Biotechnology Innovation Organization

340B DRUG DISCOUNT PROGRAM AT-A-GLANCE

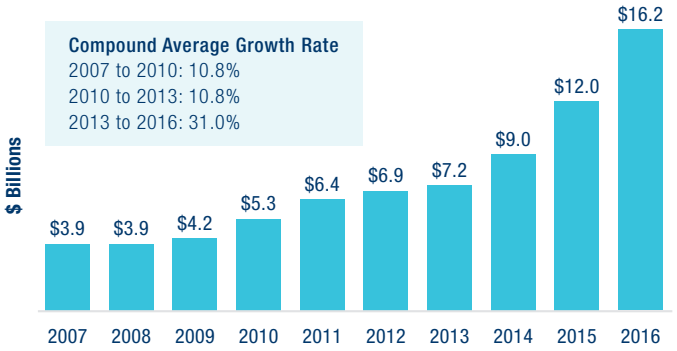
In 1992, with the support of the biopharmaceutical industry, Congress created the 340B Drug Discount Program to help uninsured and vulnerable patients gain access to affordable prescription drugs. As part of the law, drug manufacturers provide discounts on outpatient medicines and treatments to select health care entities — often referred to as safety-net providers. The program was necessitated by changes to the Medicaid program that precluded drug makers from continuing to offer steep discounts to safety-net providers voluntarily, as they previously had done. Over the years, however, there have been growing concerns that this program has expanded well past the intent of Congress and that patients may not be seeing the benefits they deserve.

How Big Is 340B?

Since its inception, the 340B program has grown dramatically. Currently, about 45% of all Medicare acute care hospitals participate in the program, and between 2014–2016, the volume of purchases made through 340B more than doubled, expanding 125%.

Discounted purchases made under the program totaled $16.2 billion in 2016 — up from $12 billion in 2015 — and the program grew at a staggering compound annual growth rate of 31% between 2013 and 2016.

Total Discounted Purchases Made under the 340B Drug Pricing Program, 2007–2016

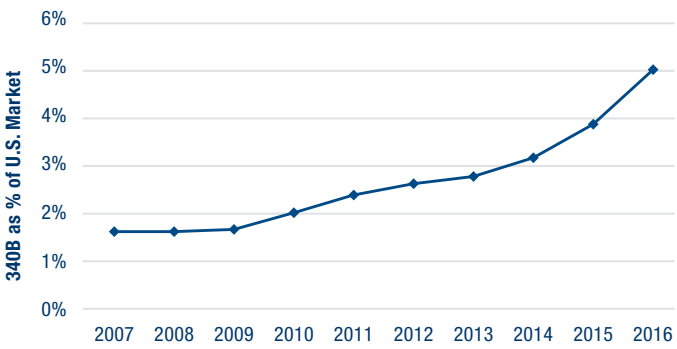


Source: Drug Channels May 2017

340B Drug Purchases on the Rise

Growth in 340B sales continues to increase consistently and research shows the program is forecasted to exceed $20 billion by 2019 and $23 billion by 2021. Since 2007, 340B has grown from 1.6% of the U.S. market to 5.0% in 2016, according to QuintilesIMS Health. **Despite this uptick in 340B sales, evidence suggests that certain hospitals are not passing on the savings associated with sales from the program to patients in the form of financial or co-pay assistance.**

340B Drug Purchases as Percentage of Total U.S. Drug Market, 2007–2016



Source: Drug Channels May 2017

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What Experts Are Saying

There is growing evidence that hospitals are pocketing the savings from 340B payments and not passing them on to the patients who need them.

> "[The 340B program has] expanded beyond its bounds."

— Kathleen Sebelius, former Secretary of Health & Human Services, appearing before Senate Finance Committee, April 2014

> "HRSA's annual audits reveal a high level of noncompliance with program requirements by covered entities, including the potential for duplicate discounts and diversion of 340B drugs to ineligible patients."

— Rep. Greg Walden (R-OR) Comments at Energy and Commerce Hearing, July 2017

> "Medicare spending grew faster among hospitals that participated in the 340B program for all five years than among hospitals that did not participate in the 340B program at any time during this period (19.1% per year vs. 13.9% per year, respectively). Among all OPDs (whether or not they were part of a 340B hospital), spending for chemotherapy drugs and drug administration services grew by 16.1% per year. Meanwhile, spending for the same set of drugs and services provided in freestanding physicians' offices rose by only 1.1% per year."

— MedPAC, May 2015

> "Notably, there is no requirement that the discounted 340B price be passed on to uninsured patients who seek treatment at 340B covered entities. As a result, the covered entity may acquire the drug at a discounted price, but the uninsured patient may still pay the full list price for the drug at the pharmacy."

— House Energy and Commerce Committee Review of the 340B Drug Pricing Program, January 2018

> "We found no evidence of hospitals using the surplus monetary resources generated from administering discounted drugs to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups in ways that would reduce mortality. These results suggest hospital responses that are contrary to the goals of the program and have a number of important policy implications."

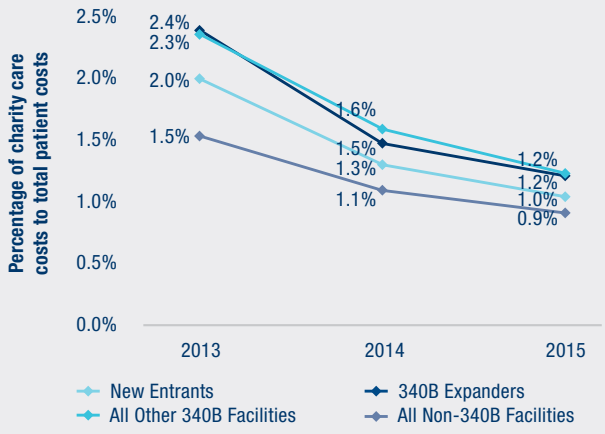
— Federally funded study published by the New England Journal of Medicine, January 2018

Charity Care Provided by 340B Hospitals Declining

Despite staggering growth in the number of hospitals — and volume of purchases — made under the program, 340B hospitals have demonstrated a dramatic decline in charity care provided since 2013. Between 2013 and 2015, 340B disproportionate share hospital (DSH) facilities decreased charity care levels more substantially than non-340B DSH hospitals, raising questions about who is benefiting from 340B — patients or hospitals.

These findings build upon recent data showing that in total, nearly two-thirds (64%) of 340B hospitals provide less charity care than the national average for all short-term acute care hospitals, including for-profit hospitals.

Median Change in Charity Care Level
(2013–2015)



Source: AIR 340B