

# Understanding 340B and Contract Pharmacy

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# Topics for Discussion

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- 340B 101
- 340B Regulatory Update
- Contract Pharmacy Basics – How It Works
- Role of 340B Vendors
- Business Opportunity/Vendor Models
- Business and Program Considerations
- Questions

340B 101

# What is the 340B Program?

- Federal program created in 1992
- Benefits providers serving the indigent
- Discounted pharmaceuticals
- Outpatient drugs only
- Compliance & administration
- Creates an opportunity for “covered entities” to contract with retail pharmacies to improve access



# 340B Covered Entities (CE's)

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- FQHC and look-alikes
- Consolidated health centers
- Family planning
- HIV / ADAP
- Black lung
- Hemophilia
- Native Hawaiian
- Urban Indian
- STD
- TB
- DSH
- Critical access hospitals
- Sole community hospitals
- Rural referral centers
- Freestanding cancer centers
- Children's hospitals

# Current 340B Challenges

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## Increased scrutiny by Congress

- Focus on program oversight and integrity provisions
- Disagreements surrounding intent of program (patient subsidy vs. covered entity subsidy)
- Focus on use of program savings or “revenue” – profiteering?
- Impact on drug shortages
- Pointed letters to hospitals and Walgreens

## PhRMA, PBMs, and Oncologists have raised concerns about program scale and patient benefit

- AIR 340B
- Negative editorials in national publications
- White Paper, “Unfulfilled Expectations...”

# 340B Policy Focus

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## 340B “Mega-Reg”

- Eligible Patient Definition
- Contract Pharmacy
- Hospital Eligibility
- Off-site Facility Eligibility
- Date of rule publication and impact in question due to...

## PhRMA vs. US DHHS

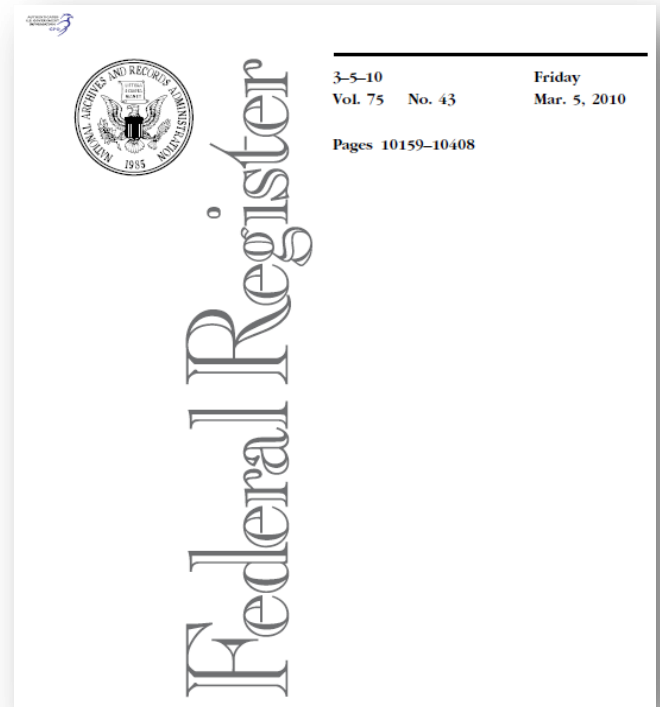
- May 2014 ruling by US District Court in favor of PhRMA
- Ruling states that HRSA does not have authority to create the orphan drug regulation published in Fall 2013
- Impact on Mega-Reg
- Impact on previous program guidance?

# Contract Pharmacy



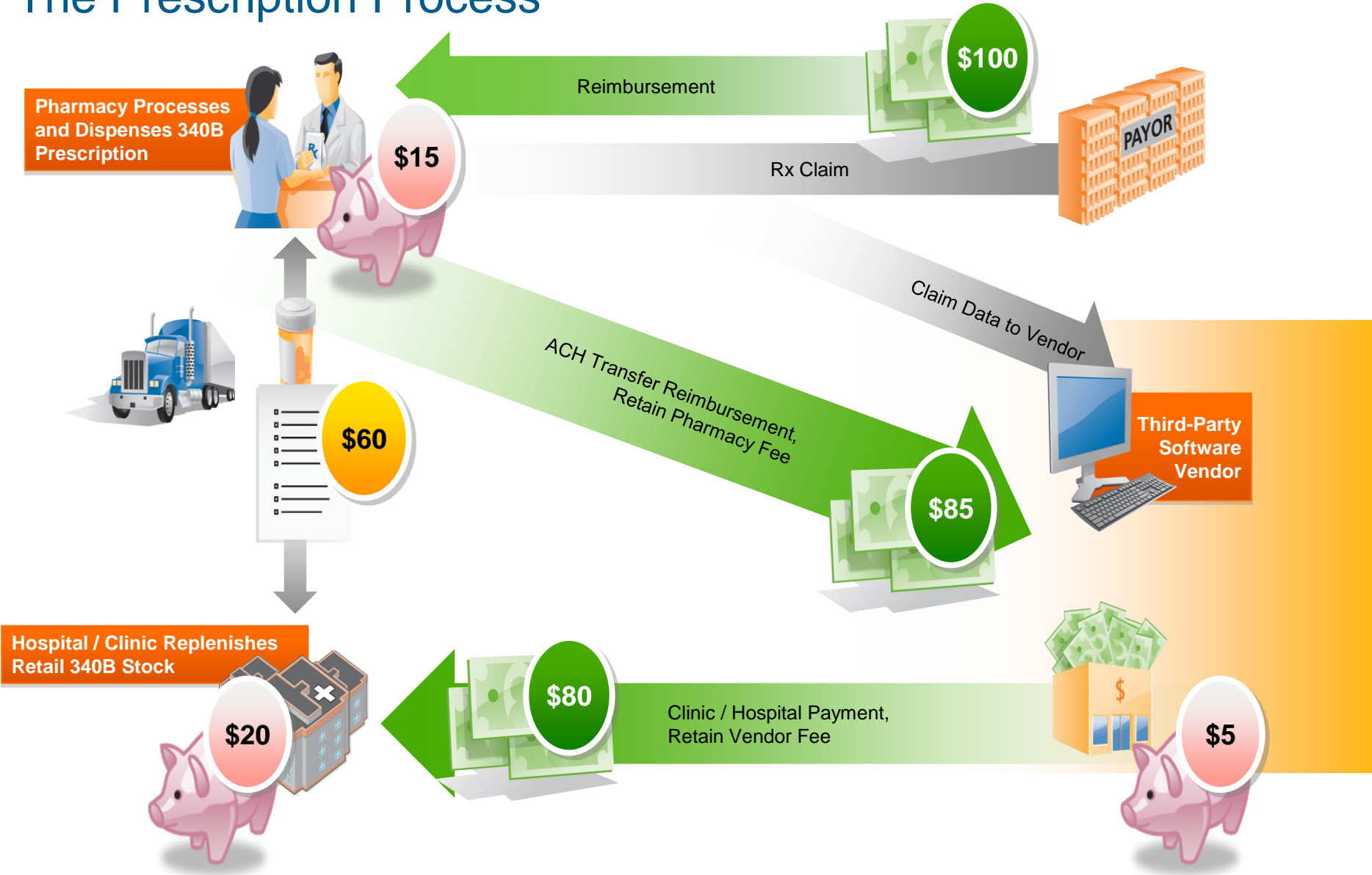
# Where did this all come from?

- Federal Register, Volume 75, No. 43 – Friday, March 5, 2010 Notice
  - Multiple contract pharmacies allowed
  - Contract requirement, suggested provisions
  - Essential compliance elements
  - Compliance expectations



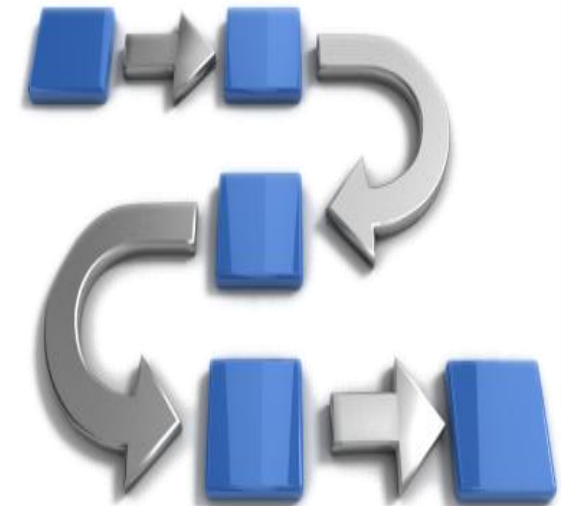
# Contract Pharmacy: How Does It Work?

## The Prescription Process



# 340B Software — What Does It Do?

- “Captures” eligible 340B prescriptions by comparing the pharmacy’s Rx records with a file of covered entity patients and prescribers
- Tallies the cost and reimbursement for the “shared” 340B Rx’s
- Maintains a “bucket” of replacement drugs for the covered entity to purchase and ship to the contract pharmacy
- Provides reports of reimbursement, dispensing fees, 340B savings and financial settlement



# Business Opportunity

# Financial Screening Model

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- Prescriptions are screened for revenue to hospital
- Screening impact varies for retail pharmacy
- Can be difficult to forecast retail pharmacy results
- Program leans on brands and high cost generics
- 340B conversion rate can be low (<20%)
- Admin fees  $\approx$  \$4 - \$6/Rx
- Dispensing fees  $\approx$  \$15 - \$25 /Rx

# All Prescriptions Model

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- All prescriptions are converted to 340B
- Hospital and pharmacy have winners / losers
- Financial results can be forecast for retail pharmacy
- Program can impact retailer's generic contracts and rebates
- Extracts maximum savings from 340B program
- Admin fees rely on pharmacy 340B fill rate
- Dispensing fees  $\approx$  \$15+
- Admin fees  $\approx$  \$0.15 - \$0.45 / Rx screened for 340B

# Gain Share Model

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- Screening methodology similar to “financial screening model”
- Admin fee  $\approx$  15% - 20% gross prescription revenue
- Some covered entity pushback owing to % admin fee
- Beltway discussions regarding % admin fees and Anti-Kickback statute
- Dispensing fee  $\approx$  \$15

# “Do it Yourself” Model

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## **Participants can and do support 340B without the use of a 340B Vendor**

However, there are multiple factors to consider, including:

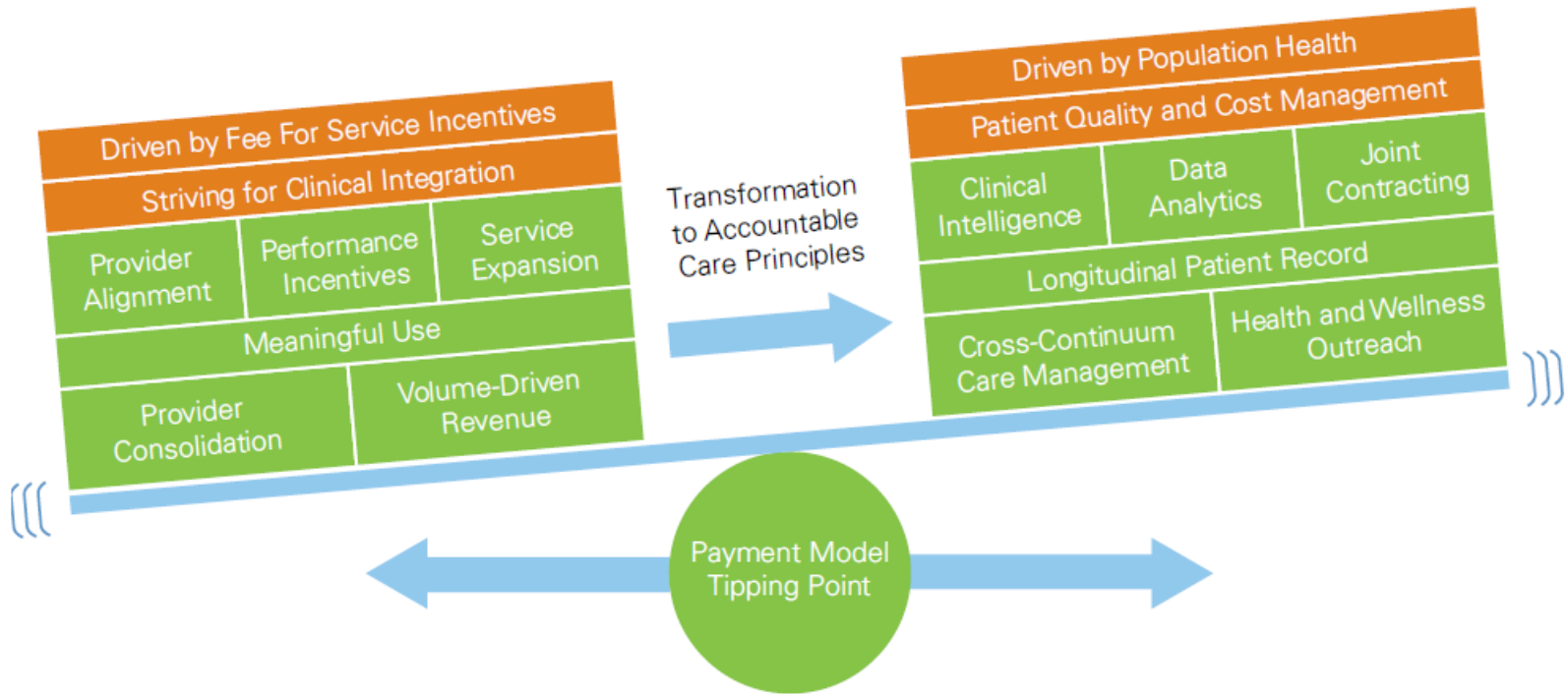
- Development of contract
- Identification of eligible scripts
- Tracking and reporting inventory use
- Financial reconciliation/identification of 340B claims from consolidated 3<sup>rd</sup> party payment
- Compliance records and reporting in the event of an audit
- Current pharmacy resources and contribution



# Business Considerations

# The tipping point towards accountable care is driving needs – and opportunity - in new areas

## Payment Model Tipping Point



★ Pharmacy well positioned to take a role

# Key Considerations

## Compliance / Politics

- HRSA / Manufacturer audits
- Congressional scrutiny
- Medicaid billing and rebates
- Federal Anti-Kickback statute

## Reimbursement

- Reduced reimbursement contracts from PBMs
- Medicaid

## Business Operations

- Inventory swell
- True-up
- Management / Finance time
- Purchase agreements
- Wholesaler totes

## Competition

- Software vendor responsibility
- Large chain networks
- Clinic / hospital pharmacies

Questions?