


# LEFT BEHIND:

## An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program

## EXECUTIVE SUMMARY

For this report, the Alliance for Integrity and Reform of 340B (AIR340B) engaged Avalere Health to update their analysis from previous AIR340B reports on charity care levels at 340B disproportionate share hospitals (DSH).<sup>1</sup> Based on that data analysis, this report continues to raise questions regarding whether the qualification criteria for DSH hospitals are appropriately aligned with Congress' goal of supporting access to prescription drugs for uninsured or vulnerable populations.

Three years after initially analyzing the amount of charity care provided by 340B hospitals, the analysis has been



**Nearly one-third (29%) of 340B DSH hospitals provide charity care that represents less than 1% of their total patient costs.**

Source: Avalere Health analysis of FY 2017 Medicare cost report data

updated to include 2017 data. The 340B program has grown from \$6.9 billion in discounted sales in 2012 to \$24.3 billion in discounted sales in 2017—an over 250 percent increase. Growing evidence has found that despite the exponential growth of the 340B program, hospitals are not reinvesting the savings into increased care for vulnerable patient populations. In fact, this analysis confirms the average amount of charity care provided by 340B hospitals has declined since 2011, with nearly two out of three 340B hospitals consistently providing below average rates of charity care.

Under the 340B program, pharmaceutical manufacturers provide steep discounts on outpatient prescription drugs to certain qualifying facilities; however, the program guidance currently does not require those facilities to extend the discounts to patients.<sup>2</sup> There is an important distinction between different types of 340B facilities in this regard. 340B eligibility is open to certain clinics that receive federal grants, known as grantees, and certain types of hospitals. Grantees—such as federally qualified health centers and hemophilia treatment centers—typically must demonstrate

that they serve a specified vulnerable population, typically on an income-based, sliding-fee scale. Grantees are also largely required to reinvest any additional resources into services for those populations. In contrast, hospitals are not subject to this requirement and typically do not have charters requiring that revenue derived from the 340B program be reinvested in care for the uninsured or otherwise vulnerable.

An analysis of charity care data reported by hospitals in fiscal year (FY) 2017 Medicare cost reports reveal many of the hospitals enrolled in the 340B program are continuing to fall short of Congress' expectation when it comes to providing care to vulnerable patients. While there are some 340B hospitals that provide considerable charity care, for nearly one-third (29 percent) of 340B DSH hospitals, charity care represents less than one percent of total patient costs.

The new data also shows that the charity care burden for all short-term acute care hospitals (STACHs) (340B and non-340B) has remained low, despite the program's ongoing significant growth. In 2011, charity care represented 3.3 percent of total patient costs at these hospitals, on average. That percentage dropped to 2.7 percent in 2017.

Further, data from the FY 2017 cost reports find that a small number of 340B DSH hospitals account for the bulk of overall charity care, despite the fact that the clear majority of 340B sales to hospitals are to DSH hospitals.<sup>3</sup>

The 340B program has grown dramatically since its inception in 1992, and it is clear that the program lacks an adequate structure for accountability and transparency for participating hospitals. Despite continuing widespread support for the program's original intent, 340B is out of sync with its mission. Changes in how the program operates via broad guidance and a lack of sufficient oversight—combined with concerns about whether and how it is fulfilling its mission, major shifts in the overall health system, and evidence that the program may be leading to market distortions—combined with the program's continuing rapid growth—all raise questions about the 340B program's design and sustainability.<sup>4</sup> Based on these recurring questions and the results of this analysis of charity care, it is critical that Congress consider revising eligibility criteria for 340B hospitals to ensure that it aligns with the program's original intent—which is to offer targeted assistance to providers that serve safety-net populations.

## BACKGROUND

Congress created the 340B program in 1992 to reinstate the deep discounts that manufacturers had voluntarily provided to many safety-net facilities before the 1990 enactment of the Medicaid drug rebate statute.<sup>5</sup> This 1990 statute established a nationwide drug rebate for state Medicaid programs, and the rebate formula took into account the “best price” a manufacturer gave to any customer. Congress failed to exempt manufacturers’ voluntary discounts to safety-net providers from Medicaid’s “best price,” which inadvertently penalized the manufacturers that provided such discounts. Later in 1992, Congress responded by amending the Medicaid rebate statute to exempt these discounts from “best price” and creating the 340B drug discount program, which established discounted prices for eligible safety-net providers based on a specific formula.<sup>6</sup> These providers, also known as “covered entities,” include select federal grantees and certain hospitals.<sup>7</sup>

### HOSPITAL ELIGIBILITY FOR THE 340B PROGRAM

Eligibility for the 340B program is defined in the 340B statute. Non-hospital 340B entities typically are eligible if they receive one of ten types of federal

grants that provide resources for health care services for low-income, uninsured individuals.<sup>8</sup> Grant-approval processes typically require clinics to demonstrate that they provide services to certain specified vulnerable populations and that the entities reinvest resources into services for those populations.<sup>9</sup> Any funds that these entities derive from 340B are therefore reinvested into services for the populations these grantees serve.

The current eligibility criteria have allowed many hospitals to qualify for 340B discounts even though they may not serve significant numbers of vulnerable or uninsured patients and may not provide significant amounts of charity care.

In contrast, hospitals are not typically required to demonstrate that they provide services to uninsured patients or reinvest resources into services on their behalf under the 340B program. Instead, hospitals qualify for the 340B program based, in part, on their disproportionate share hospital (DSH) percentage,<sup>10</sup> a measure relating to the number of Medicaid and low-income

Medicare patients treated in a hospital's inpatient unit. As demonstrated by the data summarized in this paper, a high disproportionate share adjustment percentage does not automatically correlate with high levels of charity care. In fact, declines in charity care due to uninsured patients becoming eligible for Medicaid through the eligibility expansions under the Patient Protection and Affordable Care Act (ACA) have made more hospitals eligible for 340B as their DSH percentages increase.<sup>11</sup>

When the 340B program began, Congress anticipated that only a small number of hospitals would qualify. Legislative history explains that certain private nonprofit hospitals that served many "low-income individuals who are not eligible for Medicaid or Medicare" (and met additional requirements) could participate in the 340B program; however, a private nonprofit hospital that had "a minor contract to provide indigent care which represents an insignificant portion of its operating revenues" could not.<sup>12</sup>

The DSH metric was a proxy intended to target hospitals serving a disproportionate share of needy patients. However, as discussed below, developments that could not have been anticipated by the law's drafters, combined with the lack of sufficient guidance from the Department

of Health and Human Services (HHS), have shown the program's current hospital eligibility criteria may not be the most appropriate metric. These eligibility criteria have allowed many hospitals to qualify for 340B discounts, even when they do not serve significant proportions of the populations the law intended to help.

## THE DSH METRIC

The DSH percentage used for the purposes of determining 340B eligibility was designed for use within Medicare, and determines whether hospitals receive enhanced Medicare payments.<sup>13</sup> The DSH percentage is calculated based on: (1) the share of low-income patients insured by Medicare (*i.e.*, patients entitled to both Medicare Part A and Supplemental Security Income benefits) compared to the total Medicare population treated by the hospital, plus (2) the share of Medicaid patients without Medicare compared to the total patients treated by the hospital.<sup>14</sup> The DSH percentage, therefore, is a reflection of care provided to low-income *insured* patients and does *not* reflect the share of uninsured patients or the amount of charity care provided at a hospital. Additionally, the DSH metric is based solely on *inpatient* utilization, which makes it a poor proxy for a program such as 340B that is limited to outpatient drugs.

Another criterion is that all 340B-eligible hospitals must be: (1) owned or operated by a unit of state or local government; (2) a public or private nonprofit hospital formally granted governmental powers by a state or local government; or (3) a private nonprofit hospital contracted with a state or local government to provide health care services to low-income individuals who are not Medicare or Medicaid eligible.

Importantly, under current Health Resources and Services Administration (HRSA) guidance, private nonprofit hospitals that qualify for 340B through such formally granted governmental powers or through contracts with state or local governments for health care services targeted at specific populations may use 340B discounted drugs for a 340B patient receiving any outpatient service at the hospital, not merely those services related to such governments, powers, or state and local contracts. By contrast, non-hospital grantees that qualify for the 340B program have grant requirements that require funds be used on the needy or vulnerable populations they serve.

It is therefore possible that some hospitals may have interpreted this criterion to allow a hospital to qualify for 340B based on a contract that is very limited in scope and provides

nominal care to a small number of individuals, such as providing limited health screenings for a school district. Such a contract also could be completely unrelated to providing outpatient drugs.<sup>15</sup>

## THE ROLE HOSPITAL ELIGIBILITY PLAYS IN PROGRAM GROWTH

The Medicare Payment Advisory Commission (MedPAC) noted that the number of hospitals participating in 340B increased by over 57 percent in just five years (583 hospitals in 2005 and 1,365 hospitals in 2010).<sup>16</sup> By 2018, the number of participating hospitals further increased to 2,537.<sup>17</sup> That translates to approximately 53 percent of all Medicare acute care hospitals participating in the 340B program today.<sup>18</sup>

### *Post-1992 Medicaid Expansions*

One reason for this growth is likely an increase in the share of the population covered by Medicaid. Higher Medicaid enrollment contributes to a larger share of hospitals qualifying for 340B based on their DSH percentage—because the DSH percentage used for 340B eligibility measures hospital use by Medicaid and low-income Medicare beneficiaries, not by uninsured persons. In 1996 (the earliest year for which consistent data are available), 13 percent of the population had Medicaid coverage at some point

during the year. By 2017, that percentage had increased to about 18 percent.<sup>19</sup> That percentage likely has risen further since the Medicaid expansion in the ACA began in many states in 2014. According to the Medicaid and CHIP Payment and Access Commission (MACPAC), Medicaid enrollment has continually increased, reaching 73.8 million people in 2017, up from 54.5 million in 2010.<sup>20</sup> Analysis by the U.S. Government Accountability Office (GAO) in 2011 noted state Medicaid expansions preceding the ACA may have contributed to the rise in hospitals participating in 340B.<sup>21</sup> Thus, the expanded Medicaid eligibility included in the ACA has likely further contributed to the number of hospitals eligible for 340B based on their DSH percentage.

### **RELATIONSHIP BETWEEN DSH AND HOSPITAL SHARE OF HIGH-COST PATIENTS AND CHARITY CARE**

Since 1992, the DSH metric itself has been the subject of careful analyses that have shed light on what it does and does not measure. These analyses call into question the DSH metric's use in helping determine 340B hospital eligibility.

As noted previously, the DSH metric was not specifically designed for 340B eligibility purposes and does not measure the percentage of uninsured patients a

hospital serves or the level of charity or uncompensated care it provides. MedPAC has analyzed the DSH adjustment percentage to determine whether hospitals with higher DSH payments had patients who were costlier to treat and/or were providing higher levels of uncompensated care. As early as 2007, MedPAC reported that it had found little correlation between hospitals' DSH adjustment percentages and whether they had either high-cost patients or a high percentage of uninsured patients.<sup>22</sup> In 2018, a GAO analysis of hospitals participating and not participating in the 340B program found that nearly a quarter of the 340B hospitals in the study were among those that provided the lowest amounts of charity care.<sup>23</sup>

The 340B program has transformed from a well-intentioned program targeted at true safety-net providers in 1992 to one including an unanticipated large number of hospitals today. Meanwhile, the environment in which nonprofit hospitals operate has also evolved substantially. As highlighted in a 2017 National Academy of Sciences report, "in the years since [340B's] inception, the structure of hospitals in the United States has dramatically changed, with nonprofit hospitals increasingly displaying characteristics of for-profit hospitals."<sup>24</sup>

That trend, combined with the DSH metric's inability to reflect the amount of uncompensated care hospitals deliver, raises questions about whether the program is being appropriately targeted to only those facilities that spend significant resources providing care to

disadvantaged populations. Notably, in the ACA, Congress set a precedent for revisiting the use of DSH as a policy metric for aiding hospitals that provide uncompensated care through its decision to reduce DSH payments to hospitals due to expected declines in the uninsured.<sup>25</sup>

## HOSPITAL CHARITY CARE

The charity care data analyzed in this paper reflects the cost of providing free or discounted care to low-income individuals who qualify for a hospital's charity care program. The analysis focuses solely on charity care and not the broader category of uncompensated care, which includes bad debt from non-indigent and insured patient accounts. This paper's primary focus on charity care is consistent, therefore, with the 340B program's intent, which is to sustain care for the vulnerable or uninsured.

Many hospitals provide charity care to patients who meet certain income and asset requirements. The specific nature of charity care can vary by hospital, as individual hospitals develop their own policies regarding the criteria individuals must meet to qualify. The American

Hospital Association's (AHA) voluntary policies and guidelines for hospitals suggest that care should be provided free of charge to uninsured patients with incomes below 100 percent of the Federal Poverty Level (FPL) and at reduced rates for uninsured patients with incomes between 100 percent and 200 percent of the FPL.<sup>26</sup> The ACA placed some limits on how much nonprofit tax-exempt hospitals can charge qualifying individuals; these limits are enforced through Internal Revenue Service (IRS) regulations.<sup>27</sup>

These rules require that hospitals have publicly available charity care policies, and also prohibit hospitals from charging inflated prices to those who qualify for these programs. However, neither the IRS regulations nor the 340B program have any requirements on who must be eligible for free or reduced-price care.



Even if the IRS rules are fully enforced, hospitals will still be able to set their own eligibility standards for charity care programs. Given this flexibility, the IRS guidelines do not appear sufficient to ensure that the nonprofit hospitals that qualify for 340B fulfill congressional

expectations for the safety-net program. This paper analyzes whether current 340B hospital eligibility criteria appropriately target hospitals that provide relatively high levels of free or reduced-price care to vulnerable or uninsured patients.

## METHODOLOGY:

The analysis presented in this paper is based on data obtained from FY 2017 Medicare cost reports analyzed by Avalere Health LLC (Avalere) to determine the share of total hospital costs attributable to charity care, as reported by the hospital (see Appendix A for more information on charity care and data methods).

The paper leverages data from the Medicare cost reports, which are filed annually by hospitals and were redesigned in 2010 to more accurately capture the cost of the charity care that hospitals provide. This Medicare cost report data on charity care was also used by the GAO for a June 2015 report on 340B, in which the GAO stated it “confirmed with CMS that the agency did not have any concerns about our use of the data.” The GAO also stated that it performed “data reliability assessment and concluded that the cost report data were sufficiently reliable.”

The analysis in this paper excludes Critical Access Hospitals because those rural hospitals have very different cost structures than other hospitals and qualify for 340B based on different metrics (see Appendix B for more information on Critical Access Hospitals). Additionally, Freestanding Cancer Hospitals, Rural Referral Centers, Children’s Hospitals, and Sole Community Hospitals were excluded from this analysis so that the paper could focus on hospitals entitled to 340B discounts due to meeting the DSH requirement.

# RESULTS OF CHARITY CARE ANALYSIS

The data analyzed for this paper show that the 340B program includes many hospitals that provide a minimal amount of charity care. In fact, for nearly one-third (29 percent) of the 340B hospitals studied, charity care represents less than one percent of hospital patient costs (Figure 1). These hospitals provide a level of charity care that is far below the 2.7 percent

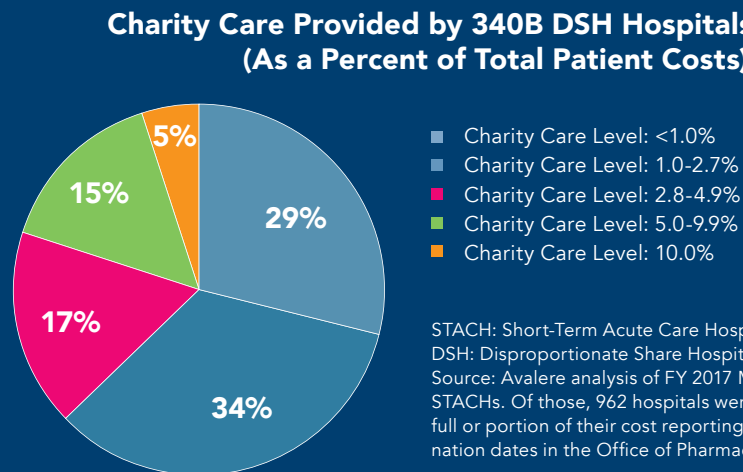
national average for all STACHs, regardless of 340B status. An additional 34 percent of the 340B hospitals studied provide charity care that represents between one percent and 2.7 percent of patient costs. In total, nearly two thirds (63 percent) of 340B hospitals provide less charity care than the national average for *all* hospitals, including for-profit hospitals.

**In total, 63% of 340B hospitals provide less charity care than the national average for all short-term acute care hospitals, including for-profit hospitals.**

Source: Avalere Health analysis of FY 2017 Medicare cost report data

FIGURE 1

## 63% of 340B DSH Hospitals Have Charity Care Rates Below the National Average for All STACHs in FY 2017 (2.7%)



STACH: Short-Term Acute Care Hospital  
 DSH: Disproportionate Share Hospital  
 Source: Avalere analysis of FY 2017 Medicare cost reports submitted by 3,449 STACHs. Of those, 962 hospitals were participating in 340B as a DSH entity for a full or portion of their cost reporting period based on the enrollment and termination dates in the Office of Pharmacy Affairs (OPA) 340B Database.

Charity care, as well as uncompensated care, has declined substantially despite the exponential growth in sales through the 340B program. Table 1 shows that for all hospitals (340B and non-340B), charity care costs as a percent of all patient costs ranged from 3.3 percent to 2.2 percent between 2011 and 2017, respectively. Nearly two-thirds of all 340B hospitals provide a below average level of charity care. Despite the growth of 340B from 2012 through 2017, this number has remained relatively steady.

Moreover, although hospitals represent around 87 percent of total 340B sales,<sup>28</sup> data reported by the AHA shows the value of all uncompensated care provided by hospitals—including both bad debt and charity care—has continued to decline: In 2017, uncompensated care accounted for, on average, four percent of expenses, down from six percent in 2012.<sup>29</sup> This translates to a reduction of nearly \$8 billion (or 17 percent) in total hospital spending on uncompensated care costs.<sup>30</sup>

TABLE 1

	2011	2012	2013	2014	2015	2016	2017
<b>National Average Charity Care Level</b>	3.3%	2.9%	2.8%	2.2%	2.5%	2.4%	2.7%
<b>% of 340B Hospitals Below National Average</b>	69.0%	61.9%	59.5%	64.4%	63%	61%	63%
<b>Sales at the 340B Price<sup>31</sup></b>		\$6.9B	\$7.2B	\$9.0B	\$12.0B	\$16.2B	\$19.3B

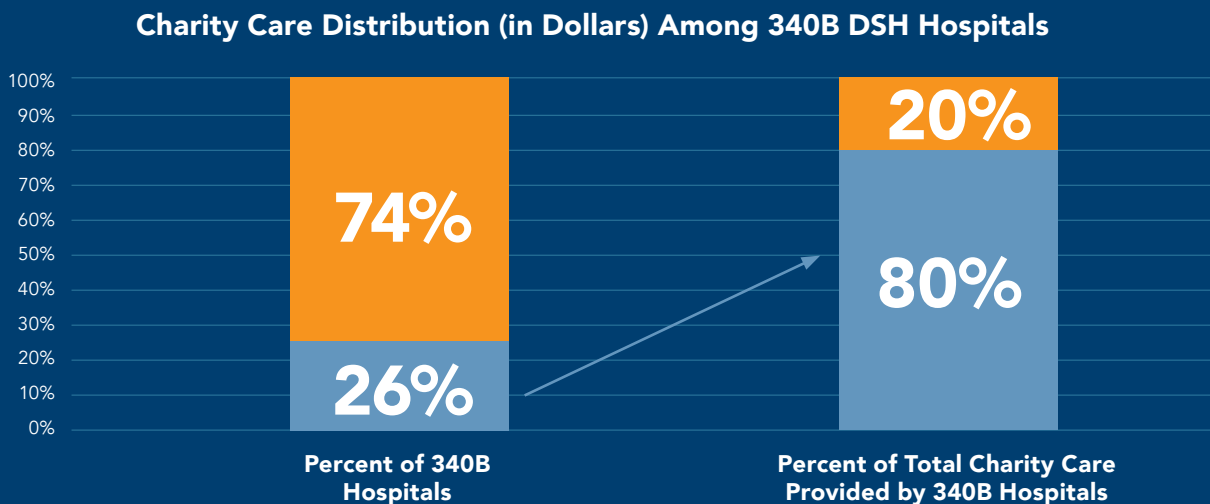


Analysis of the Medicare cost report data found in 2017, a minority of 340B hospitals provided the vast majority of all charity care provided by hospitals that receive 340B discounts: specifically, only about one-quarter (26 percent) of hospitals provide 80 percent of the total charity care provided by all 340B

DSH hospitals (Figure 2). This finding is consistent with an IRS study that found just nine percent of surveyed nonprofit hospitals were responsible for 60 percent of the community benefit expenditures provided by all of the nonprofit hospitals in the survey.<sup>32</sup>

FIGURE 2

## 26% of Hospitals Account for 80% of Charity Care Provided by All 340B DSH Hospitals in FY 2017



Source: Avalere analysis of FY 2017 Medicare cost reports submitted by 962 hospitals that were participating in 340B as a DSH entity for a full or portion of their cost reporting period based on the enrollment and termination dates in the Office of Pharmacy Affairs (OPA) 340B Database.

# ADDITIONAL SOURCES OF GOVERNMENT FUNDING FOR HOSPITALS

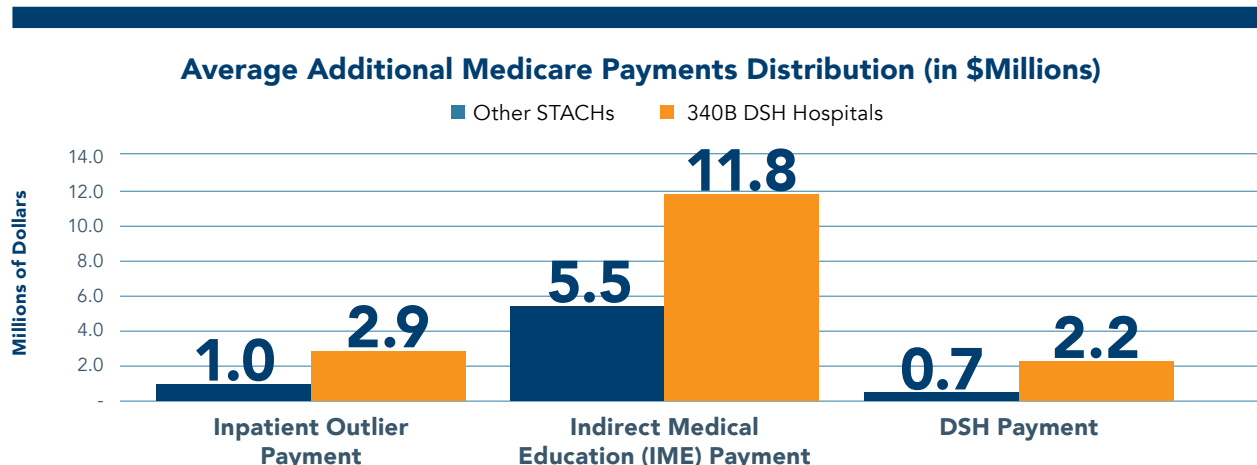
Despite evidence that some hospitals provide low rates of charity care, hospitals currently receive government funding from numerous sources to compensate them for the cost of providing charity care and to help them absorb the cost of bad debt. Additionally, all hospitals that qualify for 340B are not-for-profit, meaning they benefit from being exempt from federal, state, and local taxes. The tax benefits for nonprofit hospitals were most recently valued at \$24.6 billion.<sup>33</sup> However, a 2018 study in *Inquiry, the Journal of Health Care Organization, Provision, and Financing*, a peer-reviewed journal, found “many nonprofits [benefit] greatly

from [the tax exemption] while providing relatively few community benefits.”<sup>34</sup>

Some sources of government funding are reported in the Medicare cost reports. The analysis of FY 2017 data found the total value of inpatient outlier payments, indirect medical education (IME) payments, and Medicare DSH payments totaled \$16.9 billion for 340B DSH hospitals in 2017. As compared to non-340B STACHs, 340B DSH hospitals receive payments that are more than twice as large (Figure 3) on average. Additionally, 340B DSH hospitals account for 28 percent of all STACHs yet receive nearly 60 percent more payments from Medicare.

FIGURE 3

## The Average Additional Medicare Payment for a 340B DSH Hospital is More Than Double Any Other STACH in FY 2017



Source: Avalere analysis of FY 2017 Medicare cost reports submitted by 3,4449 STACHs. Of those, 962 hospitals were participating in 340B as a DSH entity for a full or portion of their cost reporting period based on the enrollment and termination dates in the Office of Pharmacy Affairs (OPA) 340B Database.

## CONCLUSION

The 340B program was intended to support access to outpatient drugs for uninsured or vulnerable patients through safety-net facilities. The program's design allows eligible providers to benefit from steeply discounted prices in return for their support of uninsured or vulnerable patient populations. The 340B program has grown from \$6.9 billion in sales at the discounted price in 2012 to \$24.3 billion in sales at the discounted price in 2018. Yet, this is the third iteration of this report spanning more than five years and the findings remain the same: 340B hospitals, despite generating more and more revenue through the 340B program, continue to have declining charity care rates, with most 340B hospitals providing less charity care than the average hospital. To promote a well-functioning 340B program designed to support access for needy patients and underpinned by sound policy, Congress should reconsider the eligibility criteria for hospitals.

# APPENDIX A: ADDITIONAL INFORMATION ON CHARITY CARE

## CHARITY CARE BACKGROUND

Acute-care hospitals will often provide charity care to patients who meet certain income requirements. The specific nature of charity care can vary by hospital. The ACA added section 501(r) to the Internal Revenue Code, which requires nonprofit hospitals to meet four key requirements to qualify for federal tax exemption. These four requirements include:

- Establish written financial assistance and emergency medical care policies;
- Limit the amounts charged for medically necessary care to individuals eligible for assistance under the hospital's financial assistance policy;
- Make reasonable efforts to determine whether an individual is eligible for assistance before engaging in extraordinary collection actions against the individual; and
- Conduct a community health needs assessment and adopt an implementation strategy at least once every three years.<sup>35</sup>

Each individual hospital develops its own policy regarding the specific financial criteria that must be met for an individual treated in the hospital to qualify for charity care. The AHA has developed a set of policies and guidelines hospitals may follow that suggests care should be provided free of charge to uninsured patients with incomes below 100 percent of the FPL and at reduced rates for uninsured patients with incomes between 100 percent and 200 percent of the FPL.<sup>36</sup>

## CHARITY CARE DATA

The charity care data analyzed in this report is taken from FY 2012-2017 Medicare cost reports. While the IRS 990 Schedule H forms also include data on charity care, the Medicare cost report forms were used because they include all hospitals, while the IRS forms are only available for nonprofit hospitals. Specifically, this analysis used the CMS-2552-10 form, line 23 from worksheet S-10. This line represents the estimated cost of care that was provided to patients approved for charity care. To calculate this amount,

hospitals first enter the total charges for care provided to patients approved for charity care on line 20 of the same worksheet. On that line of the form hospitals are asked to:

“Enter the total initial payment obligation of patients who are given a full or partial discount based on the hospital’s charity care criteria (measured at full charges), for care delivered during this cost reporting period for the entire facility. For uninsured patients, including patients with coverage from an entity that does not have a contractual relationship with the provider (column 1), this is the patient’s total charges. For patients covered by a public program or private insurer with which the provider has a contractual relationship (column 2), these are the deductible and coinsurance payments required by the payer. Include charity care for all services except physician and other professional services. Do not include charges for either uninsured patients given discounts without meeting the hospital’s charity care criteria or patients given courtesy discounts. Charges for non-covered services provided to patients eligible for Medicaid or other indigent care program (including charges for days exceeding a length of stay limit) can be included, if such inclusion is specified in the hospital’s charity care policy and the patient meets the hospital’s charity care criteria.”

After entering this amount, hospitals are then instructed to multiply this amount by the hospital-wide cost-to-charge ratio. This is the same ratio the Medicare program uses to convert Medicare charges into estimated costs when determining the payment rates under the Medicare Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS).

Finally, hospitals are instructed to subtract any payment they have received from patients who were approved for partial charity care services. This final step is reflected in the amount listed on line 23 of the worksheet, which is the amount used in this report.

Table 1A provides an overview of the number and type of hospitals that were included in the charity care analysis.



TABLE 1A: NUMBER OF HOSPITALS INCLUDED IN THE ANALYSIS

TYPE OF HOSPITAL	340B DSH Hospitals in analysis	Total STACHs (340B and non-340B) in analysis
<b>Short-Term Acute Care Hospitals</b>	<b>962</b>	<b>3,449</b>
Nonprofit	719	2,026
Government	231	520
Proprietary	12	903
Urban	656	2,240
Rural	210	432

1. AIR 340B, "Unfulfilled Expectations: An analysis of charity care provided by 340B hospitals," Spring 2014.
2. See 42 U.S.C. § 256b (the "340B statute").
3. Data from Apexus Update 2015 – 340B Coalition Winter Meeting.
4. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," September 2011; A. Alexander and K. Garloch, "Hospitals probed on use of drug discounts," *Charlotte Observer*, October 3, 2012, <http://www.charlotteobserver.com/2012/09/29/3566421/hospitals-probed-on-use-of-drug.html>; R. Conti and P. Bach, "Cost Consequences of the 340B Drug Discount Program," *JAMA* 2013; 309(19): 1995-1996; GAO, "Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals," June 2015.
5. See, e.g., "Hearing Before the Committee on Labor and Human Resources," U.S. Senate, October 16, 1991; "Statement of the Pharmaceutical Manufacturers Association (PMA)" at 54 ("We understand that the introduction of the bill is a reaction to the price increases to the covered entities caused by the best-price provisions of the Medicaid Rebate Program. That could be addressed by adopting the same approach that is contained in the Department of Veterans Affairs Appropriation Act; namely, to exempt the prices to the covered entities from the Medicaid rebate best price calculations.")
6. See Veterans Health Care Act of 1992, Pub. L. 102-585, § 601 (exempting prices charged to 340B covered entities from the Medicaid "best price" calculation) and § 602 (creating the 340B program).
7. See 42 U.S.C. § 256b(a)(4)(e).
8. See 42 U.S.C. § 256b(a)(4)(A)-(K); HRSA, "Eligibility & Registration," <http://www.hrsa.gov/opa/eligibilityandregistration/index.html> (listing the types of clinics that qualify for the 340B program with links to websites providing an overview of the types of grants that those entities must qualify for in order to enroll in the 340B program).
9. See, e.g., HRSA, "Black Lung Clinics Program," <http://www.hrsa.gov/gethealthcare/conditions/blacklung> ("[Black Lung Clinic] [s]ervices are available to patients and their families regardless of their ability to pay."); HRSA, "Federally Qualified Health Centers," <http://www.hrsa.gov/opa/eligibilityandregistration/healthcenters/fqhc/index.html> ("[Federally Qualified Health Centers] must meet a stringent set of requirements, including providing care on a sliding fee scale based on ability to pay and operating under a governing board that includes patients.")
10. See 42 U.S.C. § 256b(a)(4)(L)-(O).
11. A. Vandervelde, "Growth of the 340b Program: Past Trends, Future Projections," Berkeley Research Group, December 2014.
12. U.S. House of Representatives Report accompanying H.R. Rep. 102-384 (II) (1992).
13. See 42 U.S.C. § 1395ww(d)(5)(F).
14. See Department of Health and Human Services, "Medicare Disproportionate Share Hospital," ICN 006741 January 2013, <http://www.hrsa.gov/opa/eligibilityandregistration/hospitals/disproportionatesharehospitals/index.html>.
15. GAO, "Manufacturer Discounts in the 340 Program Offer Benefits, but Federal Oversight Needs Improvement," GAO-11-836, September 2011.
16. MedPAC, "Report to Congress: Overview of the 340B Drug Pricing Program," May 2015.
17. Government Accountability Office, Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program, June 2018.
18. Berkeley Research Group analysis, October 2019.
19. AIR 340B Analysis of MEPS net data for entire U.S. population. Data accessed February 25, 2016. and MACPAC. "MACStats: Medicaid and CHIP Data Book." December 2018. <https://www.macpac.gov/wp-content/uploads/2015/01/EXHIBIT-1.-Medicaid-and-CHIP-Enrollment-as-a-Percentage-of-the-U.S.-Population-2017.pdf>.
20. Berkeley Research Group analysis of the Health Resources and Services Administration's 340B Office of Pharmacy Affairs Information System, October 2019.
21. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," September 23, 2011.
22. Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Policy," March 2007.

23. Government Accountability Office, "Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program," June 2018.
24. National Academy of Sciences, "Making Medicines Affordable: A National Imperative (2018)," November 2017.
25. See Patient Protection and Affordable Care Act, Disproportionate Share Hospital, Pub. L. No. 111-148, § 2551 (2011).
26. American Hospital Association, "AHA Policies & Guidelines on Billing, Collections, Tax-Exempt Status, and Community Health," <http://www.aha.org/content/00-10/07nov-billingpolicyguidelines.pdf>.
27. Patient Protection and Affordable Care Act, Disproportionate Share Hospital, Pub. L. No. 111-148, § 9007 (2011); Fed. Reg Vol. 79, No. 250 at 78954.
28. Chris Hatwig, Apexus Update, 340B Health Summer Conference, 2016.
29. American Hospital Association, "Uncompensated Hospital Care Fact Sheet," January 2016, <http://www.aha.org/content/16/uncompensatedcarefactsheet.pdf>
30. Drug Channels analysis of AHA data. <https://www.drugchannels.net/2019/05/exclusive-340b-program-purchases-reach.html>
31. Fein, Adam. "340B Program Purchases Reach \$24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines." Drug Channels. May 2019. <https://www.drugchannels.net/2019/05/exclusive-340b-program-purchases-reach.html>.
32. IRS, "Exempt Organizations Hospital Study Executive Summary of Final Report," February 2009.
33. Herring, et al, "Comparing the Value of Nonprofit Hospitals' Tax Exemption to Their Community Benefits," January 2018, Inquiry.
34. Herring, et al, "Comparing the Value of Nonprofit Hospitals' Tax Exemption to Their Community Benefits," January 2018, Inquiry.
35. IRS, "Request for Comments Regarding Additional Requirements for Tax-Exempt Hospitals," Notice 2010-39, <http://www.irs.gov/pub/irs-drop/n-10-39.pdf>.
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