

What is the 340B program?

Congress created the 340B program in 1992 to help certain health care safety net providers that serve a large number of uninsured or otherwise vulnerable patients reduce outpatient prescription drug costs. The 340B program requires prescription drug manufacturers to provide deep discounts on outpatient drugs to specified federally-funded clinics and certain hospitals, known as covered entities. Manufacturers must participate in the 340B program or Medicaid cannot cover their drugs. The 340B program is administered by the Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services.

Who is eligible to receive discounts under the 340B program?

Under the law, a health care entity is eligible for the 340B program either by:

- receiving one of 10 types of federal grants; or
- being one of six types of non-profit hospitals that meet specified program standards.

Federal grantees that participate in the program typically include clinics that offer primary and preventive care to uninsured or vulnerable patients.

What requirements exist for how revenue generated from the 340B entity can be used?

Covered entities purchase 340B drugs at deeply discounted prices, but hospitals are not currently required to pass these discounts along to patients. Therefore these drugs may be billed at rates exceeding the covered entity's acquisition cost and generate revenue for the entity. The 340B program does not place any requirements on how hospitals use this 340B program revenue. Grantee covered entities, by contrast, must use 340B revenue in accordance with their federal grant requirements, which typically require that any grant-related revenue be reinvested in treating vulnerable communities.

What criteria are used to determine if a hospital is eligible to be a covered entity in the 340B program?

A hospital can become a covered entity under current law if:

- it has a Medicare disproportionate share hospital (DSH) adjustment percentage above a certain level, which varies depending on the hospital type. The DSH adjustment percentage is a measure relating to the number of Medicaid and low-income Medicare patients treated on an inpatient basis. It does not measure the amount of care provided to uninsured or vulnerable patients, and relates solely to inpatients.

- it meets one of the following criteria: (1) it is publicly owned or operated by a unit of state or local government; (2) it is a private nonprofit hospital formally granted governmental powers by a state or local government; or (3) it is a private nonprofit hospital with a contract with a state or local government to provide health care services to low-income individuals who are not Medicare or Medicaid eligible. The Government Accountability Office (GAO) has noted that there has not been sufficient oversight with respect to the third criterion, and that "hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts."¹

Requirements for hospital eligibility were originally intended to target true safety net hospitals dedicated to serving vulnerable populations. However, studies show many hospitals in the 340B program provide relatively little charity care (even compared with for-profit hospitals) and over time 340B hospitals have increasingly been using these discounted drugs in off-campus outpatient facilities serving more affluent communities than the parent hospitals.²

Who is a patient of a 340B entity?

The 340B statute clearly states that covered entities are not permitted to provide 340B discounted drugs to individuals who are not their patients. This prohibition has proved difficult to enforce due to a lack of clarity regarding the definition of a 340B eligible patient. The Government Accountability Office and the Department of Health and Human Services Office of the Inspector General (OIG) have both noted the need for a clearer patient definition.³

In an effort to address these concerns, HRSA proposed a revised definition for patient in draft guidance released in August 2015.⁴ That draft guidance included language clarifying that prescriptions are only eligible for 340B when there is a strong relationship between a 340B covered entity and the patient. In early 2017 the draft guidance was officially withdrawn.

Other than eligibility standards, what requirements does the 340B law impose?

Several important laws apply, including:

- As noted above, the 340B law prohibits covered entities from reselling or otherwise transferring discounted drugs purchased under 340B to anyone but their own patients, a practice known as diversion. Notwithstanding this statutory prohibition, concerns have been raised about 340B drugs being furnished to individuals who lack a genuine treatment relationship with the 340B entity. HRSA's 2015 draft guidance proposed to address this concern by requiring (among other things) that individuals who only receive drug dispensing or infusion services from a covered entity are not considered patients.⁵
- Under the 340B law, duplicate discounts are prohibited. Specifically, manufacturers cannot be invoiced by states for

¹Manufacturer Discounts in the 340 Program Offer Benefits, but Federal Oversight Needs Improvement, GAO-11-836 (Sept. 2011).

²General Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, July 2015; Alliance for Integrity and Reform of 340B (AIR 340B) (2014). *Unfulfilled Expectations: An analysis of charity care provided at 340B hospitals*. Available at: <http://bit.ly/1EiIMnz>; RM Conti and PB Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, Health Affairs, October 2014 vol. 33 no. 10.

³Government Accountability Office, *Testimony Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives; Drug Discount Program: Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight*, GAO-15-455T Mar. 2015; HHS Office of the Inspector General, *Memorandum Report; Contract Pharmacy Arrangements in the 340B Program*, OEI-05-00431 Feb. 2014 (hereafter the 2014 OIG Report).

⁴80 Fed. Reg. 53200 (Aug. 28, 2015).

⁵*Id.* at 52307.

Medicaid rebates for drugs that have been purchased at a 340B discount. Still, the OIG has found there are not adequate safeguards to prevent duplicate discounting.⁶ HRSA's own audit results also show that duplicate discounting remains a problem. The agency found instances of duplicate discounts in about one-quarter of the DSH hospitals that were audited.⁷

- The 340B law notes that covered entities must permit HRSA and manufacturers to audit records directly relevant to the diversion and duplicate discount prohibitions. However, manufacturers' ability to conduct these audits –guaranteed under the 340B law itself – has been severely hampered by HRSA guidance, which creates significant barriers to conducting such audits. Despite the fact that the program was created in 1992, HRSA only began to audit covered entities in 2012. HRSA's FY 2016, audit results show that 78 percent of the largest category of 340B hospitals (disproportionate share or DSH hospitals) audited had at least one adverse finding, and nearly half (43 percent) had multiple adverse findings, including violations of the duplicate discount provision, diversion of medications to non-eligible recipients and non-compliant recordkeeping.⁸

What is the role of contract pharmacies?

- Covered entities often purchase and dispense 340B drugs through pharmacies. Covered entities may have an in-house pharmacy (i.e., the pharmacy is located within the covered entity). Sub-regulatory guidance published by HRSA also permits covered entities to dispense 340B drugs through contract pharmacies⁹ that are not mentioned in the 340B law. Under a contract pharmacy model, the covered entity contracts with one or more outside pharmacies to dispense drugs on its behalf. Previously, HRSA only permitted covered entities that lacked an in-house pharmacy to contract with an outside pharmacy to dispense 340B drugs, and only permitted those covered entities to contract with a single pharmacy.
- In March 2010, HRSA issued revised sub-regulatory guidance permitting *all covered entities to contract with multiple outside pharmacies*.⁹ This change led to a dramatic growth in the number of contract pharmacy arrangements – a 1,245 percent increase from 2010 to mid-2013.¹⁰ This growth was noted as a potential diversion concern by GAO, which stated that, "Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."¹¹

How big is the 340B program?

Currently, about 45 percent of all Medicare acute care hospitals participate in the 340B program.¹² Sales at the 340B price were estimated to be \$16 billion in 2016, and research shows that the program is forecasted to exceed \$20 billion by 2019 and \$23 billion by 2021 (measured at discounted 340B prices).¹³ This growth has continued in recent years despite declines in the number of uninsured and lower charity care burdens for hospitals. The major drivers of this growth are threefold: 1) new entity enrollment, such as hospitals and grantees; 2) 340B hospital acquisition of physician practices and the creation of new referral networks; and 3) contract pharmacy expansion.¹⁴

There has been a dramatic increase in the number of physician practices purchased by 340B hospitals. Following these acquisitions, the formerly

independent physician practices are now treated as hospital outpatient departments and (under HRSA sub-regulatory guidance) can purchase drugs under the 340B program. These outpatient sites may be located far from the hospital itself and research has shown that they are generally in wealthier areas than the 340B hospitals.¹⁵

What is next for 340B?

In 2015, HRSA released a proposed omnibus guidance, addressing several issues, including the definition of a 340B-eligible patient. The guidance went through a notice and comment period and was withdrawn in early 2017.

The proposed guidance would have more clearly defined when hospitals are able to obtain 340B discounts by clarifying who meets the definition of a 340B patient. Under the proposed guidance:

- simply providing a referral from a covered entity to an outside provider is insufficient to qualify the drugs prescribed by the outside provider for a 340B discount;
- the dispensing or infusion of outpatient drugs to an individual at a covered entity would not be enough to establish that the individual was a patient of the covered entity;
- employees of a covered entity are not considered to be 340B patients unless they otherwise meet the patient definition; and
- a provider merely having privileges or credentials at a covered entity would not be enough to demonstrate that a patient treated by that provider is a patient of the covered entity.

The clarifications included in previously released proposed guidance would have been an important initial step toward increasing oversight and accountability in the 340B program. Beyond a strong patient definition, additional reforms will be needed to address other key aspects of the program.

- New policies are needed to address the dramatic growth of contract pharmacy arrangements between 340B entities and for-profit pharmacies.
- Reforms are needed to curb the financial incentives driving 340B hospitals to acquire community-based physician practices, particularly given the substantial increase in health care costs associated with the site of care shifting from physician offices to hospital facilities in the last decade.
- Congress should also revisit whether the current hospital eligibility criteria in the 340B law are appropriately targeting the program to true safety net hospitals.
- HRSA also should strengthen eligibility standards for non-public hospitals and work with the Centers for Medicare & Medicaid Services to develop new policies to prevent duplicate discounts.
- Hospitals that participate in the 340B program should be required to have a sliding fee scale for prescription drugs for low-income or uninsured patients.

These reforms will help put the 340B program on a more sustainable path going forward and ensure that the program is able to continue to serve true safety net facilities and the patients who depend on them.

⁶2014 OIG Report; HHS Office of the Inspector General, Memorandum Report; State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates, OEI-05-14-00430 June 2016.

⁷Analysis of Health Resources and Services Administration Audits of 340B Covered Entities, December 2016 (hereafter the FY16 HRSA Audit Results). <https://www.hrsa.gov/opa/programintegrity/auditresults/fy16results.html>

⁸The FY16 HRSA Audit Results.

⁹Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

¹⁰The 2014 OIG Report.

¹¹Manufacturer Discounts in the 340 Program Offer Benefits, but Federal Oversight Needs Improvement, GAO-11-836 (Sept. 2011) (emphasis added).

¹²Medicare Payment Advisory Commission, Report to the Congress: Overview of the 340B Drug Pricing Program (May 2015).

¹³Aaron Vanderveelde and Eleanor Blalock, 340B Program Sales Forecast: 2016-2021, December 2016, <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf>

¹⁴*Id.*

¹⁵RM Conti and PB Bach, The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities, *Health Affairs*, October 2014 vol. 33 no. 10.