The 340B Mega-Wait Is Over-Now What? (More Waiting?)

Emily Cook, Partner, McDermott Will & Emery
Anne S. Daly, Senior Director of Compliance, Banner Health
Karolyn Woo-Miles, Principal, Deloitte & Touche LLP

What is the 340B Program?
- Federal drug discount program
- Limited to eligible and registered hospitals and federal grantees/programs ("covered entities")
- Limited to certain outpatient drugs ("covered outpatient drugs") dispensed to eligible patients of covered entities
- Administered by the Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA)

Oversight of 340B

- Statute 42 USC 256b
- Regulations (340B)
Why the Changes to 340B?

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>Orphan Drugs were significantly expanded with the passage of the 2003 Medicare Prescription Drug Improvement and Modernization Act (MMA) and the enactment of additional Federal guidance in 2003 to include voluntary provisions for certain pharmacists to help serve their patients.</td>
</tr>
<tr>
<td>2009</td>
<td>Enforcement standards in reimbursement and return and exchange procedures, time frames and methodologies. A proposed rule is currently in the works. The Senate Finance Committee held hearings on the 340B program.</td>
</tr>
<tr>
<td>2010</td>
<td>The Affordable Care Act (ACA) was enacted in March, creating a new drug pricing regulation under 340B. The government issued a rule ensuring compliance.</td>
</tr>
<tr>
<td>2011</td>
<td>The FDA released additional guidance in August on an interpretive rule for the purpose of providing additional guidance on the program as a whole. The Senate Finance Committee held hearings on the 340B program.</td>
</tr>
<tr>
<td>2012</td>
<td>The Senate Finance Committee sent a letter to the FDA on the 340B program.</td>
</tr>
<tr>
<td>2013</td>
<td>In response to a ruling invalidating the definition of &quot;use,&quot; created a new interpretive rule for the purpose of providing additional guidance on the program as a whole. The Senate Finance Committee held hearings on the 340B program.</td>
</tr>
<tr>
<td>2014</td>
<td>A final rule was issued to clarify the definition of &quot;use,&quot; creating a new interpretive rule for the purpose of providing additional guidance on the program as a whole.</td>
</tr>
<tr>
<td>2015</td>
<td>The Senate Finance Committee held hearings on the 340B program.</td>
</tr>
</tbody>
</table>

Why No Regulations?

- Historical Focus
  - Pre-2010: Education, Outreach, Expansion
  - Post-2010: Compliance, Oversight, Enforcement
- Statutory Authority
  - Very limited rulemaking authority
  - As shift in focus, moved to formalize requirements
- Orphan Drug Case

Orphan Drugs

- October 24, 2015: 340B Orphan Drug Interpretive Rule struck down by D.C. District Court
  - The impact of this decision is that the orphan drug interpretive rule is invalid and all drugs designated as orphan drugs under standards established by the FDA are exempt from existing 340B pricing as to 340B covered entities subject to the 340B drug exclusion, regardless of the "use" (at which the drug is provided).
Proposed Guidance

Jan. 2007 – HRSA issues proposed guidance on patient definition

Jan. 2011 – HRSA formally withdraws the proposed guidance

April 2014 – HRSA submits the “mega-regulation” to OMB

May 2014 – A unrelated federal court decision restricts the scope of HRSA’s authority to issue notice-and-comment rules

November 2014 – In light of the decision, HRSA withdraws the “mega-regulation” from OMB

August 2015 – HRSA publishes the Omnibus Guidance

Focus of Today’s Presentation

Part A: Program eligibility and registration
Part B: Drugs eligible for purchase under 340B program
Part C: Individuals eligible to receive 340B drugs
Part D: Prevention of duplicate discounts and maintenance of auditable records
Part E: Contract pharmacy arrangements
Part F: Manufacturer responsibilities
Part G: Rebate option for AIDS drug assistance programs
Part H: Program integrity

Key Topics
- Patient Eligibility
- Drug Eligibility
- Contract Pharmacy
Patient Eligibility

Current Definition of “Patient” (finalized in 1996)

- 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 (e.g., referral for consultation) such that the responsibility for the care provided remains with the covered entity.
- The individual receives a health care service or range of services from the covered entity that is consistent with the service range of services for which grant funding or federally qualified health center lookalike status has been provided to the entity (Does not apply to hospitals)

Proposed Definition of “Patient”

1. The individual receives a health care service at a covered entity site that is registered for the 340B Program and listed on the public 340B Database.
   - Individual that sees a physician in the physician’s private practice, which is not listed on the 340B Database, would not be eligible to receive 340B drugs – including any referral or follow up care from the covered entity.
2. The individual receives a health care service from a health care provider who is employed by the covered entity or is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider.
   - Privileges or credentials at a covered entity are not sufficient.
   - If a patient is referred from the covered entity to an outside provider, and receives a prescription from that outside provider, the prescription would not be 340B eligible.

Proposed Definition of “Patient” (cont.)

3. An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in 2.
   - An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the initiation of a drug or the dispensing of a drug.
   - Telemedicine is acceptable.
4. The individual is classified as an outpatient when the drug is ordered or prescribed.
   - The patient’s classification status is determined by how the services for the patient are billed to the entities.
   - An individual who is self-pay, uninsured, or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently.

Patient Eligibility (3/16/2016)
Patient Eligibility

5. The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records.
   • Records demonstrate that the covered entity has a provider-to-patient relationship and the responsibility for care is with the covered entity.

6. For grantees, the individual receives a health care service that is consistent with the covered entity's scope of grant, project or contract.
   • Applies to each child site of the covered entity.

Changes to Patient Eligibility

Guidance moves from a 3-part test to a 6-part test on a per-prescription basis.

Patient Eligibility

- **Key Difference**
  - Tightens the nexus between the covered entity and the prescription eligible for 340B drugs

- **Practical Implications**
  - Visits at private physician offices are not eligible
  - Use of physical inventories impractical
  - Limits on "340B-only" locations/inventories
  - Referred infusion services not eligible for 340B drugs
  - Employee/dependent status is irrelevant to eligibility determination
Drug Eligibility

- "Covered Outpatient Drug"
  - Defined by reference to Social Security Act § 1927(k)(2)
  - Generally includes:
    - FDA-approved prescription drugs
    - Over-the-counter (OTC) drugs written on a prescription
    - Biological products that can be dispensed only by a prescription (other than vaccines)
    - FDA-approved insulin
  - But, also includes a "limiting definition" at § 1927(k)(3) excluding drugs bundled for Medicaid payment

Drug Eligibility

- Current Guidance
  - Covered entity may interpret the definition of "covered outpatient drug" so long as it is: "defensible, consistently applied in all areas of the entity, documented in policy/procedures, and auditable." (Apexus FAQ 1355)

Drug Eligibility

- Proposed Guidance
  - Explicitly applies the "limiting definition," but only to Medicaid
  - Drugs that are part of a bundled payment for Medicaid reimbursement, and are billed to and paid for by Medicaid as part of bundled payment are excluded from definition of "covered outpatient drug"
  - Practical Implications
    - May not be able to determine 340B eligibility at time of dispensing or billing
    - Creates risk of violation of GPO Prohibition for certain hospitals
Contract Pharmacy

- Covered entities may contract with third-party pharmacies to dispense 340B drugs
- Source of significant growth in 340B purchasing and focus of government/manufacturer oversight

Current Guidance

- Covered entity is responsible for contract pharmacy’s compliance with 340B Program requirements
- Covered pharmacies may not dispense 340B drugs to Medicaid patients unless HHS has approved a system to prevent duplicate discounts
- Covered entity is expected to conduct audits of the contract pharmacy arrangement

Proposed Guidance

- Covered entity must conduct quarterly reviews and annual audits of each contract pharmacy location

Operational and Financial Takeaways

Financial impact: Infusion centers and contract pharmacy are typically large drivers of program savings. If the proposed changes go into effect as written, what can organizations do to make up for the lost savings?

Sustainable margin opportunities such as revenue cycle maximization, supply chain and pricing optimization, and clinical reimbursements evaluations

Audit and monitoring: Proposed guidelines included detailed expectations for audit and monitoring activities. Most entities perform routine auditing and monitoring, but many lack a formal, structured, and integrated plan.

Assess the possibility of immediate corrective action versus waiting until the guidance is released in final form:
- Audit and monitoring practices
- Error reporting procedures
- Develops repository for program documentation
- Software and data infrastructure modifications

340B Conference Takeaways

1. Release of omnibus guidance
   - Expected release date is September 2016, however other factors suggest a possible extension
   - More time for pharmacy
   - Understanding budget
   - Assistance of defense

2. Anticipated HHS enforcement in 2016
   - Overriding regulations
   - Manufacturer Civil Monetary Penalties (CMP)
   - Ceiling Price Rules
   - Dispute Resolution
   - Other Updates, 340B Pricing Website & Legislation

3. Online query pricing system
   - Will allow authorized users from covered entities the ability to view, upload, and validate prices for covered outpatient drugs
   - Will improve accuracy and simplify the process for their portfolio of covered outpatient drugs and related therapeutics with the health certified 340B query pricing
MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) has backed a proposal to reduce Part B drug payment rates for hospitals participating in the 340B Drug Pricing Program.

- On January 16, 2016, MedPAC voted 14 to 3 to recommend to Congress to reduce Part B drug payment rates for hospitals by 10% of the average sales price of the drug.
- Medicare would distribute uncompensated care payments made under the disproportionate share hospital program based on data from Schedule S-10 of the hospitals' Medicare cost report.
- This change would be phased in over three years.
- The American Hospital Association estimates that this would redistribute the estimated $300 million in savings to hospitals providing uncompensated care.
- Requires additional action by Congress to implement MedPAC recommendation.


Future 340B Landscape

Pivoting in the marketplace:
Providers need to take advantage of the changes in the regulatory landscape to adapt to the marketplace.

Compliance:
The rules are complex and ever-evolving. Proceed with caution.

Moving toward a new 340B Program landscape:
Costs:
New opportunities and funding streams need to be explored.

Providers and payers:
How they define value, set rates, and respond to new incentives will set the stage.

Compliance:
The rules are complex and ever-evolving. Proceed with caution.

Moving toward a new 340B Program landscape:
Costs:
New opportunities and funding streams need to be explored.

Providers and payers:
How they define value, set rates, and respond to new incentives will set the stage.