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DFWBGH Specialty Pharmacy Workshop Report

July 25, 2022

DFW Business Group on Health hosted an "employers only" **Workshop on Specialty Pharmacy Management Strategies** on June 16, 2022. Participants included Benefits Executives from the following DFWBGH member companies: City of Arlington, City of Plano, City of Denton, Flowserve, Fluor Corporation, Jiffy Lube, and Texas Instruments.

This Workshop was led by Tom Traylor, a Specialty Pharmacy expert from ArchimedesRx.

Critical issues that were covered during this interactive discussion with the employers included:

- Overview of what Specialty drugs are and leading trends, including pending legislation that might impact employers
- How are Specialty drugs priced
- Impact of Specialty drugs on employers' healthcare budgets and employees' pocketbooks
- Examples of benefits strategies employers can use to mitigate the high cost of Specialty Drugs
- Role of the PBM (traditional or Specialty) in helping employers manage and control costs of Specialty drugs.
- Strategies employers can use to hold their PBMs accountable via timely, accurate, actionable reporting

About Specialty Drugs

- May be referred to as biologics, biotech, and/or biopharmaceuticals. Prescribed by specialists and used to treat rare or complex diseases. Can include high cost injectables, infused products, oral agents or inhaled medications and are more expensive with monthly costs in excess of $4,000 as compared to around $400 monthly for non-specialty drugs. Specialty drugs may require clinical monitoring, special supervision and handling requirements. Can be administered at home, a physician's office, an infusion center or a hospital outpatient department.

- Specialty drugs can be covered under the pharmacy benefit, the medical benefit, or both depending on the benefit design of the payer. This diversity of payment and dispensing options makes it hard for payers to get full visibility on specialty drug spending or manage drug utilization effectively.

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- Specialty drugs that are covered under the **pharmacy benefit** use national drug codes **(NDCs)** for billing. These codes provide comprehensive information that identifies the drug, dosage, and package size (number of units).

- **Medical benefit** drugs are coded by **J-codes** per the Healthcare Common Procedure Coding System. A J-code identifies the chemical name of the drug but is limited in that it does not identify the medication manufacturer, strength, or package size.

Growth In Specialty Drug Spend

More than 30% of specialty drugs are mis prescribed

Direct-To-Consumer Ads work!

75% of funding for the FDA comes from Pharma

Formularies are rebate driven

Price increases benefit PBMs

Drug pricing continues its hypergrowth: Orphan Drug Revcovi under the medical benefit costs $8,478,222 annually

PBM Revenue Streams:
* Deeper off-invoice discounts
* Higher service fees

Example of how Humira price increase benefits PBMs

Annual Spend per Patient	2009	2017	2023
Discounted List Price	$18,288	$50,000	$76,418
Rebate	$3,168	$12,000	$17,576
PBM Rebate Revenue (@20% keep)	$633	$2,400	$3,515

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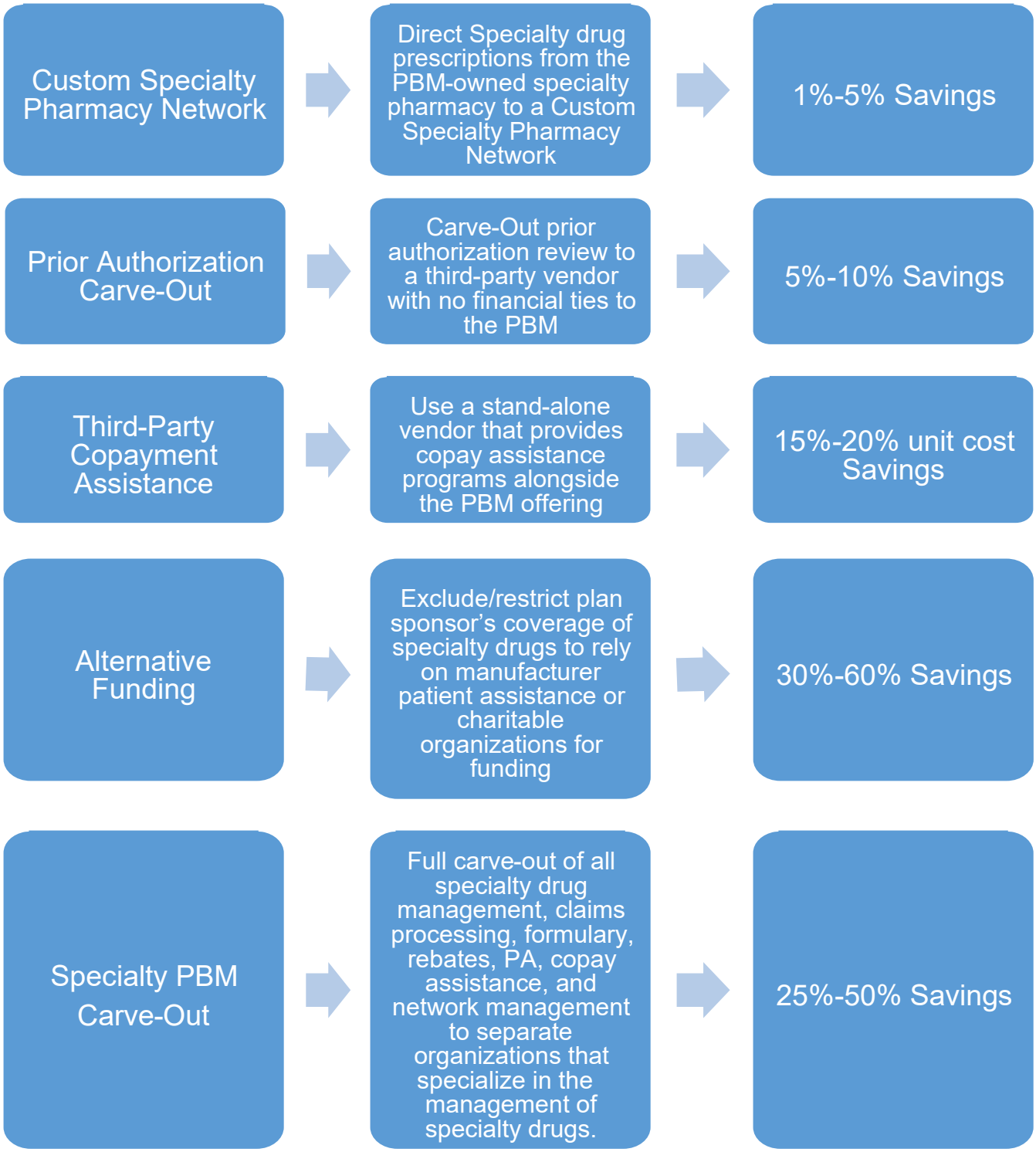
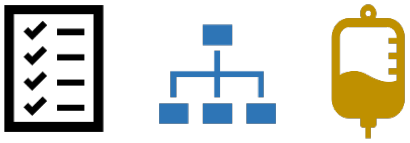
Employer Strategies for Specialty Drug Management – Beyond the PBM



Source: *Archimedes White Paper: Emerging Market Solutions for Specialty Drug Management, 2022*

Employer Action Items: Value-Based Coverage

- Implement **robust criteria**
- Implement a **rigorous PA** review process
- Actively promote **Biosimilars**



Employer Case Study - 2021

Employer with ~40,000 covered lives used the above Clinical Best Practices and realized a clinical savings in the first 6 months of **$43 PMPY**, equal to a **10 to 1** Total Program **ROI** in 2021.

Orphan Drug and Gene Therapies

Orphan Drug – Designation

Provides orphan status to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders.

Rare
Pharmaceutical manufacturers are reluctant to develop these drugs under usual marketing conditions

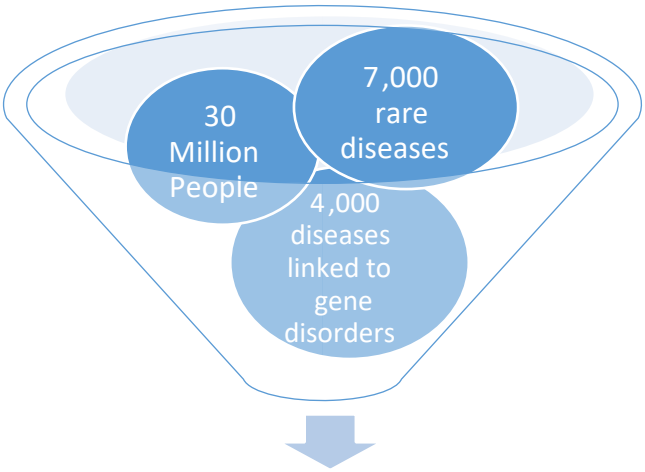
Financial Risk
May not be profitable without government assistance

Medical Breakthroughs
Might not otherwise have been achieved

Financial Incentives
Tax benefits, extended exclusivity, and accelerated approval process

770 Orphan Drugs	• Number of orphan drugs approved by the FDA since the passage of the Orphan Drug Act in 1983
560 +	• Number of orphan drugs currently in development for rare diseases
$169 Billion	• Expected global Orphan Drug market by 2022

Gene Therapy



Gene Therapy Challenges

- Complex science
- Costly treatment
- Technically difficult treatment
- Unusual regulations

Gene Therapy Limitations

- Multigene disorders like arthritis, heart disease, diabetes, and Alzheimer's
- Must give multiple rounds of therapy
- Targeting the wrong cells can cause cancer or other illnesses
- Mutations and can cause tumors
- Immune response, can cause inflammation to organ failure

Alternative Funding Models

- Risk-Sharing & Outcomes-Based Payments
  - Refund some or all of the cost of therapy, if the patient fails to achieve a sustained and expected clinical response
- Amortized Payments
  - Funding source could be the government, manufacturer, or a third-party institution. Payment is over multiple years.
- Specialized Insurance
  - CVS/Anthem and ESI/Cigna are offering insurance specific to gene therapy

Gene Therapy Best Practices

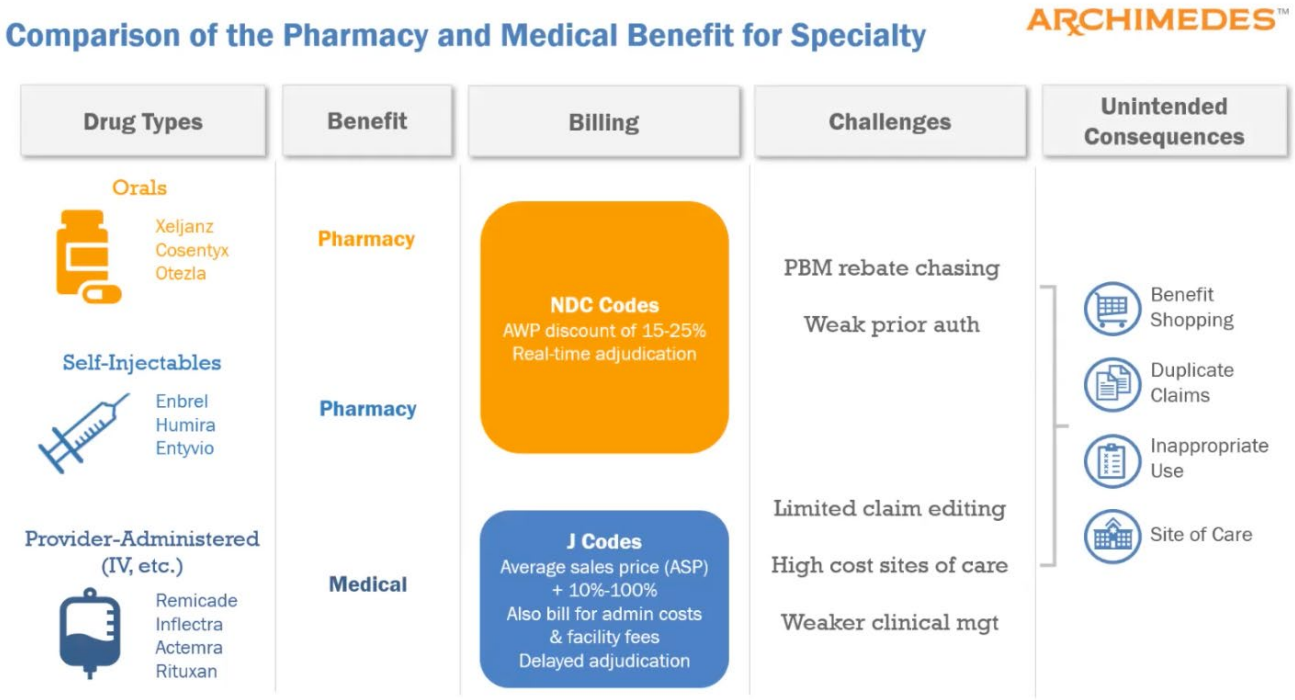
- Renegotiate high price hospital contracts to reduce drug costs
- Allow for a one-time treatment course of approved gene therapy to be administered through your claims/authorization system
- Implement strict clinical criteria for all gene therapy that is evidence-based
- Consider outcomes-based contracts with efficacy guarantees
- Ensure there is a review process for unspecified drugs for new gene therapy by your health plan
- Ensure each gene therapy contract is to be paid at a specific amount – not a % of billed charges or a general rate

Medical and Pharmacy Specialty Rx Differences

⇒ Specialty drugs that are covered under the pharmacy benefit use **national drug codes (NDCs)** for billing. These codes provide comprehensive information that identifies the drug, dosage, and package size (number of units).

⇒ Medical benefit drugs are coded by **J-codes** per the Healthcare Common Procedure Coding System. A J-code identifies the chemical name of the drug but is limited in that it does not identify the medication manufacturer, strength, or package size.

⇒ Shifting from Medical to Pharmacy Benefit could assist in reducing cost by taking advantage of more aggressive utilization management, opportunities for rebates, and deeper network discounts.



Medical Specialty Drugs – Billing Challenges

- Duplicate **Billing - without the proper edits in place, drugs can be** duplicate billed across benefits
  - Duplicate billing savings average $12K per case
- **Variable Pricing** (e.g., Remicade 600 mg infusion costs vary per site of care)
  - Outpatient Hospital
  - Physician Office
  - Home Infusion
  - Infusion Pharmacy

- **Excessive Billing**
  - Employer paid $145,530 for a drug under the medical benefit that should have cost $1,400.
  - Provider billed plan $98,647 on 10 dates of service for (1) patient. Keytruda billing is usually between $9,000-$15,000 = $500,000 mistake
- **No Real-Time Adjudication**
- **Lack of Robust Claims Adjudication Edits**
- **Understanding Unit Conversions**

NOTE: A **Health Affairs** Study found that generous reimbursement influenced which chemotherapy treatments physicians prescribed for cancer patients – often more expensive.

Billing Errors Best Practices – Action Items

⇒ Implement **billing error management program**

⇒ Understand the financials through **analytics**

⇒ Implement a **reimbursement** process

Medical Specialty Drug Management Strategies

Your medical trend is more variable than your pharmacy trend

- Focus on site of care management, clinical management, and billing errors management

Site of Care is considered low hanging fruit for Employers

- Best sites of care: Physician office and Home infusion
- Hospital Outpatient Facilities contribute to high drug costs and are the most expensive sites of care. They are reimbursed a percent-of charges by commercial payers, which is considerably higher than physician offices or home infusion

Pricing Benchmarks by Site of Care/Channel

- **Home** = ASP + 10%
- **Physician Office** = ASP + 20%
- **Outpatient Hospital** = ASP + 60%
- **Infusion Pharmacy** = AWP - 19%

(ASP = Average Sales Price | AWP = Average Wholesale Price)

Site of Care Best Practices – Action Items

⇒ Implement **site of care/ channel management program**

⇒ Understand the financials through **analytics**

⇒ Implement a **high touch concierge** process

Second Opinions

Consider using **2nd Opinion** services, like *Cancer Expert NOW* for utilization management challenges

Savings Checklist

✓ Pass Thru PBM With Aligned Business Model
✓ Lowest Net Cost Formulary
✓ Promote Biosimilars
✓ Robust Prior Authorization
✓ Copay Assistance Program
✓ Medical Specialty Management Program

Employer Case Study:

Employer implemented the following Specialty RX strategies on 1/01/21:

- Medical Drug Carve-Out
- Prior Authorization
- Copay Assistance
- Clinical Case Management
- Site of Care Management
- Billing Error Management

Employer realized $1.08M Savings in Q1-Q2, 2021

- $645K in Clinical Management Savings
- $440K in Copay Assistance Savings
- **44% Plan Spend Savings** on included drugs

Alternative Approach: Outsource medical specialty management to a third-party, such as a Specialty PBM.

Example: Cancer Therapy Costs & Management Challenges

- Cancer incidence and prevalence is growing
- Cancer cost increases are outpacing all other conditions
  - Cancer is the leading cost driver for high-cost claimants
  - Cancers accounted for 52% of the paid amount and 60% of the claims cost of stop-loss claims, according to 2019 Sun Life Stop-Loss Research Report: High-cost Claims and Injectable Drug Trends.
- Utilization Management Challenges
  - There are 70,000 genetic bio-marker tests, but only 200 lab billing codes.
- Preauthorization and Precertification Challenges
  - PA has increased from <5% to 75%+, according to NAHPC 2018 Report: *Achieving Value in Cancer Care: Striving for Patient Centered Care*.
- Clinical policy development cannot keep up with treatments
  - The market and pipeline are abundant, according to IQVIA Global Oncology Trends 2019.

DFWBGH Specialty Pharmacy Workshop Takeaways

- **Employers Should Consider Market Solutions – Beyond the PBM**
  - Custom Specialty Pharmacy Network (1%-5% Savings)
  - Prior Authorization Carve-Out (5%-10% Savings)
  - Third-Party Copayment Assistance (15%-20% unit cost Savings)
  - Alternative Funding (30%-60%)
  - Specialty PBM Carve-Out (25%-50% Savings) \
  - Second Opinions

- **Clinical Best Practices for Employers**
  - Implement robust criteria
  - Implement a rigorous PA review process
  - Actively promote biosimilars

- **Site of Care Best Practices for Employers**
  - Implement site of care/ channel management program
  - Understand the financials through analytics
  - Implement a high touch concierge process
- **Medical Billing Errors Best Practices for Employers**
  - Implement billing error management program
  - Understand the financials through analytics
  - Implement a reimbursement process
- **Alternative Approach:** Outsource medical specialty management to a third-party
- On the medical side physicians **make money** off the drugs. 80% of revenue for oncologists comes from oncology drugs.
- The process of educating a doctor about changing a medication takes about 3 minutes with a good Specialty PBM. If it's an emergency, it is better to let the process play out because the more complex the disease, the more time it takes to get the drug right.
- Consider using a good **Second Opinion service** like *Cancer Expert NOW* for utilization management on the oncology side to get the best treatment for your employees. Note: You are not moving the patient from their personal oncologist.
- **Benefits Consultants** do a good job of focusing on the traditional side of the PBM. Consultants are coming around – Specialty Rx is not as easy as managing cholesterol or diabetes drugs. This could be why it seems like consultants are not proactively discussing savings opportunities.
- **Employers want to do business with a PBM that is:**
  - Actually transparent
  - Driven by the lowest net cost
  - Paid directly by the employer, instead of through the health plan
- **Employers should take advantage of various sources of savings:**
  - **Copay Assistance:** Industry leading savings due to program design that includes ALL drugs
  - **Prior Authorization:** Documentation required for PA review; more than 40% of PA reviews result in a change in therapy
  - **High-Cost Case Management:** In-depth case management for high-cost cases, with savings averaging nearly $1 million per patient annually
  - **Medical Management:** Comprehensive solution set for the specialty drugs under medical

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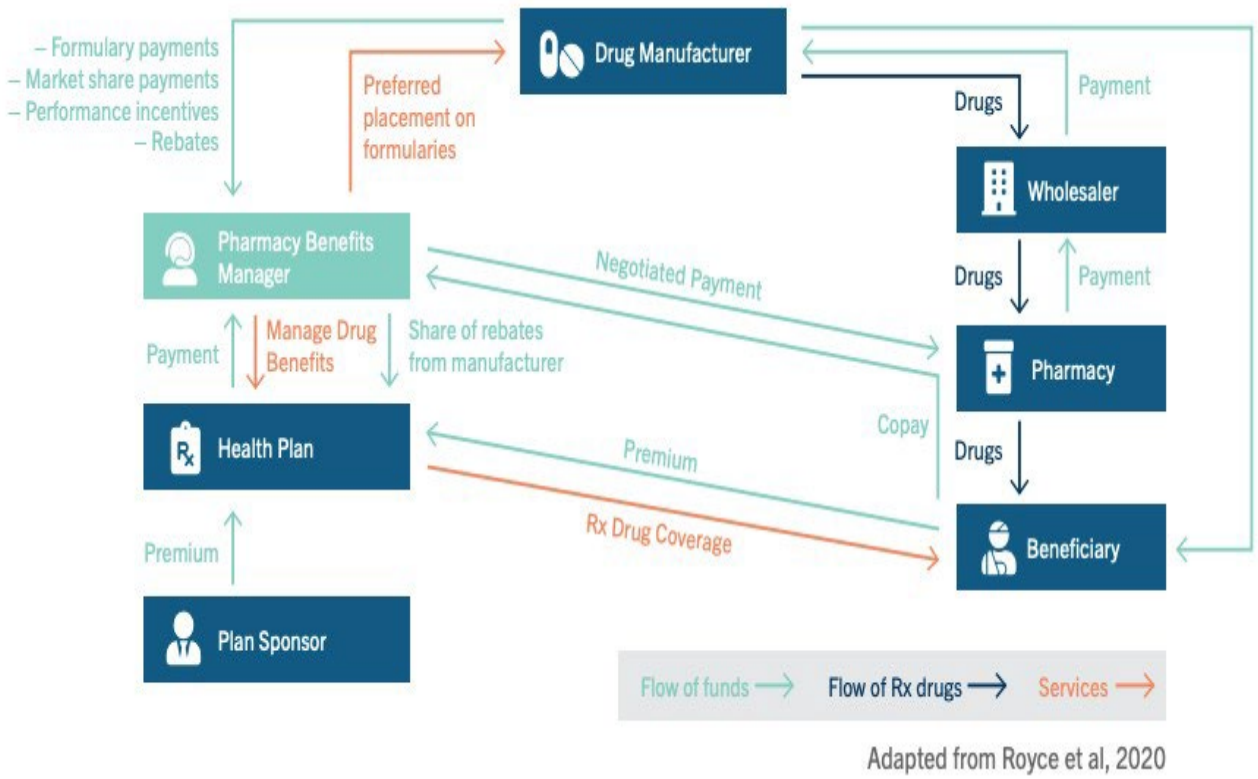
Next-Steps and Employer Follow-Up

Ask your TPA and PBM to provide the following information and examine your pharmacy data:

- Your total medical spend for 2021 and “spend trend” for the past 3 years (pre-COVID and during COVID)
- Your PBM spend for 2021 and “spend trend” for the past 3 years (pre-COVID and during COVID)
- Your total Specialty Pharmacy spend for 2021 and “spend trend” for the past 3 years (pre-COVID and during COVID)
- What percentage of your specialty spend is in the pharmacy benefit and in the medical benefit?
- What strategies do you currently use to manage specialty drug utilization and cost?

Appendix

Understanding the flow of money, products and services in the drug supply chain:



Adapted from Royce et al, 2020

Additional Resources

Archimedes White Paper: ***Emerging Market Solutions for Specialty Drug Management, 2022***

https://archimedesrx.com/wp-content/uploads/2022/02/Archimedes_Emerging-Specialtyhttps://archimedesrx.com/wp-content/uploads/2022/02/Archimedes_Emerging-Specialty-Strategies-Feb2022.pdfStrategies-Feb2022.pdf

Midwest Business Group on Health: *Designing Specialty Drug Benefits – Employer Checklist, 2020*

http://specialtyrxtoolkit.0470c2a.netsolhost.com/wp-content/uploads/Designing-Specialtyhttp://specialtyrxtoolkit.0470c2a.netsolhost.com/wp-content/uploads/Designing-Specialty-Drug-Benefits_0-updated-6-12-20.pdfDrug-Benefits_0-updated-6-12-20.pdf

DFWBGH is grateful to Pfizer for its generous support of this high value Employer Specialty Pharmacy Workshop.