IMPROVING OHIO'S MEDICAID PRESCRIPTION COVERAGE PROGRAM

Presented to:

The Joint Medicaid Oversight Committee

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Summary of Discussion

Three Part Discussion:

1. Brief Background

2. Necessary Procedural Approach
   - Don't be Defensive
   - Eliminate Conflicts of Interest
   - Basics About Conducting A PBM RFP

3. Necessary Substantive Approach
   - Review 7 Core Problems, and Discuss Solutions to Each
   - (There are many other problems that must also be addressed)

I.

A BRIEF BACKGROUND On KEY MATTERS

What Are PBMs?

- PBM = Pharmacy Benefit Manager
- PBMs were created on the theory that by aggregating many Plans' coverage, and having the PBM (i) serve as an intermediary to negotiate contracts (with retail pharmacies, manufacturers and wholesalers), and (ii) oversee coverage (through better Formularies, and Prior Authorization, Step Therapy and Quantity Limit Programs), drug costs could be better controlled and people could be steered to wiser drug use
- However, PBMs have turned every contracting opportunity into a means to increase their profits rather than control their clients' costs

Why Ohio?

Ohio is the Canary in the Coal Mine: After pharmacists spoke out about concerns about PBMs' reimbursements that were causing community pharmacies to go out of business, state officials and the Columbus Dispatch began questioning why state spending on prescription drugs was increasing while pharmacy economics were eroding.

The Truth is Exposed: The Dispatch, Ohio Department of Medicaid, and Auditor Dave Yost highlighted price distortions that amounted to $244 million in hidden *retail* PBM "spread pricing".

Ohio is Now Positioned to Pave the Way: We're here today, because we all want to determine how it can and ensure it will.

Ohio's Choices

Ohio can proceed in 1 of 2 ways:

1) Make PBMs fulfill the role they were created to fulfill, via an "airtight" PBM contract
   - The contract must be free of ALL loopholes, and give Ohio the ongoing right to customize, continually adjust & improve pricing, and monitor and get reimbursed for any violation
   - Ohio must then actually do all the above

2) Entirely cut out PBMs and have Ohio arrange all necessary contracts and run its own prescription coverage program

Ohio should consider creating a State "hub" to oversee all prescription coverage in different state programs (Medicaid, PERS, BWC, etc)

II.

NECESSARY PROCEDURAL APPROACH

Procedural Problem #1:

Do NOT Be Defensive

- No one should feel "defensive": Ohio's situation is NOT unique
- We have reviewed *hundreds* of PBM-Client contracts – and analyzed scores of entities' prescription coverage claims data
- Virtually every PBM contract is stuffed with problems, and claims data virtually always shows grossly excessive costs
- Look "backwards" to figure out what's wrong, but then -
- Look "forwards" to do what's necessary to change the State's prescription coverage program

Procedural Problem #2

Omnipresent Conflicts of Interest

- PBMs maintain a web of contracts, and secretly make money from every type of contract, including from their contracts with -
  - Retail pharmacies
  - Wholesalers
  - Manufacturers
  - Their clients (Ohio and all others....), and
- PBMs pay money to Consulting Firms
- Prescription Coverage is complex given all these contracts

Whether Ohio (i) stops using PBMs and set up Ohio's own set of contracts; or (ii) uses PBMs and takes steps to control PBMs' excessive profits, Ohio must retain "expertise" to re-structure all relationships

Most Consulting Firms Can't Be Used To Provide Expertise

Many – if not most – Consulting Firms:

- Have conflicts of interest
- Are getting paid by PBMs to feed business to the PBMs
- Are hired by PBMs to perform work & therefore have incentives to preserve their lucrative relationships with those PBMs

Ohio (and every State & Plan) needs to be aware of Consulting Firms' conflicts of interest and ensure retained Consulting Firms act solely and exclusively in the State's (and Plan's) interests

However, almost NO ONE takes effective steps to investigate and avoid Consulting Firms with Conflicts of Interest

The Solution to Consulting Firms' Conflicts of Interest

Require every Consulting Firm to execute an *effective* Conflict of Interest Disclosure Form: This requires two parts:

i. Disclosure Section – requiring disclosure of ALL potential conflicts

ii. Penalty Section for inaccurate disclosures

- Reimbursement of all fees if disclosures were inaccurate
- A "Liquidated Damages" Provision

Procedural Problem #3

States Use the Wrong Method To Select Their PBM

States select PBMs – and enter into PBM contracts – in several ways:

- They negotiate contracts 1-on-1 with their existing PBM, using a few "standards" that they think matter
- They allow MCOs to conduct RFPs based on Questionnaires, using certain required "standards"
- They conduct their own RFPs based on Questionnaires, using certain stated "standards"

What's wrong with these approaches?

- Can't rely on MCOs, given vertical integration & the obvious Conflict of Interests
- Can't rely on listed "standards": To obtain a loophole-free PBM contract - structured entirely differently - dozens of changes are needed

The Right Approach To Select A PBM

Don't ever negotiate 1-on-1 with a PBM. Instead --

Conduct a PBM RFP, but *not* based on a Questionnaire: Conduct a *Contract-Focused RFP:*

- Before starting the RFP, draft an entirely different form of PBM contract
- Bid it out at the beginning of the RFP
- Make every PBM Contestant mark it up, and insert all required pricing terms & guarantees *in the contract*
- Then use the RFP's leverage to extract the needed substantive contract terms, and best possible financial terms
- Require Semi-Finalist PBMs to execute their contract mark-ups as "binding contract offers" before you select your Finalist
- *Then* select the State's next PBM(s) and execute the contract(s)

How Much Time Is Needed to Conduct a Successful RFP?

Short Answer: At least 5 - 6 months for the RFP, plus at least 3 months after its completion for implementation. Need to:

- Develop an entirely different form of PBM contract (4 – 6 weeks)
- Bid it out and give PBMs time to respond (3 – 4 weeks)
- Review & analyze responses (2 – 3 weeks)
- Engage in repeated negotiations with each PBM (6 – 8 weeks)
- Allow each PBM to finalize its proposed contract (2 - 3 weeks)
- Review "binding contract offers" and select PBM (2 – 3 weeks)

Current Approach:

- Not privy to current status
- It's likely not feasible to conduct a meaningful PBM RFP and implement by 7/1/20
- Better not to rush the process – and doom it. Instead, ODM may need to obtain more time, and conduct an appropriate, contract-focused RFP that will be successful

III.

NECESSARY SUBSTANTIVE APPROACH

If Ohio uses a PBM, one document ultimately controls Ohio's prescription coverage costs –

The PBM CONTRACT

But it's highly likely that EVERY Ohio PBM Contract is stuffed with loopholes

Therefore, the most important activity Ohio must undertake is to change its PBM CONTRACT TERMS

Overview: Substantive Terms Needed

To create an effective PBM contract, the State must understand numerous contract problems, and restructure its PBM contract to eliminate those problems. Core problems:

1) The Pass-Through Pricing Problem
2) The Problem of Ambiguous Definitions & Worthless Price Guarantees
3) The "Metric" Problem – AWP, MAC & Other Useless Metrics vs. Actual Acquisition Cost
4) Specialty Drug Problems (several separate problems)
5) Rebate Problems (ditto)
6) The Transparency & Audit Problem
7) The Overarching Problem: PBMs aren't creating *real* competition to force manufacturers to lower their drug prices & produce better drugs

Problem #1:

DECEPTIVE PASS-THROUGH PRICING

What's the Difference Between "Spread" and "Pass-Through" Pricing

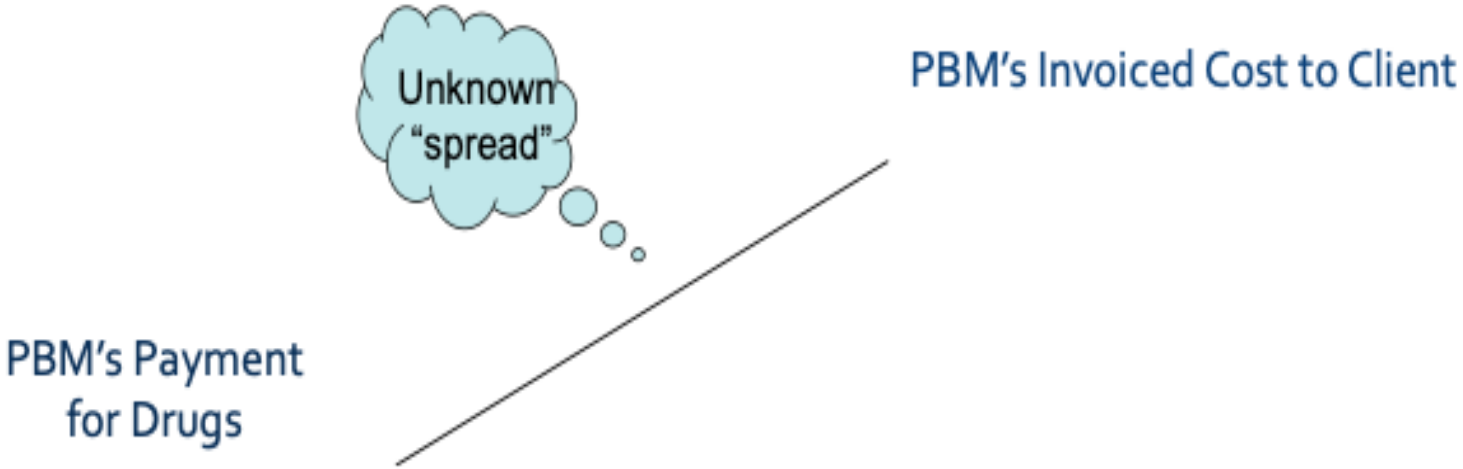
Spread Pricing: When a PBM pays one rate to a pharmacy on a drug claim, but charges the Plan a different, higher amount, with the PBM pocketing the difference

- Ohio audit found $244 million in PBM spread in one year in the Medicaid Managed Care Program (from Q2 2017 to Q1 2018)

Pass-Through Pricing: When a PBM pays one rate to a pharmacy on a drug claim and charges the Plan the same amount.

"Spread Pricing"

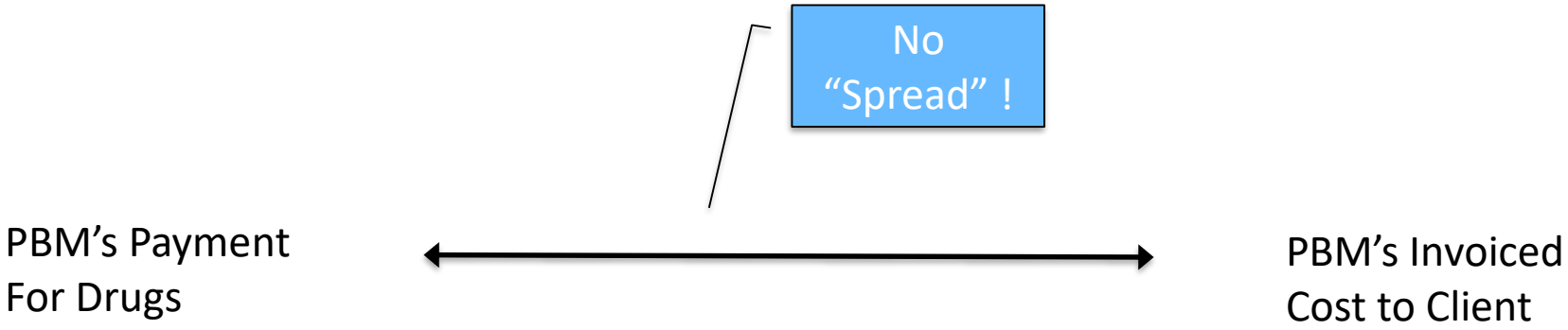
Here's a picture of "Spread Pricing":



Spread pricing allows PBMs to artificially inflate drug costs to the payer by hiding the true cost of prescriptions

"Pass-Through Pricing"

Here's a picture of "Pass-Through Pricing":



Pass-Through Pricing is clearly better, but PBMs have created at least Two Deceptions eviscerating *real* Pass-Through Pricing!

Deception # 1

Consider the difference between what "Pass-Through Pricing" can mean when -

- **A PBM is paying a 3rd party pharmacy**: The PBM will pass through its reimbursement to the pharmacy
- **A PBM is paying a subsidiary pharmacy**: Two possibilities: The PBM can pass through (i) its acquisition costs, or (ii) a "negotiated rate" with its subsidiary pharmacy. Obviously, the PBM can manipulate the latter!

Implications of Deception #1
In Each Pharmacy Channel

Retail Pharmacy: If the PBM owns its own subsidiary retail pharmacies, Pass-Through Pricing can be manipulated

- Only one major instance: Caremark / CVS pharmacies

Mail Order & Specialty Drug Pharmacies: Many PBMs own their own subsidiary mail & specialty drug pharmacies

- Of those: Virtually all PBMs are passing through their "negotiated rates" with their own mail and subsidiary pharmacies!

Deception #2 and Its Implications

- Almost all PBMs have numerous, different retail pharmacy contracts with each pharmacy.

- So when a PBM agrees to provide "Pass-Through Pricing" for retail drugs, it can decide which of many different contracted rates with each pharmacy to pass-through!

- Since a PBM's book-of-business is divided between clients with "Pass-Through Pricing" and clients with "Spread Pricing," a PBM can use its contracted retail pharmacy rates that reimburse the pharmacies the most – and thus result in the highest costs – for the PBM's "Pass-Through" clients. And the PBM can use its contracted retail rates that reimburse the pharmacies the least for the PBM's "Spread" clients – resulting in greater profit spreads overall for the PBM.

Conclusions About "Spread" & "Pass-Through" Pricing

- Pass-Through Pricing is far better: But typically, it's ineffective. Use a PBM RFP to try to make it *real.* Analyze each PBM's pharmacy relationship – for each pharmacy channel (retail, mail and specialty):
- If it's a 3rd party pharmacy relationship: Use the RFP to try to contractually require the PBM to pass-through its "best" rates
- If it's a subsidiary pharmacy relationship: Use the RFP to try to contractually require the PBM to pass-through its subsidiary pharmacy's "acquisition costs"
  - Since most don't – and won't: Realize you don't have *real* "Pass-Through Pricing" so you ***must*** find a different way to ensure lower drug costs:

Strong Guarantees – and Actual Acquisition Cost (NADAC) – will work

Problem #2:

AMBIGUOUS CONTRACT DEFINITIONS = MEANINGLESS PRICE GUARANTEES

Contract "Definitions" & Price Guarantees

- Every PBM Contract contains "Definitions" and Price Guarantees based on those Definitions:
  - Retail "Brand Drug" Guarantees
  - Retail "Generic Drug" Guarantees
  - Retail 90 "Brand Drug" Guarantees
  - Retail 90 "Generic Drug" Guarantees
  - Mail "Brand Drug" Guarantees
  - Mail "Generic Drug" Guarantees
  - A "Specialty Drug" Guarantee (or many "Specialty Drug" Guarantees)
- So 3 key terms that all PBM Price Guarantees are based on: (i) "Brand Drug"; (ii) "Generic Drug"; (iii) "Specialty Drug"
- The problem is: PBMs write ambiguous contract definitions for each of those three terms, making their Price Guarantees worthless

Why Contract Definitions Are So Important

Analogy: Suppose a grocery store has the following "Fish Guarantee":

"All Fish* guaranteed to be no more than $7.95 or less per pound"

*** Grocery reserves the right to exclude certain fish from Fish Guarantee in grocery's discretion**

- What would the guarantee be worth? (Answer: Nothing)
- If the grocery "improved" its guarantee to $5.95 per pound, would you reduce your fish costs? (Answer: Obviously not)
- As long as the key term - "Fish" - is badly defined (allowing the grocery to move fish in and out of the guarantee), the guarantee is worthless
- The same problem exists with PBM contracts: The 3 key terms – "Brand Drug", "Generic Drug" & "Specialty Drug" – are all typically badly defined

Examples of Ambiguous "Brand Drug" and "Generic Drug" Definitions

" Brand Drug means all drugs in First DataBank's National Drug File, or another nationally recognized drug source designated by PBM...."

"PBM uses its own proprietary algorithm to classify Brand Drugs ...."

"Generic Drug" means any single source or multisource drug .... "

"PBM shall use a nationally recognized pricing source (with supplements) for purposes of pricing and classifying drugs (e.g., legend vs over-the-counter, brand vs generic)...."

Example of a Strong "Brand Drug" Definition

Brand Drug(s) - The term "Brand Drug(s)" shall mean the following: The Multisource Code field in Medi-Span contains an "M" (co-branded product), or an "N" (single source brand) , or an "O" (originator brand) (except where the Claim is submitted with a DAW Code of "3","4", "5" or "6", in which case it shall be considered a Generic Drug). Claims with a Multisource Code of "O" and with a DAW Codes of "0", "1", "2", "7", "8" or "9" shall be considered a Brand Drug. The Parties agree that when a drug is identified as a Brand Drug, it shall be considered a Brand Drug for all purposes by PBM, including but not limited to adjudicating the Claim, reimbursing the relevant pharmacy, invoicing CLIENT, determining the Copayment or Coinsurance to be paid by the Plan Beneficiary, calculating the satisfaction of Average Annual Guarantees as further described in Article __ of the Agreement, calculating the satisfaction of Financial Benefit Guarantees as further described in Article __ of the Agreement, and calculating the satisfaction of generic fill rates (if any).

Example of a Weak "Specialty Drug" Definition & Replacement

Below is a typical "Fish-y" Specialty Drug definition:

> '**Specialty Drugs**' *may* be any high-cost drug that *may* require special handling or *may*....

Eliminate the useless definition, and create a meaningful one: Generate a List of every Specialty Drug (1,400+ drugs) and then cross-reference it in your Definition:

Specialty Drug(s) - The term "Specialty Drug(s)" shall mean each drug identified on Exhibit __ of this Agreement. The term "Specialty Drug" shall also include any new-to-market specialty drug that CLIENT approves the dispensing of, in writing. In each Benefit Specification Form or Benefit Change Form, CLIENT shall have the right to select which Specialty Drugs on Exhibit __ shall (or shall not) be dispensed to its Plan Beneficiaries.

Next Step To Gaining Strong Guarantees

For Retail, Retail 90 & Mail Drugs: After you pin down "airtight" Definitions for "Brand Drug" and "Generic Drug", use the State's RFP to force PBMs to provide two Guarantees – one for Ingredient Costs and one for Dispensing Fees – for each type of drug:

- Two Retail "Brand Drug" Guarantees
- Two Retail "Generic Drug" Guarantees
- Two Retail 90 "Brand Drug" Guarantees
- Two Retail 90 "Generic Drug" Guarantees
- Two Mail "Brand Drug" Guarantees
- Two Mail "Generic Drug" Guarantees

For Specialty Drugs: After you pin down an "airtight" Definition for "Specialty Drugs" by cross-referencing every Specialty Drug, require each PBM Contestant to provide a drug-by-drug Guarantee for each listed Specialty Drug (1,400+ Minimum Discount Guarantees)

Problem #3:

SLIPPERY “METRICS”
(Like AWP, MAC and U&C)
vs.
STRONGER “METRIC”
(Actual Acquisition Cost / NADAC)

"Metric" Problems

- Most PBM-Client contracts use three "metrics" for their Price Guarantees
  - AWP (Average Wholesale Price)
  - MAC (Maximum Allowable Cost)
  - U&C (Usual & Customary)

- So a Contract might contain the following retail Price Guarantee for "Generic Drug" Ingredient Costs:

"PBM guarantees that Generic Drugs will be priced at the lowest of (a) AWP-78%; or (b) MAC; or (c) U&C"

The problem is: All three metrics are shifting standards

Dubious Metrics

- **AWP** – stands for "Average Wholesale Price", but complete misnomer! AWP is typically based on manufacturers' WACs (Wholesale Acquisition Costs), which are any $ figure Manufacturers want, and are changed whenever manufacturers want (which means they typically go up over time)

- **MAC** – stands for "Maximum Allowable Cost", but PBMs can create *any* "maximum" they want, and change it whenever they want, and create different MAC Lists for different pharmacies, and for different clients

- **U&C** – stands for "Usual & Customary", but it isn't! Pharmacies can create any U&C they want and change their U&C's whenever they want!

Use A Different Metric: Actual Acquisition Cost

Rather than using fake benchmarks generated by those in the drug supply chain, Ohio should derive prices off the Actual Acquisition Cost (AAC) of each drug, which is what CMS requires in state Medicaid Fee-For-Service Programs

- AAC can be based on surveys of pharmacy acquisition costs, which some states perform on their own
- Or Ohio can use CMS' "NADAC"

NADAC

- **"NADAC" = National Average Drug Acquisition Cost.** NADAC is based on a CMS survey that asks retail pharmacies to disclose their acquisition costs from wholesalers
- NADAC has problems: (i) it's voluntary; (ii) it doesn't include big chains; (iii) it doesn't include post-acquisition rebates; (iv) it doesn't include every retail/mail drug, or most drugs dispensed from Specialty Pharmacies
- But it's a better metric for drugs dispensed from retail and mail pharmacies, and the few drugs dispensed from specialty pharmacies that have NADACs. Essentially, if there's a NADAC value, use it!
- Right now, must still obtain price control using "discounted AWPs" for -
  - Any drug dispensed from retail/mail pharmacies that doesn't have a NADAC
  - For most drugs dispensed from Specialty Pharmacies (since they are without NADACs)

Problem #4:

SPECIALTY DRUGS

MUST ADDRESS SEVERAL DIFFERENT PROBLEMS

What Are Specialty Drugs?

Specialty Drugs are extremely high-cost drugs that typically are < 5% of scripts dispensed, but 25%+ of Plans' total costs.

By 2021, Specialty Drugs may represent 50% of Ohio's total drug spend.

Examples:

Drug Name	Ohio's Approx # of Annual Rxs	Ohio's Approx Annual Drug Cost
Imatinib Mesylate 400 mg	856	$4,176,741
Capecitabine 500 mg	1,534	$2,839,465
Tenofovir disoproxil fumarate 300 mg	2,287	$893,867
Entecavir 0.5 mg	1,311	$521,809

What Can Ohio Do To Dramatically Reduce At Least Some Specialty Drug Costs?

- Most Specialty Drugs are not currently dispensed through retail pharmacies. But some are.
- For all such Specialty Drugs, most have NADACs.
- For all those Specialty Drugs: Use an RFP to require the PBM to invoice the State using the NADAC
- The State will quickly save several million in total, on a few drugs:

Drug Name	Ohio's Approx # of Annual Rxs	Ohio's Approx Annual Drug Cost	Estimated Ohio Savings if a NADAC Plus Dispensing Fee is Used
Imatinib Mesylate 400 mg	856	$4,176,741	$3,237,332
Capecitabine 500 mg	1,534	$2,839,465	$2,156,343
Tenofovir disoproxil fumarate 300 mg	2,287	$893,867	$388,090
Entecavir 0.5 mg	1,311	$521,809	$400,130

For All Other Specialty Drugs – 5 Problems

Most PBM-Client contracts -

1) Have an ambiguous definition for "Specialty Drugs" (already discussed the solution)
2) If there are Specialty Drug Guarantee(s), they're badly structured and don't control Specialty Drug prices
3) Contracts don't contain any terms related to new-to-market Specialty Drugs (including new-to-market generics & biologics)
4) Contracts lock clients into the same Specialty Drug pricing for the life of the contract
5) Contracts lock clients into using the PBM's Specialty Drug Pharmacy for the life of the contract

First, Make Sure You Write an "Airtight" Specialty Drug Definition

- It's virtually certain your current PBM contract contains a "Fish** Guarantee" for Specialty Drugs
- You need to define "Specialty Drugs" so that <u>every</u> Specialty Drug is included in the Guarantee:
  - Create an Exhibit list of all Specialty Drugs (1,400+ drugs) and define "Specialty Drug" by cross-referencing to that list
  - Make sure your "Specialty Drug" definition includes every new-to-market Specialty Drug the State chooses to cover

Second, Create Effective Price Guarantees for All Existing Specialty Drugs

PBM Contracts typically have either of two approaches to Specialty Drug Price Guarantees:

1) **A Single AWP Discount Guarantee for all "Specialty Drugs" (say, AWP-17%):** Ineffective for at least 2 Reasons:
   - The "Specialty Drug" definition is like a "Fish** Guarantee"
   - Even if it's not, many Specialty Drugs should have far better Guaranteed Discounts (like AWP-30% or even AWP-80%). Therefore, the PBM is grossly overcharging!
2) **A List of Specialty Drugs, with a Guaranteed Discount for each listed drug:** Ineffective for at least 2 reasons:
   - The List doesn't include numerous drugs (which allows the PBM to charge whatever it wants for all excluded drugs)
   - The PBM reserves the right to change the Guarantees in its discretion!

The Solution to Totally Ineffective G'ees for Existing Specialty Drugs

- Take the List you created to define the term "Specialty Drugs" (listing about 1,400+ Specialty Drugs)
- In a PBM RFP, require every PBM Contestant to propose its drug-by-drug "Minimum Discount Guarantee" (1,400+ Guarantees)
- Use the RFP's leverage to force out competitive guarantees for as many line items as feasible, focusing on those with the most use

Third, Create Price Guarantees for New-to-Market Specialty Drugs

There are about 20 to 40 new-to-market Specialty Drugs approved every year

- But most PBM-Client contracts contain no price terms for these drugs!
- This means by the end of 3 years most entities have no price controls over about 60 to 120 new-to-market Specialty Drugs!
- Require your PBM to provide a "Default Discount Guarantee" for every new-to-market Specialty Drug
- Require your PBM to provide you with a quarterly "right to negotiate" a Minimum Guaranteed Discount to improve on the Default Discount Guarantee

Fourth, Don't Allow Your PBM To Lock You Into Specialty Drug Pricing

Specialty Drugs are expensive, and their AWPs keep increasing. Therefore, you need to be able to improve your Minimum Discount Guarantees, whenever feasible.

- Better discounts ARE periodically available
- Give yourself a quarterly "right to renegotiate" any Specialty Drug Guarantee
- To provide "leverage" to get better Guarantees, in the RFP require PBMs to give you a "carve-out right" to use alternative specialty drug pharmacies or to negotiate directly with manufacturers
- Then when you implement your new PBM contract, periodically compare your PBM's Guarantees for high-use, high-cost drugs with Guarantees available from alternative pharmacies, exercise your "right to renegotiate", and when necessary, and your "carve out" right, to ensure you have the strongest possible drug-by-drug Guarantees

Fifth, Don't Allow Your PBM To Lock You Into Its Specialty Drug Pharmacy

- Many - if not most - PBM-Client contracts give the PBM's Specialty Drug Pharmacy the "exclusive right" to dispense Specialty Drugs
- This is ill-advised
- Many Specialty Drugs can be dispensed from retail pharmacies
- Retail pharmacies often provide better pricing
- Don't accept any PBM contract that grants your PBM an "exclusive right" to dispense drugs
- Otherwise, you're eliminating useful competition from retail pharmacies

Problem #5:

REBATES

MUST ADDRESS SEVERAL DIFFERENT PROBLEMS

"Rebate" Problems

There are at least THREE different core Rebate Problems:

1) Most PBMs don't pass through 100% of manufacturer payments the PBMs receive
2) The Rebates – and other secret payments – PBMs receive lead PBMs to include & favor high-cost drugs, rather than excluding or disfavoring those drugs and favoring lower-cost drugs
3) Most PBMs refuse to disclose drug-by-drug Rebates; Therefore, entities can't tell the "net cost" of any drug

First, Make Sure You Get 100% of All Payments, Not Just Mandated "Rebates"

- Under Medicaid, manufacturers are statutorily mandated to pay a certain amount of Rebates
- But PBMs frequently negotiate payments from manufacturers that exceed mandated Rebates
- Ohio should collect & benefit from all such monies
- Currently, Ohio doesn't even know about them, let alone collect them!

PBMs Execute Two Types of Contracts

PBM contracts with clients:

Rebates

PBM contracts with manufacturers:

Rebates
Admin fees
Health Mgt Fees
Data Sales Fees
Etc. Etc. Etc.

What's the Solution?

- Don't let a PBM contract require only the "pass-through" of mandated Rebates
- Invent a new term: "Financial Benefits"
- Define it to include all third party payments
- Explicitly require the PBM to pass-through mandated Rebates AND all other "Financial Benefits"
- Explicitly include audit language to be able to audit the Financial Benefit pass-through requirement

Example of a WEAK "Rebate" Definition, & A Better "Financial Benefit" Definition

Below is a typical "Fish-y" Rebate definition:

> '**Rebates**' means any payment by a drug manufacturer to PBM pursuant to a Formulary Rebate Agreement that is directly attributable to the utilization of drugs....

Create a new term – "Financial Benefits" - and require the PBM to pass through 100% of all payments:

Financial Benefits - The term "Financial Benefits" shall mean CLIENT's Pro Rata Share (as Pro Rata Share is defined herein) of all financial benefits received by PBM (as PBM is defined herein) from all Pharmaceutical Manufacturers (as Pharmaceutical Manufacturers is defined herein), including without limitation CLIENT's Pro Rata Share of all: rebates (including without limitation all formulary rebates, all growth or market share rebates, and/or all inflation protection or price protection rebates), discounts, administrative or other fees, chargebacks, grants, all other monies of any kind paid by Pharmaceutical Manufacturers, all discounts or credits or reimbursements of any kind provided by Pharmaceutical Manufacturers, all financial benefits paid by Pharmaceutical Manufacturers to PBM for Covered Items dispensed on CLIENT's behalf from any pharmacy, and all goods (or in kind services) provided by Pharmaceutical Manufacturers.

Second, Don't Collect Rebates For Unnecessary, High-Cost Drugs!

- PBMs are collecting immense sums of money from manufacturers
- Many manufacturers of high-cost drugs pay PBMs large sums to get PBMs to favor their unnecessary high-cost drugs
- Even if PBMs pass through 100% of *all* manufacturers' payments (not just mandated Rebates), the rebated high-cost drugs are often far more expensive than alternatives
- Therefore, to reduce its costs, the State should consider customizing its Formulary, and disfavoring – (or excluding) - many high-cost drugs and foregoing their rebates!

Third, Require the PBM to Provide "Net Cost" Information

- Under Medicaid, the State must cover most drugs
- However, the State has a *potentially* effective means to steer people to lower-cost drugs, namely Prior Authorization & Step Therapy Programs
- To ensure Ohio can structure such Programs, Ohio needs to know the "Net Cost" of every drug in a therapeutic category:
- "Net Cost" = the drug's cost minus the Rebates and any other monies passed through to the State
- However, most PBMs refuse to provide "Net Cost" information by drug!
- CHANGE THIS! Contractually require your PBM to provide drug-by-drug information about all monies passed through
- Then, Ohio must "customize" its Formulary – and Programs – on an ongoing basis, and probably "take control" of the "Programs"

Problem #6:

TRANSPARENCY
and
MEANINGFUL AUDITS

Transparency = Access to ALL Information

- Ohio State is spending approximately $4 billion on its Medicaid rx coverage program
- Ohio is entitled to know how that money is being spent
- It's entitled to have access to all data and all documents related to its costs and the PBM's activities
- Ohio State's PBM contract should list all such data and documents, and include a catch-all provision to enable Ohio to add additional required information, whenever necessary
- The data and documents the State obtains should be made available to the public (scrubbed of only a few items)

Example of Required Information: For Pass-Through Pricing

Recently, Ohio Medicaid changed the mandated data requirement from "invoiced costs to State" to "reimbursed amounts to pharmacies". But clearly, the State needs *both* – and must spell out with precision what it needs for each, to ensure Ohio is getting actual Pass-Through Pricing:

- <u>For Third Party Pharmacies:</u> Claims data showing reimbursement to the pharmacy - and invoiced cost to the State - for every drug
  - Break out Ingredient Cost & Dispensing Fee
  - Try to ensure the State gets data on all PBM post-reimbursement DIR and "chargebacks" from pharmacies (or better yet, BAN them !)
- <u>For Subsidiary Pharmacies:</u> Claims data showing drugs' acquisition costs (not the "negotiated rates" between the PBM and its subsidiary pharmacies) - and invoiced cost to State - for every drug
  - Require the production of all Documents & Data related to post-dispensing money flows from manufacturers and wholesalers to PBMs

Additional Audit Issue

- Virtually all PBMs impose Confidentiality Agreements on the auditors retained by the PBMs' clients
- Unbeknownst to clients, PBMs' Confidentiality Agreements restrict the information auditors can review and restrict what the auditors can tell their own clients!
- Ohio State should prevent this by drafting an auditor Confidentiality Agreement, attaching it to its PBM contract, requiring every PBM during an RFP to accept Ohio's proposed Confidentiality Agreement, and contractually barring the use of any other Auditor Confidentiality Agreement

Problem #7:

PBMs Are NOT CREATING A COMPETITIVE MARKETPLACE TO CAUSE MANUFACTURERS TO PRODUCE BETTER DRUGS & REDUCE PRICES

What are the Requirements for an Effective Marketplace?

- Purchasers must have 2 types of information:
  - "Quality" information
  - Price information
- In the Drug marketplace, purchasers (patients) and doctors (prescribing drugs) and the entities paying for drugs (like Ohio State) don't have access to either type of information

"Quality" Information Needed: An Example - Abilify (Clinical Trial Info Submitted to FDA)

Benefits / Side Effects	Abilify	Placebo	Conclusion
Change in Depression (0 to 60 scale)	9 points less depressed	6 points less depressed	Helped patients by 3 points (on a 60 point scale)
Percentage helped	26%	15%	11% more helped than on placebo
Inability to sit still (mvt disorder like Parkinsons: Akathisia)	25%	4%	Extra 21% w/ Akathisia
Gained 7% or more of body weight	6%	1%	Extra 5% gained 7% or more of body weight

Every Patient, Doctor and Plan Should Have Access to "Quality" Information on Every Drug, By Therapeutic Category

Price Information Needed & Actions Needed to Force Manufacturers To Reduce Prices

Every Patient, Doctor & Plan Should Also Be Able To Look Up "Price" Information On Every Drug

Prices Also Need To Be Dramatically Lower. To Force Manufacturers To Reduce Their Prices -

- Create a "competition":
  - On, say, Sept 1st, require every manufacturer to submit its "best price" (inclusive of all discounts)
  - Tell every manufacturer its price will be published as of January 1st, by therapeutic category
  - Tell every manufacturer its proposed price will be "fixed", until it's allowed to re-bid
- Then publish the prices on January 1st
- On the next bidding day, each manufacturer will know the lowest priced drugs in each therapeutic category, and those manufacturers that lost market share will bid prices under the lowest price
- Over time, in every therapeutic category where there are alternative drugs, prices will fall
- Combined with "Quality" information, in many therapeutic categories, drug use will decline
- Manufacturers won't waste time bringing drugs with little efficacy to market

What Can Ohio Do?

During a RFP, create an “ask” for PBM to provide “Quality” & “Price” information, by therapeutic category, via an ”App”

Talk to CMS (and the FDA) about the need for “Quality” information

Try to get other States to join together to create “Quality” information

Key Take-Aways

- Ohio has exposed excessive PBM profits and led numerous states to investigate PBM practices
- Ohio should conduct a contract-focused RFP and force a PBM (or PBMs) to provide a loophole-free contract, with "airtight" definitions, NADAC pricing for all drugs with: NADACs, competitive AWP guarantees where needed, the complete pass-through of all "Financial Benefits", full "customization" and complete transparency and audit rights
- Ohio should lead the Nation in creating competition by pursuing "price" and "quality" information