

# THE 340B PROGRAM: Perspectives on How to Promote Compliance in Your Covered Entity

Sue Veer, MBA, President and CEO  
Carolina Health Centers, Inc.

Michael Glomb, Esq., Partner  
Feldesman Tucker Leifer Fidell LLP

Coley Deal, 340B Program Manager,  
Bon Secours Mercy Health System

24<sup>th</sup> Annual HCCA Compliance  
Institute  
April 1, 2020

1

1

# PATIENT DEFINITION: Does Location Matter?

Sue Veer, MBA, President and CEO  
Carolina Health Centers, Inc.



Michael Glomb, Esq., Partner  
Feldesman Tucker Leifer Fidell LLP



2

2

## Statement of Conflicts of Interest

This presentation is for educational purposes only. It should not be considered as legal advice

- Sue Veer has no actual or potential conflict of interest in relation to this presentation.
- Michael Glomb has no actual or potential conflict of interest in relation to this presentation.

3

3

## Today's Agenda

- Summary of legal/compliance issues in defining a "patient"
- Brief overview of Carolina Health Centers, Inc.
- Opportunities and challenges related to patient definition and 340B eligibility in the health center CE;
- Discussion of 340B eligibility across the continuum of care; and
- Organizational infrastructure to support patient eligibility across the continuum of care.

4

4

## Corporate Framework for Optimal Value & Compliance

- Alignment of clinical pharmacy as a core component of primary care medical home model
- Clear and specific understanding of the benefits of an effective pharmacy program
- Over-arching board approved corporate policy
- Service delivery model that is best practice for your health center
- Multidisciplinary Pharmacy Oversight Committee
- Consideration in strategic and operational decision making
- Included in outreach and marketing material
- Corporate-wide staff education and communication
- **Optimal utilization of 340B inventory**
- Data driven performance management
- **Comprehensive “Integrity Plan”**
- Demonstrating value

5

### Why Is There COMPLIANCE Problem?

- Nothing in the statute
- Covered entities have different relationships with the persons they serve
- “Responsibility for care” subordinated to administrative requirements
- Changes/advances in delivery of health care



6

6

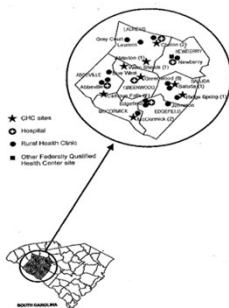
## Administration vs. Responsibility

- Site registration
- Referrals and other “off-site” scrips
- Contract pharmacy registration
- Pharmacy as a “required” service for health centers

7

7


## About Carolina Health Centers (CHC)



- FQHC serving the Lakelands region of SC since 1977
- 12 medical sites – family medicine, pediatrics, early childhood development and home visitation programs, school-based clinic, and migrant and seasonal farmworker services
  - 28,000 patients/110,000 encounters annually
  - 270 employees
  - Annual budget = \$29 million
- Opened in-house RX in 2005
- 2 stand-alone “open” community pharmacy sites (3<sup>rd</sup> location on the “drawing board”)
  - Daily delivery to outlying medical sites
  - 350,000 prescriptions per year
  - Initiated contact RX initiative in 2018

8

8



The value proposition for the 340B Drug Pricing Program lies at the intersection of :

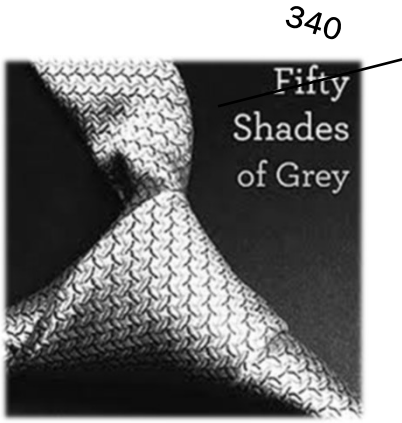
Access  
Quality  
Financial Viability

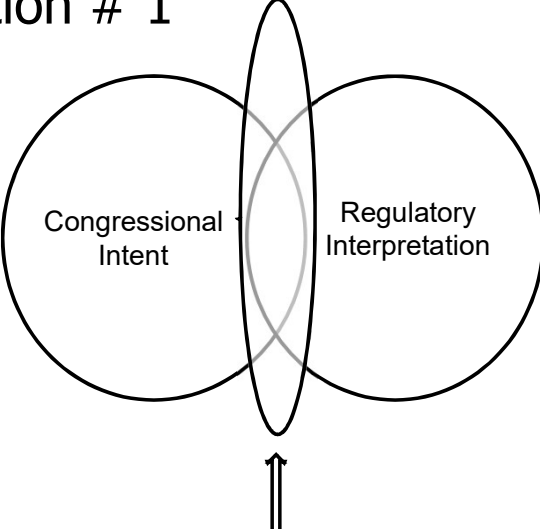
A primary responsibility of CHC leadership is to optimize and protect the 340B Drug Pricing Program.

9

9

## Assumption # 1



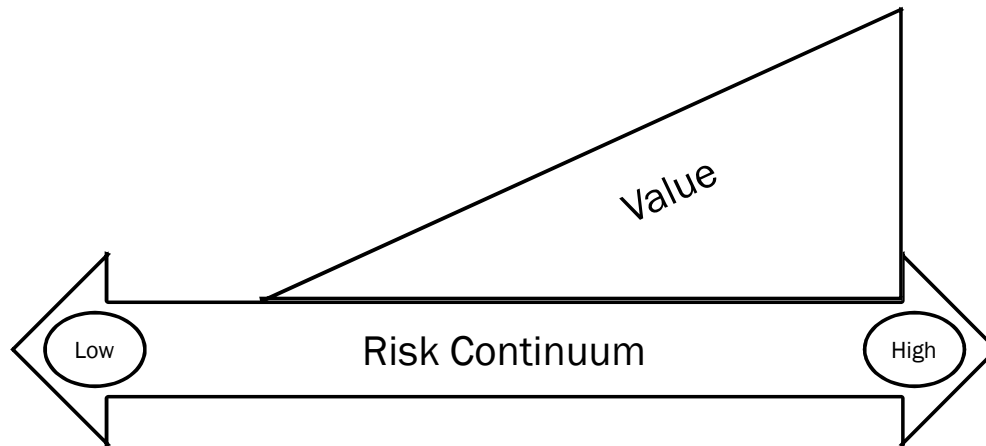


This is the space in which we are navigating with clarity

10

10

## Assumption # 2



11

11

Challenges and  
for the health  
center  
community in  
the face of  
ambiguity

- Responsibility and accountability as a Patient Centered Medical Home
  - 340B eligibility across the continuum of care
  - Impact of access and adherence on outcomes-based performance measures
- Scope of Project extending beyond the walls of physically distinct sites

12

12

### Compliance Rule # 1: No Diversion of 340B Inventory

340B drugs may only be dispensed to the "patient" of the CE as defined by HRSA and may not be resold or transferred by the CE.

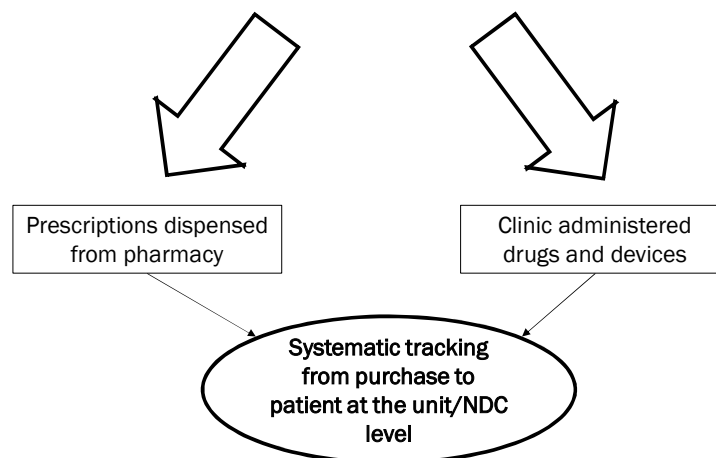
### Current HRSA Patient Definition

- The health center has responsibility for care; and
- Maintains a record's of the patients care; and
- Services are provided by a health care professional that is employed by or operating under contractual arrangements with the health center; and
- The health care services provided are consistent with the funding or designation making the entity 340B eligible; and
- The services provided are more than the dispensing of medication.

13

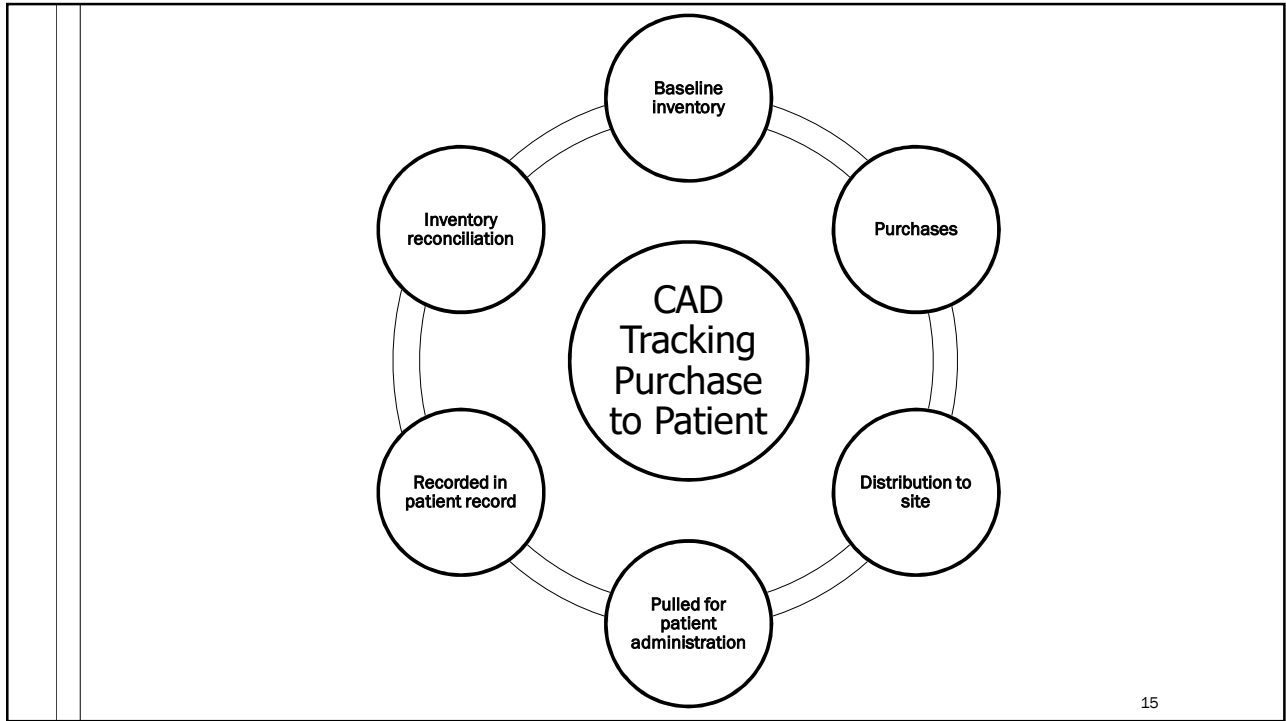
13

## PROHIBITION AGAINST DIVERSION APPLIES TO ALL INVENTORY PURCHASED UNDER THE 340B DRUG PRICING PROGRAM



14

14



15

**Let's talk about 340B eligibility across the continuum of care**

340B purchased drugs may only be dispensed to fill prescriptions that **emanate** from health center medical site that is registered on the OPAIS, or **a service that is in the health center's Scope of Project as reflected on Form 5C in the EHB.**

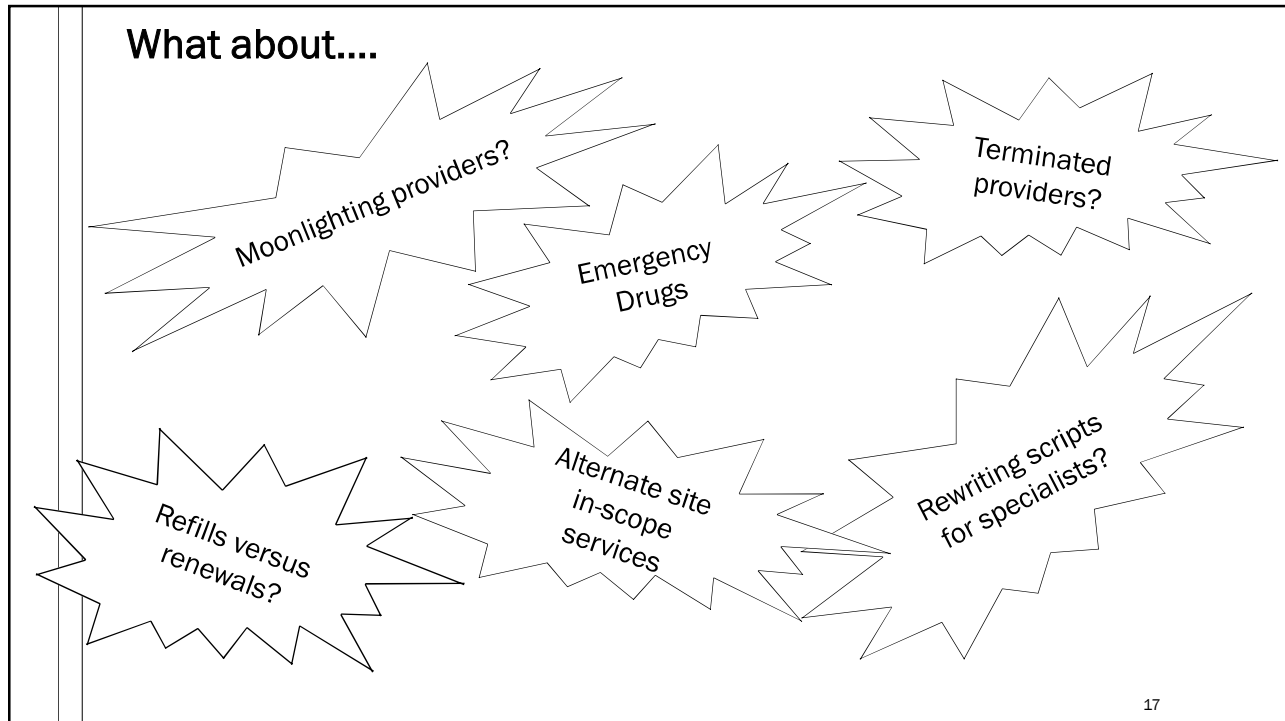
**emanate** verb  
em·a·nate | \ 'e-mə-nāt \  
emanated; emanating

**Definition of emanate**  
*intransitive verb*  
: to come out from a source  
*// a sweet scent emanating from the blossoms*

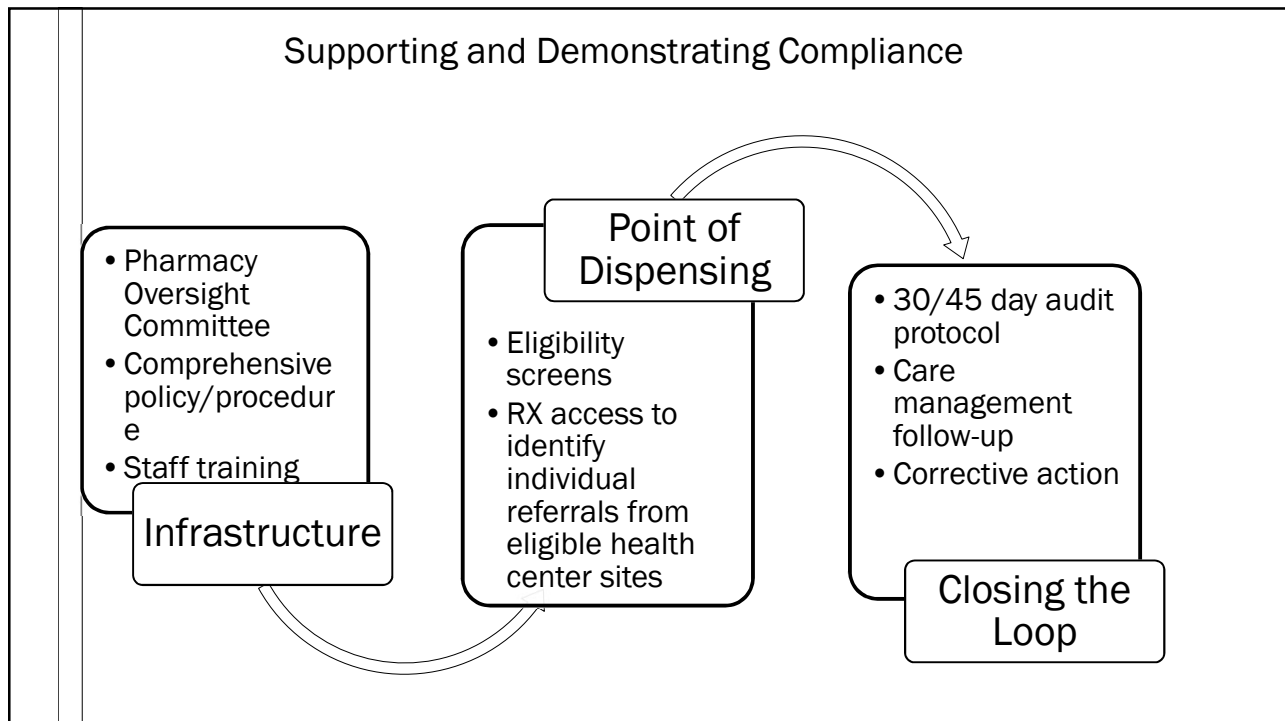
16

16





17



18

## Some Solutions

- Develop and follow a responsible policy
- Train
- Document
- Verify
- Challenge authority when warranted

19

19

## CONTACT INFORMATION

Sue Veer MBA  
President and CEO  
Carolina Health Centers, Inc  
113 Main Street, Suite 101  
Greenwood, South Carolina 29646  
864-388-0301 [sveer@carolinahealthcenters.org](mailto:sveer@carolinahealthcenters.org)

Michael B. Glomb, Esq.  
Partner  
Feldesman Tucker Leifer Fidell LLP  
1129 20th Street N.W., 4<sup>th</sup> Floor  
Washington, D.C. 20036  
202-466-896- [MGLOMBG@FTLF.COM](mailto:MGLOMBG@FTLF.COM)

20

20

# PROMOTING COMPLIANCE IN COMPLEX OVERLOOKED AREAS AT 340B HOSPITAL COVERED ENTITIES

Presented By: Coley Deal, 340B Program Manager

21

21

## 340B Compliance Agenda

### Principal Compliance Issues for Hospital Covered Entities:

1. Overview of 340B Compliance Best Practices
2. Patient Definition/Diversion
3. Duplicate Discounts
4. Group Purchasing Organization (GPO) Restriction (applicable to 11.75% DSH, Children's and Cancer Hospitals)
5. OPA Database Errors
6. HRSA Audit: Re-Audits \*NEW\*

22

22

## 340B Compliance – Sanctions

### OPA Sanction Authority for Diversion and Duplicate Discount Issues:

- Repayment to manufacturers.
- Interest on repayments for knowing and intentional violations.
- Removal from 340B for violations that are systematic, egregious, knowing and intentional. 42 USC§256b (a)(5)(c),(d)(v)(I),(II).
- HRSA Notice: “A finding of non-compliance in two or more audits, depending on the type of violation, may be considered systematic and egregious, as well as knowing and intentional, which may result in the CE being removed from the 340B Program...”

### OPA Sanction Authority for GPO Violation:

- Removal from 340B program

23

23

## System Wide Approach to 340B Compliance

### Best Practice

- Goal 1: Proactive Approach to 340B Compliance
- Goal 2: Decrease Variations to achieve compliance and efficiencies
- Core Leadership:
  - *System 340B Expert*
  - *System Compliance Officer (340B Experience and Knowledge)*
  - *System Legal Counsel (In-house or External with 340B Knowledge)*
  - *340B External consultants/auditors (Proven Experts)*
- Focus
  - *Policies*
  - *Monitoring (Internal)*
  - *Auditing (Independent and External)*

24

24

## System Wide Approach to 340B Compliance

### ■ Program Focus:

- *Compliance vs. monitoring*
- *System Level 340B Policy*
  - **Each facility will adopt policy and modifications may only be made by Core Leadership**
- *Flowcharts and Procedures*
- *On-going Education*
- ***Be Prepared for HRSA Audit 24/7/365***

### ■ Focus Monitoring:

- *Eligibility*
- *Diversion*
- *Duplicate Discounts*
- *GPO Exclusions*
- *Database Accuracy*
- *Expert external auditors*

25

25

COMPLEX AREAS OF CONCERNS

26

26

# Patient Definition/Diversion

## Area of Concern for CE's

- Hospital dispensations → Data accuracy
- Contract and Retail dispensations → over qualification from TPA filters incorrectly configured
- Child site locations

## Compliance Resolution

- Review high risk dispensations
  - Charge on dispense areas
  - Bulk charging
- Share results and expectations with report coders
- Discuss results with TPA, investigate filter options
- Map your sites and test once a year

27

27

# Duplicate Discounts

0258 IV SOLUTIONS	
0260 IV THERAPY	96375
0272 STERILE SUPPLY	
0335 CHEMOTHERAPY/IV	96413
0335 CHEMOTHERAPY/IV	96417
0636 N400409018201ML53	J9201UD
0636 N400409018301ML4	J9201UD
0636 N400409798302ML250	J7050
0636 N400409798309ML1000	J7030
0636 N408290306513ML5	J1642UD
0636 N416729036566ML5	J2469UD
0636 N467457042300ML3	J1100UD
0636 N468817013450UN1	J9264JWUD
0636 N468817013450UN3	J9264UD
0761 TREATMENT ROOM	36591

- Carve in vs. Carve out
- Hospital dispensations usually have different rules than retail and contract pharmacy claims
  - Differences between Fee-For-Service (FFS) and Managed Care Organizations within the same state?
  - Medicare with Medicaid secondary?
  - Part D claims with Medicaid secondary?
- Integrate Managed Care operations
  - 340B Education
  - Help with researching rules
- HRSA is tightening compliance with duplicate discounts
  - FFS Medicaid UBs requested for every child site
  - Medicaid enrollment or reverification forms

28

28

## Duplicate Discounts – Compliance Resolutions

- Testing UB-04s
  - *Target high risk and complex situations for modifier applications*
  - *Child sites, are they billing with the parent NPI?*
- Medicaid Enrollment or reverification forms
- Risk reductions strategies
- Advanced Testing
  - *Comparing 340B dispensations from TPA with transmitted 837 claim information*

29

29

## GPO Prohibition Compliance

### Area of Concern for CE's

- Child sites purchasing outside of hospital operations
- GPO purchasing accounts for non-340B sites

### Compliance Resolution

- Interviews and walkthroughs with child sites
- Review account naming conventions, bill to, and ship to information
- Review benefit received from these GPO accounts
  - *Consider moving to WAC*

30

30

## OPA Database Errors

### Area of Concern for CE's

- Child site relocations
- Contract pharmacy address change not reflected in agreement
- Contract pharmacy agreement does not include and/or self update with child site changes

### Compliance Resolution

- Go onsite!
- Compare OPAIS to the contract pharmacy agreement
  - *OPAIS Contract pharmacy addresses are self-updating*

31

31

## HRSA 340B Audit Update

- Becoming more in-depth and wider ranging
- More questions and more staff interviews
- Larger samples
  - *More universes*
- More in-depth reviews into:
  - *Split billing software*
  - *Medicaid*
  - *Purchasing processes*
  - *Billing processes*
  - *Storage and drug handling*
  - *Reviewing patient notes related to*

32

32



## HRSA 340B Audit Update: Re-Audits

### 9. Re-Audit

- A. Please provide a description and supporting documentation of how the CE determined the full scope of non-compliance (e.g. identified affected manufacturers, amount of repayment, communication with state Medicaid agency, etc.).
- B. Provide a list of all affected manufacturers, letter sent to manufacturers offering repayment, and list of settlements.
- C. Provide description(s) and supporting documentation of continuous monitoring with periodic assessment related to the previous audit finding(s).

33

33

## HRSA 340B Audit Update: Re-Audit Experience

- Very specific and in-depth questions onsite
- Auditor had copy of Corrective Action Plan (CAP) and had prepared questions
- Requested proof, granular detail, on CAP execution:
  - *Repayment results by manufacturer*
  - *Meeting agendas*
  - *Education trackers*
  - *Monitoring trackers*
  - *Department of Medicaid communications*
- Explanations on any deviations from CAP

34

34

# Contact Information

Coley Deal, 340B Program Manager, Bon Secours Mercy Health  
System

[Coley\\_Deal@bshsi.org](mailto:Coley_Deal@bshsi.org)

35

35



36

36