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Strategies to Maximize Your 340B Program

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As a reminder, the information offered today is for general educational purposes only and does not constitute legal advice.

What Drives Maximization?

- Understanding the policies behind the 340B drug pricing program and its basic components
- Considering how to implement HRSA/Apexus guidance and maintain and monitor compliance
- Leveraging third-party relationships effectively
- Staying current on developments and considering impact

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340B Policies and Key Components

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Policy Drivers

- Program created in 1992 to require manufacturers to provide outpatient drugs to eligible health care organizations at reduced prices.

- Program intended to allow ***covered entities*** to stretch scarce federal resources as far as possible, reach more ***eligible patients*** and provide more comprehensive services.

- To have a drug covered by Medicaid, manufacturers must enter into a pharmaceutical pricing agreement, which limits the price charged to covered entities for ***eligible drugs*** dispensed to eligible patients.

Covered Entity Enrollment

To be participate in the program as a covered entity, an eligible provider must:

- Be one of the entity types permitted under 340B
- Register itself, its child sites, and its contract pharmacies with HRSA's OPAIS during designated time frames;
- Be approved by HRSA; and
- Notify applicable manufacturers and distributors.

Eligible Patients and Eligible Drugs

- **An eligible patient is one that:**
  - has established a relationship with the covered entity such that the covered entity maintains records of the patient's care; and
  - receives services from a healthcare professional who is employed by the covered entity or provides healthcare under contractual or other arrangements with the covered entity; and
  - receives services which are consistent with the covered entity's federal grant or program designation.
- **An eligible drug is:**
  - a covered outpatient drug.

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Implementing Guidance and Maintaining Compliance

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Applying the Patient Definition…

- Does the definition of eligible patient have anything to do with an individual's ability to pay?
- How long does an individual remain an eligible patient?
- How many refills is an eligible patient permitted?
- What if a provider no longer is employed by or contracted with a covered entity?
- What if multiple covered entities consider an individual to be an eligible patient?

Interpreting Other HRSA Guidance…

- Drugs/Access
- Child Site Eligibility/Timing
- Who is an appropriate prescriber?
- Medicaid carve-in vs. carve-out
- AKS Compliance

Internal Best Practices

- Designate a 340B coordinator/central figure responsible for program and ensure they have necessary resources.
- Document decisions and compliance through robust policies and procedures.
- Track and measure savings and generally document use.
- Think through financial structure of third-party relationships and contract accordingly.
- Self-audit and carefully monitor third-party compliance.
- Be prepared for, and responsive to, external audits.

Audits

- Covered entities must ensure program integrity and maintain accurate records documenting compliance with all program requirements.
- HRSA has the authority to audit covered entities.
- Covered entities may also be audited by manufacturers.
- Failure to follow through on compliance responsibilities may result in refunds to manufacturers or removal from the program.
- A finding of noncompliance on two or more audits may be deemed systematic and egregious (or knowing and intentional) and may result in removal from the program.

Additional Audit Considerations

- Corrective Action Plans
  - Implementation within six months of approval
  - Areas for improvement clearly identified
  - HRSA authority

- Identifying Compliance Issues Through Self-Audit
  - Reporting obligations
  - Critical to define via policy what constitutes a “material breach”
  - Manufacturer coordination
  - Apexus tools

Leveraging Third-Party Relationships

Manufacturers/Wholesalers

- The maximum amount that a manufacturer may charge a covered entity for a covered drug is referred to as the ceiling price.
- The ceiling price is calculated by HRSA on a quarterly basis and is the average manufacturer price less the unit rebate amount.
  - Availability of pricing information
- ADR/Disputes regarding availability of 340B pricing

Pharmacies

- Program drugs may be dispensed by in-house pharmacies or by contract pharmacies.
- There is not a defined cap on the number of contract pharmacy relationships a covered entity may have.
- Contract pharmacy agreements must contain all HRSA-required elements.
- Covered entity is responsible for 340B compliance—critical to contract robustly and maintain oversight.
- Consider inventory model, pricing structure, etc. and negotiate carefully.

Other Third Parties

- 340B Administrators
  - Eligibility determinations, maintaining accumulators, ordering, etc.
  - Contract carefully and maintain close oversight
  - Consider data implications
- Consultants
- HRSA/Apexus
- Industry Groups

Staying Current

Key Trends and Updates

- COVID Flexibilities
- Manufacturer Actions to Scope Program
  - Limiting Contract Pharmacies
  - Requiring Contract Pharmacy Claims Data
  - 340B Pay Platform/Rebate Structure
- HRSA's Inconsistent Positioning

Key Trends and Updates Cont.

- Payor Activity
- State and Federal Legislative Activity
- Litigation/Advocacy

Breaking Update…But Not the End of the Saga

- On May 17, 2021, HRSA notified six manufacturers that HRSA has determined their policies are in direct violation of the 340B statute.
  - Placing restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy (AstraZeneca, Eli Lilly, and Novo Nordisk Inc.)
  - Placing restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform (Novartis, Sanofi, and United Therapeutics)
- Each manufacturer must provide HRSA by June 1, 2021 with an update on its "plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price."

Tying It All Together

- It is critical to understand the nuances of the 340B program components in order to implement your own program effectively.
- Ensure someone has central responsibility for your program and sufficient resources.
- Document effectively, maintain good polices & procedures, audit yourself, and monitor your numbers closely.
- Be strategic in leveraging third parties, negotiate contracts aggressively, and manage vendor performance carefully.
- Stay up to date with legislative, agency, and stakeholder activity and be prepared to push back on stakeholders and pivot as needed based on legislation and changes to agency guidance.

Questions?

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