WHAT WE PLAN TO COVER TODAY:

Part One: Program Framework
An overview of the origin and purpose of the program, structure and oversight, how it works and basic models of implementation.

Part Two: Compliance Requirements
An in-depth discussion of the requirements for a fully compliance 340B program.

Part Three: Program Integrity
An overview of the HRSA Program Integrity Initiative including a review of the audit process, recent audit findings, and suggestions for being prepared for an audit.

Part Four: Organizational Infrastructure
A discussion of the role of leadership in developing an effective organizational infrastructure to optimize the value of the 340B program.

Closing Discussion:
The legislative and regulatory landscape as it relates to the 340B Drug Discount Program.
SOME OPENING OBSERVATIONS

• Welcome to “340 Shades of Grey”

• My expertise is NOT in pharmacy operations and our focus today will be strategic and programmatic.

• We will conclude with questions…perhaps even some we hadn’t thought of when we began; however, these sessions often represent a “starting line” for continued dialogue and learning opportunities.

• There is an excellent – and growing - network of resources to support health center 340B pharmacy initiatives.
CAROLINA HEALTH CENTERS, INC.
EST. 1977

Come Home to Carolina... Your Medical Home Right Here at Home!

- Ten Family Practice Centers- one located on a hospital campus contiguous to the emergency department
- Two Pediatric Centers with integrated family support and child development services including evidence-based home visitation programs
- Seasonal Migrant Health Clinic
- Behavioral health care on-site at 2 sites and in-home counseling available through home visitation program
- Oral health services provided through a network of contracted dentists
- School Based Clinic
- Carolina Community Pharmacy – 2 locations
- Annual budget = $29 million
- Patients and Encounters = 27,000/110,000
7 rural counties
3,208 square miles
Courier route to all CHC sites >250 miles per day
Total population = 256,216
Poverty ranges from 17.2 to 23.1% in these counties
2 Critical Access Hospitals
1 community hospital
1 tertiary care facility
Limited independent pharmacies
Chains and big-box stores limited to the larger communities
THE STRATEGIC IMPERATIVE FOR 340B

Access
Quality
Financial Viability
Technological Excellence
Efficiency and Effectiveness
Effective Workforce
Business Development
Compliance
Advocacy and Social Responsibility
Governance and Leadership
CAROLINA COMMUNITY PHARMACY: DEVELOPMENTAL TIMELINE

- In-house pharmacy services initiated in 2005 with 340B pharmacy co-located in The Children’s Center
  - Opened to retail public
  - Open formulary with a list of free medications
  - Virtual inventory management
- Delivery service to all rural satellite sites implemented mid-2006
- Second pharmacy site (stand-alone) opened in 2009
  - Implemented robotic technology
- Relocated original in-house pharmacy from The Children’s Center to a 10,000 square foot stand-alone location in early 2012
  - Initiated Medication Therapy Management (MTM)
  - Implemented mail-order in 2015
- Opened a co-located primary care medical practice in 2016
- 2017 focus on integrating clinical pharmacy into the medical sites
- Entered into a contract pharmacy arrangement in 2013 but terminated in 2015 without ever implementing
CAROLINA COMMUNITY PHARMACY AT THE VILLAGE
THE IMPACT: PRESCRIPTIONS FILLED

- 2015-16
- 2014-15
- 2006-07
YEAR END DATA
FY2015-16
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<tr>
<th></th>
<th>June</th>
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<td><strong>TOTAL PRESCRIPTIONS FILLED</strong></td>
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<td>2001</td>
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<td>7</td>
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<td>5</td>
</tr>
<tr>
<td>MTM Northwest</td>
<td>7</td>
<td>5</td>
<td>4</td>
<td>6</td>
<td>3</td>
<td>5</td>
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<td>4</td>
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<tr>
<td>Inventory Village</td>
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<td>Rx Audits (NW - Village)</td>
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<td>Prescriptions - FQHC</td>
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<td>11,132</td>
<td>11,506</td>
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<td>11,896</td>
<td>11,881</td>
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<tr>
<td>Prescriptions - Retail</td>
<td>14,707</td>
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<td>15,950</td>
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<td>16,651</td>
<td>15,793</td>
<td>15,966</td>
<td>16,876</td>
<td>15,378</td>
<td>15,141</td>
</tr>
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</table>
### SLIDING FEE SCALE EXAMPLE

**COST-BASED MODEL**

<table>
<thead>
<tr>
<th>Price Tier</th>
<th>Ingredient cost +</th>
<th>Dispensing Fee</th>
<th>340B Sliding Fee B 101-125% FPL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Break 1</td>
<td>54%</td>
<td>$3.00</td>
<td>Break 1</td>
</tr>
<tr>
<td>Break 2</td>
<td>34%</td>
<td>$4.50</td>
<td>Break 2</td>
</tr>
<tr>
<td>Break 3</td>
<td>25%</td>
<td>$6.00</td>
<td>Break 3</td>
</tr>
<tr>
<td>Break 4</td>
<td>12%</td>
<td>$7.50</td>
<td>Break 4</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Price Tier</th>
<th>Ingredient cost +</th>
<th>Dispensing Fee</th>
<th>340B Sliding Fee D 151-200% FPL</th>
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<tbody>
<tr>
<td>Break 1</td>
<td>56%</td>
<td>$3.50</td>
<td>Break 1</td>
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<tr>
<td>Break 2</td>
<td>36%</td>
<td>$5.00</td>
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<tr>
<td>Break 3</td>
<td>30%</td>
<td>$6.75</td>
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<td>Break 4</td>
<td>17%</td>
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<td>Break 4</td>
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**340B Sliding Fee A <100% FPL**

<table>
<thead>
<tr>
<th>Price Tier</th>
<th>Ingredient cost +</th>
<th>Dispensing Fee</th>
<th>340B Sliding Fee B 101-125% FPL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Break 1</td>
<td>54%</td>
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<td>$4.50</td>
<td>Break 2</td>
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<tr>
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<td>25%</td>
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</tr>
<tr>
<td>Break 4</td>
<td>12%</td>
<td>$7.50</td>
<td>Break 4</td>
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**126-150% FPL**

<table>
<thead>
<tr>
<th>Price Tier</th>
<th>Ingredient cost +</th>
<th>Dispensing Fee</th>
<th>340B Sliding Fee D 151-200% FPL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Break 1</td>
<td>56%</td>
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<td>Break 1</td>
</tr>
<tr>
<td>Break 2</td>
<td>36%</td>
<td>$5.00</td>
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<td>Break 3</td>
<td>30%</td>
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<td>Break 3</td>
</tr>
<tr>
<td>Break 4</td>
<td>17%</td>
<td>$8.00</td>
<td>Break 4</td>
</tr>
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</table>

**340B Sliding Fee D 151-200% FPL**

<table>
<thead>
<tr>
<th>Price Tier</th>
<th>Ingredient cost +</th>
<th>Dispensing Fee</th>
<th>340B Sliding Fee D 151-200% FPL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Break 1</td>
<td>58%</td>
<td>$3.50</td>
<td>Break 1</td>
</tr>
<tr>
<td>Break 2</td>
<td>38%</td>
<td>$5.25</td>
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<tr>
<td>Break 3</td>
<td>31%</td>
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</tr>
<tr>
<td>Break 4</td>
<td>17%</td>
<td>$10.00</td>
<td>Break 4</td>
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</table>
# Carolina Community 340B Pharmacy Audits

Date: ____________ / Type: (Daily, Weekly, Monthly) (Circle one)

<table>
<thead>
<tr>
<th>CCP-Village</th>
<th>CCP-NorthWest</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Rx Number</th>
<th>Tech Responsible</th>
<th>Should be Retail Meds</th>
<th>Should be 340B Meds</th>
<th>Should be STC</th>
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</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Choose 5 more Rx’s to AUDIT

<table>
<thead>
<tr>
<th>ARE THEY CORRECT?</th>
<th>CORRECTED BY?</th>
<th>SHOULD BE 340B Meds</th>
<th>SHOULD NOT BE 340B Meds</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<tr>
<td>2.</td>
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<tr>
<td>3.</td>
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<td>4.</td>
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<tr>
<td>5.</td>
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</tr>
</tbody>
</table>

**BELOW** Indicates SC Medicaid Filled with 340B Meds—Correct Immediately

<table>
<thead>
<tr>
<th>Rx#</th>
<th>Date Filled</th>
<th>Date Corrected</th>
<th>Corrected BY</th>
<th>Tech Initial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

When Corrected Please Initial & File This Audit Sheet
Take-away:
The investment the organization has made in pharmacy will not yield the best return if operated in a vacuum – it requires the alignment and integration with the overall health care program to bring optimal value to the organization and its patients. Enlist the support of the C-Suite in developing a meaningful performance plan.
PART ONE: THE 340B PROGRAM FRAMEWORK
OVERVIEW OF THE 340B DRUG DISCOUNT PROGRAM

The 340B Drug Discount Program was enacted in 1992 and is a Federal program that requires pharmaceutical manufacturers to sell drugs to eligible providers at a discount, for outpatient use.

- Medicaid Drug Rebate Program of 1990 resulted in dramatically increased provider costs for other discounted drugs.
- In 1992 Congress created the 340B Drug Discount Program to protect certain clinics and hospitals (called covered entities) from those increases.
- Public Law 102-585 - Veteran’s Health care Act of 1992 - Codified as Section 340B of the Public Health Service Act limits the amount that manufacturers may charge covered entities to what is known as a ceiling price.

Take-away: The 340B Drug Discount Program is not federally funded; rather it is paid for by manufacturers. Congress intended to provide financial relief for eligible providers.
HOW DOES THE PROGRAM WORK

• Discounts are provided **up-front** (sold at lower cost) rather than a rebate after-the-fact
  • Price can be **no higher than cost to Medicaid**, but can be lower (some Rx cost only a penny)
  • Discounts average **25% - 50%** off average manufacturers price.

• Purpose is to enable eligible entities to **stretch scarce federal resources**
  • Increase access for eligible patients
  • Enable eligible entities to provide more comprehensive services

**Take-away:**
Congress intended a positive financial impact for covered entities
WHO ARE THE KEY PLAYERS IN THE 340B PROGRAM?

- The Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services is the governmental agency responsible for oversight of the program.
- The Office of Pharmacy Affairs (OPA) within HRSA is responsible for administration and oversight of the program.
- Covered entities are those health care organizations eligible to participate in the 340B program.
- Participating manufacturers – sell to covered entities at or below the ceiling price if they want their drugs to be covered by Medicaid.
- In-house pharmacies – are owned by covered entities and may or may not be in the same physical space as the medical sites.
- Contract pharmacies – that may contract with a covered entity to dispense 340B drugs to the entity’s patients.
- The Prime Vendor – contracted by HRSA to provide training and technical assistance, and is able to negotiate sub-ceiling pricing.
- Wholesale distributors – purchase from the manufacturer and sell to retail pharmacies and other entities.
340B - THE ELIGIBLE ENTITIES

- Federally Qualified Health Centers
- Family Planning Projects
- Ryan White Care Part C or EIS Grantees
- Certified AIDS Assistance Programs (ADAP)
- Black Lung Clinics
- Hemophilia Treatment Centers
- Native Hawaiian Health Centers
- Urban Indian Organizations
- Certified Tuberculosis Clinics
- Certified STD Clinics

- 2010 expansion under the Patient Protection and Affordable Care Act:
  - DSH Hospitals
  - Children’s Hospitals
  - Critical Access Hospitals
  - Rural Access Centers
  - Free Standing Cancer Hospitals
  - Sole Community Hospitals

**Take-away:**
As of January 1, 2015 there were 11,530 covered entities in the 340B Program and the $7.5 billion represented only 2.3% of the $326 billion spent annually on pharmaceuticals in this country.
WHAT DRUGS ARE AVAILABLE UNDER 340B?

Generally, the 340B Program covers the following drugs for outpatient use only:

- FDA approved prescription drugs
- Over the counter drugs written on a prescription
- Biological products that can be dispensed only by a prescription (other than vaccines)
- FDA approved insulin

Notably, vaccines are not covered under 340B; however the PVP and other group purchasing arrangements for FQHCs offer reduced pricing on vaccines.
## HOW DOES A HEALTH CENTER RETAIN SAVINGS FROM 340B PRESCRIPTIONS?

<table>
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<tr>
<th></th>
<th>Retail</th>
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<th>340B</th>
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<td>Cost of drug</td>
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</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt; party reimbursement</td>
<td>$112</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; party reimbursement</td>
<td>$112</td>
<td></td>
</tr>
<tr>
<td>Dispensing fee</td>
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<td>Dispensing fee</td>
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<tr>
<td>Total reimbursement</td>
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<td>Total reimbursement</td>
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<tr>
<td>Retained savings</td>
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<td>Retained savings</td>
<td>$80</td>
<td></td>
</tr>
</tbody>
</table>

**Take-away:**
Retained savings are intended to cover pharmacy overhead AND provide additional resources that allow the health center to stretch its scarce resources to expand and enhance services.
SAVINGS FROM THE 340B PROGRAM

• The savings generated from participating in the 340B program belong to the eligible entity
  • Only reasonable dispensing and administration fees should be paid to a partnering entity like a contract pharmacy.
• There is no mandate in the law that requires the entity to pass the 340B savings on to patients though most FQHCs choose to do so.
• HRSA provides guidance for FQHCs on expenditures of non grant funds:
  • FQHCs must reinvest 340B revenues into activities that promote the purpose of their HRSA/BPHC Scope of Project and advance their goal of providing care to medically underserved populations.
  • Examples:
    • Low cost RX without using other scarce resources
    • Expanded access to primary care
    • Enhanced services i.e. behavioral health, oral health, specialty care
    • Unfunded enabling services

Take-away:
340B Policies and Procedures should include a statement addressing how the FQHC uses savings in a manner that is consistent with Congressional intent and HRSA guidance.
FAQ: ARE THERE RULES ABOUT HOW MUCH THE HEALTH CENTER PHARMACY CHARGES THE PATIENT FOR A PRESCRIPTION FILLED WITH 340B PURCHASED DRUGS?

- The 340B statute is silent on this issue.
- **Section 330 is not!**
  - SFDS must apply to 340B drugs.
  - Rules apply to the service component only – namely the dispensing costs.
  - PIN 2014-02 states that charges for the drugs themselves “can be set to cover the reasonable cost of such items or can be further discounted to pass additional savings on to patients”.
  - Understand the impact of a flat fee versus cost-based sliding fee scale for pharmacy.
## SLIDING FEE SCALE EXAMPLE

**COST-BASED MODEL**

### 340B Sliding Fee Scale A (<100% FPL)

<table>
<thead>
<tr>
<th>Price Tier</th>
<th>Ingredient cost +</th>
<th>Dispensing Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Break 1</td>
<td>54%</td>
<td>$3.00</td>
</tr>
<tr>
<td>Break 2</td>
<td>34%</td>
<td>$4.50</td>
</tr>
<tr>
<td>Break 3</td>
<td>25%</td>
<td>$6.00</td>
</tr>
<tr>
<td>Break 4</td>
<td>12%</td>
<td>$7.50</td>
</tr>
</tbody>
</table>

### 340B Sliding Fee Scale B (101-125% FPL)

<table>
<thead>
<tr>
<th>Price Tier</th>
<th>Ingredient cost +</th>
<th>Dispensing Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Break 1</td>
<td>55%</td>
<td>$3.25</td>
</tr>
<tr>
<td>Break 2</td>
<td>35%</td>
<td>$4.75</td>
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<tr>
<td>Break 3</td>
<td>27%</td>
<td>$6.50</td>
</tr>
<tr>
<td>Break 4</td>
<td>15%</td>
<td>$8.50</td>
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### 126-150% FPL

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<th>Price Tier</th>
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</tr>
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</tr>
<tr>
<td>Break 3</td>
<td>31%</td>
<td>$7.25</td>
</tr>
<tr>
<td>Break 4</td>
<td>17%</td>
<td>$10.00</td>
</tr>
</tbody>
</table>

**Take-away:**

The design of your pharmacy sliding fee scale is a delicate balance impacting patient access and the financial viability of the health center’s pharmacy program.
BASIC MODELS FOR IMPLEMENTING 340B PHARMACY

In-house pharmacy – 46.9%
340B only or open retail - unknown

Contract pharmacy – 49.1%

Dispensary/clinic administered drugs & devices

A combination of the above - unknown
## FACTORS TO CONSIDER WITH IN-HOUSE:
Definition: Owned and operated by the health center regardless of location

<table>
<thead>
<tr>
<th>FACTORS TO CONSIDER</th>
<th>VALUE ADDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated volume</td>
<td>Flexibility</td>
</tr>
<tr>
<td>Space</td>
<td>Generics</td>
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<tr>
<td>Technology</td>
<td>Integration of clinical pharmacy into primary care medical home model</td>
</tr>
<tr>
<td>Available personnel and knowledge</td>
<td>Increased savings/margin</td>
</tr>
<tr>
<td>Capacity to support compliance framework</td>
<td>Total control of compliance framework</td>
</tr>
<tr>
<td>Start-up costs and zero barrier for break even</td>
<td></td>
</tr>
<tr>
<td>Provider buy-in and potential capture rate</td>
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<tr>
<td>Pharmacy profile in the target market</td>
<td></td>
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<tr>
<td>Geographic dispersion of patients</td>
<td></td>
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</tbody>
</table>
CONSIDERING THE CONTRACT PHARMACY MODEL
DEFINITION: OWNED AND OPERATED BY AN EXTERNAL ENTITY REGARDLESS OF LOCATION

- Ability to improve access to affordable prescription medication, improve compliance, and positively impact health outcomes
- The contract model may eliminate barriers such as:
  - Start-up costs and facility requirements
  - Time required to develop knowledge base and necessary infrastructure
  - Shortage of qualified pharmacy professionals
- Will provide an additional revenue stream – albeit reduced - to help fund the mission of the eligible entity
  - Savings you retain could be reduced by as much as 40-60%
- Supports positive relationships with independent pharmacies
- However, the eligible entity remain fully responsible for compliance with all 340B requirements and guidance
Prescriptions are “leaking” to outside pharmacies.

- Multiple factors: late night/weekend hours, one-stop shopping, preferred provider arrangements, historical patterns of behavior

- Approximately 30% of those prescriptions filled by contract pharmacies are for sliding fee patients who could benefit from 340B discount pricing.

- Contracts with outside pharmacies can enhance access to affordable prescription medication and improve the health of our patients without operating a 24/7 retail pharmacy.

- Additional revenue generated through the contract helps to support otherwise uncompensated primary and preventive services.
WHAT ABOUT AN OPEN RETAIL MODEL?

• Factor in all the considerations for in-house, plus:
  • Is there unmet need for access to affordable medication among the residents of your community who are not your patients?
  • Does the retail public already cross your threshold?
  • What do the numbers tell you?
  • Do you have the capacity to manage separate inventories?
  • Are you willing and able to purchase “gap” insurance?
• Side benefit: a retail pharmacy is likely to create an entry point into your medical practices for patients without a primary care medical home.

Take-away:
Monitor capture rate to monitor performance and inform the strategic planning process
PART TWO: THE COMPLIANCE REQUIREMENTS
A SNAPSHOT OF THE COMPLIANCE BASICS

Participation is a HRSA Program Expectation

- Participation Requirements:
  - Maintain auditable records documenting compliance with program rules;
  - Register on the HRSA Office of Pharmacy Affairs (OPA) database; and
  - Recertify with HRSA annually.

- Rule #1: No drug diversion
  - 340B purchased drugs may only be dispensed to patients that meet HRSA’s definition of a “patient”.
  - 340B purchased drugs may only be dispensed to fill prescriptions that emanate from health center medical site that is registered on the OPA database.

- Rule #2: No duplicate
  - A duplicate discount occurs when manufacturers provide both a 340 discount on the purchase of a drug and pay a Medicaid rebate to the State on the same drug.
  - The eligible entity is responsible for preventing duplicate discounts by carving in or carving out using the Medicaid Exclusion File.
“Consistent with Departmental guidance, HRSA grantees that purchase, are reimbursed or provide reimbursement to other entities for outpatient prescription drugs are expected to secure the best prices available for such products and to maximize results for the grantee organization and its patients. Eligible health care organizations/covered entities that enroll in the 340B Program must comply with all 340B Program requirements and will be subject to audit regarding 340B Program compliance. 340B Program requirements, including eligibility, can be found at www.hrsa.gov/opa.”
MAINTAIN AUDITABLE RECORDS

- Policies and Procedures
- Copies of self-audits
- Copies of external 340B audits
- Contracts related to contract pharmacy 340B operations (e.g., contracts with the pharmacy itself; PBM contracts; virtual inventory tracking systems)
- Pharmacy service agreements
- Vendor contracts
- Patient records
- Invoices for 340B drugs purchased – required 59 Federal Register 25110, 25113 (May 13, 1994)
- Reports of 340B drugs dispensed
- Inventory reconciliations

But what makes a record “auditable”?

- It exists
- It can be accessed
- It can be traced to its source
- As it related to contracts and written agreements
  - Duly executed and maintained (consider provider contracts with expired terms)
  - Executed by someone with signatory authority for the health center (consider delegated signatory authority in position descriptions)
REGISTRATION: WHAT NEEDS TO BE REGISTERED?

• Each clinical site from which prescriptions will emanate
  • Parent site/child sites
  • Designate “ship to” and “bill to” addresses for each site
• Will the covered entity dispense 340B purchased medication to Medicaid patients and bill Medicaid for those dispensed 340B drugs? – Note: this applies specifically to 340B drugs and devices billed under the NPI of the registered site
  • Contract pharmacy locations where patients may access 340B purchased drugs
• In-house pharmacies owned by a legal entity other than the FQHC are considered contract pharmacy sites
• FQHC owned pharmacies that are “stand-alone” – i.e. not located in a medical site” are not registered with OPA but must appear as a site in your Scope of Project
SPECIAL CONSIDERATION WITH REGISTERING CONTRACT PHARMACIES

If a contract pharmacy serves patients from ALL child sites, register under parent.

If a contract pharmacy is registered under a child site only, it can serve only 340B patients from that child site.
Major Intersection Between Section 330 and the 340B Drug Discount Program: Medical sites must be operational in the Electronic Handbook to be registered in the OPA Database.
PREVIOUSLY:

- New service sites and contract pharmacies could only register on HRSA’s 340B database during four two-week windows each year.
- Applicants became eligible to start participating in 340B on the first day of the following quarter.
- Resulted in a 3-6 month delay in eligibility.

<table>
<thead>
<tr>
<th>Registration Period</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>January 1 - 15</td>
<td>April 1</td>
</tr>
<tr>
<td>April 1 - 15</td>
<td>July 1</td>
</tr>
<tr>
<td>July 1 - 15</td>
<td>October 1</td>
</tr>
<tr>
<td>October 1 - 15</td>
<td>January 1</td>
</tr>
</tbody>
</table>

NEW TIMELINE – JUST FOR FQHCS!

- Applicants will still only become eligible to start participating in 340B on the first day of the quarter after they register; however, health centers will have much longer windows to register new service sites.
- Starting Jan 1, 2017, health centers have until the 10th day of the third month of each quarter to register and become eligible on the first day of the following quarter.
  - Ex: To become eligible on April 1, you must register by March 10 (instead of January 15.)
  - The maximum delay in eligibility has been reduced to only 21 days!
HOW TO REGISTER DURING THE EXTENDED WINDOW

- Be sure your site is “active” in EHB.
- Contact the 340B call center to request a “one-time registration link.”
- The authorizing official (AO) will receive an email message with a one-time registration link valid for 72 hours.
- Sorry, but it does not apply when adding contract pharmacy arrangements.
- Relocations of existing medical sites should now be handled as “changes of address” rather than the registration of a new site.
DON’T MISS RECERTIFICATION!!!

• All covered entities must recertify annually (usually February for FQHCs) and failure to do so within the specified time frame will result in removal from the 340B program for a minimum of 3-months.

• Recertification is an opportunity to identify and correct errors in the database before they result in an audit finding. Note: new sites cannot be registered during this process.

• Triggered by an email to Authorizing Official (AO) and Primary Contact (PO) of record.

---

From: Health Resources and Services Administration [mailto:hrsa@public.govdelivery.com]
Sent: Thursday, February 16, 2017 7:30 AM
To: sveer@carolinahealthcenters.org
Subject: PENDING TERMINATION NOTICE: 2017 HRSA OPA 340B RECERTIFICATION 02-16-2017(FOURTH NOTICE)

This Fourth Notification list serv message is only going to covered entities who are still pending recertification. RECERTIFICATION MUST BE COMPLETED BY 02/22/2017. Failure to recertify your covered entity will result in the removal of your covered entity from the 340B Program on the first day of the following quarter. Please be aware that due to the volume of pending recertification’s, further delay in recertification may result in limited technical assistance.

Take-away: Make sure your AO and PO information is correct and DON’T IGNORE THE EMAIL!
340B purchased drugs may only be dispensed to patients that meet HRSA’s definition of a “patient” and
340B purchased drugs may only be dispensed to fill prescriptions that emanate from health center medical site that is registered on the OPA database.

HRSA’S DEFINITION OF A PATIENT
- 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.
340B ELIGIBILITY ACROSS THE CONTINUUM OF CARE

Primary Care Medical Home

Hospital Admission and Discharge

Specialty Care

Episodic Acute Care
WHAT ABOUT….

Moonlighting providers?

Terminated providers?

Refills versus renewals?

Rewriting scripts for specialists?
RULE # 2: NO DUPLICATE DISCOUNT

• A duplicate discount occurs when manufacturers provide both a 340B discount on the purchase of a drug and pay a Medicaid rebate to the State on the same drug.

• The eligible entity is responsible for preventing duplicate discounts by carving in or carving out using the Medicaid Exclusion File (MEF).

• The MEF was originally designed to exclude FFS claims only.

• Preventing duplicate discounts has been complicated by managed care joining the dance.
As of 2010, ACA requires manufacturers to pay rebates on Medicaid MCO drugs, except for 340B drugs.

CMS Medicaid Managed Care Final Rule (May 2016) makes it clear that it is the state’s responsibility, through its contract with the MCO to ensure that 340B claims are excluded from utilization data (July 1, 2017).

A number of different methods are available to States for identifying 340B claims and preventing duplicate discounts, but they generally correspond to one of two types:

- **Provider-level methods**, which identify covered entities that use 340B-purchased drugs for their Medicaid patients and exclude drug claims billed by those entities from utilization data. The most prominent provider-level method is HRSA’s Medicaid Exclusion File (MEF).

- **Claim-level methods**, which exclude individual drug claims that covered entities have explicitly identified as 340B claims from utilization data.

Many states and MCOs have begun stepping with proposals (i.e. provider level exclusion/inclusion) that have the effect of restricting access.

Some have proposed the complete exclusion of 340B for Medicaid recipients.
WHEN DO YOU NEED SEPARATE INVENTORIES?

- In-house pharmacy with open retail component
- In-house pharmacy with Medicaid carved out
- Contract pharmacies which by definition serve more than the health center’s eligible patients
- Health center with multiple categories of 340B covered entity status served by single in-house pharmacy
- Non-eligible drugs are being dispensed
- Any circumstance in which the covered entity’s pharmacy – whether in-house or contracted – may have occasion to dispense medication to a non-eligible patient

- Drugs are allocated to 340B purchases prior to being dispensed
- Requires more space
- Increase cost and inhibit cash flow
- May necessitate a limited formulary
- Does not accommodate retrospective correction

- 340B and non-340B co-mingled
- Patient eligibility determined retrospectively
  - Drugs are allocated as 340B after purchase
  - Tracking system is necessary
  - Must be tracked and replenished by National Drug Code (NDC) number
- Errors can be corrected
- Requires care and consideration in setting up filters and screens
CONTRACT PHARMACY REPRESENTS THE #1 FACTOR IN DETERMINING YOUR RISK OF AN AUDIT!
Data show contract pharmacies as of July of each year. For 2014, data show contract pharmacies as of January.
Source: Avalere Health (2000-2012); Pembroke Consulting (2013-2014)
Note: This chart appears as Exhibit 95 in the 2013-14 Economic Report on Retail, Mail and Specialty Pharmacies. Drug Channels Institute, January 2014. (http://drugchannelsinstitute.com/products/industry_report/pharmacy/)
340B Contract Pharmacy Locations, by Chain, January 2014

n = 13,708 pharmacy locations

Walgreens 39%

All Others 37%

Safeway 2%

Kroger 2%

Walmart 6%

CVS 7%

Rite Aid 7%

24%


Note: This chart appears as Exhibit 96 in the 2013-14 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2014. (http://drugchannelsinstitute.com/products/industry_report/pharmacy/)
# 1

First step in contract pharmacy compliance is a well-written contract. Make sure you have a contract and it includes **all required elements** and clearly delineates what each party is responsible for.

- Ensure tracking system is in place to prevent diversion
- Maintain reasonable access to facilities and records to ensure efficacy of tracking system
- Establish charges for patients
- Identify mechanism to collect patient and third party payments
- Ensure patient freedom of choice
- Prohibit resale or transfer of 340B drugs
- Include recoupment/penalty for diversion (i.e. reimburse CE amount equal to the discount)
- Prohibit dispensing to FFS Medicaid patients (unless there is a HRSA approved system to prevent duplicate discounts)
- Confirm access for manufacturer and federal audits
- Confirm access for annual CE audit
- Negotiate reasonable dispensing fee
- From the field: Representation regarding debarment

* See page 52 in your NACHC 340B Manual
• Conduct independent annual audits and/or employ other adequate oversight mechanism
• Develop 340B Program policies and procedures
• Prevent diversion
• Prevent duplicate discounts by carving out Medicaid or establish alternative arrangement with state Medicaid agency
• Maintain accurate information in the HRSA 340B database
• Ensure the contract lists each location individually;
• Do not use contract pharmacy for 340B purposes until:
  • Contract is finalized and signed, and
  • Contract has been registered on the OPA database and the effective date has been reached
• Ensure that regular reporting thoroughly describes the flow of drugs and money AND that your pharmacy and senior leadership understand the reports.

* See page 56 in your NACHC 340B Manual
PART THREE: PROGRAM INTEGRITY
PREPARE TO BE AUDITED
Program Integrity

HRSA's Program Integrity guiding principles are to maximize oversight reach and manage compliance risks. HRSA's efforts to follow these principles include audits of covered entities and manufacturers to enforce requirements for these stakeholders. Other efforts include annual recertification in order to give covered entities an opportunity to review their 340B Drug Pricing Program (340B Program) responsibilities and re-attest to being currently in full compliance. Questionnaires are evaluated through HRSA grantee site-visits to serve as an initial screening tool for assessing compliance. Also, OPA's self-disclosure process allows covered entities to evaluate and correct aspects of their 340B Program through self-reporting.

Audits of Covered Entities

340B Drug Pricing Program covered entities must ensure program integrity and maintain accurate records documenting compliance with all 340B Program requirements.

HRSA has the authority to audit covered entities for compliance with 340B Drug Pricing Program (340B Program) requirements (42 USC 256b(a)(5)(C)).

Covered entities are subject to audit by the manufacturer or the federal government.
AUDIT BASICS

- What external entities might audit you?
  - HRSA
  - Manufacturers
  - News Flash – the IRS may have an interest

- Risk factors for an audit
  - Size and complexity of your program
  - Number of contract pharmacies
  - Lack of timely response to manufacturer inquiry
  - Having an open retail model
  - Negative findings on a 340B related issue during a BPHC OSV

- Potential consequences
  - CAP – Corrective Action Plan intended to ensure future compliance
  - Repayment requirements
  - Covered entities whose findings involve repayment will be subject to audit in a year
  - Posting on the HRSA website – CHANGES IN 2016
  - Termination from the program
HRSA 340B AUDITS

Audits Reported as of December 31, 2015

Includes only those finalized by 3/17/17
as of December 31, 2015

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<tr>
<th>Category</th>
<th>2015</th>
<th>2014</th>
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<td>Other 11</td>
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<td>CHC 8</td>
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<tr>
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<tr>
<td>Other 6</td>
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<tr>
<td>CHC 13</td>
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</table>
2014 CHC adverse findings are higher than average.

<table>
<thead>
<tr>
<th></th>
<th>2014-ALL</th>
<th>2014-CHC</th>
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</thead>
<tbody>
<tr>
<td>No adverse</td>
<td>20%</td>
<td>15%</td>
</tr>
<tr>
<td>Adverse</td>
<td>80%</td>
<td>85%</td>
</tr>
</tbody>
</table>

HRSA AUDIT FINDINGS - 2014
HRSA AUDIT FINDINGS - 2015

2015-ALL

- 76% No adverse
- 24% Adverse

2015-CHC

- 89% No adverse
- 21% Adverse
CHCS WITH ADVERSE FINDINGS

as of December 31, 2015

Percentage of CHCs audited with the type of error

- **No contract pharmacy oversight**: 29% (2015), 21% (2014)
- **Duplicate discounts**: 36% (2015), 38% (2014)
- **Diversion**: 21% (2015), 39% (2014)
- **Incorrect 340B database record**: 64% (2015), 85% (2014)
WHAT ABOUT MORE RECENT FINDING?

- 31 health centers audited
- 35% had no adverse findings
- 65% had adverse findings
- 54.8% with potential for repayment

- Incorrect database = 12
- Diversion = 5
- Duplicate Discount = 16
- No contract oversight = 1
MOST FREQUENT AUDIT FINDINGS BY CATEGORY

DATABASE

- Incorrect AO
- Closed facility listed
- Incorrect facility address
- Incorrect facility name
- Incorrect grant number
- Facility/site not registered

PATIENT ELIGIBILITY

- Ineligible provider
- Inadequate medical record documentation
- Service outside of scope of project/grant
- OTC drug without a prescription
- No auditable records
DUPLICATE DISCOUNT

- Inaccurate Medicaid Exclusion File listing
- Yes box not checked
- Incorrect NPI/Medicaid billing number
- Missing NPI/Medicaid billing number

CONTRACT PHARMACY

- Registered without a contract
- Contracted/dispensing but not registered
- Dispensing without contract
- Missing locations/incorrect addresses
- Ineligible patients
- Ineligible providers
- Dispensing to Medicaid FFS patients
- Oversight of contract pharmacy
ADDRESSING FINDINGS

- Contest findings of fact
  - Correct errors
  - Provide additional documentation
- Consider potential legal issues
  - Are findings grounded in the statute (e.g. site registration requirement)
  - Audit procedures (HRSA does not follow GAO “Yellow Book” standards)
  - Adequacy of “notice and hearing” (42 USC 256b(a)(5)(D))
  - Scope of audit (42 USC 256b(a)(5)(C))
TIPS FOR MINIMIZING RISK

• **Comprehensive and current policies and procedures**
  • Regular database surveillance including the Medicaid Exclusion File
  • Corporate wide training programs
  • Consideration of 340B pharmacy in all site and service related changes
  • Inclusion of pharmacy on hiring and termination notifications
  • Self audits
  • Periodic audit of filters, lists, or tables used in matching data files
  • Independent audits
AUDIT GUIDELINES

• Covered entity notification of a suspected program violation.
• CE and manufacturer have 30-days to make a good faith attempt to resolve the issue.
• Formal dispute resolution may be initiated if enough evidence exists to proceed without an audit.
• If additional evidence is necessary the manufacturer may initiate an audit by filing an audit plan with HRSA.
• Audit plan must include clear explanation of why a violation is suspected with supporting evidence.
• If approved, audit must be conducted by independent CPA according to government accounting standards and must observe patient confidentiality.
• CE has 30 days following receipt of audit report to respond and if not in agreement with findings parties may file for DHHS dispute resolution.

TIPS FOR COVERED ENTITIES

• Proactively identify an audit-response team and process before being audited to allow for timely and accurate responses to auditor requests.
• Ensure that the audit-response team member becomes familiar with the audit guidelines set forth by HRSA.
• When necessary, negotiate for additional response time.
• Try to resolve alleged violations during an informal process whenever possible.
• Make sure policies and procedures are up to date and readily retrievable upon request.
• Conduct self-audits.
• Obtain the assistance of trained 340B experts to help establish a comprehensive 340B compliance plan will help ensure success when responding to HRSA and manufacturer audits.
Does the health center have written 340B policies, procedures, and other required/related documents?

- OPA database management: registration, annual recertification, enrolling removing delivery sites, updating and verifying the database
- Procurement/inventory management/dispensing
- Internal control policies
- Internal (self) and external audits
- Corrective action
- Designation of staff responsibility for 340B operations, oversight, and compliance
- Periodic review of 340B policies and procedures
- Auditable records
- Use of 340B savings/pharmacy revenue
Focus is on:
Documentation of P&Ps
Patient eligibility
Duplicate discounts
Oversight of Contract pharmacy

4 QUESTIONS YOU SHOULD EXPECT DURING YOUR OPERATIONAL SITE VISIT

Do the policies and procedures address patient definition and duplicate discount?

- Defining and documenting patient eligibility
- Providing/updating patient lists to contract pharmacies (if applicable)
- Defining/documenting/updating providers eligible to prescribe 340B drugs (including contract RX)
- Documenting referral arrangements
- Maintaining OPA Medicaid Exclusion File
- Dispensing 340B drugs to Medicaid FFS patients
- Dispensing 340B drugs to Medicaid MCO patients
- Medicaid billing and reimbursement
- Periodic review of state Medicaid 340B policies
4 QUESTIONS YOU SHOULD EXPECT DURING YOUR OPERATIONAL SITE VISIT

Focus is on:
- Documentation of P&Ps
- Patient eligibility
- Duplicate discounts
- Oversight of Contract pharmacy

Does the health center dispense 340B drugs to patients through a contract pharmacy services model?

- Does a written contract exist?
- Does the health center document in its contract or written policies how the contract RX will ensure against diversion?
- Does the health center have within its contract or written policies a process that reflects how the contract RX will ensure against duplicate discount?
Does the health center attest that it provides oversight of the 340B drugs dispensed by the contract pharmacy?

- Utilization of contract pharmacies
- Scope of network
- Patient access and choice
- Medicaid claims
- Compliance of contract pharmacies
- Internal audits
- External independent audits
- Utilization of 340B administrators
- Compliance and oversight of administrative vendors
- Internal audits
- External audits
AND WHO ELSE MIGHT COME CALLING?
PART FOUR: ORGANIZATIONAL INFRASTRUCTURE
THE LEADERSHIP IMPERATIVE FOR 340B

Take-away:
It is the role of leadership to **protect** and **optimize** the program within the organization.
THE LEADERSHIP IMPERATIVE FOR 340B PROGRAM

• For many health centers patients, 340B may provide their **only access to affordable prescription medication** and therefore, are critical to achieving optimal clinical outcomes.

• For many health centers the savings from 340B are larger than their Section 330 grant and are critical to financial viability, ongoing operations, and service enhancement.

• HRSA/BPHC requires you to participate in either 340B or another program that yields equivalent savings and will evaluate your compliance as part of your Operational Site Visit (OSV).

• There is intense oversight of the program in an uncertain and rapidly changing environment. **What you don’t know and don’t know you don’t know can hurt you!**

• Implementing and operating pharmacy services – whether directly or through a contract model - requires a significant investment of resources; and

• The investment will not yield the best return if operated in isolation – it requires the alignment and integration with the overall health care program to bring optimal value to the organization and its patients.
Board approved strategic plan for pharmacy services

Overarching board approved policy

Corporate-wide staff education

Inclusion in management planning and decision making: new and expanded sites and services, hours of operation, personnel management, etc., etc., etc.

Internal and external communications

3 THINGS THE C-SUITE SHOULD KNOW AND DO:

Understand the intent of the 340B program and facilitate the alignment and integration of pharmacy services with the organization’s strategic plan and corporate-wide operations.
To participate in 340B an entity must…

- Ensure that it has the capacity to maintain auditable records documenting compliance with program rules;
- Register on the HRSA Office of Pharmacy Affairs (OPA) database; and
- Recertify with HRSA annually.

Ensure that your organization is eligible to participate in the 340B Program.
The basic rules that you need to know are:

- No diversion
- No duplicate discounts
YOUR POLICIES AND PROCEDURES ARE THE FOUNDATION UPON WHICH COMPLIANCE IS BUILT

• Make sure they are consistent with laws and regulations
• Make sure they are what you actually do
  • Make sure they are current
• Know and use your available resources
THE OPERATIONAL POLICY AND PROCEDURE MANUAL SHOULD EMANATE FROM AN OVERARCHING BOARD-APPROVED CORPORATE POLICY THAT INCLUDES THESE BASIC ELEMENTS...

For an example, see Appendix Seven, Part A of the NACHC 340B Manual

- The purpose and scope of the health center’s pharmacy program;
- How the health center uses savings (and revenue generated in a retail model) in a manner that is consistent with Congressional intent and in support of the health center’s mission;
- A statement affirming program compliance and outlining the compliance framework;
- Policy on patient notification of program and ensuring freedom of choice;
- Corporate-wide education;
- Assignment of responsibility to key individuals;
- Guidelines for relationship with 3rd party contractors – TPAs, PBMs, PSAOs
- Provisions for measuring and reporting performance and compliance; and
- A schedule for regular review and revision as necessary.
SAMPLE TABLE OF CONTENTS FOR DEPARTMENT OF PHARMACY POLICY AND PROCEDURE MANUAL

1. Purpose of the 340B Program
2. Use of Savings Consistent with Congressional Intent
3. Definitions*
5. Staffing, Training, and Development
6. Affirmation of compliance and supporting procedures
7. Registration, recertification and changes to the OPA database
8. Purchasing, Inventory Management, Dispensing
9. Contract Pharmacy
10. Patient Freedom of Choice for pharmacy provider
11. Monitoring and Reporting
12. Sliding Fee Discount Program

For recommended polices in each chapter, see Chapter 11, pages 59-63 in the NACHC 340B Manual
UPDATE ON RELIABLE TRAINING AND TECHNICAL ASSISTANCE

NACHC’S 340B MANUAL FOR HEALTH CENTERS

• A consolidated resource of all info we could find to help FQHCs navigate the 340B world
  • Contains input from auditors, lawyers, Pharmacy Directors, Apexus, FQHC C-Suite, policy people, etc.

• Available for immediate download
  • Just google “NACHC 340B Manual”
  • $249 for NACHC members; $349 for non-members

• First update in progress!
OTHER RELIABLE TRAINING AND TA RESOURCES

- Apexus – The Prime Vendor
- HRSA approved TA provider
- 340B University – on-site and on-demand
- 340B Certificate Program
- Online “tool-box”
- Now officially collaborating with NACHC
- 340B Coalition meetings – FQHC focused sessions
CLOSING DISCUSSION: CURRENT ISSUES AND CHALLENGES
• **Congressional Interest in 340B**
  - The push for legislation continues driven largely by drug manufacturers
  - Legislative attempt in 2015 revealed the complications of the program/ varied stakeholder positions with respect to changes to the program
  - While Health Centers are not the focus of recent scrutiny, any potential changes could unintentionally impact Health Centers
  - Other health issues will likely take priority in Congress, but legislative changes could be introduced

• **Drug Pricing and the New Administration**
  - The high cost of drugs is one of the few health issues outside of ACA repeal identified by President Trump, i.e. drug companies “getting away with murder”
  - Will this impact 340B?
“HHS will work with Congress to develop a legislative proposal to improve 340B Program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured patients.”
BREAKING NEWS: JUNE 1, 2017

The June 1st letter raises the following issues and concerns:

• Rapid program growth without additional and proportional oversight;
• No tracking of amount or use of program savings;
• Patients paying full price for deeply discounted drugs (specifically referencing hospitals);
• High rates of non-compliance indicated by audit findings of duplicate discounts and diversion; and
• HRSA failure to conduct follow-up audits consistent with its own July 3, 2014 policy update when findings involve potential repayments.

Letter signed by:
Rep. Greg Walden (OR), Chairman, Committee on Energy and Commerce
Rep. Tim Murphy (PA), Chairman, Subcommittee on Oversight and Investigations
Rep. Michael C. Burgess MD (TX), Chairman, Subcommittee on Health
As the pendulum swings away from the Congressional intent of the program to increase the benefit for third party payers
Released on January 21, 2016 the Rule requires that states reimburse at an aggregate upper limit based on actual acquisition cost (AAC) plus a professional dispensing fee.

In the retail sector, states may develop an AAC reimbursement model that is based on various pricing methodologies.

Specific to 340B covered entities:

- For drugs purchased though the 340B program, ingredient cost reimbursement shall not exceed the 340B ceiling price
- If the drug is purchased outside the 340B program the reimbursement should not exceed the provider’s AAC

States must submit SPA to comply with these provisions with an effective date no later than April 1, 2017.

• If the CE purchases at a sub-ceiling price the state may choose to allow the CE to retain those saving.

• The term “dispensing fee” was revised to “professional dispensing fee” to reinforce the position that the dispensing fee should include the pharmacist professional services and the cost to dispense. Dispensing fees are also expected to be consistent with Section 1902 of SSA, which addresses quality and adequacy of the provider network.

• Applicable to FFS only (although some MCOs are acting otherwise) unless AAC specified as ingredient cost in state’s contract with MMCO.

• Except where prohibited by law, covered entities still have the option to carve in or carve out Medicaid patients from their 340B program.
FOUR MAIN AREAS OPEN FOR DISCUSSION/NEGOTIATION/INTERPRETATION

- Universal carve-in or carve-out requirement and claims level identification methodology
  - Professional dispensing fee
    - Sub-ceiling margin
  - Application to MMCO contracts
AN EMERGING THREAT: “PREDATORY” CONTRACTING
AND THEN THERE ARE THOSE CHALLENGES SPECIFIC TO YOUR STATES....
WE NEED TO WORK TOGETHER TO SUPPORT AND PROTECT THE 340B DRUG DISCOUNT PROGRAM

Know how the program works for your health center and its patients

Quantify the value of the program in terms of its value to your patients

Tell your story
IN CLOSING, SOME PRACTICAL ADVICE FROM A C-SUITE CHAMPION

DEFINITION OF A CHAMPION: “A PERSON WHO FIGHTS FOR A CAUSE OR ON BEHALF OF ANOTHER”

- Maximize your margin.
- Don’t oversimplify your sliding fee scale.
- Develop ways to expand the footprint of your pharmacy to include your entire service area.
- Consider the possibility of being a retail “store”.
- If you are a retail store, optimize your front-end appeal.
- Expand the boundaries of performance management beyond volume metrics.
- Understand the points of intersection between 340B and Section 330 (or other related programs).
- Make pharmacy services a part of your organizational strategic and business plans.
- Include 340B in your advocacy strategy and educate your staff to be your ambassadors.
- Above all else: Think creatively and embrace innovation!
Sue Veer
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