MONITORING AND STRENGTHENING COMPLIANCE
ACCESS ACROSS THE CONTINUUM OF CARE

Does Location Matter?

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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.
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.

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
Administration vs. Responsibility

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

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 (3rd location on the “drawing board”)
  - Daily delivery to outlying medical sites
  - 350,000 prescriptions per year
  - Initiated contact RX initiative in 2018
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.

Assumption #1

This is the space in which we are navigating with clarity.
Assumption # 2

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
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.

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

- Prescriptions dispensed from pharmacy
- Clinic administered drugs and devices
- Systematic tracking from purchase to patient at the unit/NDC level
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.

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**emanate**

*verb*

em-a-nate | ˈe-mə-ˌnät |
emanated; emanating

**Definition of emanate**

*intransitive verb*

: to come out from a source

// a sweet scent emanating from the blossoms
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.**

What about....

- Moonlighting providers?
- Emergency Drugs
- Terminated providers?
- Alternate site in-scope services
- Rewriting scripts for specialists?
- Refills versus renewals?
Some Solutions

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

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