Introduction

• Caveat – This presentation is intended as an overview of a complex area of law and should not be construed as, or relied upon, as legal advice

• Take Away Advice:
  • Interpretations should be understood as opinions
  • Focus on analysis, not answers
  • Study the guidance to tell “good” opinions from “bad” ones
  • Understand your pharmacy’s operations

The Basics of the 340B Program

• Begins with the Medicaid Drug Rebate Program in 1990 in Section 1927 of the Social Security Act (42 USC § 1396r-8)
• Then Section 340B was added to the Public Health Service Act (42 USC §256b)
• 340B Program administered by Office of Pharmacy Affairs
• What is 340B? In short, a price control program for OP drugs
• CMS policies impact 340B, but it is not a reimbursement program
• Providers increase revenue from the lower OP drug cost
• OPA – Healthy margins are OK, but only if achieved in compliance with 340B Program rules
The Basics of the 340B Program

- Lower cost drugs create margin, which can be used to improve access

![](image)

<table>
<thead>
<tr>
<th>Non-340B Drug</th>
<th>340B Drug</th>
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</thead>
<tbody>
<tr>
<td>Total Reimbursement</td>
<td>Margin</td>
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Compliance Overview

- The Big Picture
  1. Remain eligible to purchase discounted OP drugs
  2. Use discounted OP drugs for permitted purposes
- 340B Program compliance focuses on four (4) general areas:
  1. Provider Eligibility
  2. Patient Eligibility
  3. Drug Eligibility
  4. Medicaid

Provider Eligibility

Providers eligible to participate in the 340B Program

<table>
<thead>
<tr>
<th>Grantees</th>
<th>Public or Private Non-Profits</th>
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<tbody>
<tr>
<td>PHS-CHS</td>
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<td>FQHC</td>
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<td>Ryan-White HIV Programs</td>
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<td>AIDS Drug Assistance Programs</td>
<td>Free-standing Cancer Hospitals</td>
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<td>TB &amp; Black Lung Clinics</td>
<td>Racial Referral Centers</td>
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<td>Hemophilia Centers</td>
<td>Sole Community Hospitals</td>
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<td>Native Hawaiian Health Centers</td>
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<td>Urban Indian Organizations</td>
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Provider Eligibility

- Eligible Entities must register with OPA to participate in 340B
- Provider cannot buy at 340B prices until listed on Database
- Database is the primary means manufacturers and wholesalers:
  - Determine whether a provider is eligible to purchase 340B prices
  - Determine whether a provider bills Medicaid for 340B
- Registration applies both to Parent Site (on-site covered entity) and Child Sites (off-site components of the covered entity)
- New registrations must be submitted within 15 day windows in October, January, April and July
- New entities become eligible only at the start of a quarter

Provider Eligibility

- Common Registration Issues or Confusion:
  - Supporting documents must be submitted on the same day as on-line registration is completed or else registration is deleted
  - "Bill to/Ship to" discrepancies
  - Database mistakes and "Upload" problems
- The "Parent/Child" Relationship – Outpatient Facilities
- Only 340B covered entities are permitted to purchase and provide 340B drugs to persons
  - In simple terms, the 340B covered entity is the facility registered to participate in the 340B Program according to the OPA Database
  - How far the “covered entity” umbrella extends may depend upon particular facts and circumstances

Provider Eligibility

- Defining who is (and is not) a 340B covered entity becomes important to assure that 340B drugs are not transferred to an ineligible provider in violation of the 340B Program’s diversion prohibition (42 USC § 256b (a)(5)(B))
- OPA looks to the hospital’s most recently filed cost report to verify the eligibility of an off-site OP facility for 340B
  - Is the OP facility an integral part of the hospital and included as reimbursable on the hospital’s Medicare cost report?
Patient Eligibility

• The 340B Program prohibits the resale or transfer (i.e., diversion) of drugs purchased under the 340B Program to a person who is not a patient of the covered entity – 42 USC § 256b (a)(5)(B)

• Illegal to use or distribute drugs purchased at 340B prices to persons who are not a “patient” of the covered entity

• Diversion may involve an analysis of at least two (2) issues:
  • Who is a “patient”?
  • What constitutes the “covered entity”? (See prior slides on Provider Eligibility)

Patient Eligibility

• Who is a “patient”?

• Guidance from Oct. 24, 1996 (61 Fed. Reg. 55156) sets 3 prongs:
  • CE has established a relationship with the individual, such that CE maintains records of the individual’s health care; and
  • The individual receives health care services from a health care professional who is either employed by the CE or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the CE; and
  • The individual receives a health care service or range of services from the CE which is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided to the entity.

Disproportionate share hospitals are exempt from this requirement

Patient Eligibility

• First prong – CE establishes a relationship with patient
  • Establish a relationship with the individual, such that covered entity maintains records of the individual’s health care
  • OPA has said, “To be eligible to receive 340B-purchased drugs, patients must receive health care services other than drugs from the 340B covered entity.”
  • The “maintains records” requirement is an express way that a CE can prove its relationship with a patient
Patient Eligibility

- Second prong – CE/Professional Relationship
  - Patient receives health care services from a professional who is either
    - Employed by the covered entity, or
    - Under contractual or other arrangements (e.g., referral for consultation)
  - Responsibility for the care provided remains with the CE
    - It is not sufficient that a CE merely dispenses the drug
    - Facts and circumstances approach
  - How do you prove contractual or other arrangement?
    - In my experience, HRSA (OPA) auditors may disagree on the proof that is acceptable to prove an “arrangement”

Patient Eligibility

- Who is not a “patient”? Look critically at these arrangements:
  - The only health care service received by the individual from the covered entity is the dispensing of a drug
  - Services that are best described as care “management”
  - Professionals providing health services are loosely “affiliated” with the CE
  - Misuse or misunderstanding of who is the CE and the location of services
  - “Deeming” employees as patients based upon insurance or administrative circumstances

Drug Eligibility

- “Covered OP Drug” is defined at 42 USC § 1396r-8 (k)(2)
- OP drugs used and billed on an OP basis are likely “covered”
- However, definition is limited by 42 USC § 1396r-8 (k)(3)
- Excluded from the definition is “any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following…”

- Inpatient hospital services
- OP hospital services
- Physician services
- Other lab & x-ray services
- Hospice services
- Dental services (w/ exceptions)
- Renal dialysis
- Nursing facility & IC/IRM
Drug Eligibility

- GPO Prohibition—42 USC § 256b (a)(4)(L)
- Certain 340B hospitals cannot purchase any covered OP drug through a GPO or other group purchasing arrangement
  - Applies to DSH, children’s hospitals, free-standing cancer hospitals
  - Does not apply to CAH, RBC and SCH
- Attestation upon enrollment in the 340B Program
  - Applies to DSH as part of the definition of a “covered entity”
  - This means compliance with the GPO Prohibition is an eligibility issue

Drug Eligibility

- Hospitals subject to the GPO Exclusion must purchase covered OP drugs at 340B prices:
  - Even if the GPO or other pricing arrangement is cheaper
  - Even for OP drugs provided to non-340B eligible patients
- Does not apply to drug purchases for IP operations
- Only applies to “covered OP drugs”
- What if the manufacturer won’t offer a 340B price?
  - The only guidance is to confront the manufacturer and inform OPA
  - Purchase at WAC?

Medicaid

- Congress says that Manufacturers should not have to pay both a rebate to state Medicaid agencies and a discount to 340B covered entities on the same drug—i.e., a duplicate discount
- Providers are prohibited from billing Medicaid for a drug purchased at 340B prices and for which Medicaid seeks a rebate from the manufacturer—42 U.S.C. § 256b (a)(5)(A)
- Language of the 340B statute places the burden on the 340B covered entity for compliance even though the rebate part of the tripartite relationship is beyond the provider’s control
Medicaid

- HHS' response was to create a Medicaid Exclusion File
- Covered entities are asked whether they intend to bill Medicaid for drugs purchased at 340B prices
- A “Yes” answer to the Medicaid question causes OPA to place the covered entities’ Medicaid provider number on the Medicaid Exclusion File
- State Medicaid agencies use the Medicaid Exclusion File to determine which providers’ OP drug claims should be excluded from rebate calculations submitted to manufacturers
  - Determination at the provider-level, not the claim-level

Medicaid

- Medicaid Exclusion File addresses duplicate discounts, but state Medicaid agencies lose the rebate
- To offset the rebate loss, in 1993 OPA directed covered entities to bill Medicaid at AAC
- In 2000, OPA issued new guidance directing covered entities to refer to state Medicaid agency policies for billing OP drug claims
  - Many state Medicaid agencies (including KY) adopted reimbursement regulations prior to 2000 requiring 340B covered entities to bill Medicaid at AAC for OP drugs purchased at 340B prices
- PPACA of 2010 requires HHS to issue new guidance for billing 340B drugs to state Medicaid

Medicaid

- OPA later approved a provider initiative seeking approval to “carve-out” Medicaid claims from its 340B drug purchases
- Medicaid “carve-out” is the name given to a covered entity’s pharmacy operations model that chooses to forego the 340B discount for drugs provided to Medicaid patients
  - Drugs resulting in Medicaid claims cannot be replenished at 340B price
  - The answer to the Medicaid question should be “No”
  - Provider should not be on the Medicaid Exclusion File
  - State Medicaid agency should be able to obtain drug rebates on the provider’s drug claims without violating the duplicate discount prohibition
  - Provider is not bound by AAC limitation on billing Medicaid
  - DSH still cannot purchase OP drugs from GPO
Compliance Considerations for 340B

- What are the consequences for non-compliance?
  - Repayment of discount – 42 USC § 256b(a)(3)(D)
  - Suspension from the 340B Program
  - Civil Monetary Penalties for knowing and intentional violations – 42 USC § 256b(d)(2)(B)(v)(I)
  - Potential for false claim liability, including Qui Tam actions

- Few published cases:
  - Allegheny Community Hosps. of PA (02/13/08) – ADR finding of $2.3M
  - Dr. Joseph Rudolph (06/13/06) – Settlement of $565K to gov’t
    - Prescription Drug Marketing Act – illegal wholesaling
  - Few published cases:

Manufacturer Initiatives

- Manufacturer program integrity initiatives and audits
- Increased activity of manufacturer inquiries to covered entities seeking assurance of compliance with duplicate discount and diversion prohibitions
  - Differing tactics – sometimes starts as a phone call with questions
  - Occasionally results in a manufacturing letter making further inquiries and may include reference to program integrity, compliance and audits
  - OPA encourages covered entities and manufacturers to work amicably toward resolving any compliance inquiries
  - Failure to respond to a manufacturer inquiry is likely to justify OPA’s approval of a manufacturer audit – 42 USC 256b (a)(5)(C)

- What are a covered entities obligations to a manufacturer?
  - OPA expects open, amicable communications between covered entity and manufacturer
    - Consider thoughtfully the answers to the questions to avoid misunderstandings
    - Document the communications
  - Manufacturers may be entitled to information, but they are not necessarily entitled to documents
  - Manufacturers have the right to request an audit, but the request must articulate specific facts – not allegations
Compliance Overview

- Compliance with 340B Program rules is important
- The Past – OPA failed to monitor or enforce 340B Program rules encouraging a culture of ambivalence toward compliance
- The Present – OPA changed its tone on compliance in 2011
  - OPA has taken affirmative steps to address compliance issues, including:
    - Recertification of covered entities
    - On-site audits by HMS (OPA’s parent agency)
    - Increased approval of Manufacturer audits
    - More restrictive FAQ guidance (Policies constricting the program)
- The Future – ?

Thank you

Wes Butler
T. 859.913.6770
Wes.Butler@BBB-Law.com