Legal Consideration, Contract Terms and Language of PBM Contracting

Presented by: Stephanie Trunk
Overview

• ERISA Considerations

• Transparency and Disclosure

• Adequate Preventive Coverage in Compliance with the Affordable Care Act

• Adequate Definitions

• Maximum Allowable Cost

• Anti-Discrimination

• Recent Trends
Is a PBM an ERISA Fiduciary?

- Fiduciaries exercise discretionary authority or control over the management of plan assets
  - Fiduciaries subject to heightened duties to ERISA plans, including duty to act in the best interest of a plan
    - Prohibition on self-dealing
    - If Breached- restore to the plan profits gained from the breach of such duty
  - Courts have found PBMs are generally not based on a functional fiduciary theory
Is a PBM an ERISA Fiduciary?

Contract Language is critical

– PBM contracts typically state in contracts with plans that the plan sponsor has “sole authority and discretion” to manage and administer the plan.

– PBM will consult and advise on plan design including formulary but the plan is solely responsible for plan design.

– “PBM does not act as a fiduciary of the Plan for purposes of ERISA when PBM contracts with Participating Pharmacies, or when PBM exercises any other cost-containment functions described in this Agreement. No amounts that are to be or are transferred to PBM shall be considered Plan assets.”
Is a PBM an ERISA Fiduciary?

– Courts have found PBMs generally not based on a functional fiduciary theory but can make a PBM a named fiduciary in contract

– Ask PBMs to represent that they are fiduciaries for specific functions in which a plan sponsor is relying upon their expertise
  – Claims processing
  – Coverage determinations and appeals
  – Formulary and plan design
Coverage Determinations and Appeals

“PBM agrees to arrange for a third party recognized in the industry to act as the appeals fiduciary for the limited purpose of hearing and rendering initial coverage determinations for prescription drug benefits and decisions on appeals made by Participants arising from the denial of claims for prescription drug benefits under the applicable Client Plan at the fees and rates set forth in Exhibit A. Client agrees that PBM shall have no fiduciary responsibility regarding initial coverage determination of prescription drug benefits or Participant appeals heard by the third party appeals fiduciary.”
Coverage Determinations and Appeals

- PBMs often contract with an independent review organization (IRO) to render initial coverage determinations and decisions on appeals.

- Such IROs will assume fiduciary responsibility.

- PBMs seek indemnity related to such determinations; plans should as well.

- Critical area given complex prior authorization criteria for more and more specialty drugs—Solvadi, Harvoni, Viekira Pak.
Coverage Determinations and Appeals

- Contract language should also require full compliance with ERISA/Affordable Care Act requirements (29 CFR 2560.503-1) and any state law requirements for coverage determinations and appeals including review timeframes for regular and urgent decisions, denial letter requirements, etc.

- Require appropriate documentation of claims determination procedure and allow for periodic plan review and audit
Transparency and Disclosure Requirements

- Best practice from conflict of interest standpoint BUT ALSO-

- May be needed for ERISA plans to assess “Reasonable Compensation”

- Useful in Medical Loss Ratio calculation- categorizing retained rebates and PBM fees are health care or administrative costs
ERISA Section 408(b)(2)

- ERISA prohibits a “party in interest” from furnishing goods, services or facilities to an ERISA plan
  - Any entity providing services to an ERISA plan is a “party of interest”

- Exception in Section 408(b)(2)-
  - arrangement is reasonable
  - goods and services are necessary for the establishment or operation of an employee benefit plan
  - “reasonable compensation”
ERISA Section 408(b)(2)

- Deemed by Department of Labor (DOL) in 2012 not to apply to employee welfare benefit plans

- Reconsidered in 2014 specifically in context of PBM Compensation and Fee Disclosure -
ERISA Section 408(b)(2)

- DOL recommended extending the “party in interest” prohibition and exception to employee welfare benefit plans

- Would require PBMs to disclose all direct and indirect compensation to ERISA plans in order for ERISA plans to evaluate whether the compensation to PBMs and downstream to pharmacies- including PBM-owned mail order pharmacies- and other subcontractors is reasonable
"Upon Client’s reasonable request, PBM shall provide to Client any and all information necessary in order for Client to evaluate whether all compensation received by PBM related to the provision of pharmacy benefit management services is reasonable as required by ERISA Section 408(b)(2) including access to participating pharmacy agreements, rebate agreements with manufacturers and intermediaries, any agreements with manufacturers and third parties set forth administrative service agreements calculated with reference to Client’s members’ prescription drug utilization and contracts with wholesalers and manufacturers for the purchase of drugs (or payment of rebates) related to PBM’s mail-order pharmacy operations.”
Transparency and Disclosure Language

- Expect PBM resistance unless and until mandated by DOL.

- PCMA and PBMs have testified to DOL that such a requirement could stifle competition by allowing pharmacies, vendors, etc. to learn PBM negotiated rates with their competitors.

- Can couch contract language for now that clause will only be triggered in the event DOL extends ERISA Section 408(b)(2) to employee welfare benefit plans.
ERISA Section 408(b)(2)

- DOL may mandate PBM audits in the future

- Need to ensure that agreement sets forth adequate audit rights in terms of time, selection of auditor and scope including all records relevant to direct and indirect compensation and documents needed to assess reasonableness of PBM compensation
Adequate Preventive Coverage

- Under the Affordable Care Act health plans that are not “grandfathered” must provide preventive items/services for free.

- Free = no cost-sharing whether a co-payment, co-insurance or deductible.

- Preventive items/services graded as A or B by the US Preventive Services Task Force.
Adequate Preventative Coverage

Most preventive services are not drugs, but some are:

- Vaccinations listed on the CDC immunization schedules
- Aspirin in men aged 45 to 79 and women aged 55 to 79 and women of childbearing age to prevent preeclampsia
- Oral fluoride supplementation 0-6 years old
- Iron supplementation in children age 0-1 year
- Folic acid supplementation for women of childbearing age
- Vitamin D age 65 and older
- Smoking cessation interventions
- Contraceptives
- Tamoxifen for breast cancer prevention
Adequate Preventative Coverage

Contract language should address that any PBM proposed formularies and plan designs will comply with all applicable law, including Affordable Care Act requirements to cover preventive care services with no cost-sharing.

Contract language should also address that any PBM proposed formularies and plan designs will comply with minimum formulary requirements-regulations governing adequacy of Medicare Part D formularies and Qualified Health Plan formularies which differ.

– State requirements may also be in play
Adequate Definitions

Definitions are the backbone of all contracts- ensure no ambiguity and both parties are talking about the same thing.

Biggest definitional issue today- what is a specialty drug?

- **AMCP definition** - It requires a difficult or unusual process of delivery to the patient (preparation, handling, storage, inventory, distribution, Risk Evaluation and Mitigation Strategy (REMS) programs, data collection, or administration) or, Patient management prior to or following administration (monitoring, disease or therapeutic support systems).

- **Medicare Part D** - greater than $600 per 30-day supply

- **Other characteristics** - high cost, special handling, rare disease, indication, patient training needed, monitoring of side effects, REMS
What is Specialty Drug?

Many PBMs include a definition of specialty drug in agreements with clients while some attach specialty drug lists subject to change at PBM discretion

- Impacts availability of such drugs- driven toward PBM-owned specialty pharmacies or specialty networks
- Price and cost-sharing

Negotiate that specialty drug list may only be modified by mutual agreement of the parties
What is Specialty Drug?

Manufacturers more often are establishing limited distribution networks for certain specialty drugs.

Specialty pharmacy(ies) proposed by PBM must be part of such networks or a specialty pharmacy must be added for such limited distribution drugs. Contract or plan design materials need to address this to ensure member access and no allegation of discrimination.
What is Maximum Allowable Cost?

MAC is another term needing adequate definition

- Reimbursement to a pharmacy for a multiple source drug with 3 or more sources. Considers common acquisition costs of drugs. May consider Medicaid Federal Upper Limit, Predicative Acquisition Cost by GlassBox Analytics, National Average Drug Acquisition Cost (NADAC) and other public cost surveys

- Common practice for PBMs to use different MAC lists and rates with different pharmacies and health plans
What is Maximum Allowable Cost?

- Ensure MAC definition specifies that the same list and rates shall be used and paid to participating pharmacies as charged to the plan if a pass-through arrangement

- Ensure disclosure provision requires PBM to periodically provide MAC list/rates to the plan to monitor for accurate pricing of claims on an ongoing basis

- Ensure PBM is required to update the MAC list/rates frequently, such as on a weekly basis
# MAC Transparency

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<tr>
<td>Arkansas</td>
<td>Act 1194; signed into law April 12, 2013</td>
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<td>Iowa</td>
<td>HF 2297; signed into law March 14, 2014</td>
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MAC Transparency- Medicare Part D

In the 2015 Final Rule, CMS has required that MAC pricing be available to the public and network pharmacies in advance in 2016.

MAC prices must reflect “market price” of acquiring the drug and be updated every 7 days.

Opportunity for pharmacies to increase reimbursement in the event less than acquisition costs and challenge payments.
MAC Transparency & Effective Rates

MAC transparency seems to be leading to more generic effective rates and manipulation of such rates

- Published rates to appear high to pharmacies and public
- Can result in money being taken back from pharmacies in a reconciliation and potentially money due back to plans if a pass-through arrangement
MAC Transparency & Effective Rates

Generic Effective Rate- ensure adequate rate and consistent definition

– Does it include all generics or just generics subject to a MAC?
– Does it consider dispensing fees or just ingredient costs?
– Does address what happens if a PBM gets money back from a pharmacy related to a generic effective rate in the pharmacy agreement
Anti-Discrimination

Section 2705 of the Affordable Care Act-

No group health plan or insurer offering group or individual coverage may set eligibility rules based on health status, medical condition, claims experience, receipt of health care, medical history, genetic information, evidence of insurability – including acts of domestic violence or disability. Permits employers to vary insurance premiums by as much as 30 percent for employee participation in certain health promotion and disease prevention programs.
Formulary Viewed As Discriminatory

Potential Discriminatory Impact

- May 29, 2014 AIDS Institute and National Health Law Program filed a complaint with DHHS Office of Civil Rights
- Alleged that 4 QHP issuers in Florida - Humana, Coventry, Cigna and Preferred Medical - violating ACA and federal civil rights laws by maintaining discriminatory plan designs; discriminate against HIV/AIDS patients
- All HIV/AIDS drugs on highest co-payment tier of formulary, even generics
- 40-50% co-insurance
- Prior authorization
Anti-Discrimination

- PBM contracts should have a provision that requires PBMs to design suggested formularies and plan designs in a manner that does not discriminate in any way, including as to a given disease/condition.

- In no circumstances should all drugs available to treat a given disease be placed on the non-preferred or specialty drug tier of a formulary. Exception would be single specialty drug for a disease.
Recent Trends

AAC for mail-order, is retail next?
- Catepillar cost plus arrangements with Wal-Mart and Walgreens
- UnitedHealthcare- cost plus reimbursement to physicians for oncology medications
- Predictive Acquisition Cost by GlassBox Analytics
- Switch from AWP to NADAC or Actual Acquisition Cost?

Specialty Drug Tiers
- 2013 Kaiser Survey indicated 25% of employer formularies used specialty drug tiers with on average 32% co-insurance
Recent Trends

**Limited Networks- QHPs, Medicaid MCOs and Commercial Plans generally**

- Florida Medicaid MCOs
- 15-20% of ESI’s volume goes through limited networks- National Plus, National –which excludes Walgreens -and Express Scripts Advantage with 32,000 pharmacies
- Consider during contracting- do you want a limited network or a broad network that complies with TRICARE access standards?
Commercial Trends

Formulary Exclusions

– CVS Caremark- removed 31 products for 2016; a total of 124 products

– ESI- removed 80 products in 2016 compared to 66 in 2015 and 48 in 2014

– Contracts and/or plan designs should specify if a plan is using the recommended formulary or using a custom formulary
Recent Trends

“White Bagging” for Specialty Drugs
- Highmark Study- transferred 50 injectables to specialty pharmacy resulting in $28.5 million in savings over 2 years
- Slow adoption of ASP-based reimbursement plus dispensing fee

Preferred generic drug tiers- 2 generic drug tiers on Formulary
- American Journal of Managed Care Article- common generics like Metformin as non-preferred generics with no alternatives
- Coinciding with generic sourcing programs at mail?
- House brand arrangements
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