340B Discount Drug Program Overview
March 2014
Section 340B of the Public Health Service Act provides access to prescription drugs at significantly discounted prices for eligible facilities ("covered entities").

- On average, covered entities receive discounts of approximately 50% of average wholesale price ("AWP") through the 340B program.
- Covered entities include disproportionate share hospitals ("DSH"), federally qualified health centers, and other healthcare facilities that serve predominately low-income, special need, and indigent patients.
- In order to maintain eligibility, covered entities must meet a number of requirements and are subject to annual recertification by the Health Resources and Services Administration ("HRSA").
  - Strict inventory control to ensure that medications reach vulnerable patient populations
  - Increased billing and reporting requirements
  - Maintenance of separate inventories and patient / claims processing records

340B Drug Pricing

As of December 2012

Sources: Pembroke Consulting and GAO analysis of HRSA data.
As a result of health reform-driven changes, drug spend through 340B is expected to reach $16 billion by 2019P from $7 billion currently.

- Since 2001, the number of covered entities has increased 6.8% annually.
- The Patient Protection and Affordable Care Act (“PPACA”) opened access to rural hospitals, freestanding oncology centers, sole-community hospitals, and critical access hospitals.
  - Expansion in Medicaid coverage codified by the PPACA has also driven an increase in the number of covered entities

### 340B Drug Expenditures
For the Years Ended and Ending December 31, 2013 to 2019P
($ in billions)

### 340B Covered Entities
For the Years Ended December 31, 2001 to 2011

Source: Avalere Health analysis of HRSA data.
Challenges of the 340B Program

Covered entities are facing increased scrutiny at a time when discounts from the 340B program are most needed.

- Due to growth in utilization of the program, HRSA increased its 340B audit activity in late 2012.
  - Manufacturers have begun to require independent audits due to revenue lost through discounts
  - Diversion – providing discounted drugs to ineligible patients
  - Duplicate discounts – receiving both 340B pricing and other government program discounts, such as Medicaid
- Meanwhile, public sector hospital margins remain under significant pressure, driving the need for covered entities to maximize savings from 340B.

Public Sector Hospital Margins\(^1\)

For the Years Ended December 31, 2007 to 2011

<table>
<thead>
<tr>
<th>Year</th>
<th>Margin</th>
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<tbody>
<tr>
<td>2007</td>
<td>(7.0%)</td>
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<tr>
<td>2008</td>
<td>(8.5%)</td>
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<tr>
<td>2009</td>
<td>(6.7%)</td>
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<td>2010</td>
<td>(5.9%)</td>
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<tr>
<td>2011</td>
<td>(7.2%)</td>
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Covered entities often lack the expertise and resources to implement and maintain a compliant 340B program, presenting an attractive opportunity for outsourced providers.

Source: MedPac.
\(^1\) Medicare margins.
The complexity of managing a 340B program has driven demand for pharmacy service providers specializing in serving the needs of covered entities.

- Pharmacy management firms with expertise in 340B are able to help unsophisticated covered entities implement efficient, profitable, and compliant 340B programs.
  - Many eligible facilities are not aware that the 340B program is available to them
  - Services include patient eligibility analysis, procurement assistance, licensing and compliance verification, and inventory control

- Contract pharmacies enable covered entities lacking in-house pharmacy services or facilities to dispense 340B drugs to patients.
  - Covered entity purchases drugs, but contract pharmacy takes physical delivery and manages dispensing to patients

**Growth in 340B Contract Pharmacy Arrangements**

For the Years Ended December 31, 2003 to 2013

**Representative 340B Pharmacy Service Providers**

Source: Avalere Health analysis of HRSA data.
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