340B Compliance & Opportunities

Texas Association for Healthcare Administrators
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Wichita Falls, TX

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Manager
WHAT WILL WE LEARN TODAY?

• How do Hospitals qualify and remain in the Program
• How do Hospitals save/make money
• Compliance concerns
• Opportunities
• Sept 1-HRSA sent final omnibus guidance to White House Office of Management and Budget for review
• OMB reviews all federal agency rules prior to publication in the Federal Register
• Reviews can take no longer than 90 days, however OMB can extend it one time for an additional 30 days
• OMB can clear the mega-guidance for publication or send it back to HRSA
• Could be published late November or early December
• Could also be delayed indefinitely
MEGA-GUIDANCE UPDATE

• Has been rumored that HRSA may have decided to move forward with parts of the proposal rather than all of the proposed topics
• Many of the topics were basically restatements of existing HRSA policies
• HRSA is not bound to address all the topics in the proposed mega-guidance
• Nothing in the notice to indicate the scope of the final document that was submitted to the OMB
MEGA-GUIDANCE UPDATE

Problematic New Policies that were proposed

• No 340B discounts for prescriptions given upon discharge from inpatient stays
• No 340B discounts for infusion administered to many outpatients
• No 340B discounts for outpatient drugs given to patients that are ultimately admitted
• No 340B discounts for outpatient drugs given to hospital patients unless the hospital bills for the prescriber’s professional service
Annual 340B Drug Purchases

• 2015- $12.0 Billion (estimated)

• Annual US Pharma Revenue for the 20 largest companies- $315.5 Billion

• 340B % to total revenue -3.8%
Purpose of 340B Program

“To permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”

H.R. Rep No 102-384 (11), at 12 (1992)
Why Congress Created 340B

• Response to the 1990 Drug Rebate Program that required manufacturers to offer the Medicaid discounts equal to their “best pricing” for any payer

• Manufacturers in turn raised prices to Safety Net Hospitals and the VA to recoup some of their lost revenue from the Drug Rebate Program
340B Evolution

• 1992-Section 340B of the Public Services Act
• 1995-Contract Pharmacies permitted
• 1998-Family Planning Centers made eligible
• 2006-Children’s Hospitals became eligible
• 2010-Affordable Care Act
  - Critical Access Hospitals, Sole Community Hospitals, Rural Referral Centers, Cancer Centers
  - Multiple Contract Pharmacies Allowed
SHOW ME THE MONEY

Hospitals benefit in two **SEPARATE** ways:

1. Lower costs for outpatient drugs
2. Revenue stream from drug prescription dispensing at retail sites
340B Means Saving on Pharmacy Costs

**Wholesale Acquisition Costs (WAC)**
15% Higher than GPO

**Group Purchasing Organization (GPO)**

**340B**
25% Lower than GPO
## 340B Retail Pharmacy Impact

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Scripts Written per Physician</td>
<td>$400,000</td>
</tr>
<tr>
<td>340B Average Discount</td>
<td>25%</td>
</tr>
<tr>
<td>Annual 340B Savings</td>
<td>$100,000</td>
</tr>
<tr>
<td>Split Among Retail Pharmacy and Hospital</td>
<td>50/50</td>
</tr>
<tr>
<td>Hospital Potential Income Per Physician</td>
<td>$50,000</td>
</tr>
</tbody>
</table>
Who is eligible to participate in 340B

- Federally-qualified health center (FQHC) and FQHC look-alikes
- Family planning project receiving a grant or contract
- Ryan White and State-operated AIDS Drug Assistance Program (ADAP), TD, STD clinics
- Black lung clinic
- Hemophilia diagnostic treatment center
- Native Hawaiian health center
- Native American/Indian organization
- *Disproportionate share hospital (DSH)*
- *Critical access hospital (CAH)*
- *Children’s hospital*
- *Free-Standing cancer hospital*
- *Rural referral center*
- *Sole community hospital*
## 340B Eligible Hospitals

<table>
<thead>
<tr>
<th>Eligible Hospital</th>
<th>Non-Profit/Gov’t Contract</th>
<th>DSH ADJUSTMENT Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSH hospital</td>
<td>Yes</td>
<td>11.75%</td>
</tr>
<tr>
<td>*Critical access hospital</td>
<td>Yes</td>
<td>No required %</td>
</tr>
<tr>
<td>*Rural referral center</td>
<td>Yes</td>
<td>8%</td>
</tr>
<tr>
<td>*Sole community hospital</td>
<td>Yes</td>
<td>8%</td>
</tr>
<tr>
<td>*Free-standing cancer hospitals</td>
<td>Yes</td>
<td>11.75%</td>
</tr>
<tr>
<td>**Children’s hospitals</td>
<td>Yes</td>
<td>11.75%</td>
</tr>
</tbody>
</table>

Health Resources and Services Administration (HRSA) – Office of Pharmacy Affairs Website -  [http://www.hrsa.gov/opa/](http://www.hrsa.gov/opa/)
340B Eligible Hospitals

State of Texas
DSH-101 Hospitals
CAH-96 Hospitals
SCH-22
  SCH-450055  DSH % 13.75%
RRC-0
Enrollment Periods

- Enrollment is quarterly
  - Docs submitted Oct 1st-15th for Jan 1st enrollment
  - Docs submitted January 1st-15th for April 1st enrollment
  - Docs submitted April 1st-15th for July 1st enrollment
  - Docs submitted July 1st-15th for October 1st enrollment
Areas of Use

• 340B purchases can be used in outpatient areas if costs are **reimbursable** on the hospital’s Medicare Cost Report
• **Also for location of where prescription is written for Retail Pharmacies**
  – Identified areas within your hospital may (not limited to) include:
    ▪ Emergency Room
    ▪ Observation
    ▪ Retail Pharmacy
    ▪ Same Day Surgery
    ▪ Infusion Center
    ▪ Cath lab
    ▪ Hospital Based Clinics
    ▪ Meds-to-beds – prescriptions filled at time of discharge
340B Hospital Patient

An individual is a patient of the 340B Entity if:

- Entity maintains records of the individual's health care;
- and patient receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity
- **Proposed Regulations** – Will determine patient eligibility based on the final billing. Would change ER, Observation and Meds-to-beds.
Audits-Compliance

- Audits currently being preformed by HRSA
  - Focused on:
    - Written Policies and Procedures
    - Drug Diversion
    - Duplicate Discount
    - Contract Pharmacy
    - Registration Issues
  - Completed the following audits (29,000 total Covered Entities):
    - 2012 – 51 (6 Texas entities)
    - 2013 – 94 (8 Texas entities)
    - 2014 – 98 (8 Texas entities)
    - 2015 – 152 (7 Texas entities)
  - 2016 and Beyond – Probably more ??????

- Manufacturer Audits
  - Manufacturer must submit audit work plan to OPA for approval before audit can begin
## 2015 Texas Audit Findings

<table>
<thead>
<tr>
<th>Entity</th>
<th>ID</th>
<th>Location</th>
<th>Finding</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Childress Regional Medical Center</td>
<td>DSH450369</td>
<td>TX</td>
<td>Incorrect 340B database record - Offsite outpatient facilities were not listed on the 340B database. Entity did not provide contract pharmacy oversight. Diversion – 340B drugs dispensed to inpatients.</td>
<td>Termination of contract pharmacies from 340B Program; Repayment to manufacturers. Pending.</td>
</tr>
<tr>
<td>Christus Santa Rosa Health System</td>
<td>DSH450237</td>
<td>TX</td>
<td>Incorrect 340B database record – Offsite outpatient facilities were not listed on the 340B database; Registered contract pharmacies without written contract in place. Diversion – 340B drugs dispensed at contract pharmacies for prescriptions written at ineligible sites, not supported by responsibility of care.</td>
<td>Termination of contract pharmacies from 340B Program; Repayment to manufacturers. Pending.</td>
</tr>
<tr>
<td>Legacy Community Health Services, Inc.</td>
<td>CHC07502-00</td>
<td>TX</td>
<td>No adverse findings.</td>
<td>None.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/A; Audit closure date: September 22, 2015.</td>
</tr>
</tbody>
</table>
Basics to Prepare For HRSA Audit

- Policies and Procedures- Are they complete? Are they being followed?
- Are you working with independent audit firm?
- Are you performing quarterly internal audits?
- Do you have an internal 340B committee that meets regularly to monitor the program?
Click to link to database

HRSA Website  http://www.hrsa.gov/opa/
Click to find Covered Entity
ENTER MEDICARE PROVIDER NUMBER
Baylor University Medical Center

Hospital chooses its 340B classification
Required DSH Percentage

- DSH Percentage for HRSA:
  - DSH Hospital > 11.75%
  - SCH and RRC > 8.0%
- CAH – No DSH

Worksheet, Part A from Medicare Cost Report
GPO Exclusion

- Pertains to Disproportionate Share Hospitals (DSH)
- Once enrolled in 340B, can only buy all outpatient medications on 340B—can no longer use GPO
  - Non-reimbursable clinics within the 4 walls of the hospital
  - Higher inventory costs
- For outpatient purchases
- Can continue to use GPO for inpatient drug purchases
- Hospitals have to set up “WAC” account in mixed use areas
Orphan Drug Exclusion

• Pertains to the eligible entities under the Affordable Care Act (ACA) 2010
  – Critical Access Hospitals
  – Sole Community Hospitals
  – Rural Referral Centers
  – Free-Standing Cancer Hospitals

• Results of 2 recent court decisions
  – HRSA has no authority to “regulate” orphan drugs
  – Manufacturers are not required to offer 340B pricing to SCH, RRC, FSCH
Orphan Drug Exclusion

• What this means for Rural Hospitals and cancer centers
  – If offered at a separate 340B price hospitals are free to purchase at the offered price
  – If covered entity purchases orphan drugs at any price, 340B diversion, GPO (CAN) and double discount provisions do not apply
340B Hospital Inventory

340B contract pharmacy and mixed use software vendors:

- Sentry Data Systems
- Verity (Talyst)
- CaptureRx
- Walgreens
- SunRx

- Wellpartner
- RxStrategies
- MacroHelix
- Ramsell
- PSG
Qualifier Information & Certification Dates

Must certify each year or will be removed from the program.
Medicaid Opt-In or Opt-Out

This is the Hospital’s choice, not the State’s
Texas Medicaid Requirements

Hospital Outpatient Pharmacy Billing

• Bill with U8 modifier along with 11 digit NDC

• Includes
  • Medicaid Fee For Service
  • Managed Medicaid Plans
  • Medicare Crossover (Medicaid secondary)
Texas Medicaid Reimbursement

• Fee-For-Service Medicaid
  • Previously reimbursed at “Cost” via the cost report
  • 340B Price plus dispensing fee
  • How does Medicaid estimate cost
    - Reported manufacturer pricing
    - Weekly data from national drug pricing publishers
    - Qtr data from Centers for Medicare and Medicaid

• Medicaid Managed Care
  • Pay according to their individual contracts
Texas Medicaid Requirements

Manufacturer Rebates

• Effective 07/01/2016 Medicaid will “only” utilize the “U8” modifier to identify 340B claims

• Texas Medicaid will bill drug manufacturers for all non-340B claims where they have paid money

• Dual eligible claims paid by either the State or by Managed Medicaid plans are also included
Authorized Hospital Contacts

These are the only people at the Hospital that will receive emails from HRSA concerning registration and program information.
Contract Retail Pharmacies

Must register all contract and owned retail pharmacies
Contract Retail Pharmacies

- March 2010- HRSA expanded contract pharmacy language from 1 contract pharmacy per covered entity to multiple contract pharmacy arrangements
- Intent was to expand access to patients geographically
- Hospitals with or without retail pharmacy can contract out to independent or chain pharmacies to serve as the “billing agent” for the hospital
- Capture discharge prescriptions, clinic visit prescriptions, employee prescriptions
- Retail pharmacy receives inventory, inventory bill goes to hospital referred to “ship to/bill to” arrangement
- Contract pharmacy subject to audits
- **OPA suggests independent audit at least annually**
- **Proposed regulations will require yearly audit**
- Make sure to add charity care program not just capture “insured” for revenue
340B Outside Retail Pharmacy

340B covered entities may contract with a pharmacy or pharmacies to provide services to the covered entity’s patients, including the service of dispensing the entity-owned 340B drugs. In order to engage in contract pharmacy services, the entity and pharmacy(ies) must have a written contract.

- Walmart
- Walgreens
- CVS
- Other Local Pharmacies
Outside Retail Pharmacy Operations

**Pharmacy**
- Co-pay $20.00
- Third Party 80.00
- Total Received $100.00
- Dispensing Fee (18.00)
- Submits to CE $82.00

**Covered Entity**
- Rec’d from Pharm $82.00
- Sentry Proc fee (5.00)
- Cost of Drugs (35.00)
- Net Profit $42.00

Note-in this example the patient received no financial benefit
Children Sites

All child site locations must reconcile to the Medicare cost report.
### Medicare Cost Report Worksheet A

#### Allowable cost centers for children locations

Lines 88-92

#### Non Allowable Cost Centers

[Table with detailed cost centers and corresponding codes]
Provider Based Sites - Changing Rules

- Effective January 2017, PPS Hospitals will not receive a reimbursement differential for offsite locations established after November 2, 2015. CAHs already had this issue.
- Provider based sites will need to be on campus – within 250 yards of main building.
- CMS indicates it will issue clarifying language in the coming months.
- Services at offsite locations may still meet the 340B patient definition.
340B Historical Dates

What has happened in the past
Sanctions for Non-Compliance

• Immediate removal from 340B Program
  – All locations and contract pharmacies of covered entity will be removed from 340B eligibility

• Possible repayment to manufacturers for period of non-compliance

• Must demonstrate compliance in order to re-enroll
  – Enrollment subject to regular quarterly enrollment windows
Implementation of the 340B Program

Key Considerations

• Areas of Use
• Inventory Management
• GPO Exclusion (DSH Hospitals)
• Inpatient Drugs
• Diversion
• Medicaid and Medicaid Managed Care Billing (prevention of duplicate discount)
• Audits
• Contract Pharmacy
• Written Policies and Procedures
• Task Force/Team
What Are Your Next Steps for Your 340B Program

- Form Task Force/Team
  - CFO/Finance Members
  - Pharmacist
  - Purchasing Agent
  - Compliance
  - IT
  - Software Vendors

- Compose Policies and Procedures
  - Impact to Hospital
  - How 340B Program benefits patients
  - Oversight and Audit Processes
  - Disclosure Process and materiality levels
  - Personnel responsibilities

- Review Registration Compliance

- Child Sites
- Medicaid
- Contract Pharmacies
- Review Retail Pharmacy
- Process/Contract
- Generic vs Name-Brand

- Review Internal Drug Ordering
  - Mapping for WAC/GPO/340B

- Monitor Process of the Proposed Regulations
  - Patient Eligibility Definition
  - Annual Independent Audit Requirements
  - Disclosure Requirements
Resources for 340B Program

HRSA - http://www.hrsa.gov/opa/
Apexus - https://www.apexus.com/
  • 340B University
  • Tools
  • Free Seminars
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