The Pharmacy 340B Program—Compliance & Internal Audit Strategies for Covered Entities

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340B Drug Discount Program (340B Program)
Discussion Outline

Topics for Discussion:

• **Overview of the 340B Program (The Basics):**
  - History/Purpose (Program and Regulations)
  - Oversight/Audit & Enforcement
  - Eligibility/Enrollment

• **340B Program Compliance Requirements:**
  - Four Key Elements of 340B compliance
  - Contract Pharmacy Arrangements- Regulatory History and Requirements

• **Strategies for Compliance & Internal Audit and Insights Based on Experience**

• **340B Program Resources**
340B Drug Discount Program (340B Program) Objectives

- Provide an overview of the purpose and regulatory history of the 340B Program.
- Highlight the types of organizations currently eligible for 340B Program participation and the basics of the program enrollment process.
- Discuss benefits and common operational and compliance challenges that come with participation in the program.
- Summarize key 340B Program federal regulations and specific compliance requirements for 340B Covered Entities.
340B Drug Discount Program (340B Program)
Objectives (Cont’d)

- Discuss 340B Program regulations and challenges related to the use of contract pharmacy services.
- Highlight the importance of compliance, internal audit and pharmacy integration.
- Provide specific recommendations and strategies, based on experience and client successes.
- Provide an opportunity for Q&A.
340B Program
Overview

• Implemented by Congress in 1992 through enactment of Public Law 102-585 Section 602.
• Statutorily\(^1\) 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.

\(^1\) 42 U.S.C. 340B(a)(4)
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%.
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:

- **5/7/1993** (Vol. 58, No. 87) Guidance on Prices of Drugs Purchased by Covered Entities
- **5/13/1994** (Vol. 59, No. 92) Final Notice on Entity Guidelines
- **6/23/1993** (Vol. 58, No. 119) Final Notice on Duplicate Discounts and Rebates on Drug Purchases
- **8/23/1996** (Vol. 61, No. 165) Final Notice re: Contract Pharmacy Services
- **9/19/1994** (Vol. 59, No. 180) Final Notice on Outpatient Hospital Facilities
- **6/29/1998** Final Notice on Rebate Option
- **10/24/1996** (Vol. 61, No. 207) Final Notice on Patient and Entity Eligibility
- **12/12/1996** (Vol. 61, No. 240) Final Notice on Manufacturer Audit Guidelines and Dispute Resolution Process
- **3/15/2000** (Vol. 65, No. 51) Program Guidance Clarification-Duplicate Discounts
- **3/5/2010** (Vol 75, No. 43) Final Notice on Contract Pharmacy Services
- **9/1/2009** (Vol. 74, No. 168) Final Notice on Children’s Hospitals
- **3/5/2010** (Vol. 75, No. 43) Final Notice on Contract Pharmacy Services
- **1/12/2007** (Vol. 72, No. 8) Notice on Definition of “Patient”
• 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:
  o Impact all 340B stakeholders (covered entities, manufacturers, oversight agencies);
  o 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;
340B Program
Healthcare Reform & Other Recent Developments (Cont’d)

- Excluded use of “orphan drugs” under 340B by newly-eligible entities and children’s hospitals (more on this);
- Specify all new 340B hospitals must either be publicly owned or be a private nonprofit contracting with a state or local government to provider 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.
Healthcare Reform Integrity Provisions:

- Government must make 340B “ceiling prices” available.
- Department of Health and Human Services (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:

- **Manufacturer Civil Monetary Penalties and Administrative Dispute Resolution Process**
- **Continued Inclusion of Orphan Drugs for Children’s Hospitals**
- **Proposed Limited Inpatient Discount Program (340B-1)**
340B Program
Oversight/Audit & Enforcement

• The HHS Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) is responsible for administration and oversight of the 340B Program.

• HRSA promulgates federal regulations related to the 340B Program and has the authority to exclude covered entities from participation in the 340B Program.

• The OPA describes its three primary functions:
  o Administration of the 340B Drug Pricing Program;
  o Development of innovative pharmacy services models and technical assistance; and
  o Service as a federal resource about pharmacy.
340B Program
Eligibility/Enrollment

- Eligible covered entities currently include Disproportionate Share Hospitals (DSH) meeting specific criteria and fifteen (15) other categories of providers.

HRSA DSH Hospital Flow Chart

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DSH criteria:

1. Owned or operated by unit of state or local government, public or private non-profit granted governmental powers by a unit of state or local government, or private non-profit with a contract with state or local government to provide health care services to low-income individuals not entitled to Medicare or Medicaid;

2. DSH percentage > 11.75%; and

3. DSH does not obtain covered outpatient drugs through a Group Purchasing Organization (GPO) or other group purchasing arrangement.
340B Program
Eligibility/Enrollment (Cont’d)

- Including newly eligible entities added through PPACA, other qualifying 340B covered entity provider categories include:
  - Federally qualified health center
  - Family planning project
  - Entity receiving a grant under subpart II of Part C of Title XXVI of the Ryan White Care Act
  - State-operated AIDS drug assistance program (ADAP)
  - Black lung clinic
  - Comprehensive hemophilia diagnostic treatment center
  - Native Hawaiian health center
  - Urban Indian organization
340B Program
Eligibility/Enrollment (Cont’d)

- Entity receiving assistance under title XXVI of the Social Security Act
- Entity receiving funds under Section 318 or 317
- Children’s hospital
- Critical access hospital
- Free standing cancer hospital
- Rural referral center
- Sole community hospital

Specific eligibility criteria for each provider type can be found at http://www.hrsa.gov/opa/introduction.htm.
340B Program
Four Key Compliance Elements

1. Patient Eligibility
2. Anti-Diversion
3. Medicaid Pricing Requirements
4. “Double-Dipping”

1. Covered Entity/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.

2. “Anti-Diversion” Inventory Controls/Compliance
   Must have a complete “audit trail” from purchase to pick-up by the patient (dispensing).

3. Medicaid Pricing Compliance
   Pricing charged to the State Medicaid Program reflects the net Section 340B invoiced price at the time of dispensing (acquisition cost) plus State approved fee(s).

4. State Medicaid Cost Rebate Verification (Compliance with “Double-Dipping” Prohibition)
   Must report outpatient pharmacy Medicaid provider number(s) to prevent rebate “double-dipping.”
340B Program
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”:
  o HRSA Final Notice (61 FR 207, October 24, 1996)
  o An individual is a “patient” of a covered entity only if three specific criteria are met:
    1. Patient relationship (“eligible patient”)
    2. Provider relationship (“eligible provider”)
    3. Qualified health care service/range of services
HRSA Notice (72 FR 8, January 12, 2007)- Proposed Clarifications to Definition of “Patient”:

- More specificity for the criteria determining whether an individual is a “patient” of a covered entity:
  1. Patient relationship- the covered entity maintains ownership, control, maintenance, and possession of records of the individual’s health care;
  2. Provider relationship- Services provided by a health care provider who is employed by the covered entity, or provides health care to patients of the covered entity under a valid, binding, and enforceable contract;
3. Health care services:

- Part of a health care service or range of services for which grant funding or Federally-Qualified Health Center look-alike status has been provided to the covered entity; or

- Provided by a DSH or by a location that qualifies as a provider-based facility within a DSH under 42 CFR 413.65.

- The covered entity must retain responsibility for the care resulting in 340B prescriptions. Referrals are acceptable, however at a minimum, the covered entity will provide health care to the individual in the DSH or the qualified provider-based facility of the DSH within 12 months after the time of referral.
• The covered entity must document in the individual’s health care records the health care service provided and the drugs prescribed or used. **The covered entity must maintain “control, ownership, maintenance, and possession” of the patient’s health care record.**

• Health care must be provided by the covered entity through providers who have an **employment or contractual relationship** with the covered entity.
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.\(^2\)

Other potential diversion risk areas

\(^2\) 58 FR 248, December 29, 1993
• 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.

• Covered entities must also consider security and theft risks.
340B Program
Medicaid Pricing Requirements

• In general, covered entities may not bill Medicaid more than the acquisition cost of the 340B drug, plus a reasonable dispensing fee.
• Acceptable dispensing fees and other billing calculation factors may vary by state.
• Does not apply if:
  o A 340B drug is dispensed to a Medicaid recipient enrolled in a capitated managed care plan; or
  o “Above-cost” reimbursement arrangements are expressly agreed to by the covered entity and state Medicaid agency.
• Covered entities are not subject to 340B billing limitations for payers other than Medicaid.
EXAMPLE:

- State defines allowable Dispensing Fee for Medicaid prescriptions of $7.00 and allows a small “markup” for inventory management, calculated based on an Inventory Management Factor (IMF) of 2%.

- \( \frac{(\text{Acquisition Cost} + \text{Dispensing Fee})}{(1-\text{IMF})} \)
  - Acquisition Cost = $10.00
  - Dispensing Fee = $7.00
  - IMF = 2%
  - \( \frac{($10.00 + $7.00)}{(1-.02)} = $17.35 \)
“Double-dipping” occurs when a state seeks a Medicaid rebate on the same unit of drug that a manufacturer sold to the covered entity at a discounted price under the 340B program.

The manufacturer would essentially incur two price concessions for the same drug.

The 340B Program’s double-dipping prohibition places obligations on both the covered entity and the state to ensure that, with respect to 340B drugs dispensed to Medicaid beneficiaries, the manufacturer incurs either the 340B discount at the time of the covered entity’s purchase or a later Medicaid rebate to the state, but not both.
340B Program
Double-Dipping (Cont’d)

- OPA Medicaid Exclusion Files:
  - OPA Medicaid Exclusion database - Medicaid officials must check to determine whether they must exclude a 340B participant from the state’s application to a manufacturer for a Medicaid rebate.
  - Covered entities must ensure they have reported all appropriate Medicaid provider numbers.

OPA Medicaid Exclusion Files
Source:
340B Program
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).

• If you are a participating 340B covered entity, you should have related policies and procedures, controls, and auditing and monitoring methodologies in place to ensure compliance with regulatory requirements.
• Compliance should not be “siloked” in Pharmacy and requires collaboration and coordinated efforts between various departments of the organization:
  o Compliance
  o Internal Audit
  o Pharmacy
  o Physician Services
  o Information Technology
  o Medical Records
340B Program
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 related to (1) patient/provider eligibility, (2) drug tracking mechanisms/audit trail records, and (3) Medicaid billing/pricing 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.
“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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<th>Strategy/Approach</th>
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<td>Policies &amp; Procedures</td>
<td>Develop and implement a specific policy/procedure related to the 340B patient eligibility requirements, including an overview of the federal regulations and the organization’s procedures to facilitate compliance.</td>
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<tr>
<td>Systems &amp; Controls</td>
<td>Evaluate existing pharmacy systems/technologies and controls in place to ensure that prescriptions filled with product purchased at 340B prices cannot be dispensed to patients who are not eligible patients of the Covered Entity.</td>
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| Auditing & Monitoring         | Incorporate a standardized process for ongoing monitoring of compliance with the patient “records of care” and provider “relationship” requirements in the organization and/or pharmacy auditing and monitoring plan.                                                                                                                             
|                               | o This may include a quarterly or semi-annual review of patient records and validation of provider relationship for a sample of 340B prescriptions to validate that the Covered Entity maintains records of the patients’ care and that the providers who ordered/wrote the prescription are either employed by or under contractual relationship with the Covered Entity. |
|                               | o Validating the provider eligibility/relationship typically requires the assistance of the Physician Services/Credentialing Department and/or access to related records or systems containing provider contractual/credentialing information.                                                                       |
| Training                      | Train compliance and pharmacy staff and members of the various departments involved with/responsible for documentation of compliance on the patient eligibility regulations and their roles in the process.                                                                                                         |
### 340B Program
Compliance & Internal Audit Strategies- Anti-Diversion

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<td>Systems Controls</td>
<td>Validate the specific controls in place to prevent the diversion of 340 drugs to patients who are not eligible patients of the Covered Entity (i.e., does the pharmacy system interface with the organization’s registration/eligibility system and prevent the filling/dispensing of 340B prescriptions if a patient is not eligible?). Are “flags” in place to notify staff and prevent them from filling a prescription if it is not for an eligible patient? Are corrective measures defined in case anything falls through the cracks?</td>
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<td>Audit Trail</td>
<td>Ensure that the organization’s pharmacy system and related data provide an “adequate” audit trail as required by Program regulations. Does it allow for tracking of/accountability for each 340B prescription through the system, including a process for documentation of any product not ultimately dispensed to an eligible patient (pill droppage/destruction, prescriptions returned to stock or not picked up by patient, etc.)? Incorporate the review of the audit trail for a sample of prescriptions on a routine basis (e.g., quarterly or semi-annually) in the organization and/or pharmacy auditing and monitoring plan.</td>
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<tr>
<td>Purchasing/Dispensing Data</td>
<td>Establish separate purchasing accounts and related reporting for 340B product with your pharmaceutical wholesaler. Confirm that the data available from the wholesaler (purchasing) and the organization’s pharmacy system dispensing data can be collectively utilized to track 340B product from purchasing to dispensing.</td>
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<tr>
<td>Covered Entity Validation</td>
<td>Validate that all entities within the organization receiving and dispensing drugs purchased through the Program are 340B eligible Covered Entities. This is particularly important if the organization is a health system that includes various outpatient clinics, or “satellites.” Any clinic at which 340B drugs are dispensed must be either an eligible Covered Entity in itself or qualify under the DSH’s Covered Entity status by meeting the CMS “provider-based” designation criteria.</td>
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# 340B Program
## Compliance & Internal Audit Strategies- Medicaid Pricing

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<td>Billing Methodologies</td>
<td>Understand the organization’s specific drug billing methodologies and Medicaid billing requirements for each State Medicaid program with which it participates (i.e., “carved-in” or “carved-out,” all-inclusive rate vs. billed separately, State-approved dispensing fees).</td>
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<tr>
<td>Audits</td>
<td>Incorporate routine audits of the Medicaid billing process and payments received for 340B prescriptions in the organization and/or pharmacy auditing and monitoring plan.</td>
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## 340B Program
Compliance & Internal Audit Strategies- Double-Dipping

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| OPA Database/Medicaid Exclusion Files | Ensure that the organization has reported all appropriate Medicaid provider numbers to the OPA if the organization bills State Medicaid programs for drugs purchased under the 340B Program.  
Annualy validate that the appropriate Medicaid provider number(s) is/are included in the publicly available OPA database/"Medicaid Exclusion Files."  
The OPA Medicaid Exclusion Files can be accessed through the OPA Pharmacy Affairs Database at [http://opanet.hrsa.gov/opa/Login/MainMenu.aspx](http://opanet.hrsa.gov/opa/Login/MainMenu.aspx). |
• Most 340B covered entities purchase and dispense 340B drugs through their own in-house outpatient pharmacies. However, many have implemented, or are exploring, a contract pharmacy model.

• In 1996, HRSA issued guidelines allowing covered entities to contract with a pharmacy to provide services to the covered entity’s patients (61 FR 165, August 23, 1996).

• Since 2001, covered entities have had to apply to the OPA and secure approval to participate in an Alternative Methods Demonstration Project (AMDP) in order to use other alternative arrangements.
340B Program
Contract Pharmacy Arrangements (Cont’d)

• In 2007, HRSA issued a contract pharmacy services Notice outlining proposed guidelines regarding utilization of contract pharmacy arrangements (72 FR 8, January 12, 2007).

• In 2010, HRSA published a Final Notice of guidelines related to the utilization of contract pharmacy services (75 FR 43, March 5, 2010). The Final Notice sets forth the government’s permission for covered entities to use multiple pharmacy arrangements.
The Catch? COMPLIANCE!...and the need for focused and routine internal and external auditing.

Key Excerpts from the Contract Pharmacy Services Final Rule (75 FR 43, March 5, 2010):

- “The covered entity has, and continues to bear, full responsibility and accountability for compliance with all requirements …”
- “All covered entities are required to have auditable records sufficient to fully demonstrate compliance with all 340B requirements.”
- “It is expected that all covered entities will have written policies and procedures …”
- “Covered entities may be well-served by ensuring that compliance terms are included in their pharmacy contracts.”
- “Annual audits performed by an independent, outside auditor with experience auditing pharmacies are expected…”
“Covered Entity Compliance Elements” (75 FR 43, March 5, 2010, 10276-10278)

- “A covered entity that wishes to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between itself and a specified pharmacy.”

- HRSA provides a list of twelve (12) “Essential Covered Entity Compliance Elements” which are expected to be addressed in contract pharmacy arrangements.

- An Appendix to the Final Rule includes “Suggested Contract Provisions” intended to provide a model format and sample provisions.
Certification (75 FR 43, March 5, 2010, 10278-10279)

- HRSA’s Final Rule requires covered entities to submit to OPA a certification that it has signed and has in effect an agreement with the contract pharmacy or pharmacies.

- “…the OPA may conduct a recertification process periodically (most likely annually) where covered entities affirmatively certify as to their ongoing compliance with 340B requirements.”

- The Final Rule includes a list of topics to which a duly authorized official would have to certify on behalf of the covered entity.
Resources

• **Health Resources and Services Administration (HRSA)- Office of Pharmacy Affairs (OPA)**
  

• **Safety Net Hospitals for Pharmaceutical Access (SNHPA)**
  

• **Pharmacy Services Support Center (PSSC)**
  
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Save the Date: August 26-29, 2012

31st Annual Conference in Philadelphia, Pennsylvania