



NAUTILUS HEALTH INSTITUTE · RESOURCE

# PBM Model Contract Clauses

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# How to Use This Document

This document provides the complete reference for all 28 Nautilus Model Contract Provisions. It is the authoritative source for provision text, fiduciary rationale, and drafting guidance.

Section I (Provisions #1-10) defines the basis for fiduciary alignment and transparency in PBM contracting. These provisions form the basis of the Contract Compliance RFI, the Contract X-Ray scoring framework, and the PBM Validation and Differentiation process. Where a PBM contract does not meet the standard defined by the model language, plan sponsors have a decision: accept the gap with documentation of the rationale, negotiate to close the gap, or treat the gap as a basis for disqualification.

Section II (Provisions #11-28) extends core protections into operational areas organized into four categories: Operational Safeguards, Clinical Governance, Financial Protections, and Transition Safeguards.

Each provision leads with Model Contract Language and, for the Top 10, an Attestation Question formatted as a binary Y/N test. Following the contract language, each provision includes the Fiduciary Rationale and Drafting Tips for context and implementation guidance.

## SECTION I

# Core Fiduciary Alignment Standards

Provisions #1-10 define the basis for fiduciary alignment and transparency in PBM contracting. Where a contract falls short of the model language, plan sponsors have three options: accept the gap (with documented rationale), negotiate to close it, or treat it as a basis for disqualification.

## #1 Fiduciary Loyalty Commitment

### Model Contract Language

*PBM acknowledges Plan Sponsor serves as a fiduciary under ERISA and related laws. In performing services under this Agreement, PBM shall act in a manner consistent with duties of loyalty, prudence, and diligence.*

*PBM shall act solely in the interest of plan participants and beneficiaries and shall not place its own financial interests, or those of affiliates or subcontractors, ahead of the interests of the Plan or its participants.*

### Attestation Question

Do you agree to perform all services for the Plan in a manner consistent with fiduciary duties of loyalty, prudence, and diligence, solely in the interest of Plan participants and beneficiaries?

### Fiduciary Rationale

Plan sponsors are fiduciaries under ERISA. Every PBM service either supports or undermines these duties. Without an explicit fiduciary alignment commitment, the PBM has no contractual obligation to prioritize participant interests over its own. This provision is the anchor for the entire contract relationship.

Emerging state laws (California SB 966) and pending federal legislation (PBM FAIR Act) are moving toward imposing fiduciary duties on PBMs directly. Contract language should anticipate this evolution.

### Drafting Tips

Focus this provision solely on securing a fiduciary support commitment. Supply chain conflicts, revenue attestations, and transparency requirements are addressed in Provisions #2-10. Watch for disclaimers that limit PBM obligations to "commercially reasonable" efforts or disclaim all fiduciary responsibility. Where state law imposes PBM fiduciary duties, ensure contract disclaimers do not override legal requirements.

## #2 Pass-Through Pharmacy Costs

### Model Contract Language

*The Plan shall be billed only the amounts actually paid by PBM to pharmacies for ingredient cost and dispensing fees, with no retained spread, markup, differential pricing, or other margin.*

*PBM shall not assess, retain, or recover value from pharmacies or from the Plan after point of sale or claim adjudication, including clawbacks, DIR fees, reconciliation adjustments, retroactive pricing changes, performance-based fees, or similar post-adjudication charges affecting Plan cost.*

### Attestation Question

Do you agree the Plan will be billed only the amounts actually paid to pharmacies, with no retained spread, markup, or post-adjudication value extraction of any kind?

### Fiduciary Rationale

Spread pricing is the most common mechanism for hidden PBM revenue. When a PBM bills the plan more than it pays the pharmacy, fiduciaries cannot evaluate cost reasonableness. Post-adjudication adjustments (DIR fees, clawbacks, retroactive pricing changes) create a second layer of invisible value extraction. The DOL proposed rule requires disclosure of spread, but disclosure alone is insufficient. A fiduciary-aligned PBM should have no spread to disclose.

### Drafting Tips

Prohibit both spread pricing and post-adjudication value extraction explicitly. Traditional pass-through language often misses DIR fees, performance-based pharmacy fees, and retroactive reconciliation adjustments. Prohibit cross-plan offsetting. Verify the prohibition covers all channels: retail 30-day, retail 90-day, mail order, and specialty. PBMs sometimes maintain pass-through on retail while retaining spread on specialty or mail.

### CAA 2026 Alignment

For contracts entered into, renewed, or extended for plan years beginning January 1, 2029, failure to provide 100% pass-through renders the PBM contract "unreasonable" under ERISA §408(b)(2)(B), creating prohibited transaction liability. Spread pricing is now not merely a fiduciary concern but a statutory violation for covered arrangements. This strengthens the employer's negotiating position: pass-through is no longer optional.

### #3 Rebate and Manufacturer Revenue Transparency

#### Model Contract Language

*PBM shall fully disclose all manufacturer revenue received in connection with the Plan, including rebates, administrative fees, service fees, data fees, formulary placement fees, market share payments, price protection payments, inflationary credits, grants, discounts, or any other consideration of value.*

*Where manufacturer revenue flows through third-party aggregators or group purchasing organizations, PBM shall disclose all amounts received by PBM and shall make reasonable efforts to obtain and disclose upstream retention amounts where available.*

*Manufacturer revenue, including rebates, fees, alternative discounts, and other remuneration, shall be passed through one hundred percent (100%) to the Plan and shall not be retained, pooled, offset, reclassified, or obscured.*

#### Attestation Question

Do you agree to fully disclose all manufacturer revenue received in connection with the Plan, including amounts received through aggregators, and to pass through one hundred percent (100%) of such revenue without pooling, reclassification, or retention?

#### Fiduciary Rationale

Manufacturer revenue is the largest hidden PBM revenue stream. PBMs receive payments through multiple channels: rebates, administrative fees, data fees, formulary placement fees, market share payments, and inflationary credits. When retained or obscured, fiduciaries cannot assess true plan costs. PBM-affiliated GPOs create additional opacity, enabling technical compliance while hiding value upstream. This provision consolidates rebate pass-through, pooling prohibition, and compensation disclosure into a comprehensive financial transparency framework.

#### Drafting Tips

Define "manufacturer revenue" exhaustively. PBMs reclassify rebates as "service fees" to exclude them from pass-through obligations. Require disclosure of GPO-level retention. Prohibit cross-contract pooling or averaging of rebates between clients. Specify pass-through timing (see Provision #20 for quarterly cadence). Longer timelines create float revenue at the plan's expense.

Contracts that include robust ongoing reporting on rebate pass-through and drug-level spending (semi-annual or quarterly cadence) demonstrate stronger transparency infrastructure and may support higher scores on Issue 3.1 where pass-through language is present but verification mechanisms differentiate between contracts.

**CAA 2026 Alignment**

The phrase "rebates, fees, alternative discounts, and other remuneration" mirrors the statutory language of ERISA §408(b)(2)(B) as amended by CAA 2026 §6702. Contracts that do not provide for 100% pass-through of these categories will be deemed "unreasonable" and trigger prohibited transaction penalties for plan years beginning January 1, 2029.

## #4 Data Ownership, Access, and Third-Party Use

**Model Contract Language**

*All data generated or used in connection with the Plan, including claims, pricing, utilization, formulary, and performance data, shall remain the property of the Plan Sponsor.*

*PBM shall provide timely, usable access to such data and shall not restrict, condition, or delay access through contractual terms, technical limitations, or non-disclosure arrangements.*

*PBM may use Plan data in aggregated or de-identified form for internal purposes, provided such use does not identify the Plan. PBM shall not sell, license, monetize, or disclose Plan data to third parties without express written authorization from the Plan Sponsor.*

**Attestation Question**

Do you agree all Plan data remains the property of Plan Sponsor, will be fully accessible for fiduciary oversight, and will not be sold or disclosed to third parties without express written authorization?

**Fiduciary Rationale**

Fiduciary oversight is impossible without data. Plan sponsors need unrestricted access to claims, pricing, utilization, and performance data. Data restrictions (gag clauses) are prohibited under the 2021 Consolidated Appropriations Act, yet many PBM contracts still contain provisions that limit who receives data and how it is used. This provision consolidates data ownership, data access, and third-party access protection.

**Drafting Tips**

Specify that all plan data belongs to the plan sponsor, including pricing data and formulary analytics generated using plan data. Prohibit both contractual and technical barriers to access (proprietary formats, restricted APIs, limited exports). Address de-identified data monetization: PBMs aggregate and sell plan data to third parties. Ensure third-party access extends to all plan-designated vendors without PBM approval or delay.

## #5 Audit Rights and Verification with Extrapolation

### Model Contract Language

*PBM shall provide the Plan Sponsor with audit rights sufficient to verify compliance with pricing, financial, clinical, and contractual obligations.*

*Audit rights shall include access to underlying records and supporting documentation and the right to extrapolate findings to the full claims population. Audit rights extend to contracts and financial arrangements between PBM's rebate aggregator and pharmaceutical manufacturers to the extent they affect Plan pricing or rebate pass-through.*

*Plan Sponsor may conduct audits directly or through independent third parties of its choosing. PBM shall not restrict, approve, or control the selection, scope, methodology, or work of such auditors. PBM shall not pay for, subsidize, or provide credits or allowances toward the cost of any audit conducted under this provision, directly or indirectly. Auditor findings shall be reported directly to Plan Sponsor without PBM pre-review, approval, or non-disclosure restrictions.*

*Reasonable operational parameters including annual frequency, advance notice requirements, and scheduling outside peak operational periods are acceptable, provided they do not impair meaningful oversight.*

### Attestation Question

Do you agree to provide audit rights including access to records, extrapolation of findings, aggregator contract audit access, and use of independent auditors selected by Plan Sponsor, with no PBM payment, subsidization, credits, or allowances toward audit costs, and without PBM approval of auditor selection, methodology, or findings?

### Fiduciary Rationale

Audit rights are the enforcement mechanism for every other provision. Without independent verification, fiduciaries cannot confirm PBM compliance. PBMs commonly restrict audit scope, sample size, methodology, and auditor selection to prevent detection of systemic issues. The DOL proposed rule allows fiduciary-selected auditors. This provision extends that to include unrestricted methodology and statistically valid extrapolation.

### Drafting Tips

Three elements are critical: auditor selection by the plan, unrestricted sample size, and extrapolation rights. Reasonable operational parameters (annual frequency, advance notice, scheduling outside peak periods) are acceptable if they do not impair oversight. Ensure audit scope covers all financial and operational elements, including rebates and manufacturer revenue. Secure post-termination audit rights (24 months).

**CAA 2026 Alignment**

CAA 2026 §6702 requires that the plan fiduciary selects the auditor and that the PBM may not pay for the auditor, directly or indirectly. It also prohibits plans from using PBM credits or allowances to fund rebate audits. Ensure PBM contracts do not include "audit credit" or "audit allowance" provisions that could create financial relationships between PBM and auditor. Post-2029, DOL will establish confidentiality restrictions for audited rebate contracts. Monitor for final guidance.

**#6 Pharmacy Ownership, Steering, and Network Neutrality****Model Contract Language**

*PBM shall not hold any ownership or financial interest in any pharmacy, including retail, mail order, or specialty pharmacies, or in any pharmaceutical manufacturer, wholesaler, or distributor. PBM shall disclose all direct and indirect ownership or financial interests in pharmacies, manufacturers, wholesalers, distributors, or other supply chain entities.*

*PBM shall not engage in practices that steer utilization toward PBM-owned or affiliated entities in a manner prioritizing PBM financial interests over participant outcomes or lowest net cost. PBM shall support cost-conscious pharmacy selection by making lower-cost alternatives visible to members where available.*

*PBM shall administer pharmacy networks, reimbursement, access standards, utilization management, and specialty distribution on a neutral basis without preferential treatment of affiliated entities.*

*Affiliated entities include any pharmacy, manufacturer, distributor, or service provider in which PBM, its parent, subsidiaries, principals, or their immediate family members hold a direct or indirect ownership, financial, or control interest.*

*PBM shall provide prompt written notice to Plan Sponsor of any material change in ownership, affiliation, or financial arrangements affecting pharmacy networks, manufacturer relationships, or specialty distribution during the term of this Agreement.*

**Attestation Question**

Do you agree to disclose all pharmacy and supply chain ownership interests, administer all pharmacy networks, formularies, and utilization management on a neutral basis without steering toward PBM-owned entities, support cost-conscious pharmacy selection, and provide prompt notice of any ownership or affiliation changes?

**Fiduciary Rationale**

Vertical integration is the defining structural conflict in PBM economics. The three largest PBMs own mail order, specialty, and retail pharmacies, creating direct incentive to steer prescriptions toward owned entities regardless of cost or quality. Steering takes many forms: mandatory mail order, specialty pharmacy restrictions, narrow networks, differential copays,

and prior authorization funneling. This provision requires network neutrality rather than merely disclosing the conflict.

### Drafting Tips

Define "affiliated entities" comprehensively, including indirect ownership through intermediaries and principals' family members. The operational test is network neutrality: reimbursement, access standards, and utilization management must apply equally to affiliated and independent pharmacies. Require prompt written notice (30 days) of ownership changes during the contract term. This provision establishes a no-ownership standard as the fiduciary ideal. Where a PBM holds pharmacy or supply chain ownership interests, the plan sponsor may accept the gap with documented rationale, provided the anti-steering, neutral administration, and disclosure requirements remain in effect.

## #7 Carve-Out and Independent Vendor Rights

### Model Contract Language

*Plan Sponsor shall retain the right to carve out or assign to independent third parties functions including clinical decision review, utilization management oversight, specialty management, analytics, pharmacy access services, alternative funding programs, international sourcing, rebate aggregation, or similar functions, excluding claims adjudication.*

*PBM shall cooperate fully with such arrangements, including timely data sharing, system integration support, and operational coordination.*

*PBM shall not impose pricing penalties, fee increases, access restrictions, service degradation, or other adverse actions as a result of any carve-out. This Agreement shall not contain exclusivity provisions preventing Plan Sponsor from engaging alternative vendors for carved-out functions.*

### Attestation Question

Do you agree Plan Sponsor may carve out designated functions to independent vendors without penalty or adverse impact, and that this Agreement contains no exclusivity provisions preventing such arrangements?

### Fiduciary Rationale

Bundling strategies restrict fiduciary choice by tying pharmacy benefits to proprietary services. Exclusivity clauses prohibit the plan from engaging alternatives, conflicting with the duty of prudence. Anti-competitive pricing (increasing costs or reducing rebates when a plan carves out a program) creates economic penalties that effectively prevent plans from exercising fiduciary obligations.

### Drafting Tips

The carve-out right should cover clinical review, utilization management, specialty management, analytics, and pharmacy access services. Claims adjudication is a reasonable



exception. Explicitly prohibit retaliation: no pricing penalties, fee increases, access restrictions, service degradation, or rebate reductions following a carve-out. Ensure no exclusivity provisions exist, including in specialty, mail order, or clinical program subsections. Require PBM cooperation with carve-out implementation.

## #8 Lowest Net Cost and Clinical Effectiveness

### Model Contract Language

*PBM shall base formulary placement, utilization management, therapeutic substitution, and product preference decisions on clinical effectiveness and lowest net cost to the Plan.*

*PBM shall not consider fees, margins, ownership interests, private-label economics, manufacturer affiliations, or other PBM financial considerations in such decisions.*

*This standard applies to all drugs, including generics, brands, biosimilars, specialty products, and drugs manufactured, licensed, or distributed by PBM or its affiliates.*

*PBM shall provide sufficient data and documentation to enable Plan Sponsor to independently verify lowest net cost determinations by therapeutic class, including the rationale for any formulary placement in which a higher-cost drug receives favorable treatment over a lower-cost clinically appropriate alternative.*

### Attestation Question

Do you agree to base all formulary and utilization management decisions on clinical effectiveness and lowest net cost, without consideration of fees, margins, ownership interests, or other PBM financial considerations, and to provide data sufficient for Plan Sponsor to verify these determinations, including formulary placement rationale where higher-cost drugs receive favorable treatment?

### Fiduciary Rationale

Formulary decisions are the most consequential and least transparent area of PBM operations. When driven by rebate maximization rather than clinical merit and lowest net cost, participants pay more while PBM revenue grows. This provision consolidates formulary management, lowest net cost determination, and anti-rebate maximization. It applies to all drugs, including those manufactured or distributed by the PBM or its affiliates.

### Drafting Tips

Define lowest net cost clearly: total cost to the plan after all rebates and manufacturer payments, evaluated by therapeutic class. The anti-rebate maximization element is the key differentiator: explicitly prohibit the PBM from considering its own fees, margins, or ownership interests in formulary decisions. Retain plan sponsor approval rights over exclusions and tier placements.

The primary verification mechanism for this provision is the formulary placement rationale report, not P&T committee minutes. P&T governance (Provision #15) confirms that a sound process exists; the formulary rationale report confirms that outcomes are sound. When a

higher-cost drug receives favorable formulary placement over a lower-cost clinically appropriate alternative, the PBM must explain why. If the rationale is manufacturer revenue rather than clinical superiority, the LNC attestation is contradicted.

#### CAA 2026 Alignment

CAA 2026 §6701 requires PBMs to report on formulary structure, prescription drug benefit design, and, critically, the rationale for higher-cost drugs receiving favorable treatment over lower-cost alternatives. This statutory reporting obligation creates a verification tool for the LNC standard: plan sponsors can cross-reference the PBM's Section 6701 formulary rationale report against its LNC attestation. Where the rationale for favorable placement is rebate revenue rather than clinical effectiveness or lowest net cost, the plan sponsor has a documented basis for remediation or disqualification.

## #9 Termination Without Penalty and Clean Exit Rights

### Model Contract Language

*Plan Sponsor shall retain the right to terminate this Agreement without punitive penalties upon PBM failure to comply with fiduciary alignment, transparency, or disclosure obligations.*

*Punitive penalties include termination fees, lost rebate claims, accelerated charges, forfeiture of accrued amounts, transition fees, or other economic barriers intended to deter termination.*

*All rebates earned through the termination date shall be paid in full per the standard payment schedule, regardless of reason for termination.*

*PBM shall cooperate promptly with transition activities, data transfer, and continuity of care. All Plan data shall be returned within thirty (30) days of termination in industry-standard format at no additional charge.*

### Attestation Question

Do you agree Plan Sponsor may terminate for fiduciary misalignment or transparency failures without punitive penalties, and that you will cooperate fully with data transfer, transition support, and pass-through of all rebates earned during the contract term?

### Fiduciary Rationale

Termination rights are the ultimate enforcement mechanism. If transparency disclosures or audits reveal PBM non-compliance, the plan must be able to exit without punitive consequences. PBM contracts commonly include economic barriers to exit: early termination fees, rebate forfeiture, accelerated expense repayment, and transition fees. Clean exit rights are the necessary complement to transparency. The DOL proposed rule creates new disclosure requirements, but if those disclosures reveal problems, plan sponsors must be able to act.

## Drafting Tips

The termination trigger should include failure to comply with fiduciary alignment, transparency, or disclosure obligations, broader than standard "termination for cause." Define "punitive penalties" explicitly: termination fees, lost rebates, accelerated charges, forfeiture of accrued amounts, or transition fees. Negotiate expense allowance repayment terms upfront. Ensure discount and rebate guarantees remain in effect through the termination date. Notice periods of 90 days are standard.

## #10 Administrative Fee Verification and Benchmarking

### Model Contract Language

*PBM administrative fees shall be transparent, fully disclosed, and verifiable. All fee components shall be itemized, including administrative fees, pass-through costs, and third-party charges. No hidden fees or undisclosed charges shall apply.*

*PBM shall certify that administrative fees represent the sole source of revenue derived from the Plan relationship and constitute bona fide service fees that are transparent, quantifiable, and consistent with fair market value. PBM receives no spread, rebate retention, or other compensation beyond the disclosed administrative fees.*

*PBM shall provide annual benchmarking reports showing Plan's PEPM costs relative to PBM's book of business, including percentile positioning, comparison to plans of similar size and utilization profile, and improvement targets for the following twelve months.*

*Benchmarking data shall be PBM-provided and sufficient to enable independent assessment of fee reasonableness.*

### Attestation Question

Do you agree to fully disclose and itemize administrative fees, certify that such fees represent the sole revenue from the Plan relationship and constitute bona fide service fees consistent with fair market value, and provide annual benchmarking reports showing Plan's PEPM costs, percentile positioning, and improvement targets relative to your book of business and comparable plans?

### Fiduciary Rationale

Administrative fees should be the sole source of PBM revenue in a fiduciary-aligned arrangement. Verifying fee reasonableness confirms transparency commitments in Provisions #2-3 are being honored. Without benchmarking, plan sponsors cannot evaluate whether fees are competitive relative to the PBM's broader book of business or comparable plans.

### Drafting Tips

Require itemization of all fees: administrative, pass-through, and third-party. The annual benchmarking requirement is the key enhancement: PEPM comparisons showing percentile positioning relative to the PBM's book of business and plans of similar size, with improvement targets for the following twelve months. Include a sole revenue attestation confirming

administrative fees are the only revenue source from the plan relationship. The sole revenue attestation establishes the fiduciary standard that administrative fees should be the only PBM compensation from the plan relationship. Where a PBM derives revenue from additional sources, the plan sponsor may accept the gap with documented rationale, provided full revenue disclosure is maintained.

**CAA 2026 Alignment**

CAA 2026 expands ERISA's "covered service provider" definition to include PBMs, requiring disclosure of all direct and indirect compensation. Combined with the 100% rebate pass-through mandate, administrative fees become the only permissible revenue source, precisely what our sole revenue attestation already requires. Post-2029, this is statutory, not aspirational. "Bona fide service fee" terminology mirrors the Medicare Part D standard and signals emerging market expectations for the commercial market.

## SECTION II

# Operational and Governance Safeguards

Provisions #11-28 extend core protections into operational areas supporting sustained fiduciary compliance.

### A. Operational Safeguards

## #11 Implementation Standards and Readiness

### Model Contract Language

*PBM shall complete implementation activities in accordance with mutually agreed timelines and readiness criteria. PBM shall not declare implementation complete until all pricing, data access, reporting, and operational requirements are fully functional and verified by the Plan Sponsor.*

### Fiduciary Rationale

Incomplete implementations create operational risk and potential plan asset loss when pricing, formulary, or network configurations are incorrect at go-live. Fiduciaries must ensure transitions do not disrupt participant access.

### Drafting Tips

Include specific readiness criteria verified before go-live. Define consequences for incomplete implementation. Require a 90-day post-implementation review with expedited issue resolution.

## #12 Ongoing Service Levels and Responsiveness

### Model Contract Language

*PBM shall maintain service levels sufficient to support Plan administration, participant access, and fiduciary oversight, and shall respond to Plan Sponsor inquiries and data requests within defined and reasonable timeframes.*

### Fiduciary Rationale

Responsive service is necessary for ongoing fiduciary monitoring. Delays in data requests, participant escalations, or clinical inquiries impair the plan sponsor's ability to act prudently.

### Drafting Tips

Define specific response times by category: data requests, participant escalations, clinical inquiries, audit support. Include measurable service level targets with financial consequences for sustained underperformance.

## #13 Change Management and Notification

### Model Contract Language

*PBM shall provide advance written notice of any material changes to pricing methodology, formulary administration, network design, clinical programs, or data systems affecting the Plan. PBM shall not implement material changes without Plan Sponsor approval.*

### Fiduciary Rationale

Material changes to pricing, formulary, network design, or clinical programs directly affect plan costs and participant access. Fiduciaries need advance notice and approval rights.

### Drafting Tips

Specify minimum notice periods: 60 days for formulary, 90 days for network, 120 days for pricing methodology changes. Require approval rather than simple notification. Define "material" to include any change affecting cost, access, or coverage.

## #14 Data Delivery Format and Usability

### Model Contract Language

*PBM shall provide Plan data in formats suitable for independent analysis, audit, and reporting, and shall not use proprietary or non-exportable formats that limit Plan Sponsor oversight or third-party review.*

*Data shall include sufficient detail to enable analysis by distribution channel, including retail 30-day, retail 90-day, mail order, and specialty pharmacy, to support identification of cost optimization opportunities.*

### Fiduciary Rationale

Provision #4 establishes data ownership. This provision ensures data is delivered in formats enabling independent analysis, preventing PBMs from technically providing data while making it practically unusable.

### Drafting Tips

Specify standard formats (CSV, Excel, or standard EDI). Require channel-level detail: retail 30-day, retail 90-day, mail order, and specialty pharmacy. Channel-level data is essential for identifying cost optimization opportunities PBMs may have incentive to obscure.

## B. Clinical Governance and Oversight

### #15 Clinical Governance Structure

#### Model Contract Language

*PBM shall maintain a defined clinical governance structure overseeing formulary decisions, utilization management, and clinical programs, and shall provide Plan Sponsor visibility into governance processes, decision criteria, and review cadence.*

#### Fiduciary Rationale

Formulary and clinical program decisions significantly affect costs and outcomes. Fiduciaries must monitor the governance structure ensuring decisions reflect clinical evidence rather than PBM revenue.

#### Drafting Tips

Request visibility into P&T committee structure, composition, decision criteria, and review cadence. Governance should include independent clinical representation, not solely PBM employees or affiliates.

This provision addresses governance process; it does not address formulary outcomes. P&T committee minutes confirm that a structured process exists, but they do not answer the question plan sponsors most need answered: why does the formulary favor a higher-cost drug when a lower-cost clinically appropriate alternative exists? That question is answered by the formulary placement rationale report required under Provision #8 and the CAA 2026 §6701 reporting framework. Governance (this provision) tells you the process is sound. Formulary rationale (#8) tells you the outcomes are sound. Both are necessary; neither is sufficient alone.

### #16 Evidence-Based Clinical Standards

#### Model Contract Language

*PBM shall administer clinical programs using evidence-based standards grounded in peer-reviewed research and recognized clinical guidelines, applied consistently across the Plan population.*

#### Fiduciary Rationale

Clinical programs deviating from evidence-based standards may impose unnecessary access barriers or promote treatments serving PBM economics over participant health.

#### Drafting Tips

Require clinical programs to reference peer-reviewed research and recognized guidelines (ACC/AHA, NCCN, ADA). Watch for clinical programs designed primarily to steer utilization toward PBM-owned dispensing channels.

## #17 Independent Clinical Review Rights

### Model Contract Language

*Plan Sponsor shall retain the right to engage independent clinical reviewers to evaluate formulary decisions, utilization management criteria, and clinical outcomes. PBM shall cooperate with such reviews and provide required data and documentation.*

### Fiduciary Rationale

Fiduciaries cannot rely solely on the PBM's assessment of its own clinical programs. Independent review is particularly important for high-cost specialty drugs where PBM financial interests are most pronounced.

### Drafting Tips

Ensure the plan can engage external reviewers without PBM approval. Require PBM cooperation including data and documentation access.

## #18 Ongoing Formulary Review and Adjustment

### Model Contract Language

*PBM shall support periodic formulary review evaluating clinical effectiveness, participant impact, and cost performance, and shall implement formulary adjustments approved by the Plan Sponsor within reasonable timeframes.*

### Fiduciary Rationale

Drug markets change continuously as generics, biosimilars, and therapeutic alternatives enter. Fiduciaries must ensure formulary management is dynamic and responsive to emerging opportunities.

### Drafting Tips

Establish quarterly or semi-annual review cadence. Require the PBM to proactively identify savings from new generics and biosimilars. Retain plan sponsor approval authority over adjustments.



## C. Financial Protections and Risk Controls

### #19 Performance Guarantees and Financial Accountability

#### Model Contract Language

*PBM shall offer performance guarantees aligned with pricing, service levels, and clinical outcomes, subject to minimum plan size requirements. Guarantee terms shall be measurable, auditable, and enforceable through financial remedies.*

*Performance guarantees represent minimum thresholds. Where actual performance exceeds guarantees, the Plan shall receive the benefit of actual performance rather than guarantee amounts.*

#### Fiduciary Rationale

Performance guarantees hold PBMs accountable to pricing, service, and clinical commitments. When enforced through service credits rather than cash penalties, the PBM benefits from its own underperformance because credits apply to future services the plan would purchase anyway.

#### Drafting Tips

Require cash penalties payable within 30 days rather than future service credits. Preserve the plan's right of setoff. Require independent verification of guarantee calculations. Ensure guarantees cover pricing, service levels, and clinical metrics across all channels.

### #20 Rebate Payment Timing

#### Model Contract Language

*PBM shall remit to the Plan one hundred percent (100%) of all rebates, fees, alternative discounts, and other remuneration received from manufacturers, rebate aggregators, or group purchasing organizations in connection with the Plan's drug utilization or spending.*

*Remittance shall occur on a quarterly basis, no later than ninety (90) days after the end of each calendar quarter in which such amounts were received by PBM.*

*PBM shall contractually require any rebate aggregator or group purchasing organization to remit all Plan-attributable rebates, fees, and remuneration to PBM within forty-five (45) days of the end of each calendar quarter.*

*Any underpayment of amounts owed to the Plan shall be corrected within ninety (90) days of written notice from Plan Sponsor.*

*PBM shall provide documentation sufficient to verify remittance amounts and timing, including confirmation of receipt dates from upstream entities.*

## Attestation Question

Do you agree to remit 100% of all rebates, fees, alternative discounts, and other remuneration to the Plan on a quarterly basis within 90 days of quarter-end, require upstream aggregators to remit within 45 days, correct any underpayments within 90 days of notice, and provide documentation sufficient to verify remittance amounts and timing?

## Fiduciary Rationale

Delayed rebate pass-through creates float revenue for the PBM and deprives the plan of funds. Fiduciaries must ensure rebates are passed through within reasonable timeframes with documentation for verification.

## Drafting Tips

CAA 2026 §6702 establishes quarterly/90-day remittance as the statutory floor for ERISA plans. Contracts entered into, renewed, or extended for plan years beginning January 1, 2029 must comply. Failure renders the contract "unreasonable" under ERISA §408(b)(2)(B), triggering prohibited transaction penalties.

The 45-day aggregator requirement ensures PBMs structure upstream contracts to meet their downstream obligations. Consider including a right of setoff for underpayments not corrected within the 90-day cure period.

## CAA 2026 Alignment

This provision replaces the v3 standard of 60 days from PBM receipt. The quarterly/90-day cadence aligns with CAA 2026 §6702 and is more auditable than a receipt-based trigger (verifying "when did the PBM actually receive the money" requires information the plan may not have). The 45-day aggregator upstream requirement is new and creates a two-tier timing cascade that closes float opportunities at the aggregator level.

## #21 Compliance Evidence and Regulatory Reporting

### Model Contract Language

#### A. Annual Fiduciary Compliance Report

*PBM shall provide annual evidence reports demonstrating compliance with pass-through pricing, rebate transparency, and fiduciary alignment obligations under this Agreement. Reports shall include verification that all rebates received were passed through to the Plan, that no spread or post-adjudication value extraction occurred, and that no cross-subsidization exists between clients in pharmacy reimbursement.*

#### B. Drug-Level Transparency Reports

*PBM shall provide the Plan with drug-level transparency reports no less frequently than semi-annually, and quarterly upon Plan Sponsor request. Reports shall be provided in plain language and in a machine-readable format, and shall include for each drug where claims were submitted:*

- (i) total net spending by the Plan and out-of-pocket costs by participants;*
- (ii) all compensation paid by the Plan to PBM and all amounts paid by PBM to pharmacies, including any spread amounts;*
- (iii) total rebates, fees, alternative discounts, and other remuneration received;*
- (iv) dispensing channel (retail, mail order, specialty pharmacy);*
- (v) brand/generic status and applicable benchmark pricing;*
- (vi) formulary tier and utilization management applied by therapeutic class, including the rationale for any formulary placement in which a higher-cost drug receives favorable treatment over a lower-cost clinically appropriate alternative;*
- (vii) for PBM-affiliated pharmacies: pricing comparison to non-affiliated pharmacies and description of any plan design features that steer utilization to affiliated entities.*

#### C. Participant Summary Documents

*PBM shall produce summary documents suitable for distribution to Plan participants upon request, containing aggregate prescription drug spending and coverage information, and a statement that participants may request their claim-specific prescription information from the Plan. Summary documents shall comply with applicable law including CAA 2026 Section 6701 requirements.*

#### D. Report Format and Compliance

*All reports required under this provision shall comply with applicable reporting formats established by the Tri-Agencies (Departments of Labor, Health and Human Services, and Treasury). PBM shall not restrict, condition, or delay delivery of reports required under this provision or under applicable law.*

### Attestation Question

Do you agree to provide: (a) annual compliance evidence reports demonstrating pass-through pricing, rebate transparency, and no cross-subsidization; (b) semi-annual drug-level transparency reports including net spending, rebates, compensation, dispensing channel, and affiliated pharmacy comparisons, quarterly upon request; and (c) participant summary documents as required by applicable law?

## Fiduciary Rationale

Annual compliance reports create a structured self-reporting obligation complementing Provision #5 audit rights. They provide ongoing verification of pass-through pricing, rebate transparency, and the absence of cross-subsidization.

CAA 2026 §6701 creates a dramatically more detailed reporting regime. The semi-annual drug-level reports (Section B) go far beyond the annual compliance report. The statutory reports are disclosure-based (here's the data); the compliance report is attestation-based (we certify we complied). Both serve distinct purposes.

## Drafting Tips

Section A: Specify report content: verification that all rebates were passed through, no spread or post-adjudication extraction occurred, and no cross-subsidization exists between clients in pharmacy reimbursement.

Section B: CAA 2026 §6701 reporting applies to large self-funded employers (100+ employees) with fully insured opt-in. Penalties are \$10,000/day for failure to report and \$100,000 per item of false information. PBM contracts should include indemnification for penalties arising from PBM reporting failures. The machine-readable format requirement will require PBMs to build new data infrastructure; early contract inclusion creates leverage.

Section C: Participant summary documents must be suitable for general distribution. Review PBM indemnification clauses. PBMs may attempt to shift reporting penalty risk to plan sponsors.

Section D: Tri-Agency format guidance is forthcoming. Include a cooperation clause requiring PBM to adopt required formats within reasonable timeframes of regulatory publication.

### CAA 2026 Alignment

CAA 2026 §6701 and §6702 collectively create the most significant PBM reporting mandate in ERISA history. Contracts entered into, renewed, or extended for plan years beginning January 1, 2029 must comply. Penalties for non-compliance (§6706) include \$10,000/day for failures to report and \$100,000 per false item. This provision expands our existing annual compliance report to incorporate the full statutory reporting framework while retaining the fiduciary self-certification that the statute does not require but that strengthens the employer's oversight position.

## #22 Fee Reasonableness Adjustments

### Model Contract Language

*PBM shall support periodic review of fees to assess continued reasonableness. Where fees are no longer reasonable, PBM shall cooperate in good faith to adjust fees prospectively.*

### Fiduciary Rationale

Market conditions and plan economics change over time. Fees reasonable at contract inception may become unreasonable. Fiduciaries need a mechanism to address fee drift without full renegotiation.

### Drafting Tips

Combine with Provision #10 benchmarking for a data-driven review process. Specify annual or biennial review cadence. Require good-faith negotiation with termination rights as backstop.

## #23 Indemnification for Misconduct and Negligence

### Model Contract Language

*PBM shall indemnify and hold harmless the Plan Sponsor for losses arising from PBM negligence, willful misconduct, material breach, or failure to comply with contractual obligations under this Agreement.*

### Fiduciary Rationale

Without indemnification, the plan sponsor bears financial risk of PBM failures including dispensing errors, misapplication of coverage terms, privacy breaches, and deceptive practices.

### Drafting Tips

Negotiate beyond direct damages to cover the full range of PBM misconduct. Most PBM contracts limit liability and exclude consequential damages, substantially disadvantaging the plan sponsor. The pending PBM FAIR Act would restrict risk-shifting provisions.

## #24 Cybersecurity and Data Breach Protection

### Model Contract Language

*PBM shall maintain safeguards sufficient to protect Plan data, shall promptly notify Plan Sponsor of any data breach or security incident, and shall bear responsibility for remediation, notification, and related costs.*

### Fiduciary Rationale

PBMs process sensitive health and financial data for millions of participants. A data breach creates plan sponsor liability and participant harm. Fiduciaries must ensure adequate safeguards and PBM accountability for breach consequences.

## Drafting Tips

Require compliance with applicable standards (HIPAA, SOC 2). Specify breach notification timelines (24 to 72 hours). Ensure the PBM bears remediation costs, credit monitoring, and regulatory penalties.

## D. Transition, Continuity, and Change Management

### #25 Transition Assistance and Data Transfer

#### Model Contract Language

*Upon termination or expiration of this Agreement, PBM shall provide transition assistance sufficient to support orderly transfer of services, data, and operations to a successor vendor, including complete data in usable form without additional charge.*

#### Fiduciary Rationale

Transition support is the practical enforcement mechanism behind Provision #9. Without adequate transition assistance, termination rights are theoretical. PBMs can make transitions so difficult that plan sponsors are deterred from exercising exit rights.

#### Drafting Tips

Require complete data transfer in usable formats within 30 days. Specify 120 days of transition cooperation. Prohibit transition or wind-down fees. Ensure data includes all historical claims, pricing, rebate, and utilization data needed by the successor PBM.

### #26 Post-Termination Rebate Pass-Through

#### Model Contract Language

*PBM shall pass through to the Plan all rebates and manufacturer revenue attributable to claims adjudicated during the term of this Agreement, regardless of when such amounts are received by PBM. This obligation shall survive termination and continue until all earned rebates have been passed through, with final reconciliation and payment due no later than one hundred eighty (180) days following the end of the Agreement term.*

#### Fiduciary Rationale

Rebates are paid with significant lag. Amounts earned during the contract term may arrive months after termination. Without explicit post-termination requirements, the PBM has incentive and opportunity to retain these amounts.

#### Drafting Tips

Specify that the pass-through obligation survives termination. Require final reconciliation within 180 days. Include post-termination audit rights (24 months) to verify compliance.

## #27 Continuity of Care Protections

### Model Contract Language

*PBM shall support continuity of care during any transition period to avoid disruption of participant access to medications and clinical services.*

### Fiduciary Rationale

PBM transitions risk medication access disruption, particularly for participants on specialty medications or complex regimens requiring prior authorization.

### Drafting Tips

Require the PBM to maintain medication access during the transition period. Ensure prior authorization approvals transfer to the successor. Provide specialty medication participants dedicated transition support and clear participant communications.

## #28 Timing Restrictions on Audits and Transitions

### Model Contract Language

*Routine audits, implementation activities, and transitions shall not be scheduled during the fourth calendar quarter unless required by regulatory action, material breach, or mutual agreement.*

### Fiduciary Rationale

Q4 is peak operational period due to open enrollment and year-end processing. Scheduling major activities during this period creates unnecessary risk for both PBM and plan.

### Drafting Tips

Include exceptions for regulatory action, material breach, or mutual agreement. This provision signals good-faith contracting by legitimate PBM operational constraints.