PBM Contract Checklist

Use components of this checklist when contracting with a PBM for pharmacy benefit services, including biologic and Specialty Pharmacy.

General Contract Provisions

☐ The following terms are to be clearly defined throughout the contract:

- Generic drug
- House generic drug
- Single source generic drug
- Brand drug
- Multi-source brand drug
- Specialty drug
- Biologic/Biopharmaceutical/Biosimilar drugs
- Compound drug
- Rebates
    - Clear definitions for ALL rebates
    - Transparency of ALL rebates with reporting
    - Guarantee of rebate returns to the Plan
    - Any processing to return rebates to members
- Average Wholesale Price (AWP)
- Contract term
- Claims processing – including any performance guarantees
- Fees
    - Dispensing fees
    - Administrative fees
    - Other processing fees?
- Drug switching/therapeutic interchange rules
- Losses
- Maximum Allowable Cost (MAC)
- MAC list

- Plan design document
- Clinical Management – Including MTM and other clinical tools (e.g. step therapy, prior authorizations, etc)
- Usual and Customary (U&C) treatment and application
- Retail Pharmacy Network – inclusive of carve-outs and network structures
- Retail 90 provisions
- Definitions provided for all dispensing channels

☐ Brand/generic categorization is based on MediSpan's MNOY coding (M, N and O codes are brands, Y code is generic)

☐ Audit language clearly defines auditing rights and any associated costs

☐ Performance criteria are clearly stated in measurable terms for all claims activity and the ability to monitor claims activity is provided

☐ Outcomes of PBM performance falling outside of performance criteria are clearly stated

☐ Client has the ability to alter the formulary on an as-needed basis

☐ All-inclusive specialty drug list and pricing are provided electronically at the beginning of each plan year and quarterly

☐ New specialty products are added to the price list within 90 days of release. Denials of coverage are not administered during the 90 days due to in-progress pricing

☐ Specialty drug pricing is defined at all dispensing channels

☐ Generic guarantees are all in

☐ Each provider channel performance guarantee stands alone, including mail, retail, retail 90 and specialty; there is no offset

☐ Vendor shall process all claims in the time and manner required by applicable federal regulations and in accordance with the terms of the client's Summary Plan Description and/or instructions of the client

☐ Drug interchanges will not result in greater cost for the client or plan participants

☐ Vendor will operate toll-free, live customer service lines twenty-four (24) hours a day, seven (7) days per week for the purpose of responding to inquiries from plan participants

☐ Specialty drug pricing includes the provision of routine supplies (such as needles, syringes, alcohol swabs, etc.) required for the administration

☐ Vendor will provide twenty-four (24) hours a day, seven (7) days per week access to a specialty pharmacy customer service agent and pharmacist to members experiencing immediate specialty drug needs that cannot be handled by a retail pharmacy

☐ Claims excluded from pricing guarantee calculations will be embedded in the contract. All of the following items are considered "OUT":

- Usual and customary claims
- OTC claims
- Zero-balance claims
- Compound Rxs
- Non-coded compounds (a claim whose primary NDC is not considered a standard/stand-alone dispensed medication, e.g. a bulk chemical)
- Non-POS claims
- Repackage indicated NDCs
- Claims filled at non-retail, specialty, specialty dispensing providers
- NDCs from non-pharma sources
- Vaccines
- 340B claims
- Coordination of Benefit (COB) claims
- Claims without a valid NDC per Medispan file
- Specialty drugs from non-specialty pharmacies
- Insulin and diabetic supplies
- Quantity error claims
- Retail brand claims with a discount greater than 30%

☐ Maximum Allowable Cost (MAC) and specialty lists will be provided quarterly in electronic format (spreadsheet, text file, non-PDF).

☐ Vendor List of Specialty Products or PBM Specialty Drug List will be utilized as the marker for specialty pharmacy (not pharmacy where filled).

- [ ] Historical comprehensive MAC, exclusive generics and specialty product lists must be provided to match any data set supplied for either audit or claims monitoring.
- [ ] Mail order claims subject to same MAC as retail network claims
- [ ] Mail order channel pharmacies allowed must be identified by NPI number prior to contract initiation
- [ ] Specialty channel pharmacies must be identified by NPI number prior to contract initiation
- [ ] All RXs filled at a mail order facility will be priced at mail order contracted rates regardless of the number of days' supply
- [ ] Data is owned by the client and may be used in any manner the client desires as long as it does not result in disclosure of proprietary information to an unapproved third party. No components of paid claims data are considered proprietary
- [ ] Data provided for any purpose must include all claims (reversals, denials, duplicates, etc.) unless there is a specific request to exclude components
- [ ] Claim date ranges for calculations are based on service date
- [ ] Mail order and specialty pharmacy may be carved out from the PBM agreement upon 180 days' notice
- [ ] MAC changes must be communicated prior to the change
- [ ] Compounded Drugs - There are limited clinical reasons for compounded drugs to be included in the formulary. Coverage considerations, as well as whether they should be excluded or not, require careful deliberation as well as clear plan design language to plan members or care providers (e.g. physician, pharmacy, hospital). If prior authorization is used, consider the following:

- Apply a prior authorization process for all compounded drugs to assure the compounded ingredients are:

    - FDA approved for use in a mixed format as well as in the manner of administration prescribed
    - Appropriate for the medical condition being treated
    - The most cost efficient available

- Do not agree to a dollar amount trigger for prior authorization as the compounding pharmacies will break the script fill into segments costing less than the trigger amount to avoid the prior authorization

- Clarify the intent of benefits coverage and proactively address erroneous coverage of single or compounded drug use for non-FDA approved uses and routes of administration by adding the following exclusions to coverage under the Plan:

    - Drugs or ingredients that are not FDA approved for use
    - Drugs or ingredients that are not FDA approved for administration through the prescribed route, except when the patient is unable to receive the drugs or ingredients through any other feasible route
    - Drugs or ingredients prescribed for topical use when other feasible or cost-efficient methods of administration are available

☐ Client, its parent, its affiliates and subsidiaries and their respective agents, officers, directors, and employees, and the Plan (Client Group) is indemnified by vendor from and against any third-party claims, loss, cost, damage or expense, fines, amounts paid in settlement, and reasonable legal fees and expenses, to the extent arising out of or and related to any of the following:

- Vendor's breach of the contract
- The negligence, gross negligence, bad faith, intentional or willful misconduct of vendor or vendor's subcontractors or their respective employees or other representatives, or
- Bodily injury, death or damage to personal property arising out of or relating to vendor's performance under the contract

☐ All exclusivity terms are clearly written. *Be careful about inclusion of language that limits your ability to carve out certain aspects of your design.*

Clinical Formulary

- ☐ New specialty products are automatically on prior authorization and must be placed on PBM specialty drug price list within 90 days of release
- ☐ Combination products identified by vendor are excluded (e.g. Vimovo, Duexis)
- ☐ High cost drug formulations identified by vendor are excluded (e.g. Metformin osmotic)
- ☐ A minimum of 60 days prior written notice is provided to members utilizing drugs within the past 120 days of the pending date of exclusion or movement on the formulary
- ☐ Vendor may not reclassify an existing drug or therapeutic class as a specialty drug without prior approval

Transparent Pass-Through Contract

- ☐ 150 non-specialty claims must be validated annually as transparent pass through pricing at the pharmacy level. Claims will be randomly selected and include 80% retail and 20% mail
- ☐ 50 randomly selected specialty claims must be validated annually as transparent pass through pricing at the pharmacy level
- ☐ Rebate contracts and retail provider contracts must be shown upon request for auditing purposes, but no more than annually
- ☐ Client may conduct an annual rebate audit, at no charge, including one year after termination of contract
- ☐ There will be an annual market check based on measurable and actionable criteria. All components of paid claims data may be used to perform the market check. Any market check results within contractual definition will result in pricing changes for those components found outside of parameters.

Communications

☐ Vendor will provide client customization to standard communication materials at no additional cost

Contract Termination

☐ Either party may terminate the contract upon 30 days prior written notice in the event of material breach of contract by the other party except any material breach described in XXX. *Make sure any exceptions are specifically listed. For example, payment default may be handled in another way*

☐ Client is entitled to terminate contract for convenience with not less than X calendar days (recommended 90 days) written notice to vendor, without any penalty, liability or further obligation

☐ Vendor agrees to provide run-out claims processing consistent with the terms of the contract for up to X calendar days (recommended 90 days) after termination of the contract.