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Crowe Healthcare Webinar Series

Balancing 340B Compliance and Exploring New Opportunities

Presented by:

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Your Presenters



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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

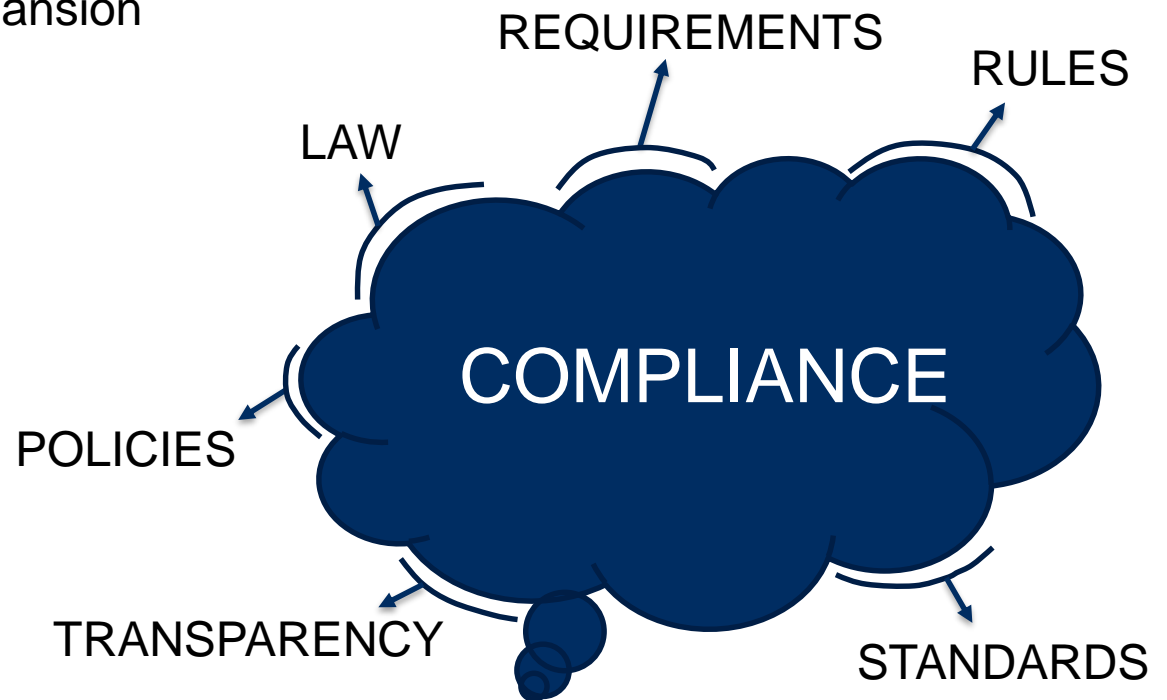
Through staff education, networking and/or engagement of 340B consultants, maintain up-to-date information on the best practices and changes occurring with the program.

Cross Department Engagement

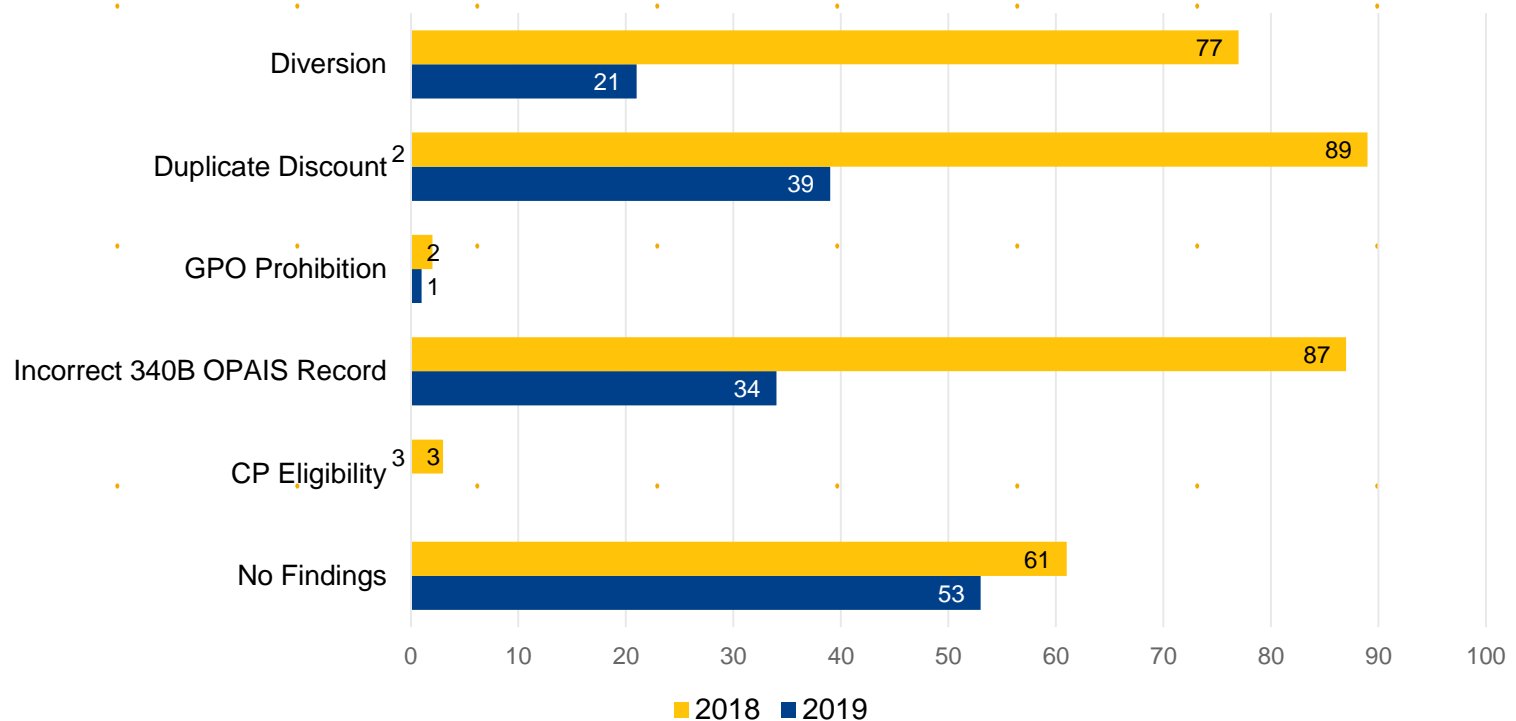
340B is not solely a Pharmacy program. Engagement of various departments that have an impact on the program is important.

Importance of Monitoring

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



Published 2018 & 2019 HRSA Findings¹



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

OPAIS

Purchasing

Vendor Settings

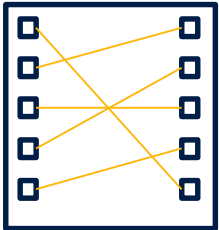
Diversion Prevention

Duplicate Discount Prevention

Inventory

Savings

Eligibility



Child Site Eligibility Crosswalk

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



Policies and Procedures

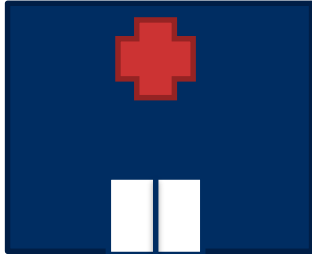
- Annually
- As changes are needed
- Committee review



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

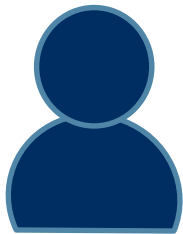
- Quarterly

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


-  WAC Spend - *Monthly*
 - Good vs. Bad


-  Penny Buys - *Monthly*
 - Availability & accumulations

-  Loan & Borrow - *Monthly*
 - Documentation review

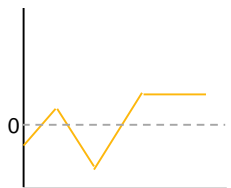
-  Auto Substitutions – *Monthly*
 - Crosswalk updates

-  340B Account Pricing Load
 - Sample by volume and/or price
 - Comparison to ceiling price website

-  Manual Invoice Uploads
 - Purchasing accounts without EDI feeds
 - Accumulation adjustments

-  Consignment Inventory
 - Replenishment accuracy by account type

Inventory



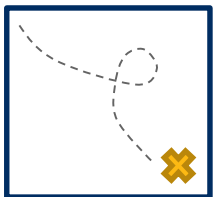
Negative & Large Accumulations

- 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

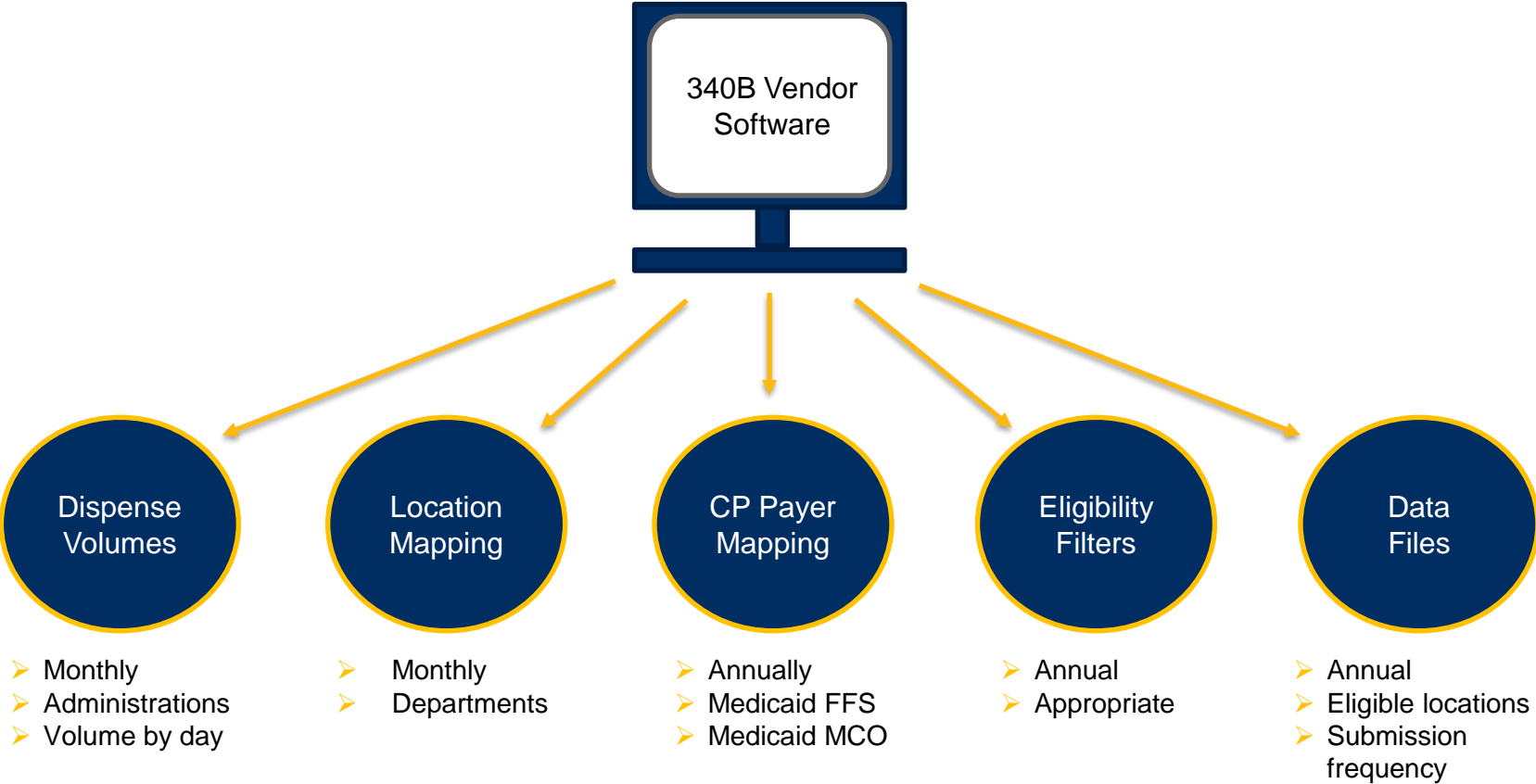
- Monthly



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



Monitor

Actively monitor responsible parties' compliance with the requirements

Monitoring Savings

If GPO

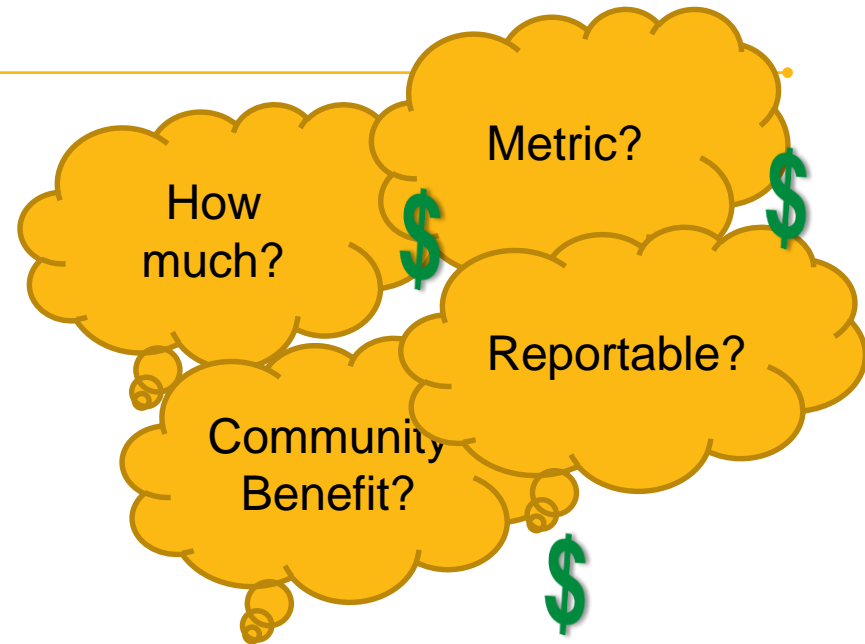
- Step 1
- GPO Price for each NDC
- - 340B Price for each NDC
- 340B Savings

- Step 2
- Purchases Non-GPO/WAC
- - Same purchase if GPO
- WAC Variance

- Step 3
- 340B Savings
- - WAC Variance
- Net Savings

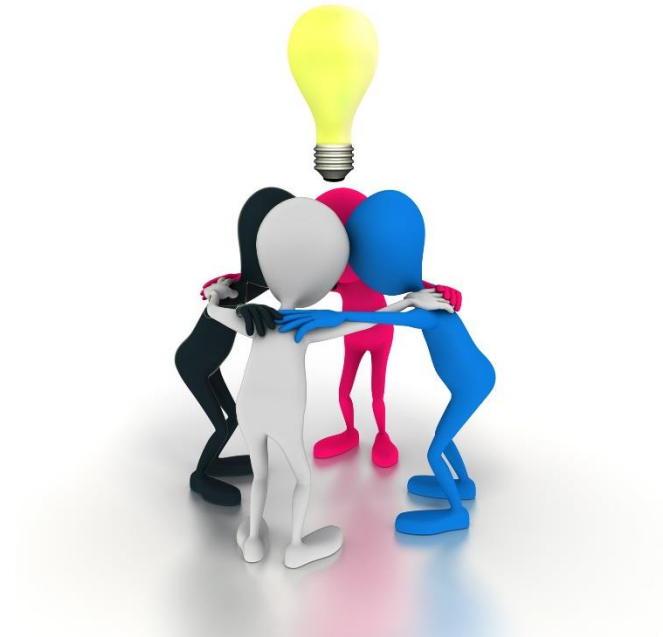
Non GPO

- 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

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