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COMPLIANCE NEWSLETTER

NAVIGATING THE MAZE

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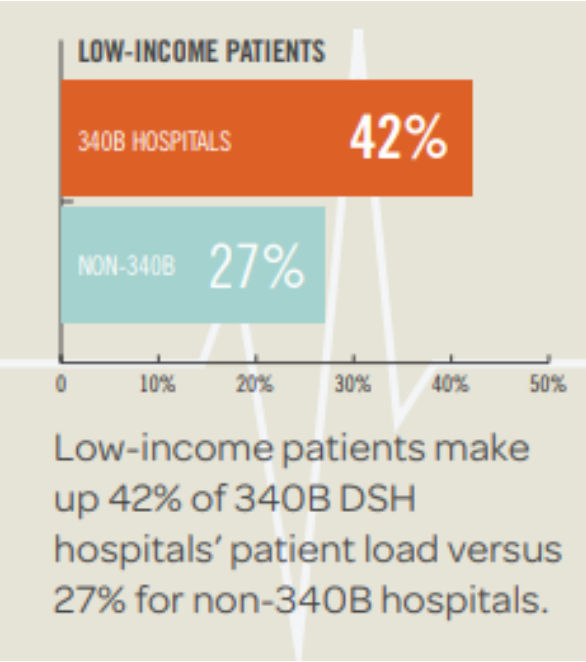
Is the 340b Program in Jeopardy?

The 340b program allows certain providers to receive manufacture discounts on covered outpatient drugs. These drugs can then be provided to eligible patients. The program was initiated in 1990 as a Medicaid rebate program for medications reimbursed by state Medicaid agencies.[1] In 1992, Section 340B of the Public Services Act was enacted to extend the discounts to covered entities, "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2] In this program, manufacturers who participate in Medicaid, agree to provide outpatient drugs to covered entities at discounted drug prices.[3]

COVERED ENTITIES

Section 340B(a)(4) of the Public Health Service Act defines covered entities as qualifying hospitals, Federal grantees from HRSA, the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs and Indian Health Service. More specifically this includes; children's hospitals, critical access hospitals, sole community hospitals, rural referral centers, hemophilia treatment centers, public and nonprofit disproportionate share hospitals who care for low income and indigent populations.[4] In order to take advantage of the program,

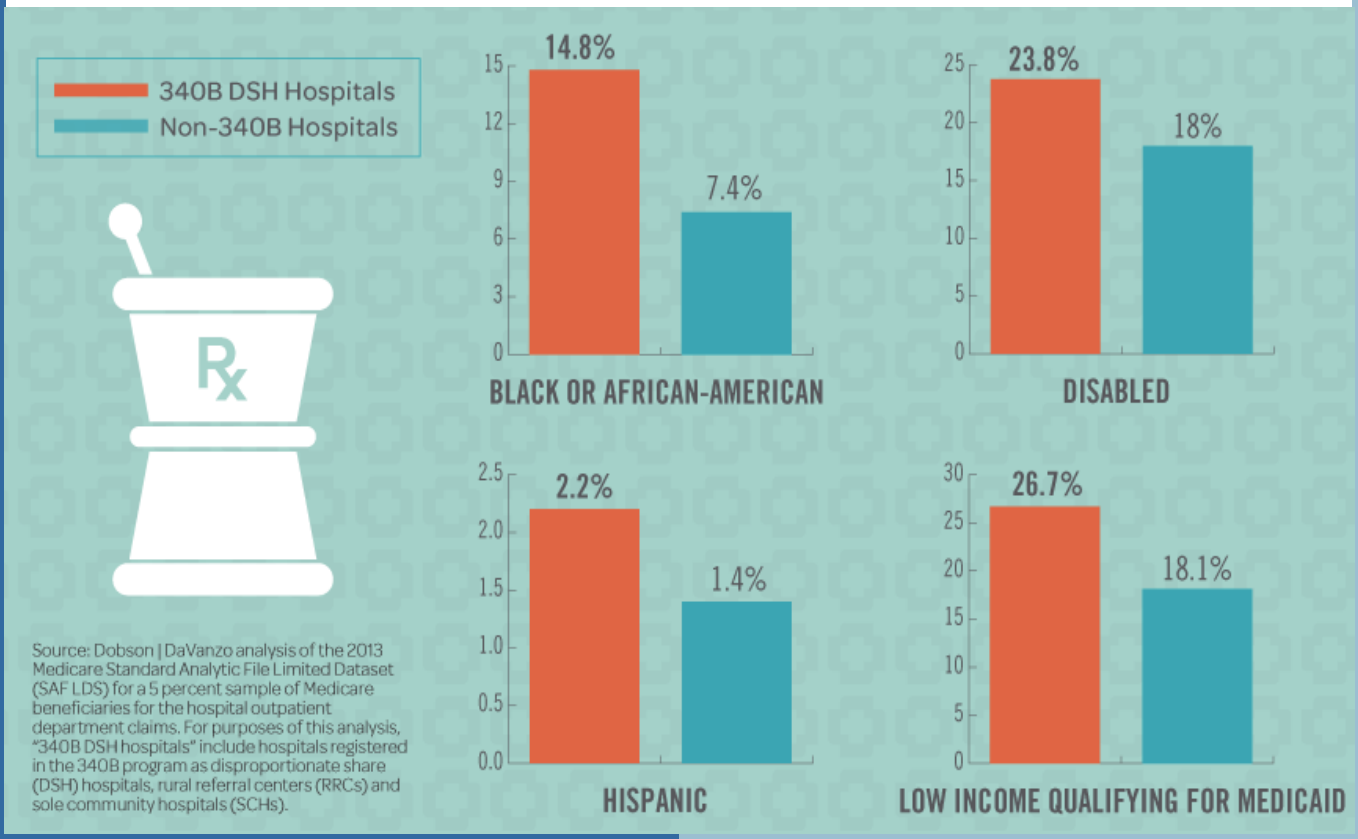


these covered entities must enroll in the program, comply with all the program requirements and must recertify their eligibility every year and notify the Office of Pharmacy Affairs anytime there is a change in their eligibility.[5] Covered entities may only sale or transfer the discounted drugs to eligible patients.

To determine if a patient is eligible, the person

1. Must have an established relationship with the covered entity such that the entity maintains records of the individuals care;
2. Must receive care from a professional employed by the covered entity or under contract or other arrangement (e.g., referral for consultation) with the covered entity such that responsibility for the care remains with the covered entity; and
3. With respect to grantees and sub-grantees, must receive health services from the covered entity that are consistent with the services for which grant funding has been provided to the entity.[6]

An individual is not a patient of the covered entity if the only health care service received by the individual from the entity is the dispensing of a drug for subsequent self-administration or administration in a home setting.[7]



Program Status

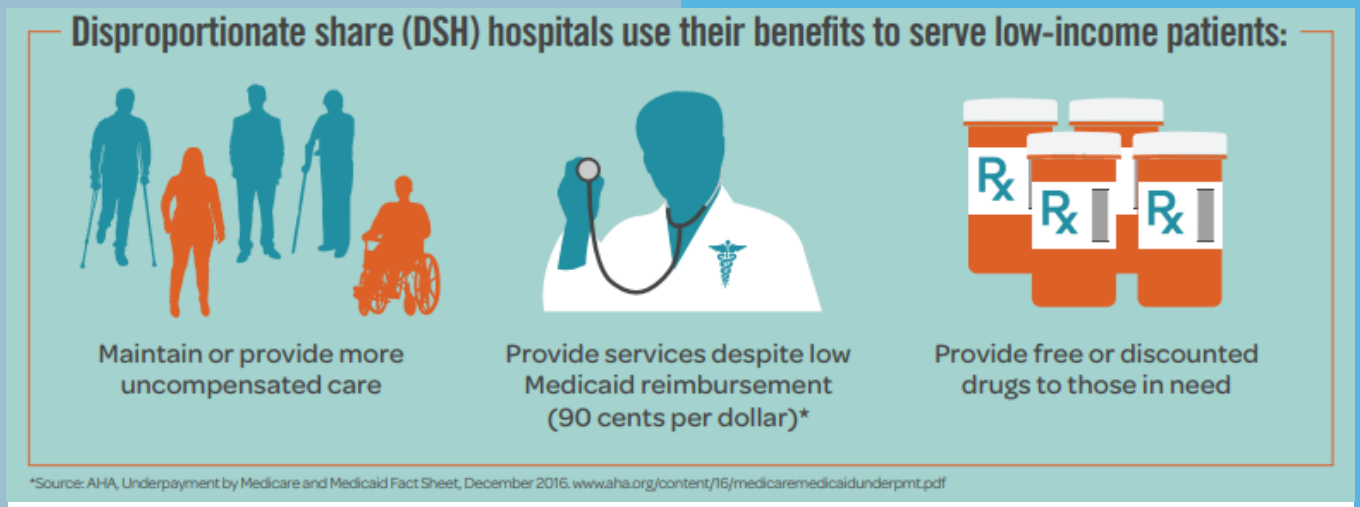
The 340B program has grown tremendously in the past 25 years. According to Sarah Tribble from Kaiser Health News, a 2015 Government Accountability Office indicates that approximately 40 percent of hospitals in the U.S. buy drugs through the 340B program. In 2017, CMS made cuts to the 2018 Medicare payments to hospitals (with a few exceptions) enrolled in the 340B program by 28 percent, a move that led several agencies to file lawsuits alleging that CMS did not have the authority to cut payments. Controversy has grown between physicians who fear that cuts to the program could keep patients from receiving lifesaving care and drug makers who argue that the program has grown past its original intent and hospitals are pocketing the discounts to help their bottom line instead of helping indigent patients.[8]

2019 Proposals

Covered entities are facing another round of changes based on CMS's proposed changes to the hospital outpatient prospective payment rules beginning in 2019. According to the American Hospital Association, CMS proposes to extend the payment rate for drugs acquired under the 340B program to those 340B drugs that furnished to non-grandfathered provider-based-departments. The proposal includes changing the payment rate for separately payable biosimilar drugs based on their average sale price instead of the reference products average sale price. Instead of wholesale acquisition cost plus 6% for new drugs and biological products, the proposal calls for that rate to decrease to wholesale acquisition cost plus 3%.

Future of the 340B Program

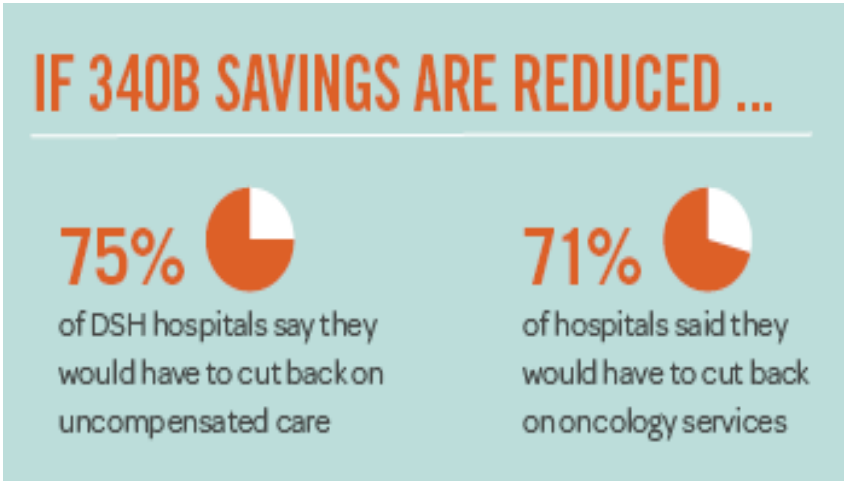
Brooke Wright, in an article for Health Industries Research Company, outlines the arguments from both the advocates and critics of the program. Advocates argue that the program allows safety-net providers to offer better care and are able to apply the profits received from



the 340B drugs to preventative and other unreimbursed care received by the uninsured, Medicare and Medicaid patients.[9] Critics however, argue that without a system in place to track how the savings are used, there is no way to ensure that the funds are used to improve care.

In 2014, HRSA Administrator, Mary Wakefield issued a memorandum detailing a study of covered entities' contract pharmacy arrangements and their oversight of those arrangements to prevent the diversion of 340B drugs to ineligible patients and the receipt of duplicate discounts through Medicaid. The results demonstrated that most covered entities are not conducting the recommended oversight activities. Results like these have led to increased federal oversight. Bills have been introduced in both the House and Senate to reign in the program to decrease the number of providers, and hold providers accountable for providing care to the uninsured.[10]

There is certainly a move towards transparency but current legislative proposals do not equally impose reporting requirements for both hospitals and manufacturers. The Office of Inspector General and the General Accounting Office are both critical of the fact that there are no requirements that hospital outpatients who are given 340B drugs receive them for less than the 340B purchase price or for free.[11] The future of the program is uncertain given the presence of court cases, which may establish precedence and ongoing legislative actions.



Infographics courtesy of www.340bhealth.org 340B HEALTH info@340bhealth.org
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[1]Overview of the 340B Drug Pricing Program. https://www.340bhealth.org/340b-resources/340b-program/overview/

[2] indem

[3] HRSA:340B Drug Pricing Program. https://www.hrsa.gov/opa/index.html

[4] AHA Fact Sheet: The 340B Drug Pricing Program. https://www.aha.org/2018-03-29-fact-sheet-340b-drug-pricing-program

[5] HRSA: 340B Eligibility https://www.hrsa.gov/opa/eligibility-and-registration/index.html

[6] Ibid #1

[7] Ibid #1

[8] Tribble, J.T. (2017, November 28). Heated and Deep-Pocketed Battle Erupts over 340B Drug Discount Program.

[9] Wright, B. (2018, March, 14). The History and Future of the 340B Drug Discount Program

[10] Indem

[11] The Uncertain State of the 340B Program: Where are we Now? *National Law Review* https://www.natlawreview.com/article/uncertain-state-340b-program-where-are-we-now

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