) NDC assigned.

PBMs may also own their own wholesalers and "sell themselves" products and repackage drugs with higher cost NDCs. While most PBMs do not directly own traditional wholesalers, they often leverage close partnerships or integrated specialty pharmacy networks to control more of the supply chain. CVS Health, UnitedHealth Group, Cigna, and others have expanded their reach into distribution through specialty and retail networks, allowing them to act similarly to wholesalers. This vertical integration helps PBMs manage costs and drug pricing, although the lack of complete transparency in these arrangements can lead to higher prices and challenges for plan sponsors in fully understanding their drug costs.

WellDyne owns WellDyneRx Pharmacy, which is integrated with a wholesale drug distribution operation. This gives the company control over both the management of pharmacy benefits and the distribution of pharmaceutical products. WellDyne's vertically integrated model allows it to manage the supply chain, potentially offering cost savings, better control over medication access, and streamlined operations for the PBM side of its business. By owning a wholesaler, WellDyne can influence both the pricing and distribution of medications, which can be advantageous for their PBM clients as they manage prescription drug benefits. However, similar to other vertically integrated PBMs, this ownership structure can sometimes raise questions about transparency and potential conflicts of interest, particularly in terms of cost savings and rebates passed on to plan sponsors.

3. Formulary Optimization or Management Fees

PBMs may receive fees from manufacturers for placing specific drugs on preferred formulary tiers or for removing competitors from the formulary. This payment can influence formulary decisions, prioritizing drugs that are more profitable for the PBM. Plan sponsors may not see these management fees or understand that formulary decisions might prioritize rebate-generating drugs over lower-cost or more clinically appropriate options.

4. Non-Transparent Performance or Outcome-Based Rebates

PBMs may negotiate outcomes-based or performance-based rebates from manufacturers based on clinical targets (e.g., reduced hospitalizations or improved patient adherence). These rebates may not be fully transparent to the sponsor, as they are often separate from standard rebate contracts. These performance-based rebates can offer significant savings, but plan sponsors may not know they exist or may not receive a share, depending on the PBM contract.

5. Administrative Fees and Service Fees

Manufacturers sometimes pay PBMs administrative fees for activities like processing claims, data management, and formulary development. These fees can be significant but are often kept by the PBM as additional revenue. These fees are not always disclosed, and sponsors might not realize they are indirectly paying for services they are not receiving, as they might otherwise be able to negotiate lower costs if these fees were transparently disclosed.

6. Price Concessions and Discounts from Specialty and Mail-Order Pharmacies

Many PBMs own or contract with specialty and mail-order pharmacies that dispense high-cost medications. PBMs often negotiate discounts or price concessions on these drugs, but they do not always pass these savings on to the sponsor. Specialty drugs are a significant cost driver, so sponsors may face inflated prices if they do not receive these price concessions, reducing potential savings on high-cost treatments.

7. Clawbacks and Reclaimed Member Copays

Some PBMs engage in "clawback" practices, where the amount a member pays in copays exceeds the drug's cost, and the PBM keeps the difference. The member and plan sponsor may both be unaware of this practice. Clawbacks inflate costs for members, and any difference in copay retained by the PBM could have been savings for the plan sponsor.

8. DIR Fees (Direct and Indirect Remuneration Fees)

While DIR fees are typically associated with Medicare Part D, they can also apply to commercial plans. PBMs may charge these fees retroactively to pharmacies, which sometimes receive funds from manufacturers for filling high-cost drugs. These funds are often retained by the PBM as additional revenue. These fees can be non-transparent, and plan sponsors may unknowingly lose out on revenue that could lower their plan costs.

9. Inflationary or Price-Protection Rebates

These rebates are paid by manufacturers when drug prices increase beyond an agreed-upon threshold. PBMs sometimes negotiate these price protection rebates to offset potential increases in plan costs but may keep these rebates instead of passing them on. Plan sponsors miss out on potential savings from these rebates, which could have protected them from rising drug prices.

10. Data and Analytics Revenue

PBMs often generate revenue by selling de-identified claims and utilization data to pharmaceutical manufacturers and other stakeholders. This data can be valuable for drug marketing, research, and development. Sponsors may not receive compensation for the use of their plan's data, despite this information's potential to generate significant revenue for the PBM.

Plan sponsors can use the following strategies to improve transparency and control over rebates:

- **Negotiate Full Pass-Through Rebate Contracts**: Demand full rebate pass-through to ensure all rebates are returned to the sponsor, minimizing hidden profits retained by the PBM.
- **Audit PBM Contracts Regularly**: Conduct independent audits of PBM contracts and claims data to uncover any retained fees or rebates.
- **Seek Transparent Reporting on All Revenue Streams**: Require the PBM to disclose all sources of revenue generated from the plan, including administrative fees, clawbacks, DIR fees, and data sales.
- **Consider Outcomes-Based or Performance Contracts with Rebates**: Sponsors can negotiate outcomes-based rebate contracts with clear terms for revenue sharing based on clinical results, enhancing alignment between plan costs and clinical effectiveness.
- **Evaluate Alternatives to Traditional PBMs**: Some plan sponsors explore working with transparent or "pass-through" PBMs, which disclose all revenue sources and pass rebates and cost savings directly to the plan sponsor.

By staying vigilant and actively seeking transparency, plan sponsors can minimize hidden costs and optimize the financial benefits from rebates, ensuring the plan aligns with their budgetary goals and members' needs.

Step Three Initiatives

Plan sponsors—such as employers, unions, and government agencies—face significant challenges in managing the high costs of specialty drugs within their prescription drug plans. To address this, they use various communication and clinical strategies designed to contain costs while ensuring patient access to these essential treatments.

Member/Patient Satisfaction

A plan sponsor might conduct an employee survey about the pharmacy benefits plan to understand employee satisfaction and address any gaps or improvements that could make the plan more beneficial, accessible, and equitable. Here's an expanded look at each of the key point:

Member/Patient Satisfaction Surveys and Communication Strategies

A well-designed pharmacy benefits plan can significantly impact employee satisfaction, which, in turn, can influence employee retention, productivity, and overall morale. Employee feedback on specific aspects of the pharmacy plan allows the sponsor to align benefits with the employees' needs. The purpose of the survey is to gather insights on satisfaction with the pharmacy benefits and out-of-pocket costs to help plan sponsors gauge how well the current plan serves employees. Questions about whether employees feel they are getting value for their money and if the plan covers necessary medications give valuable data on overall satisfaction and adequacy.

The goal of the surveys can reveal whether employees feel their needs are met or if certain coverage areas or cost burdens need re-evaluation. If employees are unhappy with costs or coverage, the sponsor can explore options to improve plan value.

Another reason to survey members is to analyze cost allocation strategies which allows the sponsor to understand if resources are being distributed equitably among all employees, especially those with high-cost or chronic conditions. Finding a balance between supporting high-need members through targeted benefits and rebates while still providing meaningful support to all employees is essential. Employee feedback can indicate if high-need members are adequately supported without impacting general member satisfaction, ensuring the plan's fairness.

Effective communication is crucial to employee satisfaction, as a lack of understanding of pharmacy benefits can lead to underutilization or dissatisfaction. A survey helps identify areas where employees feel they need more clarity on their benefits or any recent plan adjustments. By establishing a clear communication plan, sponsors can enhance employees' understanding of their coverage, copays, formularies, and any benefits changes. Improved awareness ensures employees can make the most of the plan and feel confident in its value.

Explanation of Benefits (EOB) should clarify costs, coverage, and patient responsibilities to prevent confusion. A survey can reveal if EOBs are achieving this or if employees find them confusing, incomplete, or misleading. A user-friendly and transparent EOB document allows employees to understand their pharmacy spending and coverage, which contributes to a perception of transparency and reliability. Feedback can help the plan sponsor enhance EOB readability and transparency.

Many employees interact with their pharmacy benefits through online portals or at point-of-service (POS) locations. Surveys can identify if these digital resources are user-friendly and accessible or if there are barriers to understanding and using the plan. Ensuring web portals and POS access points are intuitive and provide comprehensive plan information enables employees to easily check coverage, review benefits, and understand costs. Streamlining these access points improves satisfaction and promotes self-service, reducing administrative burden.

In summary, conducting a survey on the pharmacy benefits plan allows sponsors to make data-driven adjustments, ensuring that the benefits are meeting employees' needs, both functionally and financially. This proactive approach promotes a more supportive work environment, better healthcare outcomes, and an engaged, satisfied workforce.

Plan Design Issues

Copays versus Coinsurance and Deductibles

When designing a pharmacy benefit plan, a plan sponsor must carefully weigh the options between copay, coinsurance, and front-end deductibles, as each has a distinct impact on cost-sharing, predictability, and employee satisfaction. Here are some key considerations, along with the advantages and disadvantages of each option:

A copay is a fixed dollar amount that members pay for prescriptions, regardless of the drug's cost. For example, employees might pay $10 for a generic drug and $30 for a brand-name drug. Copays make it easy for employees to anticipate and budget for their pharmacy expenses, providing peace of mind and reducing financial stress. Fixed copays are simple to understand, which makes employees feel more comfortable with their benefit plan and can lead to higher satisfaction and utilization. With a predictable, lower out-of-pocket cost, employees may be more likely to fill and adhere to prescribed medications, potentially improving health outcomes.

Disadvantages of copays include limited cost control for the plan sponsor. For expensive drugs, the sponsor bears most of the cost, regardless of the copay. This can lead to higher plan costs, particularly for high-cost specialty drugs. Since employees pay a fixed amount, they may be less aware of the true cost of their medications, leading to potentially higher utilization and less motivation to choose lower-cost options.

Coinsurance requires members to pay a percentage of the drug cost, such as 20% for a brand-name drug. The actual cost to the employee varies with the price of the medication. Coinsurance can help the plan sponsor manage costs more effectively, as employees share a percentage of the cost, especially for high-cost or specialty drugs. Employees become more aware of the actual costs of their medications, which can encourage them to choose lower-cost alternatives or generics when possible. Since coinsurance links out-of-pocket costs to the price of the drug, employees may be more discerning about unnecessary or expensive medications, which can reduce overutilization.

However, coinsurance brings unpredictable costs for employees. The out-of-pocket expense varies depending on the drug’s cost, which can lead to financial uncertainty, especially for employees on high-cost medications. Higher out-of-pocket costs could discourage employees from filling prescriptions, especially for high-cost drugs, potentially impacting health outcomes negatively.

Front-end deductibles require employees to pay the full cost of their medications until they meet a predetermined amount (deductible) at the beginning of the plan year, after which the copay or coinsurance kicks in. By placing more of the initial costs on the employee, the plan sponsor can better control its own expenses. This can be particularly useful in reducing initial costs associated with high utilization. Employees are likely to be more selective about the medications they purchase while meeting the deductible, which can reduce unnecessary utilization and encourage generic or lower-cost drug options.

However, coinsurance can be challenging for employees, especially those with chronic conditions who may need costly medications early in the plan year, potentially leading to financial stress. The upfront cost can dissuade employees from filling necessary prescriptions, impacting adherence, particularly at the start of the year when employees are still meeting their deductible. Finally, employees pay 100% of the cost of the prescription drug without benefit of any rebates, unless the plan sponsor's PBM has point of service rebates. This may lead to employee queries about the role of rebates in overall cost reduction and the employer's exercise of fiduciary responsibilities.

Summary: Comparing Copay, Coinsurance, and Front-End Deductibles

Option	Advantages	Disadvantages
Copay	- Predictable and simple for employees - Encourages medication adherence	- Limited cost control for sponsor - May lead to overutilization
Coinsurance	- Flexible cost-sharing - Promotes cost awareness - Reduces overutilization	- Unpredictable costs for employees - May discourage adherence for high-cost drugs
Front-End Deductible	- Better cost control for sponsor - Promotes cost-conscious behavior	- High upfront cost for employees - May reduce adherence at start of plan year

The choice between copay, coinsurance, and front-end deductibles depends on the sponsor's goals. For employee satisfaction and adherence, copays might be more effective. For cost-sharing flexibility and managing high-cost drug expenses, coinsurance is a good option. If budget control is a priority, front-end deductibles help mitigate initial costs but require careful communication to avoid negatively impacting medication adherence and the role of rebates in cost reduction strategies.

Limitations and Exclusions:

When designing a pharmacy benefit plan, plan sponsors often consider limiting or excluding certain drug categories to manage costs, avoid unnecessary or risky drug use, and promote clinical effectiveness. Here are some categories of drugs that are commonly limited or excluded from pharmacy benefit plans, along with reasons for each:

1. Lifestyle Drugs

Drugs for erectile dysfunction (e.g., sildenafil), weight loss drugs, hair growth treatments (e.g., finasteride for male pattern baldness). These drugs are often not deemed medically necessary and are considered lifestyle enhancements rather than essential treatments. Excluding these drugs can reduce plan costs without compromising essential health benefits.

2. Over-the-Counter (OTC) Equivalents

Pain relievers (e.g., ibuprofen, acetaminophen), allergy medications (e.g., loratadine), some acid reducers (e.g., omeprazole). Many OTC drugs have prescription-strength equivalents that are covered by some plans. However, if an OTC option exists, sponsors may prefer to exclude these from coverage to encourage employees to purchase them directly. OTC medications are generally affordable and accessible without needing insurance coverage. However, plans sponsors should be aware that some over-the-counter medications are required by the Affordable Care Act, namely Aspirin 81mg. The ACA requires insurance plans to cover aspirin for adults 50–59 at high risk of cardiovascular disease.

3. High-Cost Specialty Drugs Without Proven Effectiveness

Some cancer therapies, rare disease treatments that have limited evidence of efficacy. Specialty drugs are often expensive and may not always demonstrate significant improvements in health outcomes. For high-cost drugs with limited efficacy, plans may implement strict prior authorization or exclude them altogether to avoid high costs for low-value treatments.

4. Experimental or Investigational Drugs

Drugs not approved by the FDA; drugs being used in clinical trials. Drugs that are experimental or investigational lack sufficient safety and efficacy data, so plan sponsors typically exclude them to minimize risks and avoid covering unproven treatments.

5. Cosmetic and Dermatological Drugs

Drugs for cosmetic purposes, such as anti-aging treatments, non-medically necessary skin treatments (e.g., certain acne treatments, drugs for wrinkle reduction). Cosmetic drugs generally aren't medically necessary, so excluding them helps limit the plan to medically essential treatments, reducing costs and focusing on necessary care.

6. Non-Formulary Brand-Name Drugs with Available Generics

Brand-name drugs with equivalent generics, such as Lipitor (brand for atorvastatin). Generic drugs are usually equally effective and much more affordable than their brand-name counterparts. By excluding brand-name drugs when generics are available, the plan sponsor can lower costs while maintaining treatment access.

7. Drugs with Potential for Abuse or Misuse

Opioid painkillers (e.g., oxycodone), some anti-anxiety medications (e.g., benzodiazepines), certain stimulants (e.g., amphetamines used for ADHD). These drugs have a high risk of misuse and dependency. Plans may limit quantities, require prior authorization, or mandate monitoring programs to minimize abuse risks while ensuring that patients with legitimate medical needs still have access.

8. Drugs That Are Primarily for Convenience

Combination drugs that contain two or more drugs available separately at a lower cost, extended-release versions of drugs that can be dosed twice daily instead. These drugs are often more expensive, and patients may achieve the same therapeutic benefit with individual or more frequent dosing. Limiting these types of drugs can reduce plan costs without compromising treatment efficacy.

9. Infertility Treatments

Certain fertility drugs, in vitro fertilization (IVF) medications. Infertility treatments can be very expensive and may not be considered essential by some plan sponsors. However, some plans do cover them in part, depending on the company's philosophy and employee needs. Further, the health plan may cover these drugs and to avoid duplicative coverage, it may or may not be cost effective to cover these drugs through the medical plan. Plan sponsors should have a discussion with its medical carrier and PBM and determine the most cost-effective strategy.

10. Non-Essential Vitamin and Mineral Supplements

General vitamins (e.g., multivitamins, Vitamin C, Vitamin E), supplements not related to a deficiency or specific medical condition. Many vitamins and supplements are available over the counter and are not generally considered medically necessary unless prescribed for a specific deficiency or condition. Excluding these from the plan helps to focus resources on more critical medical treatments.

Summary of Considerations

Drug Category	Reason for Limitation/Exclusion
Lifestyle Drugs	Non-essential, high cost
OTC Equivalents	Readily available, typically affordable without insurance
High-Cost Specialty Drugs w/ Low Efficacy	Expensive, limited clinical benefit
Experimental or Investigational Drugs	Lack of FDA approval, safety/efficacy data
Cosmetic Drugs	Not medically necessary, for cosmetic use
Non-Formulary Brand-Name Drugs	Generics available, lower cost with similar efficacy
Potential for Abuse/Misuse	High risk of dependency, abuse potential
Convenience-Only Drugs	Higher cost without additional medical benefit
Infertility Treatments	Expensive, may not be essential or covered by all plans
Non-Essential Vitamins and Supplements	Available OTC, not medically necessary in most cases

Excluding or limiting certain drugs allows plan sponsors to control costs, promote appropriate drug use, and focus on essential health needs. However, plan sponsors should carefully consider employee demographics and specific needs when making these exclusions, as what might be considered non-essential for one group could be highly valued by another. Balancing these exclusions with employee education, flexibility, and evidence-based decision-making can help achieve a pharmacy benefit plan that is both cost-effective and supportive of employee health.

Prior Authorization

Prior Authorization (PA) programs are cost-control measures used in pharmacy benefit plans to ensure that certain medications are only prescribed and dispensed when specific criteria are met. These programs require healthcare providers to obtain approval from the pharmacy benefit manager (PBM) before a prescribed drug is covered by the plan. The PA process is intended to promote the appropriate use of medications, often focusing on high-cost drugs, specialty drugs, and drugs with potential for misuse or adverse side effects.

Prior Authorization programs have several benefits but are also controversial for several reasons. PA requirements can delay access to medications, sometimes for critical treatments, while the healthcare provider and PBM navigate the approval process. Providers and pharmacies often need to complete extensive paperwork or submit detailed medical documentation, which can be time-consuming and burdensome. Patients may face barriers to receiving medications due to PA denials or delays, which can affect adherence and potentially worsen health outcomes. Both patients and providers frequently express frustration with PA processes, as they perceive it as an interference with clinical decision-making and a potential obstruction to receiving timely care.

Nonetheless, a Prior Authorization (PA) program offers critical key benefits for pharmacy benefit plan sponsors, patients, and the healthcare system especially when faced with the ever-increasing high cost of specialty drugs. These benefits primarily revolve around cost management, patient safety, and promoting clinically appropriate drug use.

PA programs are particularly effective at controlling costs by limiting access to high-cost medications to only those who meet specific clinical criteria. This helps prevent the unnecessary use of expensive drugs when equally effective and lower-cost options are available. By requiring prior authorization for certain brand-name drugs, the program incentivizes the use of generic or therapeutic equivalents, which can offer the same efficacy at a lower cost to both the plan and the member. PA programs also help plan sponsors maximize manufacturer rebates by steering utilization toward specific drugs that have favorable rebate arrangements, contributing to cost savings.

PAs can help reduce the risk of inappropriate medication use by ensuring drugs are prescribed only when medically necessary. This can help prevent adverse effects, especially in high-risk medications (e.g., opioids or certain psychiatric drugs). For certain medications with potential side effects or interactions, the PA process requires prescribers to verify that the patient's medical profile aligns with safe usage guidelines. This can prevent harm associated with off-label or contraindicated use. Specialty drugs often require specific medical conditions or monitoring for safe and effective use. PAs ensure these medications are only dispensed to patients who have a clinical indication for them, improving overall treatment outcomes and safety.

When designing a PA program, plan sponsors should consider several factors to balance cost control with member access and satisfaction, ensure that the PA criteria are transparent, clinically sound, and evidence-based. Criteria should be clear and accessible to prescribers, allowing them to understand what's required for approval. Plan sponsors should work with PBMs to establish efficient PA processes with quick response times to reduce delays in care. Faster turnaround times improve patient satisfaction and reduce administrative burdens for providers. Include an appeals process for cases where members may need access to medications outside standard criteria. Flexibility in criteria can help ensure that patients receive the care they need, even when their cases are unique. Integrate the PA program with case management or specialty pharmacy programs, where applicable, to ensure that patients who require high-cost drugs have a coordinated care plan. Drug lists for PA should be reviewed and updated regularly to ensure they remain relevant. Drugs with generic alternatives, for example, might be removed from PA requirements over time.

Lastly, approval rates for PA requests can vary based on the drug category, the PA criteria, and the PBM managing the program. Approval rates for PA requests generally range between 60% and 80%, with rates for high-cost specialty drugs sometimes lower due to more stringent criteria. These rates can fluctuate based on changes in clinical guidelines, the effectiveness of PA criteria, and how often providers are required to submit additional information for approvals.

Understanding PA approval rates is important for plan sponsors. High approval rates (over 70%) can indicate that PA criteria are too lax and are meaningless "speed bumps" that in essence provide approval for rebates retained by PBMs and result in high costs for plan sponsors. Low rates, under 30%, may suggest that criteria are too restrictive or unclear, potentially leading to unnecessary denials and delays in care. Analyzing PA approval rates can help sponsors understand how effective the PA program is at controlling costs while maintaining access to necessary treatments. Approval rates, along with cost data, provide insight into whether the program is genuinely filtering out inappropriate uses without creating excessive barriers.

Prior Authorization programs can help manage costs and ensure that only clinically appropriate medications are covered. However, due to their controversial nature and potential to delay care, it's essential for plan sponsors to work closely with PBMs to design PA programs that balance cost management with member access, transparency, and satisfaction. By monitoring and questioning PA approval rates, plan sponsors can ensure the program is efficient, effective, and aligned with employee needs.

Formularies

Prescription drug formularies are lists of medications that are covered under a pharmacy benefit plan. Formularies categorize drugs by therapeutic class, often dividing them into tiers that determine the level of coverage and cost-sharing (e.g., copay or coinsurance) for each drug. The main goal of a formulary is to manage costs while ensuring access to safe, effective, and affordable medications.

Formularies are structured to guide members toward certain medications over others. PBMs and health plans generally organize drugs into tiers, which influence out-of-pocket costs and overall access:

- Tier 1: Generally, includes generic drugs, which are the least expensive and have the lowest out-of-pocket cost.
- Tier 2: Typically includes preferred brand-name drugs, offering members moderate out-of-pocket costs.
- Tier 3: Often consists of non-preferred brand-name drugs, which are more expensive and may have higher out-of-pocket costs.
- Tier 4 and beyond: Usually includes specialty drugs, which are high-cost medications for complex conditions.

Drugs are placed on formulary tiers based on several factors, including cost, clinical effectiveness, and therapeutic alternatives. PBMs and pharmacy & therapeutics (P&T) committees make these determinations, often influenced by rebate arrangements with manufacturers. We discussed rebates in the prior section. Formularies often include utilization management tools like prior authorization (PA), step therapy, and quantity limits to further control costs and ensure clinically appropriate use.

When designing or selecting a formulary, plan sponsors should consider the balance between clinical effectiveness with cost. Sponsors should ensure that formulary decisions are guided by clinical evidence, not solely by rebates, to avoid unnecessary costs or compromising patient care. Sponsors should ensure the formulary provides flexibility, such as allowing access to non-formulary medications through an appeals or exception process. This flexibility is particularly important for members with unique clinical needs who may not respond well to formulary options.

Formularies are dynamic, often updated based on new drugs, price changes, or shifts in clinical guidelines. Sponsors should understand how often the formulary is updated and request transparency in the process, ensuring that they are informed about the changes and impacts on members.

Formularies can significantly affect member satisfaction and adherence. Sponsors should be aware that overly restrictive formularies may lead to dissatisfaction and reduced medication adherence, which can ultimately drive-up healthcare costs due to unmanaged conditions. PBMs negotiate rebates with manufacturers to reduce plan costs, especially on brand-name drugs. Plan sponsors should ask about rebate arrangements and whether savings are passed on directly to them or used to reduce plan premiums or member cost-sharing.

<u>Should Plan Sponsors Have Control Over a PBM's Formulary?</u>

The level of control that a plan sponsor has over a PBM's formulary can vary depending on the relationship with the PBM, plan objectives, and specific organizational needs. Sponsors with control over the formulary can tailor it to align with member demographics and specific healthcare needs, especially if there are unique clinical populations within the workforce. Plan sponsors can set specific cost and clinical goals that align with their organization's values and objectives, rather than deferring entirely to the PBM's standard formulary, which may prioritize rebate-generating drugs. By having input on formulary decisions, plan sponsors can ensure greater transparency, which helps them anticipate cost shifts, manage utilization, and improve member satisfaction.

However, managing a customized formulary requires time and expertise, which can add administrative burden. Sponsors might need in-house or external clinical expertise to oversee and manage formulary design and updates. If a sponsor diverges from a PBM's standard formulary, it may lose access to certain rebates and volume-based discounts, potentially increasing plan costs. PBMs have significant resources and experience in formulary management. Sponsors who exercise control might miss out on the PBM's established relationships, data, and infrastructure, which can streamline formulary management and cost savings.

Summary of Key Points for Plan Sponsors

Consideration	Description
Clinical and Cost Effectiveness	Ensure formulary is evidence-based and not solely rebate-driven.
Flexibility and Transparency	Allow for exception processes and require transparency on formulary updates.
Member Satisfaction and Adherence	Be cautious of overly restrictive formularies that could impact member satisfaction and health outcomes.
Rebate and Cost Savings	Understand rebate arrangements and how they influence formulary design and costs.
Control vs. PBM Standard	Balance desire for customization with potential administrative and cost implications.

How Can formularies be Evaluated?

Evaluating and selecting the right formulary is crucial for plan sponsors as it directly impacts cost, member satisfaction, and clinical outcomes. To assess one formulary against another, sponsors should consider multiple factors, including clinical coverage, cost structure, and overall member impact. When evaluating a formulary, it is essential that plan sponsors ask and receive a complete formulary (not just covered drugs but excluded drugs in each therapeutic category). Here's a guide on key areas to evaluate:

1. Coverage Breadth and Depth

- **Drug Categories**: Review the range of therapeutic categories covered, especially high-cost or high-need categories such as chronic conditions (e.g., diabetes, cardiovascular, and mental health medications). Ensure the formulary includes a comprehensive selection of drugs that meet the specific health needs of the member population.
- **Tier Structure and Access**: Evaluate the number of tiers (e.g., generic, preferred brand, non-preferred brand, specialty) and their placement, which affects both cost and accessibility. Consider whether the formulary provides affordable options across categories.
- **Generic and Brand Name Drugs**: Check the balance between generic and brand-name drugs. A formulary that emphasizes generics can help control costs without sacrificing quality but should still provide brand options for cases where no generic is suitable.

2. Cost Management Features

- **Member Cost-Sharing Requirements**: Compare the out-of-pocket costs for members at each formulary tier. Understanding copayments, coinsurance levels, and deductibles helps sponsors gauge the financial burden on employees and how likely they are to adhere to prescribed medications.
- **Rebate-Driven Strategies**: Examine how much the formulary relies on high-rebate drugs and how those rebates are handled. A formulary too focused on rebate-driven medications may lead to higher overall costs. Sponsors should confirm whether rebate savings are passed along to them or reinvested in reducing member costs.
- **Utilization Management Tools**: Assess tools like **prior authorization (PA)**, **step therapy**, and **quantity limits**. While these can control costs by guiding members to preferred options, excessive restrictions can create barriers to access and impact member satisfaction.

3. Clinical Appropriateness and Evidence-Based Design

- **Formulary Development and Review Process**: Inquire into the Pharmacy and Therapeutics (P&T) committee responsible for formulary decisions. A formulary developed by an independent, evidence-based P&T committee is more likely to prioritize clinical efficacy over financial incentives.
- **Adherence to Clinical Guidelines**: Check if the formulary aligns with the latest clinical guidelines. This ensures that members have access to first-line therapies recommended by medical bodies, supporting appropriate treatment and avoiding unnecessary costs.
- **Safety and Side Effect Management**: Formulary design should consider patient safety, especially in high-risk medications. Review how safety concerns are addressed, such as requiring PAs for drugs with serious side effects or abuse potential.

4. Member Access and Flexibility

- **Exceptions Process**: Ensure that the formulary includes an appeals or exception process that allows members access to non-formulary drugs if medically necessary. This is especially important for members who may not respond well to formulary drugs.
- **Formulary Updates and Notification**: Evaluate how often the formulary is updated and how changes are communicated to members. Frequent updates may reflect responsiveness to new clinical data, but they can also cause member confusion. A clear communication plan for formulary changes is essential.
- **Ease of Access to Information**: User-friendly web portals or mobile apps that allow members to check formulary status, find in-network pharmacies, and view their cost-sharing responsibilities contribute to transparency and help members make informed decisions.
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5. Member Impact and Satisfaction

- **Member Survey Data**: If available, review member satisfaction data related to formularies, as this can reveal pain points such as frequent denials or high out-of-pocket costs. A formulary with high satisfaction rates likely balances cost and access more effectively.
- **Impact on Medication Adherence**: Review data or benchmarks showing how well members adhere to prescribed treatments under each formulary. Poor adherence may indicate that the formulary structure, cost-sharing, or access barriers are preventing members from following prescribed regimens.
- **Network Pharmacy Coverage**: A wide network of pharmacies, including mail-order options, can enhance member access and improve satisfaction, especially for those on long-term medications.

6. Financial Performance and Value

- **Overall Cost Impact**: Assess how each formulary option affects total costs, including direct pharmacy costs, rebates, and potential medical savings from improved medication adherence and disease management. Some PBMs provide models to estimate the financial impact of different formulary choices on both the sponsor and members.
- **Rebate Transparency**: Plan sponsors should understand the rebate terms and confirm whether rebates are fully or partially passed through to them. This can significantly impact the net cost of drugs within the formulary.
- **Outcomes-Based Contracting**: If available, consider formularies tied to outcomes-based contracting, where manufacturers offer additional rebates if drugs do not meet certain clinical outcomes. This aligns the formulary's financial incentives with patient health goals.

By carefully evaluating formularies across these dimensions, plan sponsors can make informed decisions that support cost control, clinical effectiveness, and member satisfaction. A well-chosen formulary can enhance the overall pharmacy benefit, improving both access to needed medications and the financial sustainability of the plan.

Miscellaneous Plan Design or Program Considerations

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Mandatory Generic and Biosimilar Substitution

When generic or biosimilar versions of a specialty drug become available, the plan may require substitution of the lower-cost version. A plan sponsor may mandate the use of a biosimilar to a high-cost biologic unless a patient has a specific medical reason not to switch. Significantly reduces costs by steering members toward less expensive alternatives that are often just as effective. Not all patients may respond the same to biosimilars, and some may experience different outcomes, requiring careful monitoring.

Copay accumulator programs

Copay accumulator programs are mechanisms implemented by health insurers or pharmacy benefit managers (PBMs) that limit the impact of copay assistance from pharmaceutical manufacturers on a patient's deductible or out-of-pocket maximum. These programs specifically apply to the financial assistance that patients receive from drug manufacturers, typically in the form of copay cards or coupons, which are designed to help reduce the cost of medications.

Manufacturer Copay Assistance: Many pharmaceutical companies offer copay assistance programs to help patients cover the out-of-pocket costs for expensive brand-name medications. These programs typically offer copay cards or coupons that reduce the amount a patient has to pay for a drug at the point of service.

Accumulators: In a copay accumulator program, the amount of the copay assistance (from the drug manufacturer) is not counted toward the patient's deductible or out-of-pocket maximum. So, even though the patient benefits from a lower copay at the pharmacy, the insurer or PBM does not count the amount of assistance from the copay card when determining how much the patient has spent toward their deductible or out-of-pocket cap.
Example:

- If a patient has a $1,000 deductible and their prescription costs $500, and the pharmaceutical company offers a $400 copay card, the patient will only need to pay $100 at the pharmacy.
- With a copay accumulator program, the insurer or PBM would not count the $400 from the copay card toward the patient's deductible. So, even though the patient paid only $100 out of pocket, it still counts as though they've paid $100 toward their deductible and not the $500 total cost of the drug

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Why Are Copay Accumulator Programs Controversial?

1. Increased Out-of-Pocket Costs for Patients:
    - Patients may be misled into thinking their deductible or out-of-pocket maximum is being lowered by the copay card when it is not. This can result in higher costs for patients once they run out of copay assistance or need to meet their full deductible.
    - For high-cost medications, this can significantly increase the financial burden on patients, especially those with chronic conditions who rely on expensive brand-name drugs.
2. Manufacturer's Role:
    - Pharmaceutical manufacturers offer copay assistance to help patients afford medications. Copay accumulator programs negate part of this benefit by not applying the copay assistance toward the patient's deductible, potentially leading to higher out-of-pocket costs when assistance runs out.
3. Health Equity Concerns:
    - Accumulator programs disproportionately impact patients with high-cost medications, such as those for chronic or serious conditions (e.g., cancer, rheumatoid arthritis). These patients often rely on copay cards to afford their medications, so accumulator programs can create significant financial hardships for vulnerable populations.

4. Transparency and Trust Issues:
    - Many patients are unaware of how these programs work until they reach the pharmacy or their insurance statement. The lack of upfront transparency can cause confusion and frustration when patients realize that the assistance they received does not count toward their deductible.

Potential Benefits for Insurers and PBMs:

- Cost Savings for the Insurer/PBM: By not counting the copay assistance toward the deductible, insurers and PBMs can reduce their overall financial responsibility, as the patient will have to pay more out-of-pocket before reaching their deductible.
- Encouraging More Cost-Conscious Behavior: Some argue that copay accumulators can encourage patients to shop around for more cost-effective treatment options or generics, though this is not always feasible for patients with conditions requiring specific medications.

What Should Plan Sponsors Be Aware Of?

1. Patient Impact: Plan sponsors should consider the financial burden that copay accumulator programs place on employees, particularly those with chronic or high-cost conditions. These programs may undermine the benefits of prescription drug assistance programs and potentially harm employee satisfaction.
2. Transparency and Communication: If implementing copay accumulator programs, it's critical for plan sponsors to ensure clear communication with employees about how these programs work. Employees should be fully informed about how copay cards will or will not impact their deductible and out-of-pocket expenses.
3. Alternative Solutions: Plan sponsors may want to explore alternatives to accumulator programs, such as allowing copay assistance to count toward deductibles or out-of-pocket limits, which may help reduce the financial burden on employees and increase satisfaction with the benefit plan.
4. Legal and Ethical Considerations: Some states have introduced or are considering legislation to restrict the use of copay accumulator programs or require greater transparency. Plan sponsors should stay informed about evolving laws and regulations regarding copay accumulators.

Copay accumulator programs are designed to limit the effectiveness of copay assistance programs by not allowing the financial help from manufacturers to count toward a patient's deductible or out-of-pocket maximum. While these programs can reduce costs for insurers and PBMs, they often lead to increased financial strain on patients, especially those needing high-cost medications. The practice has become controversial due to its potential negative impact on patients' healthcare affordability and transparency. Plan sponsors should be aware of the implications of these programs and consider how they might affect their employees' health and financial well-being.

Manufacturer Assistance Programs

Manufacturer Assistance Programs are initiatives designed to help patients afford their prescription medications, particularly for high-cost brand-name drugs. These programs are typically provided by pharmaceutical manufacturers and aim to reduce the financial burden on patients who may have difficulty affording the out-of-pocket costs of their medications, especially when those drugs are not fully covered by insurance or when they are subject to high copays or deductibles.

There are various key features of these programs, including:

1. **Copay Assistance Cards and Coupons**:

   Many manufacturers offer **copay cards** or **coupons** that help lower the cost of prescription medications at the point of service. These cards can cover a substantial portion of the patient's copay, sometimes up to the full amount, depending on the program. For example, a patient might have a $500 prescription, but with the assistance program, they could pay only $50 or even $0, depending on the drug and their eligibility.

2. **Patient Assistance Programs (PAPs)**

   These are broader programs designed for low-income or uninsured patients. In these cases, manufacturers provide **free or discounted medications** to patients who meet certain financial qualifications.

3. **Access and Enrollment Support**:

   These programs help patients **enroll** in these programs by providing access to the necessary resources, helping them fill out applications, and ensuring they meet the eligibility requirements for assistance. These organizations often assist with eligibility verification, paperwork processing, and coordination between the patient and the manufacturer's program.

4. **Income-Based Qualifications**:

   Many assistance programs are based on income or insurance status. For example, if a patient has high insurance premiums or high out-of-pocket costs, they may be eligible for financial assistance through a manufacturer's program, regardless of their income level. There are usually **income thresholds** and **coverage criteria** that patients must meet to qualify for assistance. Patients may need to provide proof of income or insurance status as part of the application process.

5. **Insurance and Program Coordination**:

   These programs often help patients navigate **complex insurance structures**, ensuring that the assistance programs work alongside their insurance benefits. This might involve integrating the copay assistance into the patient's prescription benefit structure to lower out-of-pocket costs effectively.

6. **Discounted Medications for Specific Conditions**:
   Many manufacturer assistance programs focus on high-cost medications for chronic or complex conditions, such as **cancer**, **autoimmune diseases**, **diabetes**, **heart disease**, **HIV**, and other specialty medications. These drugs can be prohibitively expensive without assistance, and the programs aim to make them more accessible to patients who need them the most.

   There are challenges and controversies: As mentioned earlier, some health plans and PBMs implement copay accumulator programs that prevent the assistance from counting toward a patient's deductible or out-of-

pocket maximum. This can limit the effectiveness of these programs and increase a patient's overall costs once the copay card assistance runs out. Some programs may have eligibility limitations, such as income caps, specific conditions, or insurance restrictions, which can make them unavailable to certain patients. In some cases, the details about eligibility, the extent of assistance, or how the programs coordinate with insurance can be confusing or unclear to patients.

Carved-Out Specialty Providers

Carved-out specialty pharmacy providers are specialized entities that manage the prescription drug benefits for complex and high-cost medications, known as specialty drugs, separately from traditional pharmacy benefit managers (PBMs). By focusing exclusively on specialty medications, these providers aim to offer enhanced clinical management, cost containment, and improved patient outcomes.

Implementing tailored programs to monitor and manage the use of specialty drugs, ensuring appropriate utilization and adherence to treatment protocols. These vendors provide patient education and support to enhance medication adherence and overall health outcomes, negotiate directly with pharmaceutical manufacturers to secure favorable pricing and rebates for specialty medications and employ formulary management to promote the use of cost-effective therapies without compromising quality. These types of vendors also offer detailed reporting on specialty drug utilization, expenditures, and outcomes to plan sponsors and provide insights into cost drivers and opportunities for savings within the specialty drug category.

Benefits to plan sponsors includes additional cost savings by focusing on specialty drugs, which often represent a significant portion of overall drug spending, carved-out providers can negotiate better pricing and rebates, leading to substantial cost reductions for plan sponsors.

While there are clear advantages, plan sponsors should also be aware of potential challenges such as ensuring seamless integration between the carved-out specialty provider and existing PBM or health plan systems is crucial for maintaining data consistency and operational efficiency. It's essential to ensure that patients continue to receive high-quality support and access to medications without disruption during the transition to a carved-out specialty provider. Plan sponsors must ensure that the carved-out provider complies with all relevant regulations and standards to avoid legal and financial repercussions.

In summary, carved-out specialty providers offer plan sponsors a focused approach to managing specialty drug benefits, with the potential for cost savings, improved patient outcomes, and enhanced operational efficiency. However, careful consideration and planning are necessary to address integration, patient access, and compliance issues effectively.

EGWP Providers and Programs

EGWP (Employer Group Waiver Plan) programs are Medicare Advantage plans offered by employers or unions to provide healthcare coverage to their retirees who are eligible for Medicare. These plans are designed to give retirees access to Medicare Advantage benefits (Part C) that may include hospital, medical, and prescription drug coverage, often with additional benefits beyond traditional Medicare. EGWPs allow employers to offer comprehensive benefits to retirees, typically at a lower cost than traditional Medicare or standalone Medicare Advantage plans.

Plan sponsors (typically employers or unions) should understand several key aspects of EGWP programs: EGWPs are a Medicare Advantage plan, which means that they combine Medicare Part A (hospital coverage), Part B (medical coverage), and, in many cases, Part D (prescription drug coverage) into a single plan. This allows retirees to receive all their benefits from one plan. EGWPs are available to retirees who are eligible for Medicare, generally those aged 65 and older or individuals with disabilities who qualify for Medicare. These plans often include additional benefits beyond what is covered by traditional Medicare, such as vision, dental, and hearing coverage, as well as programs that promote wellness and preventive care. Employers can structure the plan's premium contributions, deductibles, copays, and coinsurance to reduce the out-of-pocket costs for retirees. Many employers continue to offer subsidies for premiums, making EGWPs a more cost-effective option for retirees.

EGWPs are coordinated with Medicare, and the Medicare program continues to pay a portion of the retiree's medical costs. The employer or union typically arranges for a private insurer to manage the EGWP, which must be approved by the Centers for Medicare & Medicaid Services (CMS). EGWPs often provide Medicare Part D prescription drug coverage, which is particularly important for retirees who need medication. These plans can help reduce the costs of prescription medications, which can otherwise be a significant out-of-pocket expense under traditional Medicare. Like all Medicare Advantage plans, EGWP participants can make changes to their coverage during the Medicare Open Enrollment Period (October 15 to December 7 each year).

The key difference between fully insured and self-insured EGWP programs lies in how the risk and administration of the plan are handled. In a fully insured EGWP, the employer or union partners with an insurance company (usually an insurance carrier with CMS approval) to administer the plan. The insurer assumes the financial risk for providing healthcare services to retirees, including paying claims for medical care, drugs, and other covered benefits. The employer pays a fixed premium to the insurer for each retiree enrolled in the plan. This is a predictable expense for the employer, which makes budgeting easier. The insurer assumes the risk of the plan's claims, manages the network of healthcare providers, and administers the benefits to retirees. The insurance company handles the claims processing, customer service, and regulatory compliance with CMS.

The advantage of a fully insured program is that employers know exactly how much they will pay in premiums, which makes it easier to budget. The insurance company takes on the financial risk associated with healthcare costs, which reduces the employer's exposure to fluctuations in medical claims. The insurer handles the day-to-day administration, including managing providers, claims, and regulatory compliance.

The disadvantages of a fully insured EGWP program are that employers have less control over plan design and may not be able to customize the plan as much as they would like. Premiums may be higher than a self-insured arrangement, as the insurer includes a margin for risk and administrative costs.

In a self-insured EGWP, the employer or union assumes the financial risk for providing healthcare coverage to retirees, rather than transferring the risk to an insurance company. The employer funds the claims directly, either by paying for the healthcare services themselves or working with a third-party administrator (TPA) to manage the claims. The employer bears the financial risk for claims but may have more control over plan design, plan costs, and premium structures. If the employer does not directly administer the plan, they will partner with a third-party administrator (TPA) or a third-party claims manager to process claims, handle customer service, and ensure compliance with Medicare rules.

The advantages of a self-insured EGWP are that employers have more control over the design and flexibility of the plan, allowing them to better tailor the plan to meet the needs of retirees. Self-insured plans can result in lower overall administrative and insurance costs, as there is no insurer markup. Employers can customize the plan to meet specific needs, including adjusting co-pays, formulary options, or introducing additional benefits not commonly offered in fully insured plans.

Disadvantages include that employers assume all the financial risk for healthcare costs, which can be unpredictable, especially with high-cost claims or catastrophic events. Managing a self-insured plan requires significant resources and expertise in claims management, regulatory compliance, and plan administration. It may require additional infrastructure or the help of a TPA. Self-insured plans may result in fluctuating costs year-to-year, making it harder for employers to predict their financial obligations.

EGWP vs. RDS Employer-Based Programs

RDS (Retiree Drug Subsidy) programs and EGWPs are two different ways for employers to offer prescription drug coverage to their retirees. The key differences are that RDS programs were designed by the Medicare Modernization Act of 2003 to help employers offset the costs of providing prescription drug coverage to their retirees. Under the RDS program, employers provide their retirees with prescription drug coverage that is at least equivalent to Medicare Part D. Employers can then apply to the federal government for a subsidy to cover a portion of the prescription drug costs.

Under an RDS program, employers continue to provide retiree drug coverage, employers receive subsidies from the federal government to help pay for retirees' drug claims, the subsidy is based on the cost of drugs covered by the employer's plan that meet Medicare Part D standards. An RDS is a standalone drug program and does not include medical coverage.

EGWP Programs are Medicare Advantage plans that include both medical and prescription drug coverage. Employers that provide EGWPs to retirees are offering a comprehensive health plan that includes hospital, medical, and drug coverage.

EGWPs provide a broader range of benefits than RDS, including medical benefits in addition to prescription drug coverage. Retirees enrolled in an EGWP receive their benefits through a Medicare Advantage plan, which is managed by a private insurer with CMS oversight. EGWPs are often preferred because they provide a single, integrated plan for retirees, rather than separate medical and prescription drug benefits.

The key Differences Between EGWPs and RDS Programs are that EGWPs provide comprehensive health coverage, including both medical and prescription drugs. RDS programs only provide prescription drug coverage, and employers must separately offer medical benefits, which may require retirees to enroll in a separate Medicare plan for their medical coverage. EGWPs are fully integrated Medicare Advantage plans, which are managed by insurance companies approved by CMS. RDS programs require employers to self-administer the prescription drug plan and then apply for subsidies, often making RDS more administratively complex than EGWPs. RDS programs provide a federal subsidy to employers to offset the costs of prescription drug coverage. EGWPs do not receive the same type of federal subsidy, but they may offer additional benefits and cost savings through more comprehensive plan design and better management of healthcare costs.

EGWP programs are Medicare Advantage plans designed for retirees, offering comprehensive coverage that may include medical, hospital, and prescription drug benefits. Fully insured EGWPs transfer the financial risk to an insurance company, while self-insured EGWPs allow employers to bear that risk but offer more control and flexibility. Employers must also distinguish between EGWPs and RDS programs. EGWPs provide comprehensive care, whereas RDS is focused only on prescription drug coverage and relies on federal subsidies for part of its cost. Understanding these distinctions is crucial for plan sponsors when deciding which program best fits their retirees' needs.

Site-of-Care Optimization

Specialty drugs are sometimes administered in different settings (e.g., hospital outpatient vs. home infusion). Plan sponsors can reduce costs by incentivizing administration in lower-cost settings, such as home or outpatient clinics, when clinically appropriate. A plan may cover a specialty drug administered in a home setting but require higher copayments if it's given in a hospital, where costs are typically higher. Advantages of these plans include reduction of overall drug administration costs and can improve patient convenience. Challenges include the requirement of coordination with healthcare providers and patients to ensure appropriate care settings, and some patients may require hospital-based care depending on their condition.

Disease Management Programs

There are many disease management programs available to plan sponsors that target specific issues related to disease states. Plan sponsors should be wary of these programs and make sure they are truly effective prior to implementation. Here are brief descriptions of prescription drug disease management programs:

Opioids, Addiction, and Mental Health

Targets the management of opioid use disorders, addiction, and related mental health conditions, aiming to reduce misuse and improve patient outcomes. Includes safe opioid prescribing practices, medication-assisted treatment (MAT), patient education, mental health support, and close monitoring to prevent overdose and improve recovery rates. The program may also focus on behavioral therapy and addressing underlying mental health conditions (e.g., depression or anxiety).

Diabetes/GLP-1 and Other Chronic Conditions

Supports individuals with diabetes and those using GLP-1 (glucagon-like peptide-1) receptor agonists for managing blood glucose levels and associated chronic conditions. Includes medication management for diabetes, particularly for those on GLP-1 therapies, and helps manage associated conditions like hypertension, heart disease, and obesity. The program emphasizes adherence to therapy, monitoring of blood glucose, lifestyle changes, and patient education.

COVID Testing and Medications

Provides protocols for managing COVID-related therapies, including medication and testing. Supports timely access to COVID-19 testing and the use of antiviral medications (e.g., Paxlovid), as well as ensuring that individuals with COVID-related conditions, such as long COVID, receive appropriate medications. The program also addresses vaccination support and ongoing management of COVID-related symptoms.

Metabolic Syndrome

Addresses the management of metabolic syndrome, a cluster of conditions (high blood pressure, high blood sugar, excess body fat, and abnormal cholesterol levels) that increase the risk of heart disease, stroke, and diabetes. Focuses on holistic management of these conditions through medication therapy (e.g., statins for cholesterol, antihypertensives for blood pressure), lifestyle modifications (diet, exercise), and monitoring to reduce the risk of cardiovascular disease, diabetes, and stroke.

Medication Therapy Management (MTM)

Ensures optimal medication use to improve patient outcomes, reduce medication errors, and minimize adverse effects. Involves comprehensive medication reviews, identification of potential drug interactions, ensuring adherence, and helping patients manage chronic conditions more effectively. MTM programs may also support switching therapies to more effective or lower-cost options and educate patients on proper medication use.

Conclusions

Prescription drug benefit programs are complicated, involving numerous parties – drug manufacturers, the pharmacy benefit manager, providers and patients, not to mention the plan sponsor and the various stakeholders within the plan sponsor's organization, such as the Chief Financial Officer, the Chief Human Resource Office and the Chief Executive Officer. These complexities are exacerbated by the dynamic nature of prescription drugs – new drugs are released almost every day by the FDA and manufacturers have hundreds of clinical trials in progress at any time. In addition, the cost of new therapies is very expensive, some over $1 million, yet very effective therapies continue to be pennies a pill. Sorting through which drugs are the most effective can be challenging, particularly when most Human Resource Departments lack clinical expertise.

Plan sponsors often report that the area of prescription drugs is the most confusing of the benefit plans, not just for themselves but for employees and their dependents. This guide was intended to assist plan sponsors sort through and think through the various considerations, from network management to clinical programs, from pricing alternatives to RFP projects, in a very neutral manner. Many more pages could have been written, but to keep the guide manageable, we have provided basic, unbiased materials for your review.

When designing and managing a pharmacy benefit plan, consider all the options available to you, based on the size of your organization, constraints and competition in your industry and what tolerance of change your employees and management can undertake. Many plan sponsors are already on "Step Three" initiatives. Other plan sponsors still need to lay the foundation with audits and monitoring programs. Wherever you are with your program, remember it is not a "one and done" plan. Continue to use this guide as your organization implements these best practices in effectively managing prescription drug programs.