



June 2023

Purchasing Standards for Plan Sponsors

A Tool for Plan Sponsor Management of Pharmacy Benefit Managers (PBMs)

About PBGH

Purchaser Business Group on Health (PBGH) members collectively spend more than \$100 billion annually buying health care for their employees. For more than three decades, PBGH has partnered with both private and public health care purchasers to promote higher quality, more affordable health care for America's workers and their families.

Health Care Affordability

The U.S. pays more than any other developed country for health care and has among the worst outcomes. Unsustainable health care spending has created wage stagnation with health care as the second highest business cost after labor. These costs have resulted in inequitable access to care, with pharmacy being a key driver. Few purchasers have been successful in driving drug affordability due, in part, to the consolidated nature of the PBM industry. The goal of this document is to help purchasers procure more affordable care on behalf of their workers and families.

About Pharmacy Benefits

Approximately 15-20% of a commercial population's health care cost is attributed to drugs provided through a pharmacy benefit.¹ This “drug benefit” is the fastest growing component of our collective health care spend due to new pharmaceutical innovations, better chronic condition treatment compliance and a complicated supply chain with multiple intermediaries operating under a veil of opaqueness masking misaligned incentives and profiteering.²

About the PBGH Plan Sponsor Purchasing Standards for PBMs

PBGH members have collaborated on shared principles for procuring and managing a responsible pharmacy benefit. These principles are the foundation for purchasing standards outlined in this document. The purchasing standards include approaches for addressing deceptive contracting practices and executing an effective vendor management program for PBMs.

PBGH members' consensus on pharmacy purchasing principles represent acknowledgement that the lack of transparency in our pharmaceutical supply chain and, particularly in the PBM's administration of an employer-sponsored pharmacy benefit, has led to an increase in cost that impacts affordability for plan sponsors and beneficiaries.



¹ https://healthcostinstitute.org/images/pdfs/HCCI_2020_Health_Care_Cost_and_Utilization_Report.pdf

² <https://www.actuary.org/content/prescription-drug-spending-us-health-care-system#3>

Purchasing Principles

Purchasing principles represent the values prioritized by PBGH members for procurement of a pharmacy benefit plan for their enrolled members.

PBGH has developed a proposed set of purchasing principles for its members to enable their provision of a clinically proficient and cost-effective pharmacy benefit with great customer service. Savings resulting from an improved program can be shared with beneficiaries.

<p>Transparency</p>	<p>Insist on meaningful pricing and utilization transparency from the PBM in order to:</p> <ul style="list-style-type: none"> • Meet fiduciary responsibilities to plan members • Have information necessary to support the health and well-being of workers and their families • Better inform benefit design and procurement decisions • Obtain per drug net pricing and actual administration fees • Conduct data analysis to drive better quality, cost and equity
<p>Excellent User Experience</p>	<p>Provide plan members with an excellent user experience:</p> <ul style="list-style-type: none"> • Facilitate optimal clinical outcomes through evidence-based drug selection and management • Ensure timely access through reasonable utilization management protocols, e.g., prior authorization • Provide easy-to-use, real-time and accurate consumer-facing information to support members' clinical education and financial decisions • Facilitate prescription access at the pharmacy counter by addressing formulary, utilization management and cost issues using PBM technology allowing for real-time issue resolution • Provide member education about formulary changes, cost-saving strategies (over-the-counter (OTC), generic substitution, etc.) and drug cost impact on premium
<p>Partner Requirements</p>	<p>PBMs are required to:</p> <ul style="list-style-type: none"> • Offer new generation technology supporting an improved point-of-sale and fulfillment experience for members • Enable clients' ultimate control over formulary design (not encumbered by rebates), pharmacy network partners, product and service carve-out options, drug price benchmarking (e.g., ICER and NADAC), rebate pass-through and transparency, elimination of spread pricing and comprehensive audit rights through fair and competitive contracting • Proactively provide forward-leaning insights and strategic solutions as well as excellent operational support • Comprehensively integrate with the health plan to enable best-in-class member support and data integration for clinical intelligence • Organizational commitment and actions to reduce racial and ethnic health disparities <p>Advisors are required to:</p> <ul style="list-style-type: none"> • Provide unbiased and non-conflicted guidance about formulary decisions, utilization management protocols, plan operations and other strategic plan management subjects

Background

Employers rely on PBMs to administer pharmacy benefits for workers and their families. PBMs can offer an array of services to sponsors of employment-based insurance, including:

- Claims payment and adjudication
- Formulary development and maintenance, which in practice is directly tied to negotiations with pharmaceutical manufacturers
- Negotiation with pharmaceutical manufacturers and associated rebate reconciliation, which is a function of that negotiation and utilization
- Drug pricing discounts
- Pharmacy network development and maintenance, which will include 1) retail pharmacies, 2) mail order options and 3) specialty pharmacies
- Utilization management
- Clinical care management and patient safety monitoring

The industry is consolidated amongst three key PBMs (i.e., CVS Caremark, Express Scripts and OptumRx) that collectively retain almost 90% market share of all non-clinically infused drugs in the United States.¹ That concentrated market share enables compelling price discounts and rebates from manufacturers, creating a headwind for new PBMs entering the market. Despite opportunities for savings from rebates and discounts, traditional PBMs have adopted opaque and deceptive business practices that enable them to capture revenue from multiple sources, often increasing the benefit cost. Many of the newer “next gen” PBMs are committed to principled business practices that could be more cost effective and result in better clinical outcomes despite the large discounts obtained by the market leaders. Nevertheless, the incumbent PBMs have proliferated due to misleading contracting practices, unscrupulous operating practices, limited audit rights, non-transparent financial alignment with pharmacy benefit consultants and by leveraging status quo bias.

Traditional PBM models utilize multiple undeclared revenue sources, two of which are retained rebates and pharmacy spread pricing.

¹ <https://content.naic.org/cipr-topics/pharmacy-benefit-managers>

Services Provided (partial list)

Adjudicate and pay claims

Negotiate rebates with manufacturers

Identify and contract with a pharmacy network and determine reimbursements to pharmacies



Revenues Earned (partial list)

Admin fees paid by clients

Retain a portion of the rebates (optimized through preference for high rebate drugs and GPO strategies)

Collect higher amounts from plan sponsors than paid to pharmacies (spread). Assess fees to pharmacies. Steer to owned pharmacies with higher reimbursements.

Retained Rebates

Discounts negotiated with manufacturers in exchange for favorable formulary placement and market share are called rebates, a portion of which is retained by the PBM.

- Different studies will identify variation in rebate retention.² PBMs have acknowledged (a likely understated) retention of rebates.³ Purchasers must recognize that even a small, acknowledged percentage of a very large number is in itself a very large number and is an incentive to “chase” rebates at the expense of lower net cost alternatives.
- Rebates increase the list price of medications that are incurred by patients with high deductibles and/or coinsurance based on the cost of the drug. Although refunded rebates might serve to lower costs for an employer sponsored health plan, the practice can compromise drug adherence due to affordability concerns when members with pharmacy needs are forced to pay artificially inflated prices. This has an outsized impact on low-wage earners, exacerbating health inequities.
- PBMs have adopted a practice of recategorizing payments from manufacturers to avoid rebate pass-through requirements. For instance, if the PBM sub-categorizes the manufacturer revenue as 1) a rebate, 2) a distribution fee, 3) a marketing fee and 4) an implementation fee; and the PBM returns “100% of the rebate”, the plan sponsor is NOT receiving 100% of the manufacturer revenue. A rebate, by any other name, is still a rebate.
- PBMs generate additional rebates from drug manufacturers via arrangements that are not specific or able to be allocated to a dispensed drug and are therefore not attributable to a client. These revenues will be retained by the PBM but are earned based on PBM’s book of business made up of utilization incurred and paid for by PBM clients.
- Manufacturer credits of other types, e.g., manufacturer copay assistance and coupons are sometimes counted as rebates for purposes of complying with contractual rebate guarantees.

² <https://bipartisanpolicy.org/blog/are-pbms-the-right-target/>

³ <https://www.drugchannels.net/2017/06/will-cvs-healths-point-of-sale-rebates.html> and <https://www.drugchannels.net/2018/12/new-disclosures-show-cvs-and-express.html>

When a vendor hired to negotiate with a third party takes money from that third party without the client knowing about it, it is not a discount. It is a kickback.

Spread Pricing (and other revenues from pharmacies)

PBMs determine the amount that pharmacies will be paid when they dispense a drug. The PBMs also determine the amount that the group health plan will pay the PBM for the drug that was dispensed by the pharmacies. Not unlike TPA-plan sponsor arrangements, the PBM is using health plan or plan sponsor funds to pay pharmacy costs after adjudicating the claim. However, it has become accepted practice for the PBMs to charge the health plan or plan sponsor an amount that is greater than what they pay the pharmacies. For example, the PBM will pay the pharmacy \$10 for the dispensed drug but charge the health plan \$30. The PBM keeps the difference (\$20 in this example). This is called “spread pricing” and increases the cost of the drug to patients as well as overall costs to plan sponsors. Moreover, the amount of spread is not transparent to the plan sponsor, making it impossible for them to know the true cost of the drug versus revenue to their PBM vendor.

Additionally, PBMs will assess fees to retail pharmacies called DIR (Direct and Indirect Remuneration, e.g., “network management fees” or “reimbursement reconciliations”), GER (generic effective rate) and BER (brand effective rate) fees that are often irreconcilable by the pharmacy. These fees are not attributed and difficult to allocate but add to the cost of drugs purchased by plan sponsors and their members while lining the pockets of PBMs.

Plan sponsors must be aware that spread pricing takes multiple forms. For instance, it might appear that there is no spread pricing with PBM-owned or PBM-affiliated pharmacies when in fact, the amounts paid to those pharmacies are higher than the amounts paid to non-owned or non-affiliated pharmacies. This point is particularly pertinent given the market share and steering mechanisms of the big three PBMs. Drugs purchased by those owned/affiliated pharmacies include the largest discounts, which are not passed along to plan sponsors. Identifying and guarding against this owned/affiliated pharmacy circumstance will be discussed in the contracting language section below.

Rebate retention and spread pricing are two primary avenues for profiteering by PBMs. As their clients come to understand and guard against the hidden revenue streams, PBMs have developed strategies to preserve them. PBGH’s Purchasing Standards for employers recognize the disingenuous clauses and the need to adopt counteractive contracting language.

Purchasing Standards

Purchasing standards translate the principles above ([see page 4](#)) into consideration for contracting. The purchasing standards outlined in this guide will enable the principles to be manifested into contract language. The standards are listed here with priority objectives. These standards support the contract language proposed for consideration later in the document.

Standard	Objectives
<p>1 Transparency that supports a clear understanding of drug cost, drug utilization and revenues paid by the plan to PBMs.</p>	<ul style="list-style-type: none"> • Enables a plan sponsor’s fiduciary committee to pay only reasonable compensation for services to the plan and to otherwise act in the best interest of the plan and its beneficiaries. • Informs a plan sponsor about the nature and terms of all fees paid to or captured by a contracted PBM from all sources, current and future, so that that the plan sponsor can execute an informed procurement process and prudent ongoing vendor management. • Full transparency is mandatory to assure compliance with the contract such as 100% rebate pass-through, no rebate exclusions, no spread pricing and other terms are as contracted.
<p>2 Clarity of definitions that cannot be manipulated to mislead plan sponsors and allow PBM profiteering.</p>	<ul style="list-style-type: none"> • Contracts should deploy clear, concise and consistent definitions to prohibit definition manipulation that provides opportunities for revenue streams to the PBM, such as varying definitions to suit the PBM’s best interest, utilizing multiple price lists and applying misleading descriptions.
<p>3 Customization that allows plan sponsors to provide an excellent benefit optimizing clinical outcomes and cost effectiveness.</p>	<ul style="list-style-type: none"> • Plan sponsors should be permitted to identify and implement best-in-class solutions within the PBM contract, e.g., specific drug or clinical care management carve out, formulary customization, pharmacy network adjustments and plan sponsor benefit design preferences without unreasonable financial consequence. • Plan sponsors must determine audit rules in order to assure compliance with contractual terms.
<p>4 Client and Member-centric customer and account management that prioritizes member clinical outcomes, financial well-being and member satisfaction and that supports plan sponsors with trustworthy strategic guidance.</p>	<ul style="list-style-type: none"> • PBMs should act solely as a service organization that has Member experience as a priority. • PBMs should act in good faith to align their incentives with those of plan sponsors and to serve in the best interest of the Client in exchange for a fair and transparent fee. • PBMs should provide consultative services accessing data as necessary to advise the client of best practices and high-quality outcomes. • PBMs should strive to continuously innovate and disrupt the status quo to drive a higher functioning and higher value pharmacy benefit for the Plan and its Members.

These contracting standards are in direct alignment with the Purchaser Principles agreed upon by PBGH’s 2023 PBM work group. PBGH members are among the leaders in pushing for greater transparency and more accountable PBM contracting practices. To that end, purchasers should assure that consultants and other advisors are aligned with the Principles and the Standards as a minimum requirement before soliciting a request for proposal (RFP) or market check. New rules mandated under the Consolidated Appropriations Act (CAA) of 2021 can lead towards validation of alignment.

How Plan Sponsors can Leverage the CAA

The CAA introduced a host of transparency provisions, which are the ultimate responsibility of the ERISA plan administrator who is the plan fiduciary (in most cases, the plan sponsor is the ERISA plan administrator). Some transparency provisions apply directly to pharmacy benefits such as Section 204, which requires annual reporting to applicable government agencies by group health plans about information on pharmacy benefits, historical drug costs and the financial impact of rebates on plan premiums and employees' out-of-pocket costs.

Other CAA transparency provisions apply indirectly to pharmacy benefits. Specifically, Section 201 prohibits group health plans from entering into or renewing contracts with third-parties that restrict access to health care cost and quality information (including PBMs, per Department of Labor guidance). Section 202 requires a "responsible plan fiduciary" (i.e., generally, the plan sponsor in its role as the ERISA administrator) to request, obtain and carefully analyze compensation disclosures from each covered Service Provider. This impacts the pharmacy plan in multiple ways: (1) by explicitly requiring benefits brokers and consultants to report any direct and indirect compensation they expect to receive from a PBM in connection with the plan, (2) by implicitly requiring the PBM to report any direct or indirect compensation it expects to pay a Covered Service Provider (e.g., broker, consultant) in connection with the plan and 3) by requiring the PBM to report all revenue streams received for its own services to the plan as a Covered Service Provider under the CAA.

1. Plan fiduciaries should insist on receiving a copy of their annual Section 204 reporting. In many cases, TPAs and PBMs are the reporting entities on behalf of the plan sponsor and are reporting aggregate book-of-business data, (as is legal, per CMS's guidance.) Plan fiduciaries should insist on receiving a copy of their plan-specific data. If obtained, plan fiduciaries could use or work with independent pharmacy consultants to use this information to drive better pharmacy benefit

decisions in the future. Even if not obtained, plan fiduciaries should demonstrate they have made reasonable efforts to access this information. This is an important step toward documenting fiduciary prudence.

2. Plan fiduciaries and non-ERISA plan sponsors covered by CAA should ensure their PBM contract does not contain any restriction on accessing cost or quality information regarding the plan's prescription drugs. To ensure this is the case, plan sponsors may want to consider working with a specialized PBM ERISA counselor and with a PBM consultant who is well-versed in PBM contracting.
3. Plan fiduciaries should scrutinize their benefit consultants' compensation disclosure for remuneration they expect to receive from the PBM, including but not limited to rebate-related compensation, per-script compensation, referral fees or contingent bonuses. Plan sponsors should be sure to query for "indirect" fees as well, those fees not directly related to their business but that flow from PBM to the consulting firm for other projects. If no PBM-related compensation is disclosed, plan fiduciaries should confirm in writing with their consultant that none exists. Documentation of this effort is an important step toward documenting fiduciary prudence.
4. Plan fiduciaries should affirmatively request full compensation disclosures from their PBM, as a "Covered Service provider" under CAA to the plan. If the PBM disagrees that they fall under the definition of a "Covered Service Provider" and therefore does not furnish a compensation disclosure, the plan fiduciary should document that the plan requested such information and that the PBM refused to disclose the information.¹ Documenting this effort, again, is an important step toward documenting fiduciary prudence.

1 As of writing this document, it is still somewhat ambiguous whether PBMs are considered "Covered Service Providers" under the CAA. All indications are that Congress intended for them to be classified as such originally (and clarifying legislation is expected). If PBMs are explicitly clarified to be Covered Service Providers, and the PBM fails (or refuses) to provide a compliant disclosure within 90 days of request, the plan sponsor would then be required to notify the Department of Labor of the PBM's failure to disclose and would need to consider whether to terminate the contract as an ERISA prohibited transaction "as expeditiously as possible, consistent with [the fiduciary] duty of prudence." (See ERISA § 408(b)(2) as modified by the CAA 2021).

Translation of Purchasing Standards into Sample Contract Language

The following sample contract language is a select set that aligns with the purchasing principles and standards that PBGH members agree are critical for a best-in-class pharmacy benefit that, assuring program transparency, excellent member experience and prudent vendor management. This proposed language is not intended to be comprehensive; contracts will include multiple other sections about confidentiality, indemnity, service requirements, pricing specificity, etc. Users of this information are urged to be diligent in ALL contract terms and consult with contracting and legal teams. As an example, although contractual confidentiality clauses are not illustrated in this language, it is important to ensure that confidentiality terms allow the plan sponsor to release confidential information, with appropriate protection, to legal, clinical and pharmacy benefit advisors.

The language offered here should be used only in consultation with your legal counsel. This language is intended to help protect plan sponsors against the manipulative business practices of PBMs that have plagued the industry causing unsustainable high costs for plan sponsors and their members. This proposed contract language by itself will not protect plan sponsors or plan fiduciaries. Plan sponsors, administrators and other managers with responsibilities for ERISA plan oversight are strongly encouraged to hire a specialized legal advisor with PBM contracting expertise. Not all ERISA attorneys are equipped to advise on PBM contracts. Assure you are working with an unbiased, non-conflicted expert with both PBM and legal expertise to protect your plan from unnecessarily high costs and potential liability exposure. Use this contracting language as a starting place for your discussions with trusted experts.

This proposed contract language is not intended to be comprehensive and has not been approved by an ERISA attorney. Please use the language as a discussion guide for your engagement with qualified legal consultation.

An Important Note about Drug Pricing

The language in this Purchasing Standards document suggests ideas to protect against “gotcha clauses” long in play by PBMs. One means used by PBMs to manipulate purchasers’ perception of their performance is the use of Average Wholesale Prices (AWP). Despite the name, these are not wholesale prices and particularly in the case of generic drugs, bear absolutely no rational relationship to wholesale or retail prices. However, AWP is the primary benchmark against which discounts are applied. Although that is a common business practice and somewhat assumed in this language as well, purchasers should be weary of the arbitrary and exploitable nature of the AWP benchmark.^{1,2}

In recent years, the National Average Drug Acquisition Cost (NADAC) has been considered an alternative pricing benchmark.³ NADAC is collected and reported by CMS based on voluntarily self-reported pharmacy data and although it might more accurately reflect prices paid by pharmacies for drugs and is a more transparent price point, it only covers about 70% of the drugs in the marketplace. Additionally, large pharmacy chains tend to not voluntarily report, which skews NADAC pricing higher. The benchmark is also not comprehensive in that it does not disclose dispensing or other fees. All that said, studies have observed a decrease in NADAC prices at the same time that AWP benchmarks have increased. The result is less meaningful discounting from AWP prices⁴ and general confusion for purchasers about optimal management of their pharmacy benefit manager relationship.

Note that the PBGH Purchasing Standards address common contracting ploys in play with conventional PBM contracts, which typically engage AWP benchmarks, but purchasers are encouraged to examine alternative pricing benchmark approaches.

1 [Average wholesale price for prescription drugs: is there a more appropriate pricing mechanism? - PubMed \(nih.gov\)](#)

2 [How PBMs distort and undermine specialty drug pricing guarantees — 46brooklyn Research](#)

3 [NADAC-plus: An emerging paradigm in pharmacy pricing? \(milliman.com\)](#)

4 [Capital Rx and 3 Axis Advisors Study Finds Potential for Billions in Prescription Drug Savings With Transparent Pricing Practices | Business Wire](#)

Standard 1

Why is this important?

When vendor revenues derived from a book of business are not transparent to the purchaser of services, costs are built into the price of the product or service. In the case of pharmacy benefit management, those costs are built into the price of medication that is partially incurred by the patient acquiring the drug and by all enrolled members through their premium contributions. The lack of transparency makes it impossible for plan sponsors to know the actual cost of drugs vs. the revenues to the PBM and makes it impossible for the plan sponsor to prudently evaluate and compare PBM performance for procurement purposes.

Standard	Objectives
Transparency that supports a clear understanding of drug cost, drug utilization and revenues paid by the plan to PBMs.	<ul style="list-style-type: none">• Enables a plan sponsor’s fiduciary committee to pay reasonable compensation for services to the plan and to otherwise act in the best interest of the plan and its beneficiaries.• Informs a plan sponsor about the nature and terms of all fees paid to or captured by a contracted PBM from all sources, current and future, so that that the plan sponsor can execute an informed procurement process and prudent ongoing vendor management.• Full transparency is mandatory to assure compliance with the contract such as 100% rebate pass-through, no rebate exclusions, no spread pricing and other terms are as contracted.

Sample contracting language to address transparency, rebate pass-through and elimination of spread pricing.

1. Rebate Pass-Through. PBM has entered or will enter into agreements, either directly or indirectly, with pharmaceutical manufacturers and/or rebate aggregators for rebates for which certain claims may be eligible. PBM will pass through 100% of Rebates to the Client pursuant to the terms of this agreement, the definitions included therein and any applicable statement of work.
 - 1.1 Only those claims for which the PBM or its Group Purchasing Organization (GPO) or its rebate aggregator is unable to collect Rebates will be excluded. This will include only those claims that are ineligible for Rebates.
 - 1.2 All medications, without exception, for which the PBM received a Rebate are included in this Pass-Through provision. This includes but is not limited to:
 - 1.2.1 Biosimilars
 - 1.2.2 Vaccines
 - 1.2.3 Diabetic supplies (e.g., strips, syringes)
 - 1.2.4 Exclusive and Limited Distribution Drugs
 - 1.2.5 Medical devices (e.g., glucose monitoring equipment)
 - 1.2.6 Dispensed-as-written (DAW 1, 2, 5, 9) drugs
 - 1.2.7 Multi-sourced brand
 - 1.2.8 Formulary exceptions
 - 1.2.9 HIV/Antiviral, PSK9s, Migraine meds

Standard 1

(cont.)

- 1.2.10 OTC drugs eligible for rebates
- 1.2.11 Drugs subjected to a co-pay penalty because a brand was dispensed
- 1.2.12 Drugs for which a co-pay coupon or patient assistance was accessed
- 1.2.13 Zero balance claims
- 1.2.14 Newly launched specialty drugs
- 1.2.15 Specialty drugs dispensed at retail
- 1.3 Rebates received by the PBM that are more than minimum guaranteed Rebate amounts will be passed through to the Client (in addition to the minimum guaranteed amounts).
- 1.4 All revenues received by PBM from the manufacturer or the Rebate Aggregator or a GPO shall be deemed a Rebate. All manufacturer revenue paid to a GPO or rebate aggregator shall be declared a Rebate.
- 1.5 Manufacturer credits shall NOT be considered Rebates, including but not limited to clinical program savings and cost share assistance or manufacturer coupons, for purposes of calculating actual Rebates against minimum guaranteed amounts.
- 1.6 All inflation cap Rebates are to be passed through to the Client in full but are NOT to be included in calculations of actual Rebates against minimum rebate guarantees.
- 1.7 There will be no conversions of any 30-day Specialty Drug prescription to a longer refill period, e.g., 60 or 90 days, unless the drug is exempted from this clause in writing as part of this contract and agreed to by the plan sponsor.
- 1.8 PBM agrees that in the case of a pharmaceutical manufacturer's, GPO's or rebate aggregator's failure to pay Rebates, Client will be informed. Further, PBM agrees that Client will be provided concurrent information about steps undertaken to correct the failure to pay. Further, PBM agrees they will not accept alternative offers from the pharmaceutical manufacturer, GPO or rebate aggregator to provide discounts or any other price concession in lieu of Rebates without the Client's written concurrence. Any such deviation from a Rebate agreement will be accompanied by a full rationale and accounting.
- 1.9 PBM's payment to Client for Rebates will be on a quarterly basis. PBM agrees to pay Client the Rebates received based on Client utilization within 60 days following the end of each calendar quarter in which such amounts are received. PBM will report, at that time, any additional Rebates anticipated following a final audit and validation of accuracy.

Standard 1

(cont.)

- 1.10 PBM's end-of-year annual reconciliation of Rebates pay-out will be provided within 60 days of year-end. It will include a full accounting of Rebates paid vs Rebates guaranteed.
 - 1.11 PBM is responsible for interest, late fees and offsets to the extent PBM does not promptly pay Rebates, guaranteed minimum Rebate amounts, coupon savings, pharmacy audit recoveries or any other amounts due to Client.
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2. Prohibition of "Spread" Pricing
 - 2.1 Claims adjudicated and paid by PBM on behalf of Client will be paid at the pharmacy-negotiated discounted rate, minus Member Cost Share, plus paid dispensing fees and will be reimbursed by Client to PBM at that exact paid amount. There will be no variation between the amount paid to the pharmacy and the amount reimbursed by the plan sponsor. Dispensing fees will be disclosed to the Client with other pricing information attached to this contract as an exhibit.
 - 2.2 From time to time, there may be fees assessed by the PBM to the pharmacy for missed quality metrics, pricing guarantees or other service fees. Those collected fees will be allocated to the Client based on the Client's proportion of the PBM's book of business with the pharmacy and will be reported as such on routine quarterly reporting. All DIR, GER and BER fees will be returned to the Client via direct Pass-Through based on the Client's prescription drug spend with the pharmacy.
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3. Reporting Requirements
 - 3.1 PBM shall prepare and provide Client with PBM's standard management and utilization reports as described in this contract. Non-standard management and utilization reports and ad hoc reports may be available with an agreed upon fee arrangement.
 - 3.2 PBM will issue routine Claims invoices and shall make available to Client a defined set of the Claims data associated with each invoice in PBM's standard format at no additional charge. Claims data will include total paid (split by plan paid and member paid) per drug.
 - 3.2.1 Claims data will also include, but is not limited to:
 - 3.2.1.1 Patient identifier
 - 3.2.1.2 Prescriber identifier
 - 3.2.1.3 Diagnosis
 - 3.2.1.4 Date of prescription

Standard 1

(cont.)

- 3.2.1.5 Generic, Brand, Multi-source brand indicator
- 3.2.1.6 Ingredient cost paid by plan
- 3.2.1.7 Zero Balance Due (ZBD) marker
- 3.2.1.8 Dispense as Written (DAW) marker
- 3.2.1.9 Limited Distribution Drug (LDD) marker
- 3.2.1.10 Co-pay penalty marker (where the brand is chosen over the generic)
- 3.2.1.11 Biosimilar marker
- 3.2.1.12 Specialty drug marker
- 3.2.1.13 Non-conformance to Medi-Span MONY codes marker
- 3.2.1.14 Newly launched drug marker
- 3.2.1.15 Specialty coupon applied marker
- 3.2.1.16 Formulary tier level
- 3.2.2 Summary claim reports will include the same, aggregated, for each drug classification.
- 3.2.3 Upon instruction by the Client, PBM will supply same or a Client-specified subset of same reporting to Client's designee subject to confidentiality and HIPAA protections.
- 3.3 Unless otherwise instructed by Client, PBM will submit an electronic reconciliation statement quarterly to Client that details minimum Rebate guaranteed amounts assigned to each Claim and Rebates actually paid for each claim.
 - 3.3.1 In the event a Claim is not eligible for a minimum Rebate guarantee, PBM shall provide exclusion rationale for each Claim within the reconciliation statement. Note that all Brand drugs will have a minimum rebate guaranteed unless it is expressly excluded from rebates and included here with rationale for exclusion provided.
 - 3.3.2 PBM will also provide actual and estimated Rebate revenue, as well as cumulative performance meeting Rebate Guarantees.
 - 3.3.3 Rebate reconciliations will include a breakdown that illustrates traditional Rebates vs. manufacturer administrative fees vs. Formulary placement fees and all manufacturer allocated revenues regardless of classification.

Standard 1

(cont.)

- 3.4 PBM will report to the Client the Client's share of the fees paid by pharmacies related to missed quality metrics, DIR, BER or GER fees or any other fees assessed by the PBM to the pharmacy or pharmacy network. The Client's share of the fees will be calculated by determining a ratio that is the total cost of drugs paid by the Client and Client's members at the pharmacy divided by the PBM's total spend (including plan sponsor and member spend) at the pharmacy. This ratio will be applied to the total fees recouped by the PBM from the pharmacy with the intention of remitting those captured fees to the Client.
- 3.5 For those Specialty drugs for which an excepted conversion from 30 days to 60 or 90 days was permitted, PBM will report the drug name and paid amount (including the plan sponsor paid and the member paid amounts).
- 3.6 PBM will report to the Client the following information on a semi-annual basis or as otherwise agreed upon by the Client.
 - 3.6.1 Top 25 drugs by total drug spend
 - 3.6.2 Top 25 drugs by utilization
 - 3.6.3 For each of the categories "3.6.1" and "3.6.2" above, PBM will report:
 - 3.6.3.1 Plan sponsor paid amount per drug
 - 3.6.3.2 Member paid amount per drug
 - 3.6.3.3 Received or anticipated Rebate revenue per drug
 - 3.6.4 PBM will report as outlined in "3.6.1", "3.6.2" and "3.6.3" above stratified by PBM-owned pharmacy vs. non-PBM-owned pharmacy if applicable

Standard 2

Why is this important?

There is evidence that conventional PBM contracting practices have not honored employer-sponsored plan intentions by manipulating definitions that optimize revenues for the PBM. This manipulation is not reasonable or in alignment with the spirit of the client/vendor relationship and is in direct conflict with the Client achieving more affordable drug pricing as a prudent fiduciary for its organization and its plan members.

Standard

Objectives

Clarity of definitions that are not manipulated to mislead plan sponsors and allow PBM profiteering.

Contracts should deploy clear, concise and consistent definitions to prohibit definition manipulation that provides opportunities for revenue streams to the PBM, such as varying definitions to suit the PBM's best interest, utilizing multiple price lists and applying misleading descriptions.

Sample contracting language to control contract manipulation by virtue of adjusting definitions to suit the PBM's best interest.

1. Pricing Benchmark
 - 1.1 PBM shall use Medi-Span Master Drug Database (Medi-Span) MONY indicators and their associated files in determining the classification of drugs (e.g., prescription vs. over the counter (OTC), Brand vs. Generic, single-source vs. multi-source) for purposes of this Agreement.
 - 1.2 PBM will not vary master drug database source for any purpose. Any use of any source other than Medi-Span must be agreed upon in writing by the Client.
 - 1.3 There is one and only one MAC price list used for paying pharmacies and for accountability to Client. The MAC List includes all drugs by NDC and one unit cost per drug by NDC. PBM will make available to Client its current MAC price list and will provide an updated list to Client as updates are registered.
 - 1.3.1 The Client may assign a delegate to receive the MAC price list and all MAC price list updates on the Client's behalf and the PBM agrees to provide such MAC price lists to the delegate providing that all relevant confidentiality assurances are made.
 - 1.4 PBM will make available to Client a distinct Specialty drug discount guarantee for both Brand and Generic Specialty drugs, which will be outlined in this contract. There will be NO drugs excluded from the calculation of that guarantee, including Limited Distribution Drugs and Biosimilars.

Standard 2

(cont.)

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2. Brand/Generic/Specialty Clarifications
 - 2.1 Any drug classified as a Brand drug will be so classified for any and all purposes addressed by this agreement regardless of where it is dispensed. Any Brand drug classified as a “house generic” or dispensed with a DAW 5 code will be priced as a Generic and any associated Rebate will be payable to the Client under the Rebate Pass-Through terms of this contract. DAW 9 conversions, either formally implemented or implemented by the PBM, are prohibited under this contract.
 - 2.2 Any drug classified as a Generic will be so classified for any and all purposes addressed by this agreement regardless of where it is dispensed.
 - 2.3 Any drug classified as a Specialty Drug will be so classified for any and all purposes addressed by this agreement and will be dispensed by a select set of Specialty Pharmacies as outlined in this contract, agreed upon by the Client.
 - 2.4 Any drug classified as a Biosimilar will be so classified for any and all purposes addressed by this agreement regardless of where it is dispensed.
 - 2.5 Any drug classified as a Limited Distribution Drug will be so classified for any and all purposes addressed by this agreement regardless of where it is dispensed.
 - 2.6 The consistency of classification as described in this section relates to, but is not limited to Rebate guarantees, discount guarantees, Generic dispensing rates, Brand effective rates, Generic effective rates.

Standard 3

Why is this important?

The role of Plan sponsors includes designing a pharmacy benefit program that best meets the clinical and financial needs of its covered population and also complies with the Fiduciary responsibilities of all self-insured Plan sponsors under the Employee Retirement Income Security Act of 1974 (ERISA) to act in the best interest of plan members. Fulfilling this role requires the Plan sponsor to have flexibility of program design and contract customization.

Standard

Objectives

Customization that allows plan sponsors to provide an excellent benefit optimizing clinical outcomes and cost effectiveness.

- Plan sponsors should be permitted to identify and implement best-in-class solutions within the PBM contract, e.g., specific drug or clinical care management carve out, formulary customization, pharmacy network adjustments and plan sponsor benefit design preferences without unreasonable financial consequence.
- Plan sponsors must determine audit rules in order to assure compliance with contractual terms.

Sample contracting language to support Plan sponsors' interest in program design and responsible fiduciary oversight by the self-insured Plan sponsor.

1. PBM services to be considered under the domain of this contract may include the following that are provided at the pleasure of the Client and may be “carved out” of this agreement in whole or in part.
 - 1.1 Pharmacy network
 - 1.2 Select drug or set of drugs
 - 1.3 Formulary development and related utilization management
 - 1.4 Clinical management
2. Pharmacy Network. PBM will establish a network of licensed pharmacies, which are independent contractors, to provide prescription drugs and related products and services to Members across the U.S. PBM will negotiate discounts with pharmacies on behalf of the Client in good faith and in the Client’s best interest.
 - 2.1 Retail pharmacies
 - 2.1.1 At no time will the PBM assess a Member Cost-Share contribution that is greater than the U&C or cash price or discounted ingredient cost of the drug and then “Clawback” the excess amount as revenue to the PBM.
 - 2.1.2 There will be no “Gag” Clauses in contracts with the pharmacies prohibiting pharmacists from disclosing information about lower cost therapeutic alternatives including over-the-counter options.
 - 2.1.3 Reimbursement to pharmacies will be equal to the amount billed to the client. There will be no “Spread Pricing” at any pharmacy.

Standard 3

(cont.)

- 2.1.4 When reporting claims information, including but not limited to plan sponsor and member drug costs per drug, PBM will stratify reporting by PBM-owned or affiliated pharmacies vs PBM non-owned or affiliated pharmacies.
- 2.2 Mail Order Pharmacy. Upon Client's request, PBM will provide Client a Mail Service program through which the Mail Service Pharmacy will fill prescriptions for members and will mail such prescriptions to members subject to the terms set forth in this agreement.
 - 2.2.1 The Client may request and the PBM may provide a mandatory mail order feature for specific ongoing prescriptions and under that circumstance, the PBM is guaranteeing mail order prices at least as low as retail prices.
- 2.3 Specialty Pharmacy. Upon Client's request, PBM will provide Client a Specialty Pharmaceuticals program which provides a distribution channel for certain Covered Products that are classified as "Specialty" according to the terms of this contract.
 - 2.3.1 A Specialty Drug List applicable at the signing of this contract will be included with the contract. Any amendments to the Specialty Drug List will be provided to the Client in writing at least 30 days prior to the change being effective. The Client may access, at any time, a Specialty Drug List.
 - 2.3.1.1 The Client may assign a delegate to receive the Specialty drug list and all Specialty drug list updates on the Client's behalf and the PBM agrees to provide such Specialty Drug lists to the delegate providing that all relevant confidentiality assurances are made.
 - 2.3.2 The Specialty Drug List will identify Brand vs. Generic, preferred vs. non-preferred and reference drug vs. Biosimilar.
 - 2.3.3 Any Specialty Drug excluded from coverage must be attached to this contract as an appendix.
 - 2.3.4 A list of Participating Pharmacies and Specialty Pharmacies will be made available to Client and will be available to members.
 - 2.3.5 When reporting claims information for Specialty Drugs, including but not limited to plan sponsor and member drug costs per drug, PBM will stratify reporting by PBM-owned or affiliated Specialty Pharmacies vs PBM non-owned or non-affiliated Specialty Pharmacies.

Standard 3

(cont.)

- 2.4 Client has the right to directly contract with pharmacies and include those pharmacies in the PBM network. PBM shall have no liability for the Client-contracted pharmacy but will adjudicate and pay claims in accordance with the Client contract. As is the case with PBM-contracted pharmacies, there will be no Spread, no Gag Clauses and no Clawbacks.
 - 2.5 Client has the right to request the addition of a pharmacy to the PBM pharmacy network and providing agreement can be reached between the PBM and the requested pharmacy, the pharmacy will be added to the PBM pharmacy network for use by, at the very least, plan members of the Client.
 - 2.5.1 If an agreement cannot be reached between the PBM and the requested pharmacy, the Client will be notified with an explanation about the discrepancy.
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3. The Client may elect to “carve-out” a specific drug or set of drugs to fall under the procurement and management of a third-party vendor.
 - 3.1 The PBM agrees to provide the Client with necessary data or insights to inform a drug carve-out decision.
 - 3.2 The Client will provide the PBM with advance notice of at least 60 days prior to a drug carve-out arrangement and the parties will negotiate any ASO fee adjustment associated with that change.
 - 3.3 The PBM will agree to fully cooperate with a vendor enlisted to procure and manage a Specialty Drug carve-out including the sharing of information for purposes of accumulating benefit cost share and the integration of said carve-out drug(s) into pharmacy utilization reporting.
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4. Formulary. PBM shall provide a recommended drug Formulary to Client. PBM attests that the PBM recommended Formulary prioritizes low net cost drugs and places low net cost drugs in lowest appropriate tier.
 - 4.1 The following Formulary rules will be implemented and cannot be amended without the explicit written consent of the Client.
 - 4.1.1 In the case of all drugs with an existing approved Generic, the Generic will be included in tier one of the formulary and the Brand will not be unless the PBM demonstrates to the Client that the Brand drug is low net cost and that the Client agrees to the exception.
 - 4.1.2 All FDA-approved Biosimilars will be preferred over their reference product.

Standard 3

(cont.)

- 4.1.3 In the case that multiple versions of the same Generic or Biosimilar is available for a Brand or reference product, the least expensive Biosimilar will be placed in a lower cost sharing tier. Specifically, this clause applies immediately to drugs including but not limited to Semglee and Amgevita.
- 4.2 Client may make recommendations to amend Formulary and PBM will respond with data outlining the impact of that Formulary change based on transparent assumptions about utilization and cost. Upon client request, PBM will implement Client's requested change.
- 4.3 Client may adjust PBM's categorization of a drug from Specialty to Brand or Generic. Client has the authority to designate how drugs are classified for purposes of discount and Rebate guarantees. The manner in which drugs are classified will stay consistent for all purposes unless otherwise agreed to, in writing, by the Client.
- 4.4 PBM will make sound and data-based recommendations to Client to support a value-based benefit design that supports adherence to high value drugs for chronic condition management.
- 4.5 PBM may make Formulary adjustments from time to time. All PBM-driven Formulary adjustments will be discussed with Client at least 90 days prior to implementation including the sharing of member-facing communication materials. Client will be provided with a full rationale for the adjustment including clinical explanation, cost assumptions and population impact. Client may accept or reject Formulary adjustment and/or may elect to "grandfather" the change for existing utilizers of the drug in question.
- 4.6 The PBM will consult with the Client or the Client's clinical advisor on Client's behalf, about certain Formulary decisions, e.g., coverage of OTC, "lifestyle" and certain compound medications. The ultimate Formulary coverage decisions will be made by the Client.

Standard 3

(cont.)

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5. Clinical services.
 - 5.1 Prior Authorization (including Step therapy). At Client's request, PBM will provide Prior authorization ("PA") services for drugs designated at the time of implementation of its Plan(s) and, upon reasonable notice, in accordance with any subsequent written instructions of Client. In determining whether to authorize coverage of such drug under the Prior Authorization program, PBM will apply only the pre-determined guidelines mutually agreed by the Parties (the "Guidelines"), reviewing all patient information (including discussion with the prescriber), clinical indications approved by the FDA and all other preconditions for safe and effective treatment. PBM and/or Client may rely upon protocols established and maintained by a Pharmacy and Therapeutics Committee and subsequently a Business Committee and/or other external clinical experts, based upon factors such as safety, availability, potential for misuse and cost. Client acknowledges that PBM may suspend processing of claims for Covered Products subject to Prior Authorization in the event (i) The PBM has promptly requested specific information in writing from the practitioners and (ii) the practitioner fails to provide the requested information, which is necessary for the proper processing of such claims.
 - 5.1.1 PBM agrees that denials and corresponding rationale will be directly communicated to the member and preserved for retrospective audit.
 - 5.1.2 Prior Authorization services may be carved out to a third-party vendor that specializes in that service for all drugs or for some select portion of drugs.
 - 5.1.3 Prior Authorization may allow for only a 15-day or 30-day fill with select drugs when clinical prudence requires a check-in with the patient to assure the drug is effective and/or side effects are not impacting adherence.
 - 5.2 Drug Utilization Review. PBM will perform standard concurrent and retrospective drug utilization services, including review of prescribing, dispensing and use of prescription medications reflected in the Claims.
 - 5.2.1 Drug utilization review may be carved out to a vendor that specializes in that service for all drugs or for some select portion of drugs.

Standard 3

(cont.)

- 5.3 Alternative Treatments. Client agrees that PBM may contact plan members to provide refill reminders or information about treatment alternatives, including, but not limited to, Brand and Generic Covered Products or other health-related benefits and services that may be of interest to such members.
 - 5.3.1 All outreach campaigns and other routine outreach will be approved by the Client in writing in advance of the communication. PBM will provide information about the manner and degree to which the communication proposed represents cost savings or improved clinical outcomes for plan participants.
 - 5.3.2 Any such contact, after approved by the plan sponsor, will include live interaction whenever possible that outlines clinical and financial benefit to the patient. Any such contact will also include an opportunity for the patient to request additional information.
 - 5.3.3 PBM agrees that for specific drugs of a clinically involved nature, outreach may be more successful coming from the patient's provider and PBM will use its best clinical and historically informed judgment to engage providers as appropriate.
 - 5.3.4 PBM agrees that Client may review this and any pre-planned member communications including scripts, written materials or electronic communications.
- 5.4 Generic Substitutions. PBM shall be required to cover Generics substituted for Brands where permitted under applicable law and where clinically appropriate, unless Prescriber requires the prescription to be Dispensed as Written (DAW 1).
- 5.5 Other Clinical Programs. PBM will make available to Client PBM's standard clinical programs, which services will be delivered only upon Client's written request, in accordance with PBM's terms and conditions for the applicable services as the same may be modified from time to time by PBM.
 - 5.5.1 Descriptions of PBM standard clinical programs and amendments to those programs will be made available to Client and/or Client's delegate provided appropriate confidentiality considerations have been made.
 - 5.5.2 Any additional clinical programming with additional charges assessed will be clearly delineated including associated fees and payment terms and must be agreed to in writing by the Client.

Standard 3

(cont.)

- 5.6 Reporting. PBM will routinely report to client information about number of Prior Authorization and utilization management queries that includes approvals, denials, incomplete PAs and Appeals information.
 - 5.6.1 A PA inquiry initiated but not completed does NOT constitute a denial and should not be reported as such. All reported denials will include, but is not limited to, the following information:
 - 5.6.1.1 Date of prescription
 - 5.6.1.2 Date of PA request
 - 5.6.1.3 Date of Denial
 - 5.6.1.4 Prescriber
 - 5.6.1.5 Drug or service queried
 - 5.6.1.6 Reason for denial

- 6. Benefit Design Preferences of the Client will be enabled via the PBM's claims payment and adjudication technology.
 - 6.1 Implementation Services. Prior to commencement of any Plan year, PBM will configure the Plan(s) in the adjudication platform to enable PBM to deliver the Services in accordance with the Client's wishes and such implementation will be in accordance with the Benefit Requirement Documents completed during the discovery process and approved by Client prior to such Implementation.
 - 6.2 Verification Eligibility. PBM will verify members throughout the plan year based on the eligibility file provided by Client or its designee. Specifications for the provision of such information will be agreed upon in advance but will not be less frequent than monthly.
 - 6.3 Claims Management and Processing. PBM will perform electronic claims processing for products dispensed by Participating Pharmacies with dates of fill on or after the go live date, through and including claims with dates of fill up to and including the termination of this agreement.
 - 6.4 PBM shall not have discretionary authority to deviate from the plan, the summary plan document or any Benefit Requirements Document that has been formally adopted by the Client and provided to the PBM.

Standard 3

(cont.)

- 6.5 Coordination of Benefits. If Client or member notifies PBM that a member has a primary insurer other than the plan, then PBM will pay claims for such member as a secondary payor rather than as a primary payor.
 - 6.5.1 PBM will recommend best practices for establishing coordination of benefits filing order for subsequent coverages, the ultimate decision for which will be that of the Client.
 - 6.5.2 PBM will coordinate benefits with other third parties in the case of workers' compensation and subrogation.
 - 6.5.2.1 Activities related to coordination of benefits will be reported to Client.
- 6.6 Direct Member Reimbursement. Upon request, PBM will provide a member with an approved claim form that can be used when submitting a claim for reimbursement for Covered Products provided by a Participating Pharmacy. When such a claim is submitted, PBM will process the claim according to the Benefit Requirement Document.
 - 6.6.1 The decision to allow coverage at a Non-Participating Pharmacy will be that of the Client and will be documented in the Benefit Requirements Document. In the case that coverage is permitted at Non-Participating Pharmacies, all terms of this contract that apply to Participating Pharmacies will apply to covered Non-Participating Pharmacies under agreements outlined in the Benefit Requirements Document. This includes but is not limited to Clawbacks and Spread pricing.
- 6.7 Collection of Deductible, Co-payment or Coinsurance by Pharmacies. PBM will contractually require Participating Pharmacies to collect from members or their representative the amount of any applicable Member Cost Share. PBM also will contractually require Participating Pharmacies to agree not to recover from members any unpaid balances due from PBM and/or the plan.
 - 6.7.1 Upon request of the Client, PBM agrees to facilitate the pharmacy's administration of Members' Cost Share in alignment with Client's adopted benefit designs including but not limited to Point-of-Sale rebate programs, OTC coverage policies and coupon accumulator or maximizer programs. Such terms will be outlined in the Benefit Requirements Document.

Standard 3

(cont.)

- 6.7.2 PBM will assist Client in benefit design-related decisions by providing data in accordance with this contract and as requested by the Client.
 - 6.8 Participating Pharmacy may, but shall not be obligated to, dispense a prescription even if the prescription is not accompanied by a Member Cost Share that is allocated to the transaction according to the Client's benefit design.
 - 6.9 PBM or Participating Pharmacy will credit any amount submitted by member in excess of the member contribution to the Client with full accounting enabling monies' return to the member.
 - 6.10 In the event a member submits to PBM or Participating Pharmacy an insufficient Member Cost Share and the member fails to remit the balance of the Member Cost Share amount to PBM or Participating Pharmacy within thirty (30) days of PBM's request, then PBM or Participating Pharmacy shall have the right to invoice Client for and Client shall have an obligation to pay PBM or Participating Pharmacy, the amount of the uncollected member contribution.
 - 6.10.1 In such an event, the Client will receive all necessary information to contact the member and initiate collection processes on behalf of the plan.
 - 6.10.2 Routine reporting about pharmacy-specific uncollected cost share will be included in quarterly reporting and if deemed unreasonable by the Client, the pharmacy will be notified that uncollected cost share will no longer be covered by the Client. This term applies to all retail, mail-order and Specialty Pharmacies.
 - 6.10.3 In the event that the insufficient Member Cost Share is due to miscalculation or other error made by the PBM or the pharmacy, the responsibility of the Client to make the PBM or the pharmacy whole is not applicable.
-
7. Audit Rights. The Client shall have the audit rights set forth in this Section in addition to the Client's right to receive the pricing reconciliation, rebate reconciliation, claim files and other reports set forth elsewhere in this agreement.

Standard 3

(cont.)

- 7.1 The Client may select any qualified, independent third-party auditor to conduct a claims audit and/or rebate audit for any open contract year. An audit may not be commissioned for any open contract year which ended more than three years prior to the formal notice of the audit being provided to the PBM. For example, formal notice of an audit of the 2019 contract year must be provided to the PBM by December 31, 2022. The foregoing time limit shall not apply to specific topics if material PBM underperformance is identified by an auditor for an open year which may have occurred in a closed contract year.
 - 7.1.1 Any PBM objection to the auditor selected by the Client must be accompanied by written evidence of a lack of qualification or lack of independence of said auditor. PBM must accept the auditor if Client is not provided such evidence.
- 7.2 Auditor shall be entitled to all agreements with pharmaceutical manufacturers, affiliated GPOs, rebate aggregators, Participating Pharmacies or other providers of products or services to PBM as part of a Claims or rebate Audit as permitted by law.
 - 7.2.1 In accordance with the Consolidated Appropriations Act of 2021, Section 201, all new contracts between PBM and vendors, pharmaceutical companies, pharmaceutical manufacturers, rebate aggregators, Participating Pharmacies or other providers of products or services to PBM shall include no “Gag Clauses” prohibiting the sharing of information with PBM clients provided appropriate confidentiality clauses are in place.
- 7.3 Notwithstanding the foregoing, PBM agrees to promptly provide all of the following items to the third-party auditor retained by Client at the commencement of the claims or rebate audit.
 - 7.3.1 Reports, data, analyses or other information provided by PBM that demonstrates the Pass-Through of Rebates and Rebate Program Fees to the Client; and
 - 7.3.2 Reports, data, analysis or other information provided by PBM that demonstrates there are no unreported revenues received by pharmaceutical manufacturers, either directly associated with the Client’s drug utilization or indirectly paid to PBM for any other type of service.

Standard 3

(cont.)

- 7.3.3 Documentation as necessary to assure that payment recouped from the Client is equal to payment made to pharmacies ensuring the absence of Spread pricing. This might include HIPAA Forms 835 or other similar documentation.
- 7.3.4 All claims files arising from PBM's service of plan necessary to ensure that PBM is complying with the terms of this Agreement.
- 7.3.5 Documentation outlining the prompting event for Prior Authorization with details of the process including all communications with the member, providers or pharmacies and including approval, denial and appeal statistics.
- 7.3.6 The outlined auditable information shall be made available provided, (a) such third party auditor shall not be entitled to report any information to Client other than pursuant to a written report; (b) the written report provided by such third party auditor to Client shall be provided to PBM not less than five (5) business days after it is delivered in any form to Client and PBM shall have five (5) business days to present additional information to such third party auditor should PBM reasonably believe that the information set forth in the report is inaccurate, incomplete or misleading, and (c) Client agrees that it shall agree to reasonable confidentiality measures requested by PBM, including any measures that would prevent disclosure of Rebates or pharmacy rates publicly or to any party other than the third party auditor (unless required by law).
- 7.3.7 A Client request for a routine claims audit of PBM will be directed to the Client's account manager either in writing on Client's letterhead or by e-mail. Claims audits require forty-five (45) days prior written notice, including receipt of fully executed confidentiality, detailed audit scope document and a complete claims sample, if applicable.
 - 7.3.7.1 An audit catalyzed by substantially sized identified errors in claims processing or claims adjudication by the PBM may be conducted with seven (7) days' notice.

Standard 3

(cont.)

- 7.3.8 Upon PBM's receipt of a request for a claims audit, PBM or auditor will organize and conduct an initial teleconference between Client, Client's retained third party auditor and PBM. This teleconference will include, but is not limited to: (a) individual audit participants, (b) requirement and purpose of an approved confidentiality agreement (for use with outside audit firms), (c) onsite requirements, (d) mutually established timelines, (e) prescription copies (if there are specific inquiries), (f) guidelines for acceptable verification of audit questions, (g) PBM's right to respond within a reasonable time after questions arise (h) execution of an audit process confirmation letter, (i) any Client input and (j) other appropriate issues.
- 7.3.9 Client, Client's retained third party auditor and PBM will mutually agree upon an audit timeline, taking into consideration individual circumstances and constraints. Upon finalization of audit results and agreement between Client and PBM on any identified financial discrepancies, the audit period under review will be closed. Any adjustments, payments and/or reimbursements determined to be necessary as a result of any examination or audit shall be paid by the appropriate party within forty-five (45) days of execution of an appropriate release document covering the audit period.
- 7.3.10 Client shall be responsible for all expenses of the claims audit unless the audit reveals discrepancies greater than five percent (5%) of the net amount owed between the parties, in which case the PBM will pay for the audit in addition to reimbursement of the identified shortfalls.
- 7.3.10.1 The PBM will be accountable for any and all attorney fees incurred by the Client to recover underperformance amounts identified by the auditor but not voluntarily paid by the PBM to the Client without reasonable justification.
- 7.3.10.2 If the auditor or subsequent investigation resulting from aforementioned litigation uncovers evidence of intentional PBM negligence, malintent or concealment of material information to assist the audit process, the PBM will be held accountable for damages to the Client (including attorney fees) and to the plan members.

Standard 4

Why is this important?

PBMs play an important role in not only effectively administering a pharmacy benefit but in the enrolled members' perspective of that benefit's value. As the industry insider, the PBM should align its practices with the Client's best interest and advise the Client accordingly using data and historical context for insight.

Standard

Objectives

Client and Member-centric customer and account management that prioritizes member clinical outcomes, financial well-being and member satisfaction and that supports plan sponsors with trustworthy strategic guidance.

- PBMs should act solely as a service organization that has Member experience as a priority.
- PBMs should act in good faith to align their incentives with those of plan sponsors and to serve in the best interest of the Client in exchange for a fair and transparent fee.
- PBMs should provide consultative services accessing data as necessary to advise the client of best practices and high-quality outcomes.
- PBMs should strive to continuously innovate and disrupt the status quo in order to drive a higher functioning and higher value pharmacy benefit for the Plan and its Members.

Sample contracting language to document expectation that the PBM acts as an aligned partner, providing expert strategic insights and transparent operations as well as outstanding customer and member service.

1. Any revenue, including commissions, brokerage fees, referral fees, co-management fees or any other fees or monies of any categorization that pass from the PBM to an advisor working on behalf of Client will be disclosed to Client. There is no exception. PBM will also disclose all payments to the Client's benefit consultants or other advisors, including the purpose for those payments, even if those payments are not directly related to the Client's contract.
2. Account Management. PBM shall provide account management services to Client, which shall include a designated account management team that shall serve as a liaison to ensure continuity of PBM Services.
 - 2.1 The team will include, at minimum, one operational manager to address day-to-day tactical matters and one strategic advisor to consult on new solutions and approaches for more effective pharmacy benefit management.
 - 2.2 The account team is responsible for assuring that all routine and ad hoc reporting agreed to in this contract and elsewhere are provided in a timely fashion. This includes, but is not limited to:
 - 2.2.1 Formulary updates
 - 2.2.2 MAC list changes
 - 2.2.3 PA Drug list
 - 2.2.4 Specialty drug list

Standard 4

(cont.)

- 2.2.5 Non-covered drug list
- 2.2.6 New drug launches and upcoming pipelines
- 2.2.7 Pharmacy network lists and changes

-
- 3. Customer Service and Communications.
 - 3.1 PBM shall provide a toll-free customer service line twenty-four (24) hours a day, seven (7) days a week for the purpose of responding to inquiries from members through PBM's call centers.
 - 3.2 PBM will provide a web portal and a member app where members can access information about drug type, drug interactions and drug costs.
 - 3.3 PBM will provide communications to members and Client regarding drug recalls or withdrawals.
 - 3.4 As requested and approved by Client, PBM shall provide member-facing communications, including welcome kits, member ID cards and member letter fulfillment services. The prices for member communications will be established as part of this agreement.
 - 3.5 Client shall review and approve any member communications planned in advance, including scripts, written materials and electronic communications.
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- 4. Performance Guarantees and Remedies will be negotiated and will include money-back guarantees. Two categories of guarantees: 1) administrative and 2) performance will be outlined as exhibits to this contract and might include but are not limited to:
 - 4.1 Rebate guarantees for both Brand and Specialty categories
 - 4.2 Discount guarantees
 - 4.3 Member satisfaction (NPS)
 - 4.4 Service guarantees, e.g., resolved appeals
 - 4.5 Member medication adherence
-
- 5. Pricing. Client agrees to pay PBM for Covered Product claims in accordance with the prescription pricing schedule set forth in this agreement and administrative service fees as outlined in this agreement.
 - 5.1 Administrative service fees are inclusive of all outlined services.

Standard 4

(cont.)

- 5.2 If additional services are requested, service fees will be proposed and agreed upon prior to initiation of the service unless the Client requests otherwise.
- 5.3 At no time will the PBM receive revenues from any aspects of the Client's plan administration that are not transparently reported to the Client. There will be NO service fees recouped from the drug claim expense.
- 5.4 Retained Rebates are not allowed and are not considered administrative service fees under any circumstance. All administrative services will be explicitly and transparently outlined in the statement of work or service agreement.

Definitions for Use in a PBM Contract

This is NOT a comprehensive list of terms that must be defined in a PBM contract, nor are these definitions to be considered adequately robust. Please use them as a guide for discussions with aligned and expert PBM legal counsel or specialized consultants.

Average Wholesale Price or **AWP** means the average wholesale price of a prescription drug from the most current published pricing information provided to PBM by Medi-Span Prescription Pricing Guide (with supplements). PBM will use a single data reporting source for determining Client's AWP pricing. The AWP pricing for all Claims is based on the 11-digit National Drug Code ("NDC") as of the date of service, as reported and is verifiable by the Medi-Span national pricing source. It will be the AWP of the package size used for the fulfillment of the drug dispensed.

Benefit Requirement Document means the benefit control document, hierarchy structure and clinical requirement documents mutually agreed by the Parties that sets forth the design of the Plan(s), including co-payments, deductibles, maximum limits, formulary, clinical programs and other administrative support functions, for purposes of the configuration of the Plan(s) in the adjudication platform. The Benefit Requirement Document shall include a description of Client's Plan related to pharmacy benefits and limitations thereto, including the framework of policies, interpretations, rules, practices and procedures applicable to such benefits. The Benefit Requirement Document is the one and only source of information for how the PBM will manage the plan and can only be amended by Client written approval.

Brand Covered Product or **Brand** shall be defined as all drugs and supplies that meet all of the following criteria: (i) Medi-Span Multi-Source Code of "M", "N" or "O" and (ii) DAW Code that is not 2, 3, 4, 5 or 6. In limited

cases, not all NDCs will meet the outlined criteria and Client may overriding the Medi-Span indicator based upon additional attributes provided; provided however that this override of the Medi-Span indicators will only occur when it is more beneficial to both the Client and the Member for all financial aspects of the Agreement. For avoidance of doubt, Brand Drugs include, but are not limited to vaccines, supplies, medical devices, kits, diabetic supplies, OTCs and test strips. Unless explicitly agreed to in writing by client, once a product has been deemed a Brand Drug, it must be considered a Brand Drug for the purposes of all financial measurements including, but not limited to, AWP discounts, dispensing fees and rebate sharing arrangements.

Biosimilar means a biologic product that is approved based on demonstrating that it is highly similar to an FDA-approved biologic product, known as a reference product and has no clinically meaningful differences in terms of safety and effectiveness from the reference product.

Clawbacks are monies recouped by the PBM when the member's allocated cost share is greater than the U&C, cash price or negotiated price of a drug, whichever is lower. Claw backs are not allowed in this contract.

Covered Products means a drug which is covered under the Benefit Requirement Documents adopted by the Client. A Covered drug might include OTC medicines that do not require a prescription if the Client requests coverage of select OTC drugs. Unless approved by the Client Covered OTC drugs will be delineated in the Benefit Requirement Document approved by the Client.

Definitions for Use in a PBM Contract (cont.)

Deductible means a predetermined amount of money that a Member must pay before benefits are eligible for payment as indicated in Client's Benefit Requirement Document. The deductible applies to each Member each contract year unless otherwise outlined in the Client's Benefit Requirement Document.

Dispense as Written (DAW) are codes ranging from 0-9 that explain if and why a drug dispensed was different from a drug prescribed. DAW 0, for instance, indicates that a generic was substituted for a brand.

Formulary or **Formularies** means the list of FDA-approved Covered Products developed by PBM's or its designee's Pharmacy and Therapeutics Committee or the Client's designated Pharmacy and Therapeutics Committee. A pharmaceutical product's inclusion on the formulary is ultimately the decision of the Client with clinical and financial counsel provided by the PBM.

Gag Clauses include any contractual obligation involving the PBM, i.e., with pharmaceutical manufacturers, pharmacies or any other parties, that prohibits the protected sharing of information with the Client or on the Client's behalf. There will be no gag clauses in PBM's contracts with pharmacies. Any gag clauses in PBM contracts with pharmaceutical manufacturers are voided as the Consolidated Appropriations Act requires.

Generic Covered Product or **Generic** shall include any drug, vaccine, supply, medical device, kit, diabetic supply, OTC supply and/or test strips identified as generic, using the Medi-Span Master Drug Database (Medi-Span) "Y" code from the MONY indicators and other associated files. Generic drugs include all single source generics, branded generics, DAW 5 house generics, non-MAC generics, generics in patent litigation and all authorized generics. A drug classified as "generic" for one portion of the contract will be classified for the entirety of the contract unless the Client agrees otherwise with justification provided by the PBM.

Limited Distribution Drug (LDD) means Specialty medications that are only available through certain identified pharmacies. They are usually expensive and treat complex or rare medical conditions. They require special handling, administration or monitoring. Manufacturers restrict distribution to a few specialty pharmacies based on product needs and commercialization strategy.

Mail Service Pharmacy means a pharmacy licensed as a mail order pharmacy where prescriptions are filled and delivered to Members via the United States Postal Service, United Parcel Service or other delivery service and which has entered into an agreement to dispense Covered Products.

Maximum Allowable Cost ("MAC") means the maximum allowable cost for Generic Drugs and Brand Drugs that have generic versions available. The MAC list is established by PBM, which list may be amended from time to time by PBM. Current MAC lists, with changes noted, must be supplied to the Client within 24 hours of any amendment. The MAC list is used for all pharmacies, including PBM-owned or affiliated pharmacies and mail-order pharmacies. There will NOT be different MAC lists for owned/affiliated vs non-owned/affiliated pharmacies. For any Covered Drug, the MAC list that is used as the cost owed by the Client under this Agreement shall be the same MAC list that is used to reimburse the pharmacy that dispenses the Covered Drug.

Member Cost Share means the amount which a Member is required to pay for a prescription in accordance with the Benefit Requirement Documents, which may be a Deductible, a percentage of the prescription price, a fixed amount and/or other charge or penalty.

Definitions for Use in a PBM Contract (cont.)

Non-Participating Pharmacy means a pharmacy that does not have an agreement with PBM to dispense Covered Products. Coverage of said products will be the discretion of the Client and outlined as such in the Benefit Requirement Document.

Participating Pharmacy means a retail, mail or specialty pharmacy that is licensed as such and that participates in a contracted network established, directly or indirectly, by PBM, or that has entered into a direct contract with the Client. All PBM-owned or affiliated pharmacies that are eligible for member use are also considered Participating Pharmacies for all reasons including but not limited to prohibition of spread, prohibition of gag clauses and prohibition of claw backs.

Pass-Through means that all Claims are invoiced to Client at the net amount PBM pays the Participating Pharmacy for such Claims and Rebates are provided to Client as received and PBM does not retain any Rebates or any other direct financial benefits from drug manufacturers or pharmacies and pays all such amounts to Client, unless otherwise set forth in a Statement of Work.

Point-of-Sale Rebates means a benefit design that can be implemented by request of the Client and that adjusts the cost of the drug by applying the rebate at the point of sale. In this case, the member's cost share is applied to the more accurate cost of the drug after applying expected rebates. The proportion of the rebate applied to the Client portion of the drug cost will be provided to the Client as part of the pass-through agreement. The rebate applied at point of sale will be as close to 100% as possible recognizing that there might be retrospective reconciliation.

Prior Authorization means a prospective review to verify that certain criteria required by Client are satisfied for specific Covered Products prior to processing the claim for such Covered Products.

Rebates means any and all payments including fees, charges or other forms of monetary payment paid by a pharmaceutical manufacturer or received from a rebate aggregator and collected by PBM or its designee, including GPOs, on behalf of the Client or on behalf of the PBM's Book of business to which the Client contributed, in compliance with the Client' Drug utilization, which shall include, but not be limited to, Rebate Program Fees.

Rebates or credits by any other name, including but not limited to those payable under the auspice of an inflation cap guarantee, manufacturer co-pay credit and patient assistance program should be reported but are NOT to be attributed to a rebate guarantee.

Rebate Program Fees means any fees, expense reimbursement or other forms of compensation passed on to PBM by the pharmaceutical manufacturer or rebate aggregator or captured by a GPO. This includes but is not limited to retroactively paid fees based on drug utilization and fees that are not specific to the Client's business but might be "book of business" rebates paid to the PBM.

Specialty Drug means those biotech Products identified as specialty pharmaceuticals from time to time. A list of Specialty Drugs will be provided to the Client with updates provides as they occur. Any pharmaceutical product defined as specialty for one part of the contract is so defined throughout the contract.

Specialty Drug List means those specialty pharmaceuticals that are Covered Products identified as specialty pharmaceuticals consistently throughout the agreement. A current specialty drug list may be obtained at any time by contacting PBM and will be made available to the Client, with changes noted, whenever the list is amended. Clients who elect to customize a formulary have input into the specialty drug list, including the Brand vs. Generic categorization of Specialty drugs.

Definitions for Use in a PBM Contract (cont.)

Specialty Pharmacy means a pharmacy that has entered into an agreement with PBM or directly with the Client to dispense Covered Products Including Specialty Drugs to Members.

Spread is any difference between the price the plan pays for the drug and the price the PBM pays to the pharmacy for the drug. Spread does not include dispensing fees paid by the PBM to the pharmacy as agreed to in Client's contract with the PBM. PBMs are prohibited from engaging in spreads. Spread includes any fees assessed to the pharmacy or the pharmacy network by the PBM and paid to the PBM by the pharmacy or pharmacy network. Such fees will be treated as spread and credited to the Client in alignment with the Client's book of business spend with the pharmacy as a proportion of the PBM's book of business spend with the pharmacy.

Usual and Customary Price or **U&C** means the retail price charged by a Participating Pharmacy for a particular drug in a cash transaction on the date the drug is dispensed as reported by the Participating Pharmacy.

Wholesaler Acquisition Cost or **WAC** means the wholesale acquisition cost pricing data for a given pharmaceutical product on a given day, as published by Medi-Span database.

Zero Balance Due (ZBD) Claims are those pharmacy claims where the member cost share (co-pay) pays the full cost of the prescription drug claim and the plan sponsor is billed \$0.

How Plan Sponsors Can Use the PBGH Purchasing Standards for PBM Contracting

Plan sponsors should consider their alignment with the principles agreed upon by PBGH Member participants of the 2023 PBM work group. Assuming concurrence, this document provides a useful tool for PBM and advisor management.

- Discuss these terms with your ERISA counsel. PBM contracting is a specialized area and your ERISA counsel might not be familiar with some of these terms. If that's the case, consider hiring a specialized PBM ERISA attorney who has expertise in PBM contracting and who is willing to partner with your ERISA counsel. Non-ERISA plans also have responsibilities to members and other constituents for prudent vendor management supporting cost-effective and high-quality health care.
- Ask your advisor/consultant to review the document and attest to their alignment. Use this opportunity to discuss with them the prevalence of information about misaligned incentives for consultants and ask them to report any direct or indirect fees they receive from various PBMs. This is required reporting under the Consolidated Appropriations Act.
- Ask your PBM to review these proposed contracting terms and report to you their concurrence. Ask them to discuss their rationale for any of the terms they don't accept. Ask them what alternative assurance they can offer to assure you're protected against conventional misaligned PBM contracting.
- Always reconcile what was agreed upon with actual experience.
 - If your PBM estimates Rebates of \$1M and you use that estimate to make your procurement decision, be sure to reconcile that the actual experience matches what was promised.
 - If your PBM estimates that an additional 5% will be returned to you via Rebates following run-out reconciliation, be sure to reconcile that you received those payments and do NOT check the performance guarantee box for your Rebate guarantee until you do.
- Take your role as the purchaser of services and as a fiduciary seriously. As the former, you and your peers are shaping the marketplace, which will respond to what you are willing to purchase. As the latter, the stakes are steep and getting steeper when due diligence for transparency, member experience and vendor management are not adequately addressed.

Author

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For more information about PBM procurement, contracting and/or management or for information about PBGH and the value proposition for health care purchasers, please direct all inquiries to info@pbgh.org.

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Lauren Vela, MBA is an independent consultant to multiple stakeholders invested in using market and policy solutions to bring higher quality and value to employer sponsored insurance programs. Lauren has spent many years working with large, self-insured purchasers in her tenure with Purchaser Business Group on Health and as Executive Director of the Silicon Valley Employers Forum. Lauren was also directly employed by Walmart as a member of the Benefits team where she focused on value and innovation in Benefit design delivery. Lauren can be reached on [LinkedIn](#).

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