



Smart decisions. Lasting value.™

# Crowe Healthcare Webinar Series

Balancing 340B Compliance and Exploring New Opportunities

Presented by:

Kim Ott, Healthcare Consulting Manager

Lisa Robbins, Healthcare Consulting Manager

November 5, 2019

# Your Presenters

---



**Kim Ott**  
Healthcare Consulting Manager  
(574) 261-2643  
[kim.ott@crowehrc.com](mailto:kim.ott@crowehrc.com)



**Lisa Robbins, CIA**  
Healthcare Consulting Manager  
(314) 802-2098  
[lisa.robbins@crowehrc.com](mailto:lisa.robbins@crowehrc.com)

# Course Objectives

---

- ❑ Assess your current internal monitoring processes for the 340B Program
- ❑ Identify gaps in monitoring and compliance efforts and next steps for remediation
- ❑ Outline new opportunities for 340B Program expansion, next steps, and communication strategies for developing a plan of action

# Cornerstones To Compliance

---

## **Oversight**

Committees and/or dedicated staff to facilitate monitoring, issue identification and resolution, and department engagement.

## **Continuous Monitoring**

Ongoing assessment of key compliance risks expedite detection of issues and ensure the program supports the healthcare facilities goals.



## **Program Knowledge**

Through staff education, networking and/or engagement of 340B consultants, maintain up-to-date information on the best practices and changes occurring with the program.

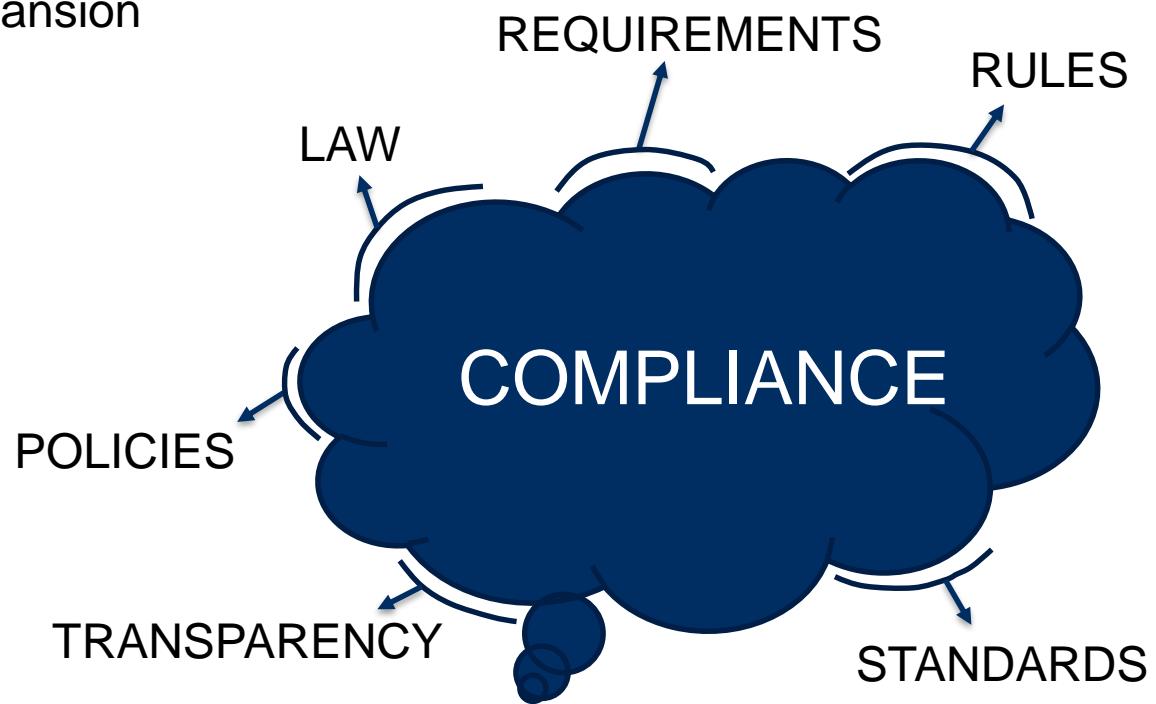
## **Cross Department Engagement**

340B is not solely a Pharmacy program. Engagement of various departments that have an impact on the program is important.

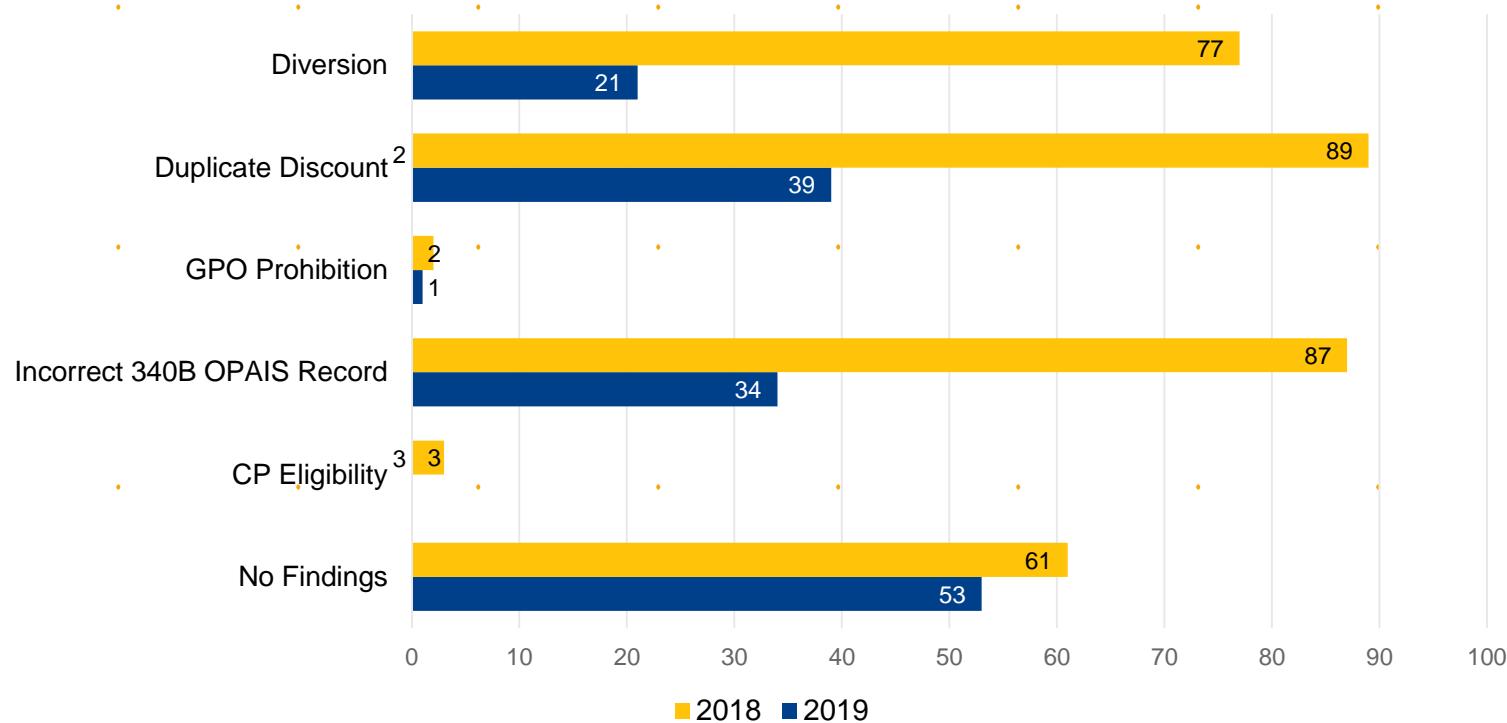
# Importance of Monitoring

---

- Compliance risks exist
- Prompt identification of risks
- Program optimization / expansion
- HRSA audit preparation



# Published 2018 & 2019 HRSA Findings<sup>1</sup>



1. Findings posted as of October 10, 2019 for all covered entity types. Source: <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results>.
2. Duplicate discount finding count includes Medicaid Exclusion File inaccuracies that were determined not to have resulted in duplicate discounts.
3. CP Eligibility findings are those stated, "Entity did not provide contract pharmacy oversight." and the sanction was termination of the contract pharmacy(ies).

# Monitoring Categories

---

Eligibility

Diversion Prevention

OPAIS

Duplicate Discount Prevention

Purchasing

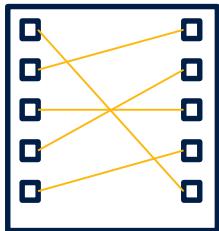
Inventory

Vendor Settings

Savings

# Eligibility

---



## Child Site Eligibility Crosswalk

- Quarterly
- To trial balance accounting units
- Additions / terminations / changes



## Policies and Procedures

- Annually
- As changes are needed
- Committee review

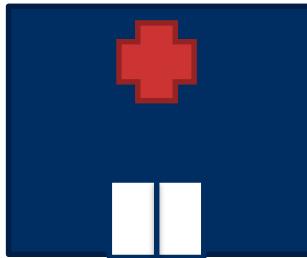


## Eligibility Documentation

- Annually
- Record maintenance of:
  - Ownership / Contract with State/local Government
  - MCR and TB
  - Notice of Grant Award
  - FQHC / FQHC-LA Documentation

# 340B OPAIS

---



## Covered Entity Physical Addresses

- Quarterly

## Owned Retail / Contract Pharmacy Addresses

- Quarterly

## Bill-To / Ship-To Addresses

- Annually



## Authorizing Official & Primary Contact

- Annually



## Medicaid Billing Numbers

- Annually

# Diversion Prevention

---



## 340B Transactional Testing

- Monthly
- Various operational models
  - Drug administrations (mixed-use & clean-use)
  - Owned retail pharmacy prescriptions
  - Contract pharmacy prescriptions
- Random & targeted



## Eligible Healthcare Professional List

- Monthly
- Terminations
- Inclusion of all professionals administering & prescribing



## External Audit

- Annual
- Independent
- Various operational models

# Duplicate Discount Prevention

---



## 340B Transactional Testing

- Monthly
- Various operational models
- Transactions with Medicaid as a payer
  - In-State & Out-of-State
  - FFS & MCO



## State Medicaid Regulations

- Annually, or as changes are posted



## Medicaid Exclusion File

- Annually

# Purchasing

---



## GPO Prohibition Adherence - *Monthly*

- Exclusive purchases on GPO
- IP/OP utilization volumes



## Auto Substitutions – *Monthly*

- Crosswalk updates



## WAC Spend - *Monthly*

- Good vs. Bad



## 340B Account Pricing Load

- Sample by volume and/or price
- Comparison to ceiling price website



## Penny Buys - *Monthly*

- Availability & accumulations



## Manual Invoice Uploads

- Purchasing accounts without EDI feeds
- Accumulation adjustments



## Loan & Borrow - *Monthly*

- Documentation review

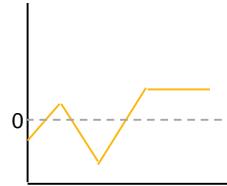


## Consignment Inventory

- Replenishment accuracy by account type

# Inventory

---



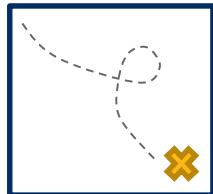
## Negative & Large Accumulations

- Monthly
- 5 highest & 5 smallest
- Compliance and optimization opportunities



## Reversals

- Monthly
- Contract pharmacy prescriptions
- Particularly for 'per click' fee models with 340B Vendors
- Why are RXs not eligible



## Unmapped CDMs / NDCs

- Monthly

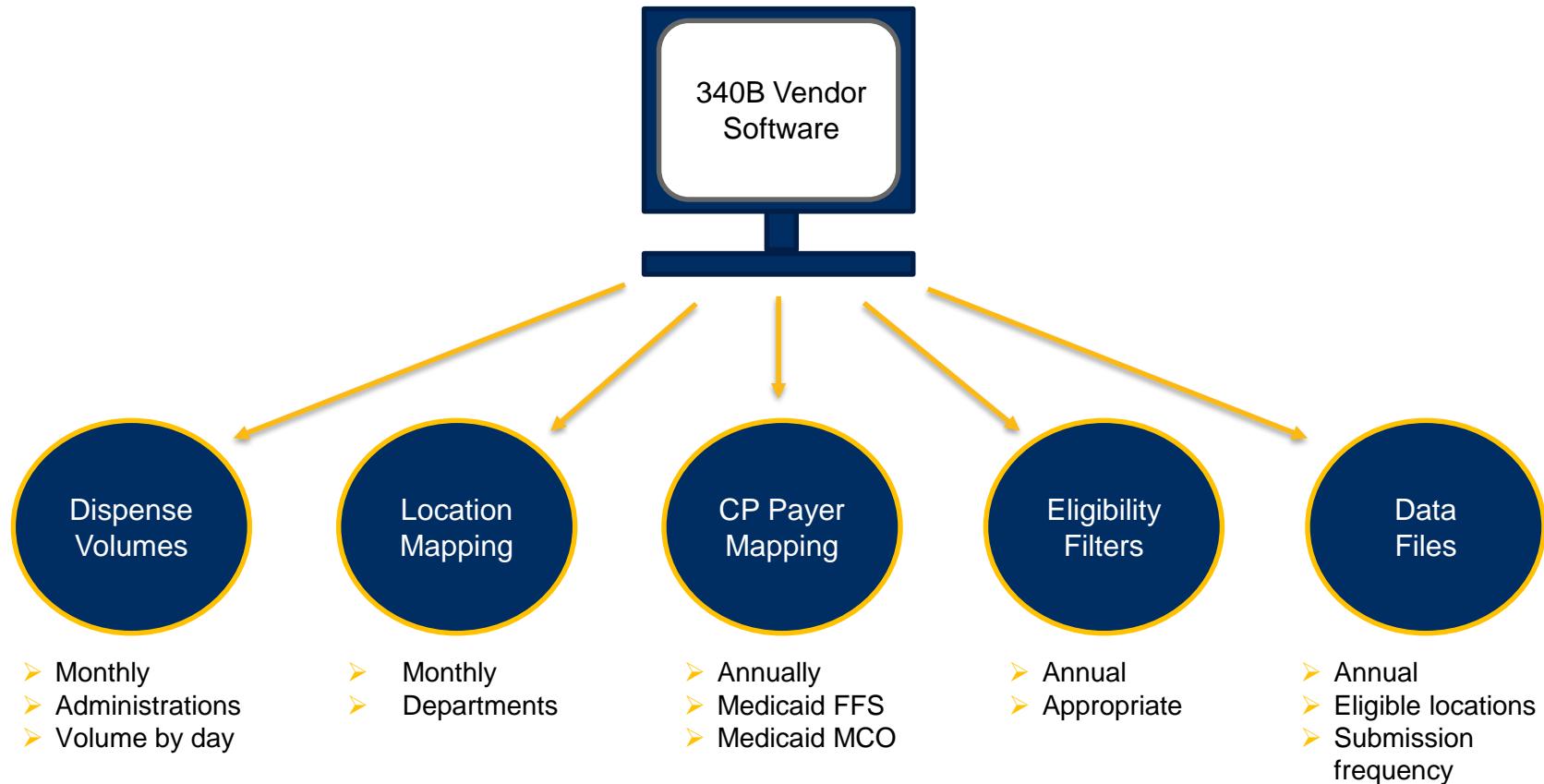


## Conversion Factors

- Monthly
- Targeted sample by utilization volume
- Multi-dose, inconsistent quantities, compounds, etc.

# Vendor Settings

---



# Compliance Issue Resolution

---



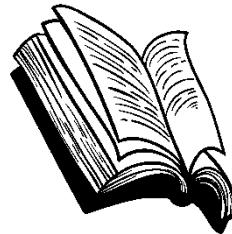
## Investigate

Assess each instance of suspected or alleged non-compliance



## Respond

Actively pursue non-compliance resolution with impacted parties



## Educate

Assist responsible parties to understand their obligations



shutterstock.com • 1115579756

## Monitor

Actively monitor responsible parties' compliance with the requirements

# Monitoring Savings

If GPO

- Step 1
- GPO Price for each NDC
- - 340B Price for each NDC
- 340B Savings
  
- Step 2
- Purchases Non-GPO/WAC
- - Same purchase if GPO
- WAC Variance
  
- Step 3
- 340B Savings
- - WAC Variance
- Net Savings

Non GPO

- Current Pricing - 340B Pricing = 340B Savings



# Expansion Opportunities

---

- Owned retail pharmacy
- E-Prescribing
- Specialty Pharmacy
- Contract pharmacy financial analysis
- Medicaid carve-in/out decision





# Thank You

**Kim Ott**

Healthcare Consulting  
Manager

(574) 261-2643

[kim.ott@crowehrc.com](mailto:kim.ott@crowehrc.com)

**Lisa Robbins, CIA**

Healthcare Consulting  
Manager

(314) 802-2098

[lisa.robbins@crowehrc.com](mailto:lisa.robbins@crowehrc.com)