The Pharmacy 340B Drug Discount Program-Overview and Emerging Issues

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340B - Overview and Emerging Issues

Discussion Outline

Topics for Discussion:

- Overview of the 340B Program (The Basics):
  - History/Purpose/Benefits
  - Applicable Statute & Other Legal Authorities
  - Government Agency/Oversight
- Recent 340B Program Developments
- 340B Program Eligibility-Covered Entities & Registration Process
- 340B Discounts & Savings-Amounts and How to Obtain
- Prime Vendor Program
- 340B Drug Inventory Issues
- 340B Program Compliance Requirements:
  - Four Principle Restrictions
  - Related Compliance Issues
  - Contract Pharmacy Arrangements
- Operational Compliance & Internal Audit Strategies
- 340B Program Resources
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Objectives

• Provide an overview of the 340B Program and compliance requirements
• Highlight healthcare reform changes and other recent developments related to the 340B Program
• Examine key 340B Program compliance requirements and challenges
• Discuss new audit expectations for 340B covered entities
• Share operational suggestions for reducing the risk of non-compliance and meeting the government’s expectations for controls, documentation, and audits, including recommendations for integrating 340B issues into covered entities’ compliance and internal audit functions

Overview-History/Purpose/Benefits

History/Purpose:

• Implemented by Congress in 1992 through enactment of Public Law 102-585 Section 602.
• Statutorily requires pharmaceutical manufacturers to provide outpatient drugs to certain qualified “covered entities” at reduced pricing.
• In plain language, participation in the program provides various “safety net” providers with access to significant pricing discounts on covered outpatient drugs.
Benefits:

- Provide vulnerable patient populations with improved access to pharmaceuticals necessary for their continuum of quality care.
- Covered entity providers achieve cost savings on outpatient drug purchases.
- The Health Resources and Services Administration (HRSA) estimates that participation in the program results in savings of approximately 20% to 50%.

- **Section 340B of the Public Health Service Act (42 U.S.C. § 256b)** requires pharmaceutical manufacturers to enter into an agreement with the Department of Health and Human Services (HHS) to provide discounts on “covered outpatient drugs” purchased by certain providers called “covered entities” that serve the nation’s vulnerable patient populations as a condition of receiving reimbursement from Medicaid and Medicare Part B.
- 340B Program guidance is issued through Federal Register Notices, Policy Releases, and FAQs.
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Overview-Statute & Other Legal Authorities (Cont’d)

- Over the years, the government has released numerous Federal Register notices including guidelines relevant to the 340B Program.
- Key Federal Register Notices related to the 340B Program*:

* This diagram is not representative of all federal notices/regulations. Notices can be found on the HRSA website at http://www.hrsa.gov/opa/programrequirements/federalregisternotices/index.html

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Overview-Government Agency/Oversight

- The Office of Pharmacy Affairs (OPA) within HRSA is responsible for administration and oversight of the 340B Program.
- HRSA issues guidance related to the 340B Program and has the authority to conduct audits and exclude covered entities from participation in the 340B Program.
- The OPA describes its three primary functions:
  - Administration of the 340B Drug Pricing Program;
  - Development of innovative pharmacy services models and technical assistance; and
  - Service as a federal resource about pharmacy.
The Patient Protection and Affordable Care Act ("PPACA" or "Healthcare Reform"), signed March 23, 2010, implemented the most significant changes to the 340B Program since 1992.

**Healthcare Reform changes to 340B:**
- Impact all 340B stakeholders (covered entities, manufacturers, oversight agencies);
- Added four (4) new eligible entity types, effective January 1, 2010:
  1. Free-standing children’s hospitals
  2. Free-standing cancer hospitals
  3. Critical access hospitals
  4. Sole community hospitals and rural referral centers;
- Excluded use of "orphan drugs" under 340B by newly-eligible entities and children’s hospitals (more on this);
- Specify that all new 340B hospitals (like existing 340B hospitals) must either be publicly owned or be a private nonprofit contracting with a state or local government to provide indigent care;
- Increased Medicaid rebate percentages—expected to yield deeper 340B discounts;
- Extended 340B to the inpatient setting for all of 7 days—The Budget Reconciliation Bill, signed March 30, 2010, limited 340B to outpatient drugs; and
- Added new integrity provisions:
  - Government must make 340B “ceiling prices” available.
  - HHS must develop new controls and oversight requirements.
  - HHS must issue guidance on Medicaid billing requirements for covered entities.
  - New fines and penalties.
  - Annual recertification of 340B database information.
Other Recent Developments:

- In March 2010, HRSA published a Final Notice of guidelines related to the utilization of contract pharmacy services (75 FR 43, March 5, 2010), including permission for covered entities to use multiple pharmacy arrangements.
  - Findings suggest that more oversight is needed, specifically by HRSA/OPA.
  - Significant growth of the 340B Program has led to increased use of contract pharmacy services and corresponding compliance and protocols requirements (or lack of).
  - Key recommendations included the following:
    - Conduct selective audits of covered entities with respect to all 340B program requirements;
    - Finalize new and/or revised guidance on the 340B patient definition;
    - Further specify 340B nondiscrimination policy for cases in which drug distribution is restricted and require reviews of manufacturers’ plans to restrict distribution of drugs at 340B prices; and
    - Issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for 340B.

- OPA audited covered entities for first time in 2012
  - AUDITING (42 USC 256b(a)(5)(C)): A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary’s or the manufacturer’s expense the records of the entity that directly pertain to the entity’s compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.
  - Results of 18 covered entity audits performed during FY 2012 are available on the HRSA/OPA website (current as of February 8, 2013). Adverse findings were indicated for 2 (or 11%) of the 18 audits. (http://www.hrsa.gov/opa/programintegrity/auditresults/340bauditreport02082013.pdf)

- Reports of manufacturer audits for first time in 2013
- Three new/revised Policy Releases issued by HRSA during February, 2013:
  - 02/07/13-Statutory Prohibition on Group Purchasing Organization Participation (2013-1)
  - 02/07/13-Clarification on Use of the Medicaid Exclusion File (2013-2)
  - 02/08/13-Clarification of HRSA Audits of 340B Covered Entities (2012-1.1)-replaced 2012-1
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340B Program Eligibility-Covered Entities

- There are currently over 20,000 340B covered entities and affiliated child sites (OPA covered entities database at http://opanet.hrsa.gov/opa/Login/MainMenu.aspx). Figure 1 below shows 340B growth from 2001-2011.
- Only nonprofit health care organizations that have certain Federal designations or receive funding from specific Federal programs are eligible organizations.
- Eligible covered entities currently include Disproportionate Share Hospitals (DSH) meeting specific criteria and fifteen (15) other categories of providers.

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340B Program Eligibility-Covered Entities (Cont’d)

**Hospital Criteria:**

- The definition of "covered entities" includes six (6) categories of hospitals (some of which must meet specific eligibility requirements):
  1. Acute care DSH hospitals;
  2. Children’s Hospitals;
  3. Cancer Hospitals exempt from IPPS;
  4. Sole Community Hospitals (SCHs);
  5. Rural Referral Centers (RRCs); and
  6. Critical Access Hospitals (CAHs).

- Hospitals in each of the categories must be: (1) non-profit, (2) owned or operated by or under contract with state or local governments, and (3) with the exception of CAHs, have Medicare DSH payment percentages above 11.75% (acute care, children’s and cancer) or at or above 8% (SCHs and RRCs).

- Note-DSH payment percentage is different than the DSH patient percentage:
  - DSH patient % of .2733 results in DSH payment % > 11.75%
  - DSH patient % of .2277 results in DSH payment percentage ≥ 8%
“Non-Hospital” Entities:

- In addition to hospital categories, and including newly eligible entities added through PPACA, other qualifying 340B covered entity provider categories include:
  - Federally Qualified Health Centers (FQHCs)-Community Health Centers, Migrant Health Centers, Health Care for the Homeless, and Health Centers for Residents of Public Housing
  - Federally Qualified Health Center “Look-Alikes”-Community-based health care providers that meet requirements of HRSA Health Center Program (HCP), but do not receive HCP funding
  - Native Hawaiian Health Centers
  - Tribal/Urban Health Centers
  - Ryan White HIV/AIDS Program Grantees (Parts A, B, and C grantees (other than State and local governments))
  - Black Lung Clinics
  - Comprehensive Hemophilia Diagnostic Treatment Centers
  - Title X Family Planning Clinics
  - Sexually Transmitted Disease Clinics
  - Tuberculosis Clinics

*Specific eligibility criteria for each entity category can be found at http://www.hrsa.gov/opa/eligibilityandregistration/index.html

340B Program Eligibility-Registration

- Facilities that meet the criteria of a “covered entity” apply to participate in the 340B Program by completing the online registration process during the first two weeks of the calendar quarter (e.g., January 1-15) for an effective date on the 1st of the next calendar quarter (e.g., April 1).

- Hospitals must register all off-site outpatient clinics that participate. HRSA defines off-site as outside the “four walls” of the hospital:
  - Off-site clinic must appear on the hospital’s as-filed cost report to register, which means that only provider-based clinics may register for the 340B Program (freestanding clinics owned by hospital are not eligible).

- Cost report requirement can lead to long delays for registration of off-site clinics.

* Registration forms and related instructions are available for each eligible covered entity type on the HRSA/OPA website http://www.hrsa.gov/opa/eligibilityandregistration/index.html
The 340B drug discount is the average manufacturer price (AMP) reduced by a minimum rebate percentage of:
- 23.1 percent for most brand name prescription drugs;
- 17.1 percent for brand name pediatric drugs and clotting factor; and
- 13 percent for generic and over-the-counter drugs.

Manufacturers must offer even greater discounts on brand name drugs if the manufacturer’s best price for a drug is lower than AMP minus 23.1 percent for that drug and/or the price of the drug has increased more quickly than the rate of inflation. (This is also true for innovator, multi-source drugs, i.e., brand name drugs that have generic competition.)

Covered entities are free to negotiate discounts that are lower than the maximum allowable statutory price.

340B prices for brand name drugs are, on average, 51 percent* of average wholesale prices, according to a report released by the Congressional Budget Office.

Another government study found 340B prices to be 27 percent* lower than prices available to group purchasing organizations.

* Note that these estimates were determined before manufacturers were required to adjust their AMP and minimum rebate percentage calculations as a result of the ACA.

Upon registration, a covered entity should contact its wholesaler to set up its 340B account and to request a 340B price list.

The entity also may request a 340B pricing file from a manufacturer.

Manufacturers should check the OPA website each quarter to identify the providers that are participating in the program.

The manufacturer may not charge more than the 340B ceiling price to those entities regardless of whether the covered entity purchases pharmaceuticals through a wholesaler or directly from the manufacturer.

If a covered entity suspects that it is not receiving the 340B price for a given outpatient drug (pricing issue), it should immediately notify the wholesaler or manufacturer.

The entity should not contact OPA regarding a potential pricing issue without first trying to resolve the issue by working directly with the wholesaler and manufacturer.

In many cases, the absence of a 340B price is the result of human error and is resolved when the mistake is identified and brought to the wholesaler or manufacturer’s attention.
The 340B statute mandated the creation of a Prime Vendor Program (PVP) to negotiate sub-340B pricing on drugs.

The PVP acts as a group purchasing organization (GPO).

The current PVP contract is with Apexus.

A covered entity does not have to join PVP in order to participate in the 340B program and may negotiate sub-ceiling discounts on its own.

To learn more about PVP, go to http://www.340Bpvp.com.

Because the 340B program is for outpatient drugs only, Covered Entities must have inventory controls to ensure that 340B drugs are not dispensed to inpatients.

Covered Entities may maintain a physically separate 340B inventory or, more commonly, use a replenishment system under which drugs dispensed to a 340B eligible patient are replaced with a 340B drug.

OPA requires that there be an exact match between the drug used and the replenished drug using the National Drug Code (or NDC, which is issued by the FDA and specifies drug identity, package size and manufacturer).

Covered Entities may request HRSA approval for an “Alternative Method Demonstration Projects” (AMDP) to implement a different inventory management system.
## 340B Program Compliance Requirements

### 1. “Anti-Diversion” and Patient Eligibility Compliance
- 340B prescriptions must be prescribed by eligible providers for qualified patients, and 340B product must not be diverted to non-qualifying patients.
- Must have a complete “audit trail” from purchase to pick-up by the patient (dispensing).

### 2. Duplicate Discount (“Double-Dipping”) Prohibition
- Purpose is to prevent both 340B discount and Medicaid rebate on the same drug.
- Must report outpatient pharmacy Medicaid provider number(s) to prevent rebate “double-dipping.”

### 3. Group Purchase Organization Restriction
- Statutory prohibition against obtaining covered outpatient drugs through a GPO for certain covered entities.

### 4. Orphan Drug Restriction
- Certain hospitals (SCHs, RRCs and Cancer Hospitals) may not use 340B pricing for orphan drugs.

### “Anti-Diversion”:
- The anti-diversion requirements of the 340B program prohibit the resale or transfer (e.g., dispensing) of 340B outpatient drugs to individuals who are not considered “patients” of the covered entity.
- Program regulations define the three basic categories of prohibited diversion as diversion to:
  - “Non-patients” of the covered entity;
  - Ineligible facilities within the same facility; and
  - Excluded services of the covered entity.
- Physically separate drug inventories not required, but covered entities must maintain separate (inpatient and outpatient) purchasing and dispensing tracking systems and track by National Drug Code (NDC) to provide a clear audit trail.
- Other potential diversion risk areas (Covered entities must also consider security and theft risks).

* 58 FR 248, December 29, 1993
Patient Eligibility:

- It is illegal for covered entities to sell medications purchased under the 340B Program to persons who are not considered “patients” of the covered entity.
- Definition of “patient”:
  - An individual is a “patient” of a covered entity only if three specific criteria are met:
    1. **Patient relationship (“eligible patient”):** The covered entity maintains records of the individual’s health care (“maintenance-of-record” or “record maintenance” test).
    2. **Provider relationship (“eligible provider”):** The individual must be under the care of a physician or other health care professional who is employed by, under contract with, or in a referral relationship to the covered entity such that responsibility for the individual’s care remains with the covered entity (“professional care test”).
    3. **Qualified health care service/range of services:** The individual must receive a range of health care services that are consistent with the services for which grant funding or FQHC look-alike status has been provided to the covered entity. (This requirement is not applicable to hospitals.)

Patient Eligibility (Cont’d):

- The definition of “patient” is different for 340B and Medicare.
- The 340B definition includes individuals who have a prescription written at a covered entity to be filled at a retail pharmacy.
- HRSA issued a proposed clarification to the definition of patient in 2007 but OMB announced that HRSA withdrew the proposed clarification and will publish a new proposed patient definition.
### Duplicate Discount ("Double-Dipping") Prohibition:

- Drug manufacturers are required to give rebates on drugs reimbursed under State Medicaid programs, either FFS or managed care, but are protected from giving both a 340B discount and a Medicaid rebate on the same drug.
- Covered entities may elect to use 340B drugs for Medicaid patients ("carve-in") or may elect not to use 340B for Medicaid patients ("carve-out").
- Medicaid programs submit for rebates on carve-out 340B drugs, but forgo rebates for entities that carve-in.
- Covered entities must notify OPA of their election and OPA maintains an “exclusion file” that State Medicaid agencies may use to determine if an entity has carved-in.
- Information on a covered entity’s carve-in or carve-out option must be accurate. The covered entity bears the liability if a duplicate discount is paid on a FFS drug.
- HRSA issued a Program Notice on 02/07/13—"Clarification on Use of Medicaid Exclusion File."

### GPO Restriction:

- Certain hospitals (acute care with DSH > 11.75%, children’s and cancer) may not purchase any covered outpatient drugs through a GPO.
- Inpatient drugs may be purchased through a GPO. Hospitals may purchase outpatient drugs through the Prime Vendor Program (Apexus).
- HRSA issued a Program Notice on 02/07/13 - “Statutory Prohibition on Group Purchasing Organization Participation.” This guidance states:
  - Violations of the GPO restriction will result in termination from the 340B program.
  - Provider-based departments of a hospital may elect not to participate in 340B if they meet four requirements:
    - Are located at a different physical address than the parent;
    - Are not registered on the OPA 340B database as participating in the 340B Program;
    - Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and
    - The hospital maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B database.
  - Detailed instructions regarding inventory replenishment models. Hospitals have until 04/07/2013 to comply.
Orphan Drug Restriction:
- Certain hospitals (SCHs, RRCs and cancer) may not use 340B pricing for orphan drugs.
  - HRSA issued proposed guidance in May 2011 to implement orphan drug exclusion.
  - Proposed that orphan drug restriction only "to uses for the rare disease or condition for which the orphan drug was designated."
  - Final regulations currently at OMB for release.

Related Compliance Issues:
- Medicaid Billing:
  - There are no federal statutes or regulations that dictate the amount that state Medicaid programs may reimburse for 340B drugs, although officials in some state Medicaid programs mistakenly believe that federal guidance requires 340B covered entities to bill for 340B drugs at actual acquisition cost (AAC), particularly with respect to retail pharmacy drugs.
  - Some States have explicit requirements to bill at AAC for 340B drugs, usually for retail pharmacy drugs, so that the State can get the benefit of the 340B discount.
  - Covered entities need to be aware of any special Medicaid billing requirements for 340B.
- Program Income Requirements:
  - For non-hospital covered entities, all 340B savings are considered “program income” for purposes of the grant and for Grantees.
**Contract Pharmacy Arrangements:**

- **Covered entities may contract with retail pharmacies** to dispense 340B drugs to the covered entity's patients.
- Covered entities purchases the drugs, and manufacturers and wholesalers bill the covered entities, but ship the drugs directly to the contract pharmacy.
- A contractor **must provide the covered entity quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records.**
- The contractor also **must establish and maintain a tracking system to prevent diversion of drugs** to individuals who are not patients of the covered entity.
- **Covered entities are expected to have an independent audit of the contract pharmacy performed at least annually**, to monitor pharmacy compliance and to self-report any instance of noncompliance to HRSA.

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**Operational Compliance & Internal Audit Strategies**

- The complexity of pharmacy operations and lack of focus on compliance and internal audit can result in breakdowns leading to financial consequences, undesired negative attention, or even loss of covered entity status (HRSA has authority to exclude covered entities).
- 340B covered entities should have policies and procedures, controls, and auditing and monitoring methodologies in place to ensure compliance with 340B regulatory requirements.
- Compliance should not be "silied" in Pharmacy and requires collaboration and coordinated efforts between various departments of the organization:
  - Compliance
  - Internal Audit
  - Pharmacy
  - Physician Services
  - Information Technology
  - Medical Records
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Operational Compliance & Internal Audit Strategies (Cont’d)

- Key compliance assessment and internal audit steps for evaluating and auditing 340B compliance:

  - **Prescription-Level Testing** - Perform initial and routine audits to test compliance with 340B requirements

  - **Review Overall 340B Controls, Documentation and Procedures** - Interview pharmacy leadership and staff to gauge their understanding of 340B Program compliance requirements and evaluate overall controls and processes related to the organization’s participation in the 340B program; Obtain and review any existing policies and procedures; Conduct “site reviews” at covered entity outpatient pharmacies.

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Operational Compliance & Internal Audit Strategies (Cont’d)

- Key compliance assessment and internal audit steps for evaluating and auditing 340B compliance:

  - **“Inventory Control Testing”** - Perform a process and controls review and prescription-level testing to (1) evaluate the pharmacy’s inventory tracking capabilities and “accountability” for 340B inventory and (2) compare purchasing/invoicing to utilization.

  - **Medicaid “Double-Dipping” Prohibition** - Confirm that each of the organization’s pharmacies for which 340B inventory is purchased and dispensed are included in the OPA’s Medicaid Exclusion Files.
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340B Program Resources

- Health Resources and Services Administration (HRSA)- Office of Pharmacy Affairs (OPA)
  http://www.hrsa.gov/opas/

- Safety Net Hospitals for Pharmaceutical Access (SNHPA)
  http://www.snhpa.org

- Drug Discount Monitor (SNHPA news service re: 340B Program)
  http://www.drugdiscountmonitor.com

- Prime Vendor Program (PVP)
  http://www.340Bpvp.com

Questions?

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