340B Program - Overview

340B: High Level

HRSA: Section 340B limits the cost of covered outpatient drugs sold to certain federal grantees, FQHCs and hospitals. The purpose of the 340B Program is to enable these entities to stretch scarce federal resources, reaching more eligible patients and providing more comprehensive services.
340B Program - Overview

- Estimated Savings: 25% - 50% of a drug’s Average Wholesale Price
- Manufacturers that want to receive Medicaid payment for drugs required to enter into PPA
- May not condition 340B discounts upon a Covered Entity’s assurance of compliance with 340B Program provisions
- 340B Program benefits access expansion

340B Program Participation

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Covered Entity Sites Participating</th>
<th>Number of Contract Pharmacy Arrangements</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>12,639</td>
<td>1,799</td>
</tr>
<tr>
<td>2008</td>
<td>13,285</td>
<td>2,088</td>
</tr>
<tr>
<td>2009</td>
<td>14,258</td>
<td>2,483</td>
</tr>
<tr>
<td>2010</td>
<td>15,530</td>
<td>6,099</td>
</tr>
<tr>
<td>2011</td>
<td>16,869</td>
<td>8,318</td>
</tr>
<tr>
<td>2012 (proj)</td>
<td>18,176</td>
<td>11,236</td>
</tr>
<tr>
<td>2013 (proj)</td>
<td>19,736</td>
<td>14,153</td>
</tr>
</tbody>
</table>

- Covered Entity Sites (2007-12): + 43%

Source: Health Resources and Services Administration, January 2012.

- Contract Pharmacies (2007-12): + 687%

Source: Health Resources and Services Administration, January 2012.
According to GAO (2011 Report):

**Legacy “Covered Entities”**
- **LEGACY** Covered Entities Include:
  - FQHCs
  - DSH hospitals
  - Government or Non-profit with a “contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under…” Medicare or Medicaid
  - > 11.75% disproportionate share adjustment percentage

**New “Covered Entities”**
- **NEW** Covered Entities Include:
  - Children’s or Freestanding Cancer Hospitals
    - but must meet all requirements applicable to (d) hospitals (see above)
  - SCHs or RRCs
    - Government or Non-Profit with a “contract” with state or local government to provide care to non-Medicare/caid patient; **AND**
    - DSH Payment Percentage >= 8% (not 11.75%)
    - RRC = ½, not was (not grandfathered)
340B Program - Expansions

NEW “Covered Entities” Also Include:

- CAHs
  - Government or Non-Profit with a contract with state or local government to provide care to non-Medicare/caid patients
  - No DSH Payment Percentage requirements

340B Program - Orphan Drugs

Orphan Drug Issue

- Affordable Care Act contained a restriction on the use of Orphan Drugs by New Covered Entities. Restriction includes:
  - SCH
  - RRC
  - CAH

Orphan Drug Issue (Cont.)

- Drug is designated by FDA as an “orphan drug” at request of sponsor if FDA finds that the drug is being or will be investigated for a rare disease or condition
- Orphan drug must have received FDA marketing approval to meet the definition of 340B covered outpatient drugs
- Some of the restricted 340B entities are large orphan drug users
Orphan Drug Issue (Cont.)

- Some manufacturers waiting for Federal policy before taking action
- Other manufacturers have indicated they will stop selling orphan drugs through 340B Program to newly-eligible entities - whether or not used for purpose related to orphan status
- Affordable Care Act – NPRM issued May 20, 2011 (comments deadline passed)
  - Proposed rule would limit the prohibition to uses for the rare disease or condition for which the orphan drug was designated
  - Non-orphan / common indication uses would be permitted

How to Obtain 340B Status?

- Apply to HRSA – Office of Pharmacy Affairs to obtain approval
  - DSH % based on most recently filed cost report
    - See Wksht E, Pt. A, Ln. 8
  - The new DSH List that OPA is posting is based on the 2007 SSI Ratio that has been provided by CMS
How to Obtain 340B Status?

- New Quarterly Enrollment Schedule – Covered Entities, OP facilities, Contract Pharmacy Arrangements

- New deadlines:
  
<table>
<thead>
<tr>
<th>Registration Period</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 1 - October 15</td>
<td>January 1</td>
</tr>
<tr>
<td>January 1 - January 15</td>
<td>April 1</td>
</tr>
<tr>
<td>April 1 - April 15</td>
<td>July 1</td>
</tr>
<tr>
<td>July 1 - July 15</td>
<td>October 1</td>
</tr>
</tbody>
</table>

- Prior deadlines:
  
<table>
<thead>
<tr>
<th>Registration Deadline</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 1</td>
<td>January 1</td>
</tr>
<tr>
<td>March 1</td>
<td>April 1</td>
</tr>
<tr>
<td>June 1</td>
<td>July 1</td>
</tr>
<tr>
<td>September 1</td>
<td>October 1</td>
</tr>
</tbody>
</table>

340B Program - Scope

340B Scope and Applicability

- “Covered Drugs” purchased by “Covered Entity” at a 340B discount and dispensed to “Eligible Patients,” reimbursed by payors in ordinary course of business

340B Program - Implementation

“Covered Drugs”

- Program Drugs Only for a Covered Entity’s Outpatients

- Outpatient drugs
  - FDA-approved prescription drug
  - Prescribed OTC drug
  - Biologicals that can be dispensed only by prescription
  - FDA-approved insulin
  - Excludes vaccines
  - BUT NOT Orphan Drugs
What is an “Eligible Patient?”

- Program NOT limited to Medicare, Medicaid or low income patients
  - Any patient of a Covered Entity may receive covered O/P drugs purchased under the 340B Program
- But, Covered Entity must
  - Maintain control of the patient's medical records
  - Maintain primary responsibility for patient's care

Definition of a Patient from HRSA Website (and 1996 Guidance):
- Individual is a “patient” of a covered entity only if:
  - Covered entity has established a relationship with the individual, such that covered entity maintains records of the individual's health care; and
  - Individual receives health care services from 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 care provided remains with covered entity

Questions related to HRSA “proposed” 2007 guidance:
- Use of word “arrangement”
- Use of word “clarification”
- Exact scope of nexus?
  - Referral for care provided “ongoing responsibility” for service remains with covered entity
  - Care referred for the “same condition”
  - 12 month rule
- Analysis is highly fact-specific
What is an “Eligible Patient?” (Cont.)

- According to HRSA – New EP Definition is being developed
- NOTE: HRSA public statement (Lt. Cmdr. Hardin) that 1996 definition “is current guidance.”
- BUT then note statement that pending guidance “Clarifies previous FR Notices of 1996 and 2007.”

What is an “Eligible Facility?”

- Program discount extends to all main campus and provider-based location patients
- Definition of Covered Entity refers to the provider-based rules
  - Patient must be treated at a facility that is provider-based to the Covered Entity
  - Generally, sites must be within a 35 mile radius of the Covered Entity’s main campus (some exceptions)
- Register sites with OPA
  - Remember quarterly enrollment process when preparing pro forma for new or prospective sites

What is an “Eligible Facility?” (Cont.)

- Any “outpatient facility” which is an “integral component” of a DSH will be “included on the MCR” and therefore eligible for 340B pricing (1994 guidance)
- What does “included” mean?
  - HRSA position = As-filed
  - Federal Register language = “included on the hospital’s Medicare cost report”
  - Statutory language = “hospital” and “patient of the entity”
What is an “Eligible Facility?” (Cont.)

2007 Proposed Guidance:

- Reference to provider-based regulations

- “Ultimately, the facility’s provider-based status must be reflected in the covered entity’s Medicare Cost Report.”

- “Covered entity may provide a copy of the attestation... pursuant to 42 CFR 413.65 to demonstrate compliance... until such time as the facility is listed on the [MCR].”

- “…this clarification provides covered entities with more explicit guidance...”

340B Program - Contract Pharmacies

Contract Pharmacies

- No distance or proximity limitation on contract pharmacy arrangements

- No (longer a) limit on number of contract pharmacy arrangements

- Covered Entity responsibility to comply - particularly important to remember for contract pharmacy arrangements
340B Program - Contract Pharmacies

Contract Pharmacies (Cont.)

- Challenges:
  - Diversion tracking
  - Audits & records
  - Discount management and tracking
  - Data exchange
  - Inventory management
  - Pharmacist/Pharmacy services scope
  - Advertising/marketing approval
  - Business terms (payment risk, dispensing fees)

340B Program - Integrity

- Intent of 340B According to HRSA:
  - Permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”
### 340B Program - Integrity

#### Issues to Track
- Medicaid duplicate discounts
  - Medicaid patients may be excluded
- Who is a patient?
- What is a facility?
- Compliance with state laws
- Contract pharmacy commingling
- Contract pharmacy patient tracking
- **Data exchange (PHI, remote hosting, etc.)**

#### How do I Track?
- Methods used to ensure compliance with Program standards
  - Up to the Covered Entity
- Program and non-Program drug stock
  - Need not be physically separated (generally - not all states)
- Main obligation for Covered Entities
  - Maintain *auditable records* that can be used to prove 340B drugs used only for covered outpatients

#### New Penalties (for CEs)
- Affordable Care Act statutory updates
- Consistent with HRSA guidance issued December 1996
- Clearer program integrity standards
New Penalties (CEs) (Cont.)

In addition to repaying discount, provisions addressing provider-related enforcement options provide for the following remedies "in appropriate cases as determined by the [HRSA] Secretary":

- Where a covered entity knowingly and intentionally diverts Covered Drugs:
  - Required to pay monetary penalty to applicable manufacturer
  - Forfeiture of the discount received for the inappropriately dispensed drug(s), plus interest thereon

- What does this mean?

- Where diversion of Covered Drugs was systematic and egregious as well as knowing and intentional:
  - Covered Entity may be removed from the 340B Program and be disqualified from re-entry into the 340B Program "for a reasonable period of time to be determined by the Secretary."

- What does this mean?
New Penalties (CEs) (Cont.)

- Notwithstanding the foregoing, HRSA may also:
  - Refer matters to appropriate Federal authorities within the FDA, the HHS OIG, or other Federal agencies for consideration of appropriate action under other Federal statutes, (e.g., PDMA).

Program Integrity – Increased Scrutiny

GAO Report

- 9/23/2011 GAO report critical of 340B Program oversight
  - "HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define situations under which an individual is considered a patient of a covered entity for the purposes of 340B and thus, covered entities could interpret it either too broadly or too narrowly."
9/23/2011 GAO report critical of 340B Program oversight

This lack of clarity has led “covered entities and drug manufacturers...[to] raise concerns that the guidance will be interpreted too broadly, leading to cases of unintended diversion—that is, using 340B drugs for individuals who HRSA did not intend as eligible patients, but who may not be clearly prohibited in the guidance.”


“With the lack of oversight, the taxpayers through state and federal governments could be grossly overpaying for prescription drugs and not know it, and that situation could continue to accelerate.”

2/10/2012 Letter to Covered Entities

“The [HHS] Program Integrity Initiative is designed to target the greatest risks of fraud, waste and abuse...”

Growing support for more 340B Program oversight
Joint Congress/Senate Letters

3/5/2012 Letters to 340B Program Groups - Manufacturer, Hospital, Prime Vendor

From:
- Congressman Pitts
- Senator Hatch
- Senator Enzi
- Senator Grassley

"Of greatest concern is the GAO finding that, 'the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater.'"
Joint Congress/Senate Letters

PhRMA Letter
- Looking for information regarding diversion:
  - "Are you aware of any examples of diversion...? If so, please identify them and provide any supporting materials."
  - "Are you aware of any audits of covered entities conducted by drug manufacturers...? If so, please provide details on what companies conducted such audits and which covered entities were involved."
- Also questions designed to confirm that discounts are in fact being provided.

340B Program - Integrity

Senate Letter

UAB Letter - 5/10/2012 Letter from Senator Grassley to the President of the University of Alabama Hospital.

"Of greatest concern is the GAO finding that, 'the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater.'"

UAB Letter - 5/10/2012 Letter from Senator Grassley to the President of the University of Alabama Hospital.

"On February 16, 2011, Donna Evans, R. Ph., Senior Pharmacist, with University of Alabama (UAB) Hospital gave a presentation at the 340B Annual Conference in San Diego, California. In this presentation Ms. Evans states that the purpose of the Purchasing Committee is, among other things, to 'maximize savings opportunities.'"
340B Program - Integrity

Senate Letter
- UAB Letter - 5/10/2012 Letter from Senator Grassley to the President of the University of Alabama Hospital.

"Ms. Evans' presentation goes on to state that UAB Hospital tracks the top drug expenses for 'possible change in admission[s] process.'"

"Ms. Evans' presentation is deeply concerning. The recommendation to change an individual's admissions status or their treatment can have serious health consequences and should be based on a medical determination of what is best for the patient."

Detailed information request to assess and quantify UAB 340B Program processes and impacts.

340B Program - Integrity

HRSA Letter
- 7/18/2012 Letter to the HRSA Administrator from Congressmen Pitts and Cassidy. Requesting issuance of an updated Eligible Patient definition.

"The outdated definition of a 340B patient has contributed to growing concerns with the integrity of the 340B program."

340B Program - Integrity

HRSA Letter
- 7/18/2012 Letter to the HRSA Administrator from Congressmen Pitts and Cassidy. Requesting issuance of an updated Eligible Patient definition.

"While the program has grown dramatically, ... [there has been] little guidance from HRSA on the program's intent."

(GAO report quote) "... guidance on program requirements often lacks the necessary level of specificity to provide clear direction, making participants' ability to self-police difficult and raising concerns that the guidance may be interpreted in ways inconsistent with the agency's intent."
HRSA Letter

- 7/18/2012 Letter to the HRSA Administrator from Congressmen Pitts and Cassidy. Requesting issuance of an updated Eligible Patient definition.

"Information received to date from various stakeholders reflects a program that has diverted from its original intent." Requesting that new definition "...ensures the program's eligibility is for those truly in need and curbs any misuse of the program."

HRSA Audits

- HRSA announced Covered Entity audits to begin in January/February of 2012
- Purpose: to confirm compliance with applicable 340B Program standards
- Audit results expected 2 to 3 months after completion

- March 5 and June 19, 2012 HRSA Program Notice and Audit Guidance
  - Random targeted audits
    - Will include a "thorough investigation of policies and procedures, (and a) review of auditable records and system compliance to prevent diversion and duplicate discounts."
  - 340B issues also to be addressed in A-133 audits
HRSA Audits

- March 5 and June 19, 2012 HRSA Program Notice and Audit Guidance
  - Will evaluate:
    - Covered Entity eligibility status
    - Eligible patient definitions
    - Contract pharmacy implementation mechanisms
    - Group purchasing organization exclusion
    - Drug diversion
    - Prohibition on duplicate Medicaid discounts

HRSA Audits

- March 5 and June 19, 2012 HRSA Program Notice and Audit Guidance
  - HRSA stated that the audit protocol will be made publicly available at some point in the future
  - Would assist in preparing for potential audits
  - Would provide useful guidance regarding 340B Program standards
  - We're still waiting
  - No audit standards released

HRSA Audits

- March 5 and June 19, 2012 HRSA Program Notice and Audit Guidance
  - Covered Entities at highest risk of being audited will be:
    - Those [with] higher program risk due to volume of purchases, [with] increased complexity of program administration, and [who] use contract pharmacies.
  - Audits also triggered by allegations of 340B Program violations
    - Not just whistleblowers - manufacturers or covered entities themselves
HRSA Audits

- March 5 and June 19, 2012 HRSA Program Notice and Audit Guidance
  - Audit process:
    - Pre-audit review of Covered Entity policy and procedure documentation
    - Confirmation of implementation mechanisms during onsite audit – includes sample testing of 340B covered drug transactions
    - Exit interview - will share preliminary findings and address areas of concern
    - OHA will review findings and discuss with Covered Entity any corrective actions or disciplinary procedures

- Risk Factors:
  - High outpatient volumes (relatively?)
  - Large-scale contract pharmacy implementations (relatively?)

- Audit guidance - Contract pharmacies to be involved also

- Take Aways: How to address prior to release of audit guidelines and results?

Annual Recertification

- Authorized Officials “certify” that Hospital:
  - Has continuously met all 340B Program eligibility requirements since being listed as eligible on the 340B database;
  - Complies with all requirements and restrictions of the Program
  - Maintains auditable records
Annual Recertification

- Authorized Officials “certify” that Hospital:
  - Has systems/mechanisms in place to reasonably ensure ongoing compliance with Program requirements
  - Contract pharmacy arrangements performed in accordance with OPA requirements
    - Obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements
    - Utilizes an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism)
  - Acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material breach by the hospital or any of the foregoing, and
  - Acknowledges that it may be required to remit payment back to manufacturers which would represent the difference between the 340B discounted price and the drug’s non-340B purchase price.

Authorizing Official Attestation Statement – Key Language:

“I further acknowledge the hospital’s responsibility to notify [HRSA]... immediately if there is a material change in the 340B eligibility of any facility or information listed on the 340B Database.”
340B AND ACOs

340B Eligibility and ACOs

- May 23, 2012 HRSA Program Notice
  - Inclusion of a Covered Entity within an ACO does not make entire ACO eligible for receiving Covered Drugs
  - ACO associated entities must independently satisfy the Program eligibility requirements to access discounted drugs
  - ACO Final Rule states that Covered Entities are "... prohibited from purchasing or transferring drugs to non-340B entities and patients of non-340B providers, including those which are part of an ACO."

Non-Discrimination by Manufacturers

- November 21, 2011 HRSA Policy Statement and May 23, 2012 HRSA Program Notice:
  - Where available supply of a covered drug is not adequate to meet market demands, manufacturers may develop alternate allocation procedures
  - Must demonstrate that 340B providers are treated same as non-340B providers
  - Prior (1994) HRSA guidance
    - May not single out covered entities from other customers for restrictive conditions that would undermine statutory objective
    - May not implement discouraging limitations (e.g., minimum purchase thresholds)

Non-Discrimination by Manufacturers (Cont.)

- November 21, 2011 HRSA Policy Statement and May 23, 2012 HRSA Program Notice:
  - Must notify OPA in writing prior to actual implementation (preferred four weeks) with a plan that includes:
    - Description of product
    - Details including rationale for restriction on all purchases (including non-340B)
    - Plan for notification of wholesalers and Covered Entities
  - If OPA has concerns about plan, will work with the manufacturer to incorporate revisions prior to posting the plan on HRSA/OPA website
Non-Discrimination by Manufacturers (Cont.)

- OPA will publish all submitted allocation plans on OPA website.
- Covered Entities with plan concerns encouraged to resolve them in good faith with manufacturers.
- Where not resolved, Covered Entities should contact OPA for action or involvement of other federal agencies (e.g., OIG, DOJ).

Manufacturer Compliance (340B Pricing)

- Affordable Care Act – NPRM Issued.
  - Comments deadline passed.
- More transparent 340B ceiling prices - covered entities to be granted web access to 340B ceiling prices.
- HRSA to perform spot checks of sales and selective audits of manufacturers and wholesalers.
- Procedures for manufacturer refunds to covered entities if an overcharge occurs.
- Imposition of CMPs (shall not exceed $5,000) for each instance of knowing and intentional overcharges.

340B User Fee

- From Senate Appropriations Committee – 2013 Appropriations Bill:
  "The Committee includes a provision to institute a new 0.1 percent user fee on 340B discount drugs. The fee is expected to generate $6,000,000 in fiscal year 2013, which will be used to implement program integrity work recommended by GAO and mandated by PPACA."
- Not adopted.
Questions?

340B Program - New Developments and Increasing Scrutiny

Todd Nova
Hall Render
tnova@hallrender.com
414-721-0464
Wisconsin Office of Rural Health
Hospital Finance Workshop
August 24, 2012