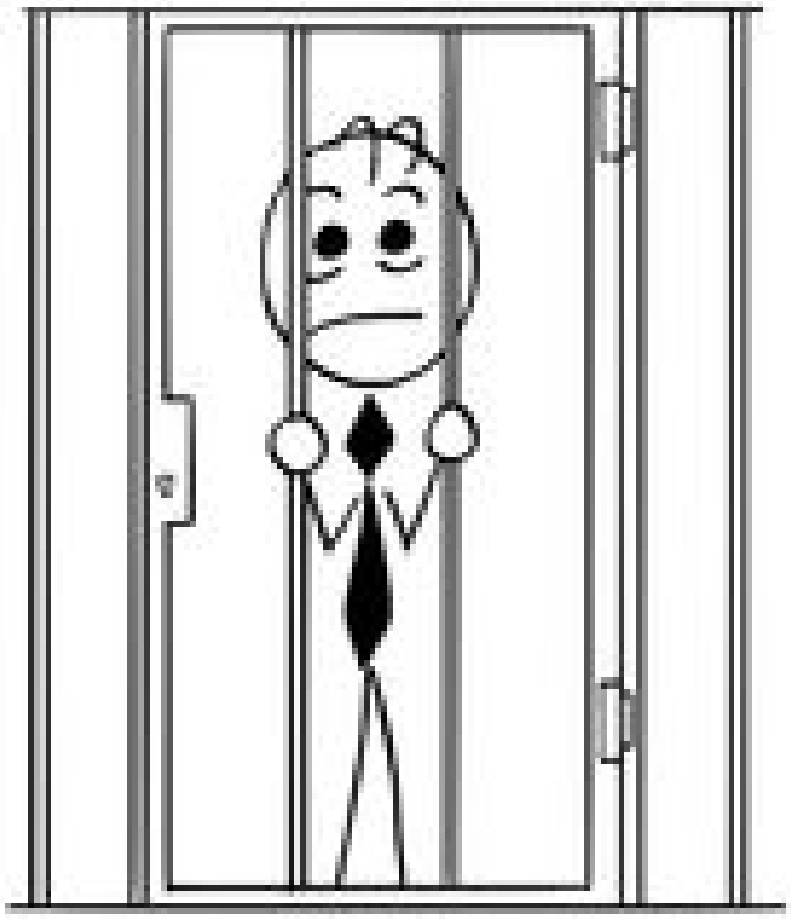
pshp ANNUAL ASSEMBLY

BRIDGING THE FUTURE OF PHARMACY 2022

PITTSBURGH, PA | NOVEMBER 2-5, 2022

Navigating the 340B Covered Entity Hostage Crisis



NO-WIN SITUATION

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DISCLOSURE

I declare no conflict of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holding, and honoraria.

Objectives

- ❑ 340B Purpose and Eligibility Requirements
- ❑ Patient Definition
- ❑ Where is 340B used?
- ❑ Diversion, GPO Prohibition, Duplicate Discounts
- ❑ "No wins" for Covered Entities
- ❑ Manufacturers Actions
- ❑ Legislative issues

340B Purpose:

The 340B Program “enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”. (HRSA)

What is 340B?

Not-for-profit organizations ONLY

Designate an Authorizing Official (AO) and Primary Contact (PC) **considerations**

Allows purchase of drugs for eligible **outpatients** at a discounted rate

What entities may qualify?

- DSH, Children's Hospitals (PED), Free Standing Cancer Centers (CAN)
- SCH, RRC, CAH
- CH, CHC, FQHC
- Multiple others (Ryan White, Hemophilia Treatment Centers)

Eligibility Requirements (with rules and restrictions)

Hospitals (DSH, SCH, RRC, CAH, Children's, Free Standing Cancer Centers)

Medicare Cost Report DSH > 11.75% or Medicare Cost Report DSH > 8%	Not-for-profit	Type of Control	Child Sites on MCR
MEF (Carve-in/Carve-out)	Annual Recertification	GPO Prohibition or Orphan Drug	Exclusion

Registrations

- Parent – Within four walls
- Child Sites
- Contract Pharmacies
- Entity-Owned Pharmacies (shipping address)

Mixed-Use/Clinic Define Eligible Patient

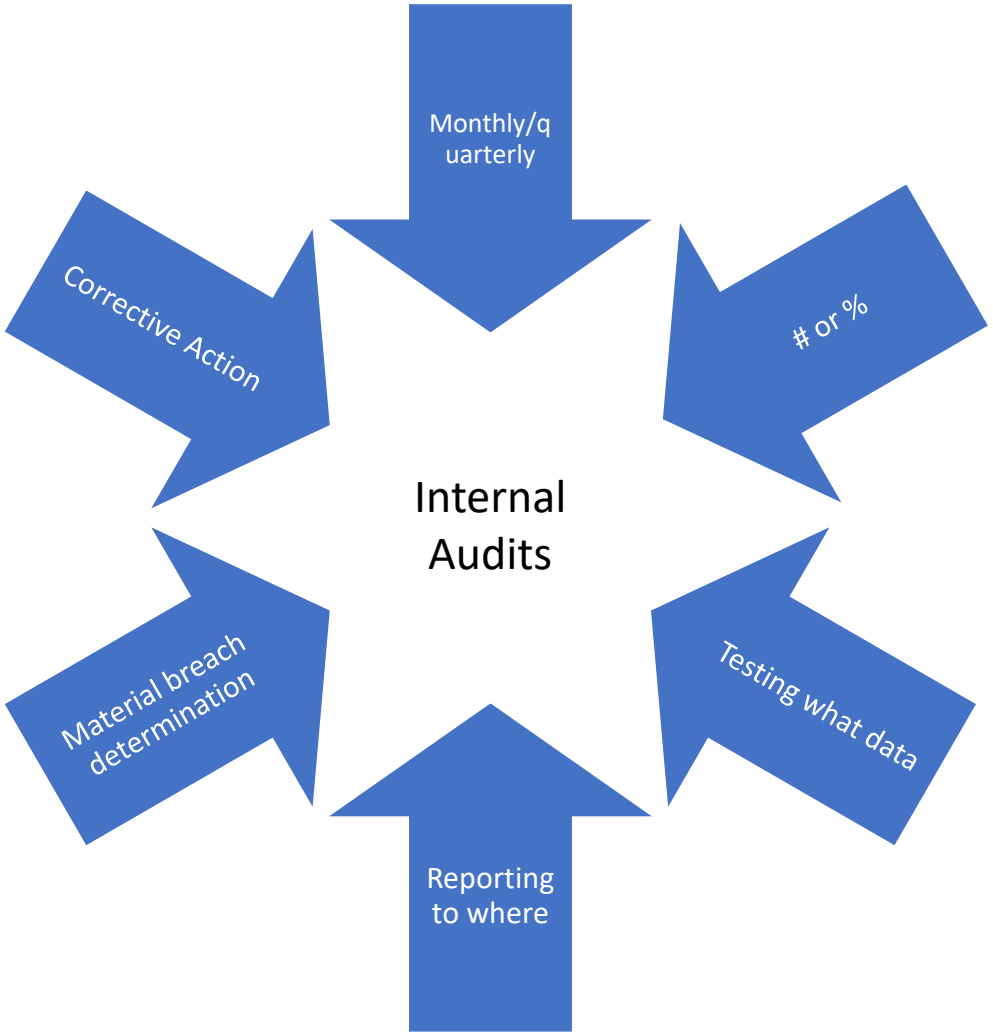
https://www.stockfreeimages.com/p1/patient-hospital-bed.html

- Responsibility of care is with the Covered Entity
- Eligible provider
- Eligible location
- Outpatient status
- Insurance coverage (Carve-in/Carve-out)
  - N/A for Carve-in

Contract Pharmacy 340B Eligible Patient

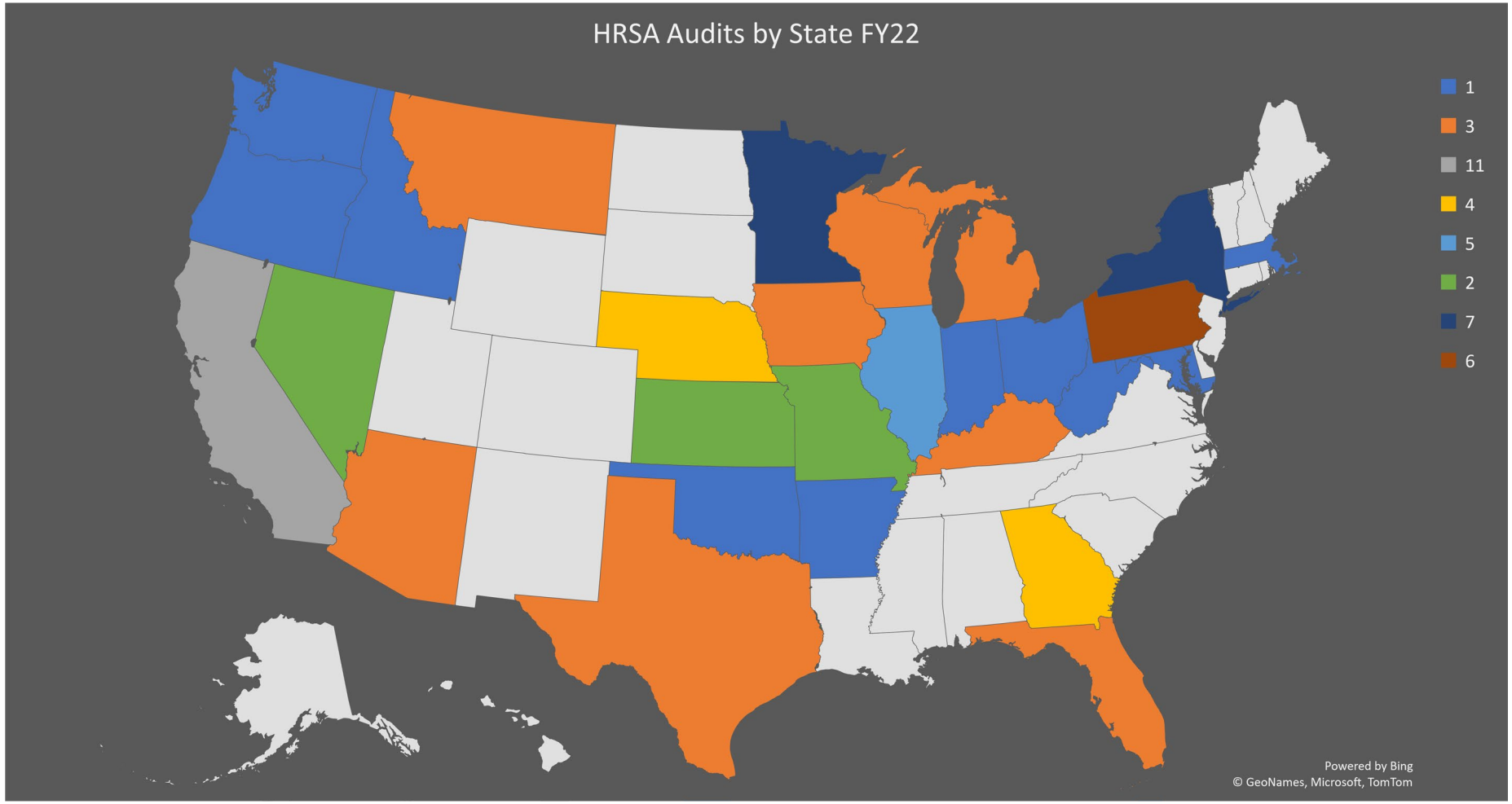
- Responsibility of care remains with the Covered Entity
- Eligible provider (or referral)
- Eligible location (or referral notes)- documentation of prescription in EMR
- Outpatient status
- Insurance coverage – NON-Medicaid

340B Program Oversight



External Audits (Annual Independent)

- Proof of audit for HRSA/Bizzell
- Testing what data
- Sample numbers
- Analyzing as many areas as possible
- Value Added Service, not a checkbox


HRSA Audits by State FY22
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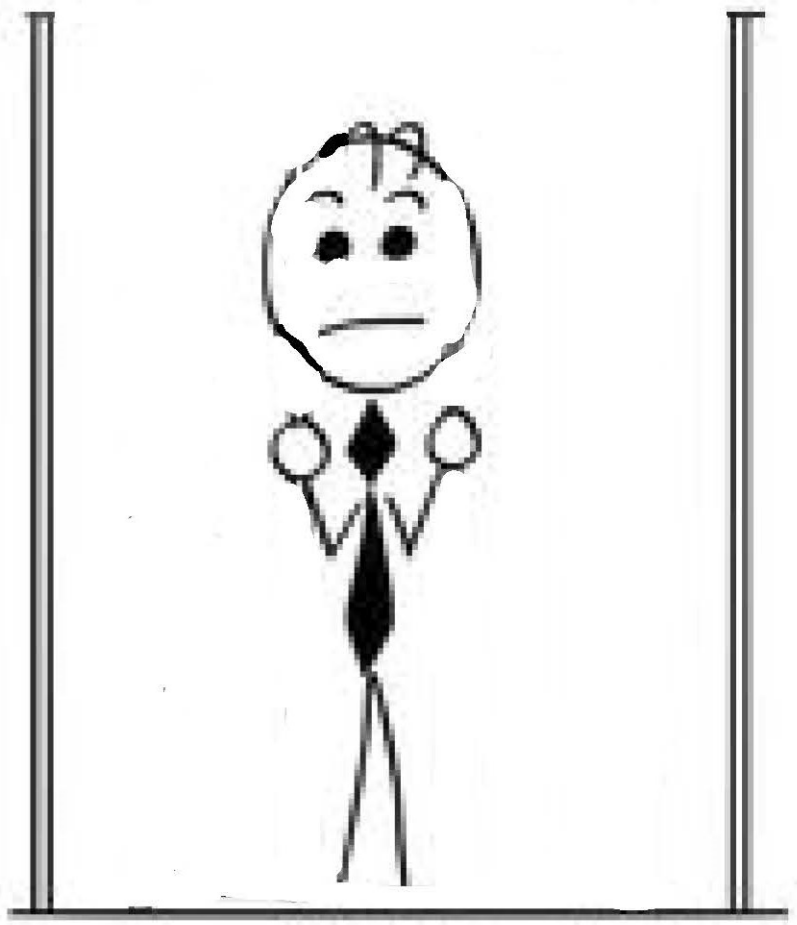


Feeling a little restricted…

MORE RULES AND RESTRICTIONS

- GPO Prohibition
- Diversion
- Duplicate Discounts

GPO Prohibition

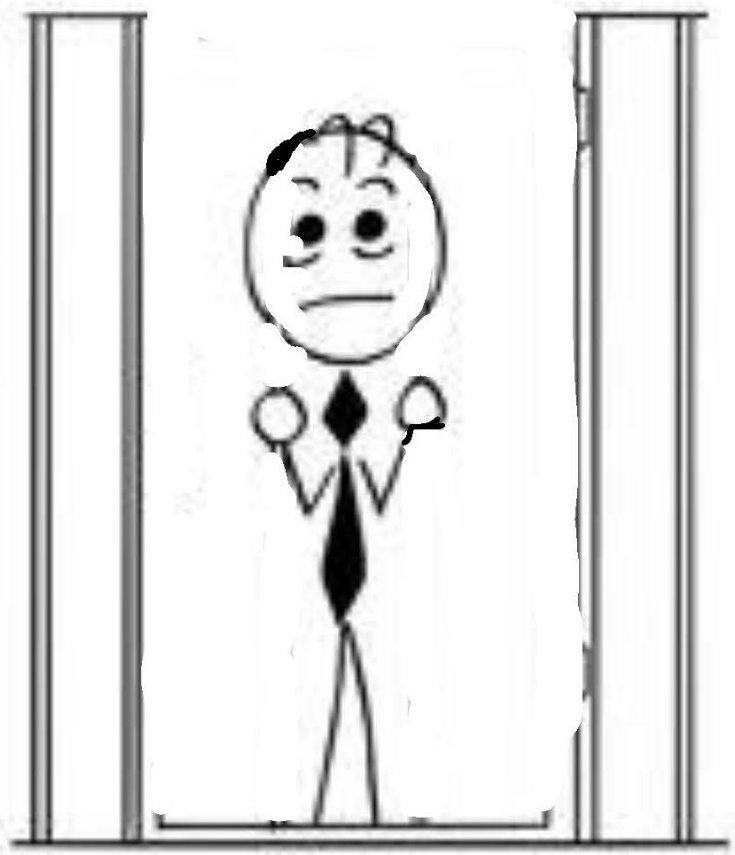
1. Group Purchasing Organization (GPO)
- DSH, Pediatric Hospitals, Free Standing Cancer Centers
- GPO may only be used to purchase medications for inpatients
- Any ineligible outpatients would have to be purchased at WAC

2. REVIEW of Pharmacy Ordering Accounts:
    a. WAC $$$ Wholesale Acquisition Cost
    b. GPO $$ Group Purchasing Organization
    c. 340B $

Diversion

Use of 340B on Ineligible Patient

- 340B dispensed at Contract Pharmacies for RX from ineligible location
- 340B dispensed at Contract Pharmacies not supported in medical record
- 340B dispensed for inpatients
- 340B drugs not properly accumulated

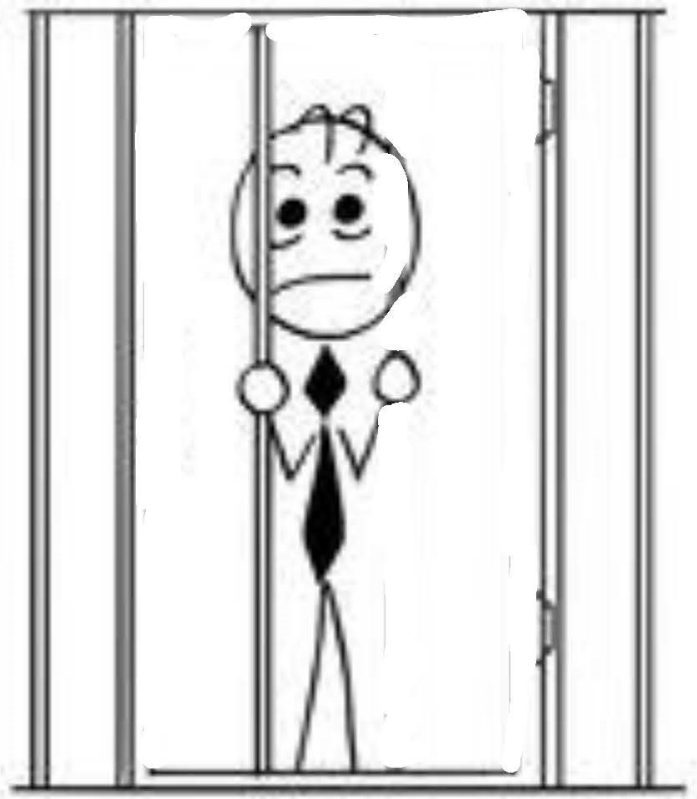


Starting to feel a little boxed in…

Duplicate Discount

Covered entity is responsible

- Incorrect or incomplete information in MEF
- No controls in place to prevent duplicate discounts
- Entity was billing Medicaid contrary to info in MEF



Walls forming…

The "NO WINS"

...for Covered Entities

TPA Potential Pitfalls and Promises

Financial Structure

Projections

Misleading terms

- Eligible claims
- Approved claims

Switch fees

Minimums per month

Reporting capability

True-ups vs reversals

Dispensing fee negotiations

Settings

Brand only

Winners Only

All claims

Slow movers

Payment terms- only upon replenishment?

Auto replenish

Exclusivity

Sole vendor rules

Length of contract

"out clause"

Notification requirements of termination

Contract Pharmacy Dispensing Fees

Why does a retail pharmacy want to partner with a CE?

Normal process retail pharmacy

"Normal Process"

RX
- Sent to Pharmacy
- Entered into computer

Switch
- Determine Co-pay
- Determine Insurance

Dispense
- Fill and give to patient
- Re-order drug from wholesaler

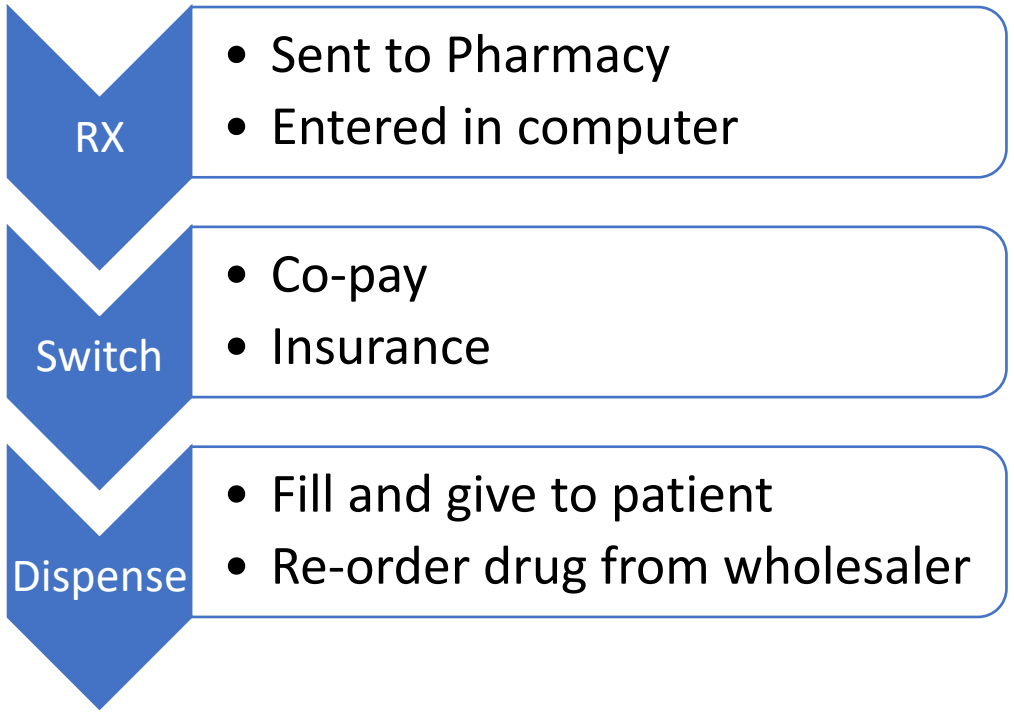
Money Flow For Retail Pharmacy

Co-Pay	**+**	**$20**
Insurance	**+**	**$550**
Buy drug from wholesaler	**-**	**$540**
		$30

Net of $30 to cover overhead costs

What is different? (Flat fee)

"Contract Pharmacy Process"



Money Flow For Covered Entity

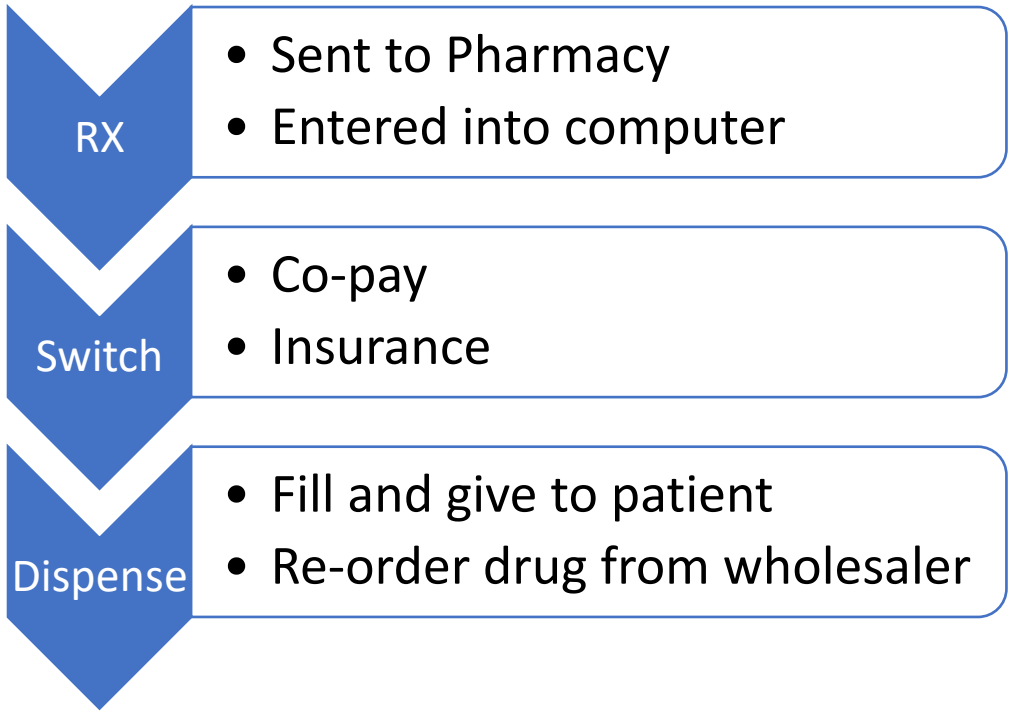
Co-Pay (CE)	**+**	**$20**
Insurance (CE)	**+**	**$550**
Bill To/Ship To (CE)	**-**	**$200**
Dispensing Fee to Retail Pharmacy	**-**	**$ 35**

$335

Net of $335 to cover overhead costs with TPA and remainder new revenue

We are going to need a larger piece of the pie! (percentage based)

"Contract Pharmacy Process"



Money Flow For Covered Entity

Co-Pay (CE)	**+**	**$20**
Insurance (CE)	**+**	**$550**
Bill To/Ship To (CE)	**-**	**$200**
Dispensing Fee to Retail Pharmacy ($15 plus 20% gross)	**-**	**$ 129**

$241

Net of $241 to cover overhead costs with TPA and remainder new revenue

Walls closing in…

At least 18 manufacturers

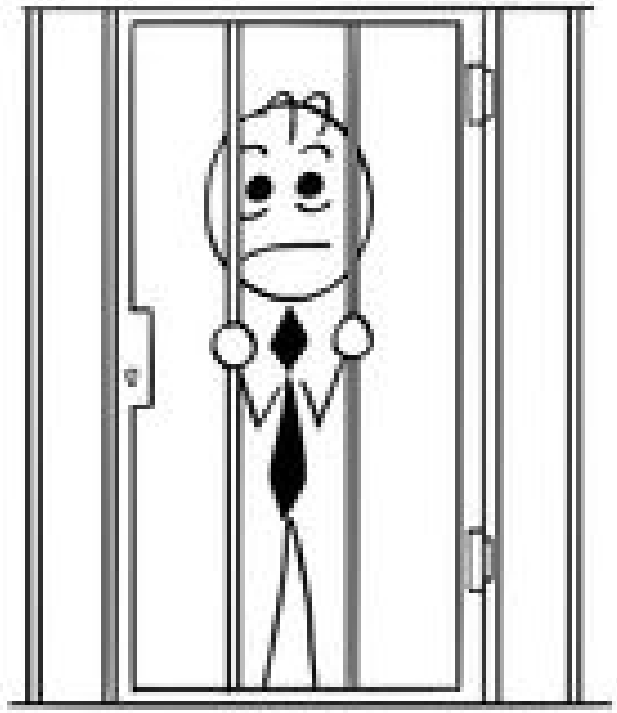
List of Some of the Manufacturers (examples)

MFR	AS OF DATE
AstraZeneca	10-1-20
Eli Lilly	9-1-20
Sanofi	10-1-20
Novartis	10-1-20
NovoNordisk	1-1-21
United Therapeutics	5-13-21
Boehringer Ingelheim	8-1-21
Merck	9-1-21
UCB	12-13-21
Amgen	1-23-22
AbbVie	2-1-22
Bristol Myers Squibb	3-1-22

Types of Restrictions

KEY- these do not apply to Entity-Owed Retail Pharmacy *some will include a retail part of common ownership in a health system
Some only include hospitals but do not apply to Federal grantees
Some will allow selection of one contract pharmacy if the CE does not have an entity-owned retail. May allow to apply directly with manufacturer and some register in ESP
One (Novartis) will allow only those w/I 40 miles of the CE
May allow if CE provides ALL claims to ESP Some participate in a rebate model (Kalderos)

Feels like being held hostage…



Fighting Back…

How do we navigate this situation?

Legislative Actions

- New State Laws with prohibition of discriminatory reimbursement
- Court Cases – seemingly split
- HRSA refers some manufacturers to HHS Inspector General – possible civil fines

Navigating For Now

TPA issues

- RFP
- Educate Yourself
- Counter
- Know before you sign (terms/out clause/exclusivity/auto-increases)

Navigating For Now

Contract Pharmacy Agreements (PSAs)

- Read thoroughly
- Winners ONLY if possible
- Pay upon replenishment (most clean method)
- Counter-offer if dispensing fee is high (challenge with large chains)
- IF POSSIBLE, ENTITY-OWNED retail pharmacy

Navigating For Now

Manufacturer Restrictions

- Entity-owned pharmacy if possible
- Designate a single contract pharmacy
- Consider providing data if financially unable to withhold it
  - Monitor contracts and the ESP database for “at risk”

Navigating For Now

Look for missed opportunities

- Add referral prescription capture if feasible
- Ensure maximizing opportunities in mixed-use areas
  - Clean sites
  - Waste billing
  - Maintenance of mapping in TPA
- Consider providing data if financially unable to withhold it
  - Monitor contracts and the ESP database for “at risk”

Navigating For Now

- 340B Health urges CEs to continue reporting any drug company refusals to offer 340B pricing to the Health Resources & Services Administration (HRSA) by sending an Apexus form or a 340B Health template letter to 340BPricing@hrsa.gov as soon as the overcharges occur. These reports will be especially important to initiate enforcement actions against the manufacturers.

WIN-WIN SITUATION

Freedom from the 340B Covered Entity Hostage Crisis

Questions?

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