340B Drug Pricing Program

A Survey of the Program’s Past, Present, and Future
Disclaimer

- The views expressed today are those of the speaker and do not constitute legal advice.
Fatherly Wisdom

My Dad always said, “If it was easy, then everyone would be doing it.”
Section 340B: A Brief History and Overview

- Section 340B is intended to provide additional support to providers who furnish services to patients who are uninsured or underinsured.
- Section 340B requires pharmaceutical manufacturers to enter into an agreement with the Health Resources and Services Administration whereby those companies agree to sell outpatient medications to eligible covered entities (e.g., certain hospitals) at a reduced price in exchange for Medicaid reimbursement eligibility.
A policy question that currently hangs over the program is whether the drug discount is designed to benefit the providers, patients or both.

The heart of the pharmaceutical manufacturers’ current argument to reduce the scope of the program is that it is designed to benefit patients and that providers are using the advantageous pricing only to benefit themselves.

The covered entity providers argue that it benefits both the provider and the patient (i.e., the provider is able to stretch its resources further to continue to provide charity care and other assistance to the uninsured and underinsured.)
Drug Purchases:
- A covered entity may contract with pharmaceutical companies directly to purchase covered outpatient drugs, or
- The covered entity may participate in the Prime Vendor Program (PVP) – a free, federally-managed distribution network for covered outpatient drugs.
  - Prime Vendor, Apexus, recently awarded a new agreement with HRSA to remain the Prime Vendor through September 2019.

“Covered Outpatient Drug” is summarized as:
- “An FDA-approved prescription drug, an over-the-counter drug that is written on a prescription, a biological product that can be dispensed only by a prescription (other than a vaccine), or FDA-approved insulin.”
Covered Entities purchase covered medications either at a statutory “ceiling price”, or at another, lower price negotiated independently between the manufacturer and the covered entity.

Ceiling Price differs depending on the nature of the drug:
- Brand Name Drugs are discounted 23.1%;
- Generic Drugs are discounted 13%;
- Hemophilia and Pediatric Drugs are discounted 17.1%. 
Covered Entities may arrange to dispense the drugs through:
- In-house pharmacy;
- External, contracted pharmacies; or
- In-house dispensing through a state-licensed provider.

Distributions may only be made to eligible patients.
- However, income and insurance status are not criteria for eligibility.
Participation is Growing

- Medicaid reimbursement eligibility has attracted many pharmaceutical manufacturers to participate in the program.
- Additionally, the number of covered entities has greatly increased, particularly since PPACA expanded the categories of covered entities.
- As of February 2014, there were 2,048 hospitals participating in the 340B program.
Statutory Requirements

- Health Resources and Services Administration (HRSA) must first enter into an agreement with pharmaceutical manufacturers that provides Medicaid reimbursement eligibility for covered drugs in exchange for the manufacturers selling those drugs to medical care facilities at a reduced price.

- Eligible hospitals must register with HRSA to seek participation approval.
Upon approval, the covered entity must:

- notify wholesalers and retailers of its 340B participation;
- develop adequate safeguards to prevent 340B medications from being distributed to non-qualifying patients, and prevent duplicate discounts or prohibited resale of discounted drugs;
- maintain accurate, auditable records that show compliance;
- keep the 340B database up-to-date with accurate information; and
- register any new outpatient facilities or contract pharmacies.

Certain hospitals are expressly prohibited from participating in any group purchasing organization for covered outpatient drugs.

- See HRSA Program Notice- February 7, 2013
Government and Manufacturer Audits

BE PREPARED.

Participation in the 340B program subjects the covered entity to involuntary audit, either by the federal government or individual pharmaceutical manufacturers, to ensure that the covered entity has neither:

- (1) received duplicate discounts, nor
- (2) resold the drug to a non-qualifying patient.

Over the past year or so, the number and intensity of audits has increased.

- June Program Update from HRSA indicated more money was made available for program integrity efforts.
Mechanics of an Audit

- See July 2014 Monthly Program Notice from HRSA
- Pre-Audit
  - Receipt of letter, introductory conference
- On Site Audit
  - Review of data and internal controls
  - Review of policies and other documents
- Post Audit
  - Issuance of report and corrective action plan, if applicable
- Notice and Hearing
  - Review of final report
  - Covered Entity response
Audits (cont.)

- HRSA has increased the number of staff dedicated to audits and has begun to use more sophisticated auditors.
- Covered entities are to work with manufacturers to correct mistakes, while communicating with HRSA.
- The results of audits are publicly available on HRSA’s website.
What is a Covered Entity?

- There are two broad categories of entities eligible for 340B participation:
  - Entities receiving certain federal grants administered by different agencies within HHS (e.g., Comprehensive Hemophilia Diagnostic Treatment Centers); or
  - Entities that fall into one of six qualifying hospital types.
Eligible hospitals include:

- Disproportionate Share Adjustment (DSH) Hospitals – that is, hospitals serving a certain percentage of low-income patients;
- Children’s Hospitals;
- Freestanding Cancer Hospitals;
- Rural Referral Centers;
- Sole Community Hospitals; and
- Critical Access Hospitals.

Certain hospital categories were added by PPACA.

Hospitals may add outpatient clinics as additional sites under their covered entity registration.
In order to participate, hospitals must meet certain criteria to ensure that they provide care to the medically underserved. For-profit hospitals are not eligible for 340B participation.

All eligible hospitals must meet specified DSH adjustment percentages. For example, in order to be eligible for 340B, Sole Community Hospitals must have a disproportionate share adjustment percentage greater than eight percent (8%) for the most-recently filed cost report.
Registration Process

Registration is only available during four time periods each year:
- January 1-15 for a start date of April 1
- April 1-15 for a start date of July 1
- July 1-15 for a start date of October 1
- October 1-15 for a start date of January 1

The process requires the covered entity to:
- Identify a person capable of legally binding the entity and have that person submit the required forms;
- Complete the online registration form in a single session; and
- Submit all necessary information at the same time registration is completed.
Required information includes:

- Basic contact information;
- Medicare Cost Report worksheets:
  - Worksheet E, Part A or S-3;
  - Worksheet S;
  - Worksheet S-2; and
  - Worksheets A and C.
- 340B Program Eligibility Documents; and
- Medicaid billing information.
340B Program Documents:

- These will differ depending upon the type of entity involved.
- If the hospital has a contract with state or local government to provide healthcare services to low income patients, then a Certification of Contract form must be submitted.
- If the hospital is owned or operated by a state or local government, then a Hospital Certification of Ownership/Operation by a unit of State/Local government form is required.
- If the hospital has been formally provided with a governmental grant, then some documentation identifying the granting government, a description and rationale for the grant, and an official document reflecting the grant are required.
Medicaid billing information generally requires informing HRSA whether the hospital intends to provide 340B drugs to its Medicaid patients.

- The decision has ramifications for “duplicate discounts”, prohibited under 340B.
- Any changes to Medicaid billing for 340B drugs require notification to HRSA prior to effecting the change.
Diversion of Drugs

- HRSA’s criteria for “patient” are:
  - The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care;
  - The individual 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 such that responsibility for the care provided remains with the covered entity; and
  - The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or federally qualified health center (FQHCs) look-alike status has been provided.
An individual is *not* considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

Covered entities are permitted to use drugs purchased at the 340B discounted price for all qualifying individuals, regardless of income or insurance status.

However, participants are expressly prohibited from diverting 340B drugs to individuals not falling within HRSA’s definition of “patient”.

The covered entities must therefore track 340B dispenses and prescriptions to ensure compliance.
In 2011, the GAO criticized HRSA’s lack of specificity with regard to HRSA’s “patient” criteria. 
  - e.g., HRSA has not defined the term “other arrangements”.

Covered Entity policies and procedures regarding the definition of “patient” are recommended. 

Some covered entities that read the criteria too broadly risk exposure to sanction for diversion of 340B drugs to ineligible patients.
Alternatively, concerns over inadvertent diversion have led some covered entities to read the criteria narrowly, thereby limiting the program’s effectiveness by denying eligible patients access to 340B drugs.

- See February 2014 OIG report for varying covered entity applications of the patient definition.

- The ambiguity remains unresolved.

- The “mega-reg” from HRSA was reportedly going to address some of these ambiguities. However, the mega-reg’s status may be in jeopardy due to recent court decisions.
Impermissible Duplicate Discounts

- Duplicate discount – that is, a manufacturer providing a 340B discount and a Medicaid drug rebate for the same drug – is expressly prohibited.
- Participants must have mechanisms in place to prevent duplicate discounts.
- Part of the Medicaid billing choice depends on whether the participating hospital would like to use 340B drugs for their Medicaid patients (carve-in), or provide drugs to those patients through another mechanism (carve-out).
Carve-In

- Covered entities that will carve-in are required to inform HRSA (by providing their Medicaid provider number/NPI) at the time they enroll in the 340B Program that they will purchase and dispense 340B drugs for their Medicaid patients.

- If a covered entity decides to bill Medicaid for drugs purchased under 340B with a Medicaid provider number/NPI, then all drugs billed to that number must be purchased under 340B and that Medicaid provider number/NPI must be listed on the HRSA Medicaid Exclusion File.

- In other words, the covered entity cannot pick and choose certain Medicaid claims which are 340B claims. The approach must be uniform.
Carve-Out

For covered entities that opt to purchase Medicaid drugs outside of the 340B Program, *all* drugs billed under that Medicaid provider number/NPI must be purchased *outside* the 340B Program, and that Medicaid provider number/NPI should not be listed on the HRSA Medicaid Exclusion File.
Contract Pharmacies

- Covered entities may contract with pharmacies to dispense 340B drugs.
- In recent years, the role of the contract pharmacy has expanded.
- This has led to compliance concerns on the part of HRSA and the OIG.
- Guidance was issued in 2010 allowing an expanded use of contract pharmacies by covered entities.
The 2010 guidance from HRSA set forth certain requirements and program protections in connection with contract pharmacies, including:

- registration of contract pharmacies;
- a contract between the covered entity and contract pharmacy, which must contain certain provisions; and
- audit rights.
If a hospital desires to contract with pharmacies in connection with the 340B program, it must abide by the current guidance issued by HRSA and ensure oversight of its contract pharmacies.

Covered entities are ultimately responsible for compliance with the 340B program rules.

In contracting with a contract pharmacy, a covered entity must ensure that it has the right to audit the pharmacy and may desire to include indemnification language in the event of a breach or violation of law by the contract pharmacy.
Third Party Administrators

- Many covered entities have elected to use third party administrators to assist the entities in tracking 340B claims and re-ordering drugs from manufacturers and wholesalers.
- There are positives and negatives in using third party administrators.
Positives

- Expertise
- Software for tracking
- Industry awareness
- Resource to determine the approach of other covered entities in the event of a “gray area”
- Templates
Negatives
- Compliance risk (diversion)
- Cost
- Loss of control
- Lack of specific direction
Contracting Issues
- Audit rights
- Indemnity
- Coordination with contract pharmacies
- Change in Law
- Privacy/HIPAA
- Dealing with templates (effect of program expansion)
- Fees
- Ensuring that roles are defined
Upcoming Regulations?: The Road Ahead for 340B

- HRSA was scheduled to issue a proposed “mega-reg” this past summer addressing issues such as:
  - patient definition
  - outpatient facility eligibility
  - contract pharmacies
- This regulation was sent to the CBO for review and was thought to be ready for release.
However, recent court decisions and court filings have resulted in a delay in the issuance of the regulation and may cause HRSA to decide not to issue it at all.

The cases involve the so called “orphan drug rule.”

- Under the provisions of Section 340B added by PPACA, certain covered entities were not allowed to treat orphan drugs as covered drugs under the program.
- HRSA issued a legislative rule interpreting the statute. PhRMA sued HHS (HRSA) to challenge the rule.
On May 23, 2014, the US District Court for the District of Columbia held that HHS did not have the authority under the statute to issue the regulation and vacated the rule.

Shortly thereafter, HHS stated that it stood by the substance of the rule and its interpretation of the statute.

On July 21, 2014, HRSA issued an “interpretive rule” affirming its interpretation of the statutory requirements related to orphan drugs.
Pharmaceutical manufacturers are in a tough position, as HHS is directing them to provide 340B pricing on orphan drugs used for non-designated purposes, even though the rule was invalidated.

PhRMA filed an appeal on the first case seeking to invalidate the interpretive rule.

On August 27, 2014, the Court denied PhRMA’s request to invalidate the interpretive rule and indicated PhRMA would have to bring a new lawsuit to do so.

On October 9, 2014, PhRMA filed a new complaint in the U.S. District Court in Washington, D.C. seeking to invalidate the interpretive rule.
The effect of these lawsuits for covered entities and other stakeholders is that the “mega-reg” has been put in doubt.

Specifically, there is now a question whether HHS has the authority to issue the “mega-reg” covering various subjects for which it does not have authority to issue rules under the statute.

In addition, there is pressure from drug manufacturers and other stakeholders to delay the regulation or to not issue the regulation.

There is no deadline for publication.
If HHS decides not to issue the “mega-reg,” it may issue interpretive guidance, as it has done in the past. This does not have the same force of law as that of legislative rulemaking, which goes through the notice and comment process. Courts do not give interpretive guidance as much deference as formal regulations. It is important for covered entities and other stakeholders to monitor HRSA’s website for program updates.
Perhaps Congress will pass legislation granting HHS more authority to issue legislative regulations for the Program.

As you know, this will not be a quick process.

In any case, the delays in the publication of the mega-reg have come at a time in which stakeholders are in need of guidance.
Compliance Recommendations

- Establish comprehensive policies and procedures
  - Utilize Apexus website as a resource
- Train employees on the policies and procedures
- Monitor contract pharmacy arrangements
- Regularly update and check data that is provided to vendors and pharmacies
- Conduct regular internal audits and audits of third party vendors
- Monitor actions of third party vendors
  - Remember, the covered entity is ultimately responsible for compliance
Questions?