Growth in the 340B Program: Trends & Challenges

Laurel Todd
Managing Director, Reimbursement and Health Policy
Biotechnology Industry Organization
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Executive Summary
Growth in the 340B Program: Trends & Challenges

Basics of the 340B Program

Four primary sources of growth in 340B:
1. Organic growth of entities already enrolled
2. Affordable Care Act-authorized new entity eligibility
3. Medicaid Expansion
4. Proliferation of contract pharmacies/contract pharmacy networks

Ongoing challenges and advocacy
Basics of the 340B Program
Summary of the 340B Program

- Created in 1992 in response to the Medicaid drug rebate program

- According to the U.S. House of Representatives report that accompanied the legislation creating the 340B program:
  
  - “The Committee bill also provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans.” [emphasis added; Source: U.S. House of Representatives, 1992]

  - “...to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”
Requires manufacturers to charge a heavily discounted price for outpatient drugs and biologics to certain safety-net providers who then distribute them to all of their patients, regardless of a patient’s insurance status.

The program has grown from a few hundred entities in 1992 to more than 16,000 in 2012 with total program purchases of approximately $6 billion. [Source: BRG, 2012]
**Covered Entities**

- Disproportionate share hospitals
- Federally-qualified health centers or “look-alikes”
- Family planning and STD clinics
- Ryan White Care Act grantees
- State operated AIDS drug assistance programs
- Comprehensive hemophilia diagnostic treatment centers
- Black lung and tuberculosis clinics
- Urban Indian clinics
- Native Hawaiian health centers

- Certain free-standing cancer hospitals
- Critical access hospitals
- Rural referral centers
- Certain sole community hospitals
- Children’s hospitals

Added by ACA
The Health Resources and Services Administration (HRSA) manages 340B program oversight generally through the use of sub-regulatory notices, policy statements and FAQs posted to its website.

While PPACA required some regulatory activity, HRSA has taken minimal steps to meet deadlines, citing a lack of resources to pursue further compliance.

*Note: Multiple dots indicates number of category released in that year
The program has certain prohibitions such as:
- No duplicate discounts
- No diversion to non-patients or to the inpatient setting
- No group purchasing organization contracts (for certain entities)

Along with expanding the definition of “Covered Entities”, the ACA provided for increased 340B program reporting requirements, penalties/sanctions, and audits and created an orphan drug exemption to the newly-eligible entities.

Historically, there has been little Congressional oversight of the program, and HRSA implementation of compliance provisions has not been comprehensive.
Sources of 340B Growth:
1. Organic Growth
Growth of Section 340B Covered Entity Sites

Source: Avalere Health analysis of Health Resources and Services Administration Office of Pharmacy Affairs files.
Covered Entity Participation Rates

Figure 6: 340B Participation Rates by Covered Entity Category

Notes: FQHC = federally qualified health center
STD = sexually transmitted diseases

In a 2014 study conducted for BIO by the Berkeley Research Group (BRG), BRG found that both the absolute number of Acquired Sites in the study’s sample and the number of Acquired Sites per Acquiring Covered Entity in the study’s sample increased over time from 2009 to 2012.

Trend in Physician-based Oncology Practice OPA Registrations (2009 - 2012)

<table>
<thead>
<tr>
<th>Acquiring Covered Entities</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013 [1]</th>
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<tbody>
<tr>
<td>New Child Sites in OPA Data</td>
<td>56</td>
<td>58</td>
<td>73</td>
<td>194</td>
<td>45</td>
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<tr>
<td>Oncology-related Child Sites</td>
<td>32</td>
<td>23</td>
<td>21</td>
<td>65</td>
<td>18</td>
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<tr>
<td>Acquired Within Date Range</td>
<td>25</td>
<td>21</td>
<td>21</td>
<td>38</td>
<td>0</td>
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<tr>
<td>≥ 10% Increase in 340B Purchases</td>
<td>18</td>
<td>19</td>
<td>11</td>
<td>15</td>
<td>0</td>
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<tr>
<td>Cumulative Total</td>
<td>18</td>
<td>37</td>
<td>48</td>
<td>63</td>
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</tbody>
</table>

<table>
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<tr>
<td>473</td>
<td>592</td>
<td>278</td>
<td>1,523</td>
<td>450</td>
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<td>79</td>
<td>68</td>
<td>30</td>
<td>166</td>
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<tr>
<td>39</td>
<td>90</td>
<td>107</td>
<td>144</td>
<td>144</td>
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</tr>
</tbody>
</table>

[1] Represents registrations through April 1, 2013

Physician-based Oncology Practice Acquisitions: Chargebacks

- To determine the financial ramifications of these acquisitions, BRG studied total study-eligible 340B chargebacks as a proxy for savings to the hospitals as a result of 340B participation.
- Acquiring Covered Entities and their Acquired Sites accounted for an increasing percentage of total Chargebacks over time (12% in 2009 vs. ~25% in 2012)
  - This result is particularly notable because the number of Non-Acquiring Covered Entities grew over time due to new registrations in the 340B program

Physician-based Oncology Practice Acquisitions: Chargebacks vs. Charity Care Costs

- BRG found that for ~45% acquiring covered entities, the study-eligible 340B chargebacks paid by manufacturers exceeded the charity care costs provided by those entities and were not correlated with charity care levels.
- Acquiring covered entities appear to be selecting physician-based oncology practices located in higher median-income communities.
- Half of all Acquired Sites were located 10 or more miles from the Acquiring Covered Entity.

Sources of 340B Growth:
2. ACA’s 340B-specific provisions
Effective January 1, 2011, the ACA expanded the types of entities eligible for 340B discounts.

By some estimates, the ACA expansion of 340B program eligibility enabled up to 1,500 additional facilities to participate in the program.

There are currently more than 16,300 registered providers with access to the 340B discount.

New Entities under the ACA
- Certain qualifying children’s hospitals*
- Free-standing cancer hospitals
- Critical access hospitals
- Rural Referral Centers
- Sole Community Hospitals

Inpatient utilization was originally included in ACA expansion but did not remain a part of the final legislation.

* Children’s Hospitals were initially added by the Deficit Reduction Act and later through HRSA policy in 2009; Codified by ACA.
Program Management Timeline

Sources of 340B Growth:
3. Medicaid Expansion
Medicaid Expansion as of August 2014

Where the States Stand on Medicaid Expansion
26 states, DC, Expanding Medicaid—May 22, 2014

Notes: Based on literature review as of 4/22/14. All policies subject to change without notice.
HHS has announced that states can obtain a waiver to use federal funds to shift Medicaid-eligible residents into private health plans.
The District of Columbia plans to participate in Medicaid expansion and will operate its own exchange.

Current eligibility depends on DSH adjustment percentage, which must be:
- Greater than 11.75% for non-profit & government hospitals
- Greater than 8% Sole community hospitals

DSH adjustment percentage is calculated from DSH Patient Percentage (DPP):

\[
DPP = \frac{\text{Patient Days of Medicare Part A & SSI Enrollment}}{\text{Patient Days of Medicare Part A Entitlement}} + \frac{\text{Patient Days of Medicaid Eligibility & Not Medicare Part A}}{\text{Total Hospital Patient Days}}
\]

**Bottom line:** as Medicaid Eligibility increases:
- A hospital’s DSH adjustment percentage will increase,
- More hospitals are pushed over the threshold of 340B eligibility, and
- The 340B program expands.

*Source: Vandevelde, A. Berkeley Research Group. February 2012.*
Sources of 340B Growth: 4. Contract Pharmacies
Contract Pharmacies

- Covered Entities may contract with retail pharmacies for the physical dispensing of 340B drugs.
  - A Covered Entity may contract with multiple pharmacies to provide drugs at 340B discounted prices to the Covered Entity’s patients.
  - There are no limits on the number of contracted pharmacies that a Covered Entity may have, nor is there a geographic proximity requirement.
  - Contract pharmacies must be on HRSA/OPA website and listed on website as linked to the Covered Entity.

- Bill to/Ship to: typical arrangement has product shipped to contract pharmacy but 340B entity receives invoice and pays for product

- Contract Pharmacies do not necessarily know at the point of sale whether a given Rx is 340B or not.
The Contract Pharmacy Model

340B Product Distribution
Traditional Model

340B Product Distribution
Contract Pharmacy Model

Drug Manufacturer

Wholesalers

Covered Entity
(Physical Inventory)

Patient

Drug Manufacturer

Wholesalers

Drugs distributed to
Contract Pharmacies are
purchased and owned
by the Covered Entity

Covered Entity

Contract Pharmacy
(Virtual Inventory)

Patient

Growth in Contract Pharmacy Arrangements

Figure 3: Growth in 340B Contract Pharmacy Arrangements, 1999–2013 (as of July of Each Year)

*2012 and 2013 reflect HRSA projections.
Source: Avalere Health analysis of HRSA 340B contract pharmacy arrangements files.
Growth of the 340B Contract Pharmacy Cottage Industry

Vendors and Consultants Provide Split-Billing & Other Services
Contract Pharmacy Arrangements Raise Key Questions

- How do covered entities with multiple contract pharmacy networks interact with the Medicaid Managed Care Organizations (MCOs), States, for duplicate discount compliance?

- What oversight exists to assess the logic used in contract pharmacy systems to verify compliance with program prohibitions?

- Transaction status is often not known at the point of sale, what are the implications for program compliance and, notably, for uninsured and low income patients?
Challenges Posed by 340B Growth
While originally intended to be a program for safety net providers, today, one third of all U.S. hospitals participate in 340B. [Source: GAO, 2011 and KFF, 2011]

A 2014 RAND Corporation report estimated that hospitals participating in the 340B program account for approximately 48 percent of total outpatient hospital visits in the U.S.

The 340B Program is expected to continue experiencing a 3-4 percent growth in covered entities per year.

A 2012 analysis by BRG estimates that drug purchases through the 340B program will double from $6 billion in 2010 to $12 billion by 2016.

- Recent policy changes will drive much of this growth
- The proliferation of multiple contract pharmacy networks is predicted by BRG to drive over half of the growth in the program
Potential Impact of Significant, Continued 340B Growth

- Congress has stepped up interest in 340B oversight and compliance
  - Oversight letters to 340B stakeholders
  - Inquiry regarding need for revised Definition of a Patient
  - Impact of 340B on other Federal programs
  - Inquiry into hospital generation of funds and charity care levels
  - Potential to reevaluate intent of program
  - 2014 $6 million appropriation

- Areas of ongoing discussion
  - Medicaid MCO and Duplicate Discounts
  - Contract Pharmacy
  - Definition of a Patient
  - GPO Prohibition
Recent Data Highlight Program Challenges

- Contract Pharmacy Arrangements in the 340B Program (OIG 2014)
- Unfulfilled Expectations: An analysis of charity care provided by 340B hospitals (AIR340B 2014)
- 340B Covered Entity Acquisitions of Physician-based Oncology Practices (BRG/BIO 2014)
- Cost Consequences of the 340B Drug Discount Program (Bach, Conti: JAMA 2013)
- How ObamaCare Hurts Patients (Gottlieb: WSJ 2013)
- Dispute Develops Over Discount Drug Program (Pollack: NYT 2013)
- Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (OIG 2011)
- State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs (OIG 2011)
Over the last several years, GAO and OIG have released several studies raising compliance concerns in the 340B program, likely exacerbated by the program’s rapid growth.

- In a February 2014 OIG report, the OIG noted that in particular there is a lack of clarity on how HRSA’s patient definition should be applied in contract pharmacy arrangements—many covered entities appear to have differing interpretations of what HRSA guidance requires.

Additional concerns raised by stakeholders include:
- Whether the program is meeting the needs of the low income uninsured population it was intended to serve;
- The potential that the program may be skewing clinical decision-making to take advantage of the 340B discount; and
- Potential unintended consequences for non-340B providers.
Biotechnology Industry Organization
References