Topics for Discussion

- 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)

- 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

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, PBMAs, 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

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

Pharmacy Processes and Dispenses 340B Prescription

Hospital / Clinic Replenishes Retail 340B Stock

Reimbursement

Rx Claim

Claim Data to Vendor

Third-Party Software Vendor

Pharmacy Processes

$15

$60

$80

$100

$85

$5

$20

$60

$85

$100

$15

$80

$100

$20

$80

$5

Proprietary Information of McKesson Corporation
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

- 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 ≈ $4 - $6/Rx
- Dispensing fees ≈ $15 - $25/Rx
All Prescriptions Model

- 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 ≈ $15+
- Admin fees ≈ $0.15 - $0.45 / Rx screened for 340B
Gain Share Model

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

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 3rd 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

Driven by Fee For Service Incentives
- Striving for Clinical Integration
  - Provider Alignment
  - Performance Incentives
  - Service Expansion
  - Meaningful Use
  - Provider Consolidation
  - Volume-Driven Revenue

Driven by Population Health
- Patient Quality and Cost Management
  - Clinical Intelligence
  - Data Analytics
  - Joint Contracting
  - Longitudinal Patient Record
  - Cross-Continuum Care Management
  - Health and Wellness Outreach

Transformation to Accountable Care Principles

Pharmacy well positioned to take a role
## Key Considerations

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Questions?