

# 340B COMPLIANCE CHAMPIONSHIP:

*ARE YOU IN THE  
RUNNING?*

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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.





# 340B: Coordinators/Analysts Training to Win

# Training Objectives

- ☐ Oversight and Education
- ☐ Contracts
- ☐ Quality Assurance



# 340B – Oversight and Education

- ❖ Oversight Committee
- ❖ 340B Education
- ❖ TPA Certification and/or training
- ❖ Data Maintenance

# 340B Oversight Committee

## Team Effort

- ❖ Not just pharmacy
- ❖ Not just finance
- ❖ Best are multi-disciplinary: AO/PC/340B Coordinator/billing/finance/credentialing/IT/pharmacy buyer/legal
- ❖ Frequency and Content
- ❖ Material Breach Definition



# Education

- ☐ 340B University
- ☐ Apexus ACE
- ☐ Current legal activity
  - A. HHS
  - B. Manufacturers
  - C. HRSA
  - D. Courts

# TPA Training and/or Certification

## Choosing TPA(s)

- ▶ No choice for some contract pharmacies
- ▶ Demos
- ▶ Ask questions/amount of training
- ▶ Quotes with detail
- ▶ References
- ▶ Exclusivity
- ▶ Viable option for future plans

## Inheriting TPA(s)

- ▶ Contracts
- ▶ Training
- ▶ Settings
- ▶ Financial structure
- ▶ Evaluate performance
- ▶ Viable option



# Data Maintenance

- ☐ Mapping CDM/NDC
- ☐ Coordination with billing
- ☐ HCPCS updates
- ☐ Orphan drug status list updates (if applicable)
- ☐ G and K status drug list updates (if applicable)

# CONTRACTS



# TPA Contracts

- ☐ Effective dates and term length
- ☐ Notice for termination
- ☐ Payment terms
- ☐ Rate increases
- ☐ Orphan Drugs and Medicaid Carve-Outs
- ☐ Exclusivity
- ☐ Retention of data post termination

# Pharmacy Services Agreements

- ☐ Fully executed prior to OPALS registration
- ☐ Addresses for pharmacies
- ☐ Payment terms (on replenishment?)
- ☐ 12 essential elements for HRSA
- ☐ Applicable to CE and registered sites
- ☐ Reconciliation terms
- ☐ Cooperation with audits/ blackout days/dates



# Quality Assurance

# Best Practices for Quality Assurance

Annual Internal Audit Plan/ P&P

Choose a good sample

Comprehensive approach

Annual Independent Audit



# Annual Internal Audit Plan/P&P

- ❖ 340B Oversight Committee should approve
- ❖ Frequency, quantity, content, results go where?

# Policies and Procedures



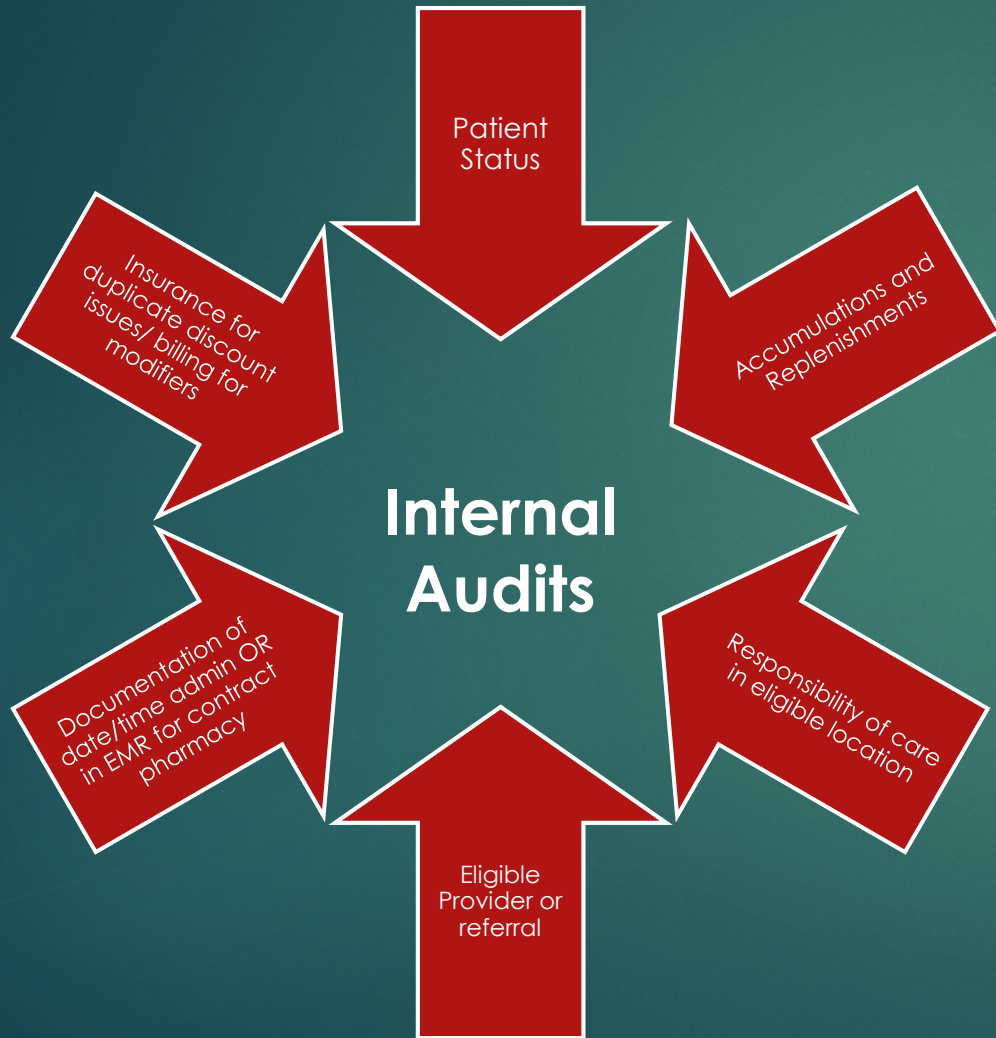
- ☐ Backbone of your 340B Program
- ☐ A-M on Data Request Form
- Question #1
- ☐ Ideally “searchable”
- ☐ Detailed
- ☐ Must reflect actual practice



# Choose a great sample

- ❖ Representative of all universes
- ❖ Random – not entirely
- ❖ Mixed-use (different departments)
- ❖ High-cost drugs
- ❖ G and K status drugs (if applicable)
- ❖ Dispenses requiring Medicaid modifiers (if applicable)

# Comprehensive Approach



## Spreadsheet to track results

- No PHI
- Understand WHY some of the data elements are important
- Fix all “fall outs”
- Test for Material Breach
- Look for trends and opportunities for education



# GO THE EXTRA MILE

## A shot at the championship

### ❖ OPALS database review

1. Addresses of contract pharmacies/signature dates versus registration/shipping addresses
2. AO/PC information correct
3. Medicaid Exclusion File correct
4. Child sites/associated sites registered

### ❖ Contract pharmacy- update BIN/PCN/Group numbers for state Medicaid for carve-out

### ❖ Team with Accounts Payable

1. Review payments compared to what is expected
2. True-ups or reconciliations?
3. Full package sizes just “sitting there”?

# GO THE EXTRA MILE

## ❖ Team with IT

1. Files crossing as intended-when did last encounter file or eRx file cross?
2. Content of files

## ❖ Team with Credentialing or Medical Affairs

1. Provider file accuracy- create a sub-committee if necessary
2. Exclusive vs Non-exclusive provider

## ❖ Team with Billing

1. HCPCS units/modifiers/billing tables for AAC
2. CMS status drugs
3. Waste billing

## ❖ Wholesaler price file updates monitoring



# Annual Independent Audit

- ❖ It is an expectation, AFI on HRSA reports
- ❖ Value Added
- ❖ Practice creating a CAP
- ❖ Monitor completion through committee

Know Your Value-  
Claim the  
Championship



## References

Apexus 340B Prime Vendor Program. *340B Tools*. Retrieved from <https://www.340bpvp.com/education/340b-tools/>



# Thank you!

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# Questions?

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