Unfulfilled Expectations:

An analysis of charity care provided by 340B hospitals

AIRx340B

Alliance for Integrity and Reform

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EXECUTIVE SUMMARY

Twenty-two years ago, Congress created the 340B program to support access to prescription drugs for vulnerable, uninsured and indigent patient populations. The program reduced outpatient drug costs for certain safety net providers by reinstating the deep discounts manufacturers had voluntarily provided before enactment of federal Medicaid mandatory rebate legislation, which had inadvertently discouraged these discounts.

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 needy patients.[1] There is an important, emerging 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 on an income-based, sliding-fee scale, and are required to reinvest any additional resources into services for those populations. In contrast, hospitals for the most part neither have this requirement, nor charters requiring that revenue derived from the 340B program be reinvested in care for the indigent.

More than two decades into the program, this paper looks at the concept of "safety net hospitals" by examining how much charity care 340B hospitals are actually providing today, and questions whether the qualification criteria for hospitals are appropriately aligned with Congress' goal of supporting vulnerable patient access to prescription drugs.

Analysis by Avalere Health of newly available data indicates that many of the hospitals enrolled in the 340B program are not fulfilling Congress' expectations. While there are some 340B hospitals that provide considerable charity care, charity care represents 1% or less of patient costs at approximately one-quarter of 340B hospitals. For more than two-thirds of 340B hospitals, charity care as a percent of patient costs is less than the national average of 3.3% for all hospitals. That is, less than a third of 340B hospitals are providing more charity care than the average for all hospitals combined–including for-profit hospitals. Moreover, this analysis makes clear that a small number of 340B hospitals are taking the laboring oar in overall 340B charity care: approximately one-fifth of 340B hospitals provide 80% of all charity care delivered by 340B hospitals, even though these hospitals account for less than half of all 340B hospital beds.

> *"About one-quarter (24%) of 340B hospitals provide charity care that represents 1% or less of their total patient costs."*
>
> Source: Avalere analysis of 2011 Medicare Cost Report data

The 340B program has grown substantially since its beginning in 1992, and it is clear that today the program lacks an adequate structure for accountability and transparency. Despite continuing widespread support for the program's original intent, 340B is out of sync with its mission. Changes in how the program has come to operate, concerns about whether and how it is fulfilling its mission, major shifts in the overall health system, and the program's continuing rapid growth raise questions about its current design and sustainability in the form that has emerged.[2] Based on these repeated questions and this new analysis of charity care, this paper concludes that Congress should consider revising the eligibility criteria for hospitals to ensure that the eligibility criteria align with the program's original intent, which was to offer targeted assistance to providers serving safety net populations of uninsured or vulnerable patients.

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.[3] This 1990 statute established a nationwide drug rebate for state Medicaid programs with a rebate formula that took into account the "best price" a manufacturer gave to any customer. In crafting this rebate formula, Congress failed to exempt voluntary discounts to safety net providers from Medicaid "best price," which inadvertently penalized the manufacturers that provided such discounts. Two years later, Congress responded by amending the Medicaid rebate statute to exempt these discounts from "best price" and creating the 340B program, which establishes discounted prices for eligible safety net providers based on a specific formula.[4] These providers, also known as "covered entities," include select federal grantees and certain hospitals.[5]

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 10 types of federal grants that provide resources for health care services for low-income, uninsured individuals.[6] These 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.[7]

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

In contrast, hospitals are not generally 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,[8] 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.

When the 340B program began, Congress anticipated that only a small number of hospitals would qualify for 340B discount prices. The 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.[9]

The DSH metric was a proxy intended to target hospitals serving a disproportionate share of needy patients. However, developments that are discussed below, which 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, have shown the program's hospital eligibility criteria to be wholly inappropriate. These eligibility criteria have allowed many hospitals to qualify that do not serve significant proportions of the populations the law intended to help.

BACKGROUND

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.[10] 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 number of patients treated by the hospital.[11] 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 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.

Importantly, 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 all outpatient services at the hospitals, not merely those related to such powers or contracts. By contrast, non-hospital grantees that qualify for the 340B program have more limited missions that focus directly on the needy or vulnerable populations they serve.

The Health Resources and Services Administration has released a sub-regulatory clarification stating that a "hospital is 'formally granted governmental powers' when a state or local government formally delegates to the hospital a power usually exercised by the state or local government."[12] This guidance does not, however, specify the types of "governmental powers" that would meet this requirement, or the volume of care that would qualify.

There is currently no guidance regarding what a contract with a state or local government would need to obligate the hospital to provide in order for the hospital to qualify for 340B. It is 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 only nominal care to a small number of individuals, such as providing limited health screenings for a school district. Such a contract could also be completely unrelated to providing outpatient drugs.

The Role Hospital Eligibility Plays in Program Growth

As of February 2014, 2,048 hospitals participated in the 340B program,[13] accounting for about one-third (34%) of all hospitals, and more than half (62%) of all hospital outpatient drug spending in the United States.[14] Many of the factors driving this dramatic expansion were unanticipated when the 340B statute was enacted.

"We found little evidence of a relationship between the DSH payments hospitals receive and the amount of uncompensated care they provide."

Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (Washington, DC: MedPAC, March 2007)

BACKGROUND

Post-1992 Medicaid Expansions

One key 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% of the population had Medicaid coverage at some point during the year. By 2011, that percentage had increased to 18%.[15] The Government Accountability Office (GAO) has noted that state Medicaid expansions may have contributed to the rise in hospitals participating in 340B.[16] As discussed later in the paper, expanded Medicaid eligibility included in the Patient Protection and Affordable Care Act (ACA) will likely further increase 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. Congress' Medicare Payment Advisory Commission (MedPAC) has analyzed the DSH adjustment percentage to determine whether hospitals with higher DSH payments had patients who were more costly to treat, and/or whether hospitals were providing higher levels of uncompensated care. In 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.[17] In 2011, GAO noted that because the DSH adjustment percentage is not correlated with uncompensated care, questions have been raised as to whether the DSH adjustment percentage is an appropriate metric for determining 340B eligibility.[18]

Since 1992, 340B has transformed from a well-intentioned program targeted at federally funded, true public health safety net providers, to one including an unexpectedly large number of hospitals today. This growth, combined with subsequent analyses demonstrating DSH's lack of relationship to the amount of uncompensated care hospitals deliver, raises questions about whether the program is being targeted appropriately 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.[19]

HOSPITAL CHARITY CARE

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

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 voluntary policies and guidelines for hospitals suggest that care should be provided free of charge to uninsured patients with incomes below 100% of the Federal Poverty Level (FPL), and at reduced rates for uninsured patients with incomes between 100% and 200% of the FPL.[20] The ACA placed some limits on how much nonprofit tax-exempt hospitals can charge qualifying individuals,[21] but the Internal Revenue Service (IRS) has not yet issued the final regulations necessary to enforce these limits. As a practical matter, these voluntary policies and guidelines may not create the parameters necessary to ensure that 340B hospitals fulfill Congressional expectations. This paper analyzes whether 340B hospital eligibility criteria is properly tailored for hospitals that provide relatively high levels of free or reduced price care to indigent, uninsured patients.

Methodology:

The analysis presented in this paper is based on data obtained from 2011 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).

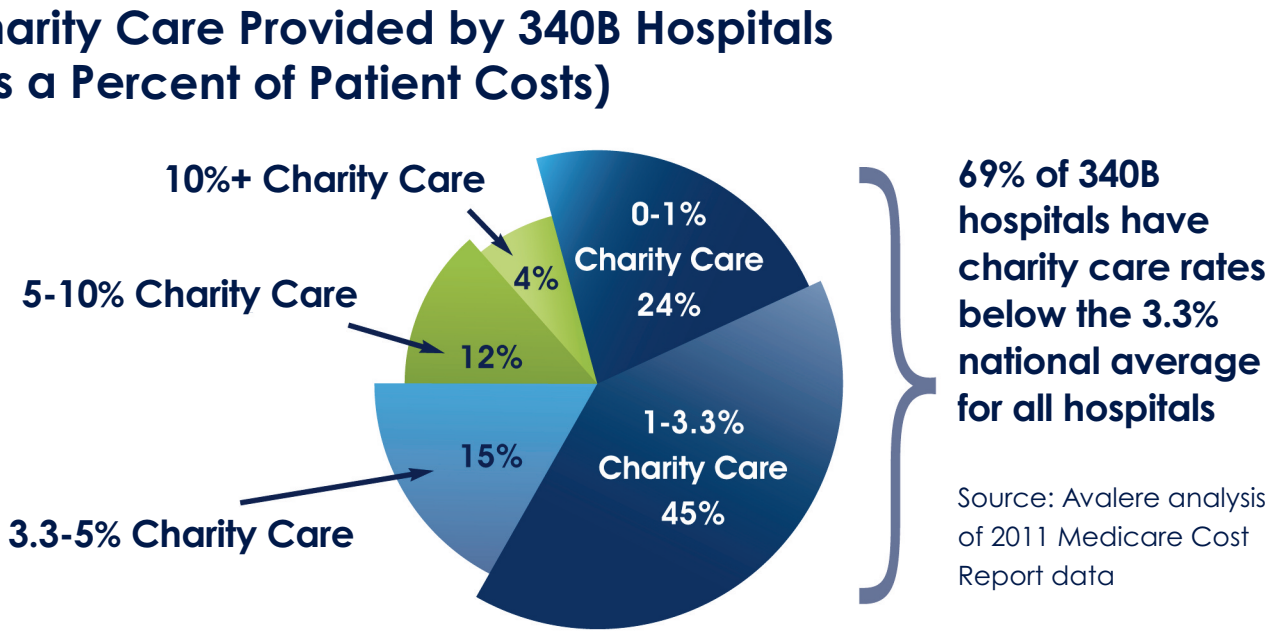
The paper leverages newly available data from the Medicare cost reports, which are filed annually by hospitals and were redesigned in 2010 to more accurately capture the cost of the charity care that hospitals provide. Because the greatest amount of data was available on DSH that qualify for 340B under 42 U.S.C. § 256b(a)(4)(L), this paper analyzes these types of entities. The analysis excludes Critical Access Hospitals because those rural hospitals have very different cost structures from other hospitals and qualify for 340B based on different metrics (see Appendix B for more information on Critical Access Hospitals). Additionally, Free-Standing Cancer Hospitals, Rural Referral Centers, Children's Hospitals and Sole Community Hospitals were excluded from this analysis because they have very different cost structures from DSH, and because the most recent data available is from 2011 and therefore only few of these hospitals (which were newly eligible effective in 2010 under the ACA) were participating in 340B at that time.

RESULTS OF CHARITY CARE ANALYSIS

The data analyzed for this report show that the current 340B program includes many hospitals that provide only a minimal amount of charity care. In fact, for approximately one-quarter (24%) of the 340B hospitals studied, charity care represents 1% or less of hospital patient costs (Figure 1). These hospitals provide a level of charity care that is far below the 3.3% national average for all hospitals, regardless of 340B status.

An additional 45% of the 340B hospitals studied provide charity care that represents between 1% and 3.3% of patient costs. In total, 69% of 340B hospitals provide less charity care than the national average for all hospitals, including for-profit hospitals. Only 4% of 340B hospitals provide charity care that represents more than 10% of their patient costs.

Figure 1:

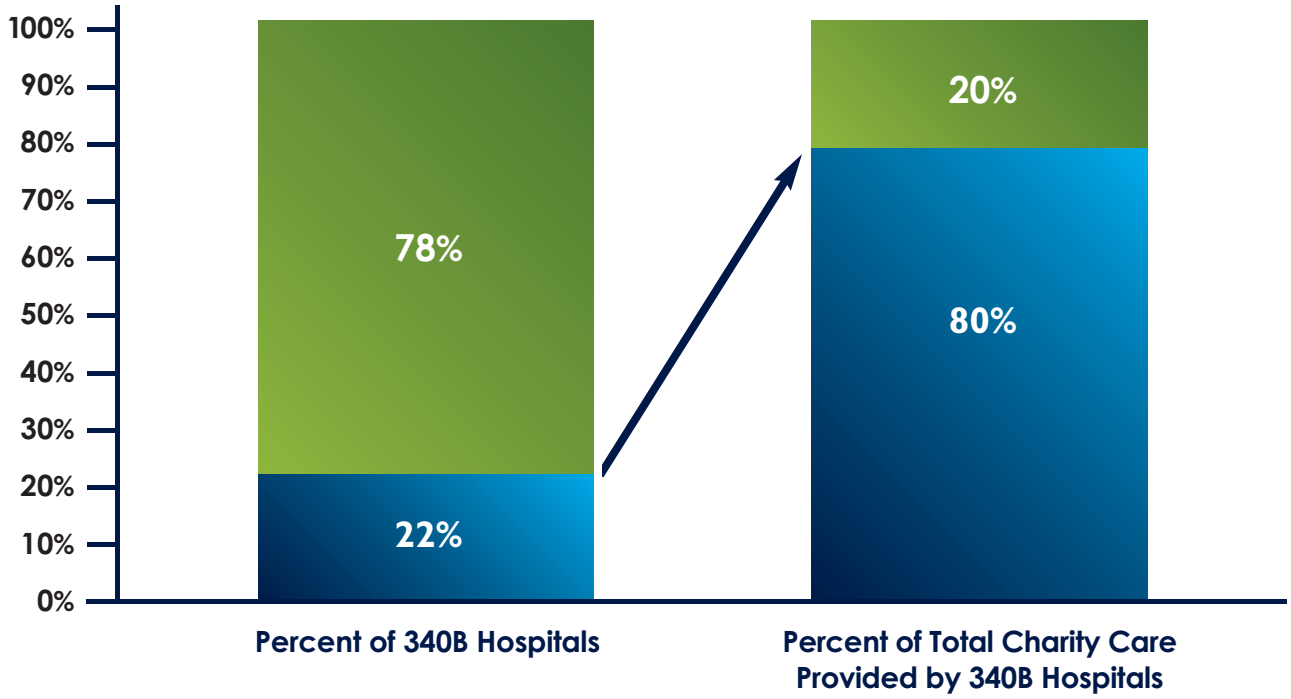


Analysis of the hospital-reported data also found that a small minority of 340B hospitals provides the vast majority of all charity care provided by hospitals that receive 340B discounts. Just over one-fifth (22%) of all 340B hospitals provide 80% of the total charity care provided by 340B hospitals (Figure 2). These same hospitals represent only 47% of total patient costs, and 41% of total hospital beds in all 340B facilities, meaning that they are providing a disproportionately high level of charity care relative to their size. Conversely, the remaining 78% of 340B hospitals provide just 20% of the total charity care, even though they represent more than half of all 340B hospital beds and hospital costs. This finding is consistent with an IRS study that found that just 9% of surveyed nonprofit hospitals were responsible for 60% of the community benefit expenditures provided by all of the nonprofit hospitals in the survey.[22]

RESULTS OF CHARITY CARE ANALYSIS

Figure 2:

22% of 340B Hospitals Account for 80% of Charity Care Provided by all 340B Hospitals



Source: Avalere analysis of 2011 Medicare Cost Report data

Note: The 22% of 340B hospitals that provide 80% of the charity care at all 340B hospitals represent 47% of total patient costs and 41% of beds.

Charity care represents a substantial share of patient costs for only a small minority of 340B hospitals. Similarly, the data also show that some non-340B hospitals–including some that are for-profit hospitals–provide more charity care than the vast majority of 340B hospitals. Specifically, almost one in twelve (8%) non-340B hospitals provide charity care that represents 5% or more of the hospital's costs.

ADDITIONAL SOURCES OF GOVERNMENT FUNDING FOR HOSPITALS

Despite the fact that many hospitals provide very little charity care, hospitals currently receive separate funding from numerous government 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 nonprofit, meaning that they benefit from being exempt from federal, state and local taxes. A 2008 study of government funding for uncompensated care across all hospitals found that, even after accounting for Medicaid's relatively low reimbursement rate, government funding from Medicare, Medicaid, and direct funds from state and local governments reimburse hospitals for 82% of their total charity care and bad debt.[23] These government payments include Medicare and Medicaid DSH payments, Indirect Medical Education payments for hospitals with graduate medical education programs, and payments made through the Upper Payment Limit program that increases hospital Medicaid rates.

Moreover, nonprofit hospitals may be able to fund all–or a portion of–their remaining charity care and bad debt through private donations and profits from insured patients.

In addition to these payments, the Medicare reimbursement system intended to apply for most hospitals when it was enacted in 1983 has been changed and amended many times in order to increase hospital reimbursements. A recent GAO report examining changes to Medicare hospital reimbursements concluded that the changes to the Inpatient Prospective Payment System (IPPS) enacted from 1997 to 2012 "had the cumulative effect of most hospitals receiving modifications and add-ons to the basic payment formula that increase Medicare spending. In fact, over 90 percent of hospitals were subject to either IPPS payment adjustments or exemptions in 2012."[24] Additionally, teaching hospitals–many of which participate in 340B–receive federal direct medical education payments.

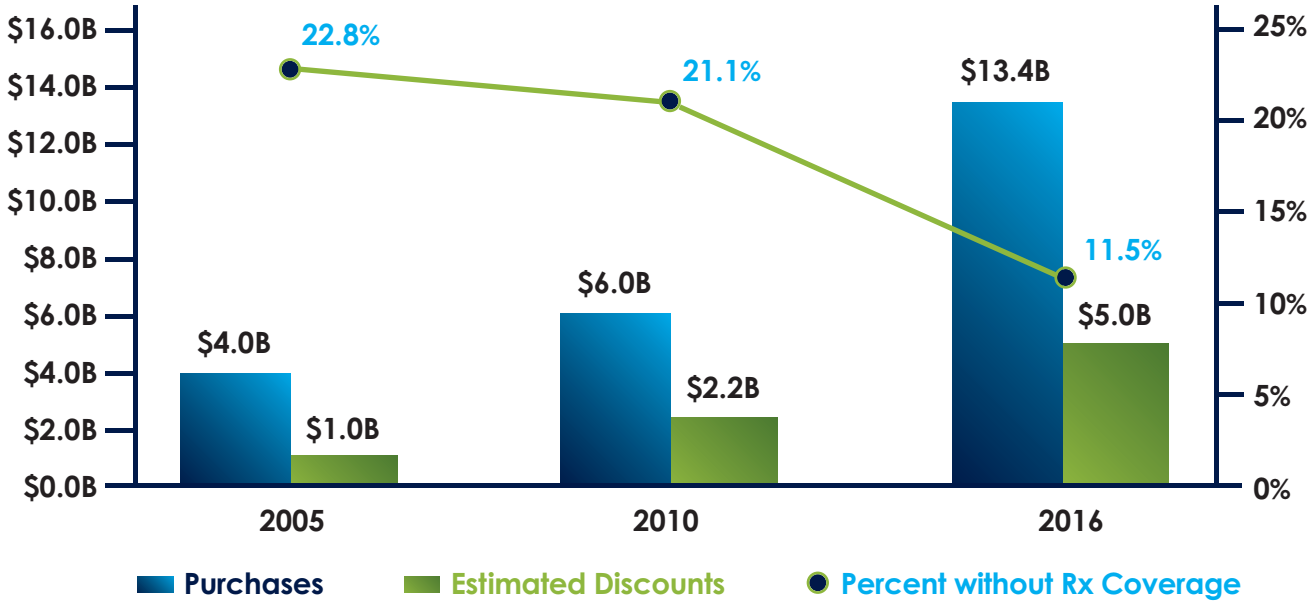
IMPACT OF ACA ON 340B PROGRAM GROWTH

By 2016, the ACA is expected to cause a 45% decline in the number of uninsured patients, according to the most recent Congressional Budget Office estimate.[25]

Figure 3:

Trends in 340B Drug Purchases and Percent of Total Population without Prescription Drug Coverage

Drug purchases through the 340B program will more than double from $6B in 2010 to $13.4B by 2016, at the same time the share of the population without prescription drug coverage will almost be cut in half.



Source: Historic coverage data is from Avalere analysis of the Medical Expenditure Panel Survey and represents the entire population (all ages). Coverage projections are for the total population and are from Avalere analysis of CBO, Census and Medicare Trustees report data; 340B data is from A. Vandervelde A. Oliphant, 340B Compliance Monitoring, 10th Annual Oncology Economics Summit, February 26, 2014, San Diego, CA.

However, the number of hospitals eligible for the 340B program is expected to rise because of increased Medicaid enrollment under the ACA (recall that the disproportionate share adjustment percentage is based in part on a hospital's share of Medicaid patients without Medicare, compared with total patients). The fact that a lower number of uninsured patients could lead to an increased number of hospitals eligible for a program designed to *help uninsured, indigent and vulnerable patients* further suggests that the disproportionate share adjustment percentage is not an appropriate measure to determine hospital eligibility for 340B.

CONCLUSION

The 340B program was intended to support access to outpatient drugs for uninsured and vulnerable patients. The program's design allows eligible providers to benefit from steeply discounted prices in return for their support of uninsured, indigent and vulnerable patient populations. The analysis presented in this report demonstrates that current eligibility criteria for hospitals have allowed the majority of hospitals participating in the program to receive 340B discounts without providing meaningful levels of charity care. To promote a well-functioning 340B program underpinned by sound policy and designed to support access for needy patients, 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 Patient Protection and Affordable Care Act (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.[26]

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 American Hospital Association 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% of the Federal Poverty Level (FPL), and at reduced rates for uninsured patients with incomes between 100% and 200% of the FPL.[27]

Charity Care Data

The charity care data analyzed in this report is taken from 2011 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

APPENDIX A: ADDITIONAL INFORMATION ON CHARITY CARE

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 that 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.

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.

In order to account for potential impact of data reporting errors (by hospitals that did not report the data on their cost reports accurately), Avalere removed from the analysis any acute-care hospital whose calculated revenue-per-bed rate was outside two standard deviations from the mean. Avalere chose this metric to determine which hospitals to exclude from the analysis because most hospitals reliably report total revenue and number of beds. In order to control for the non-normal distribution of the data, Avalere calculated the natural log of revenue-per-bed to use in the exclusion process. Under this procedure, approximately 913 acute-care facilities were excluded from the analysis – of those, 237 were 340B facilities. The exclusion of those 913 acute-care facilities does not appear to disproportionately exclude hospitals with higher rates of charity care. When the average charity care for all hospitals was recalculated with those hospitals included, the average charity care percentage decreased from 3.3% to 3.0%. [28]

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

Table 1: Number of Hospitals Included in the Analysis

Type of Hospital	340B Hospitals in Analysis	Total Hospitals (340B and Non-340B) in Analysis
Short-term Acute-Care Hospitals	907	2,517
Non-profit	682	1,569
Government	225	340
For-profit	0	608
Urban	624	1,878
Rural	283	639

APPENDIX B: CRITICAL ACCESS HOSPITALS

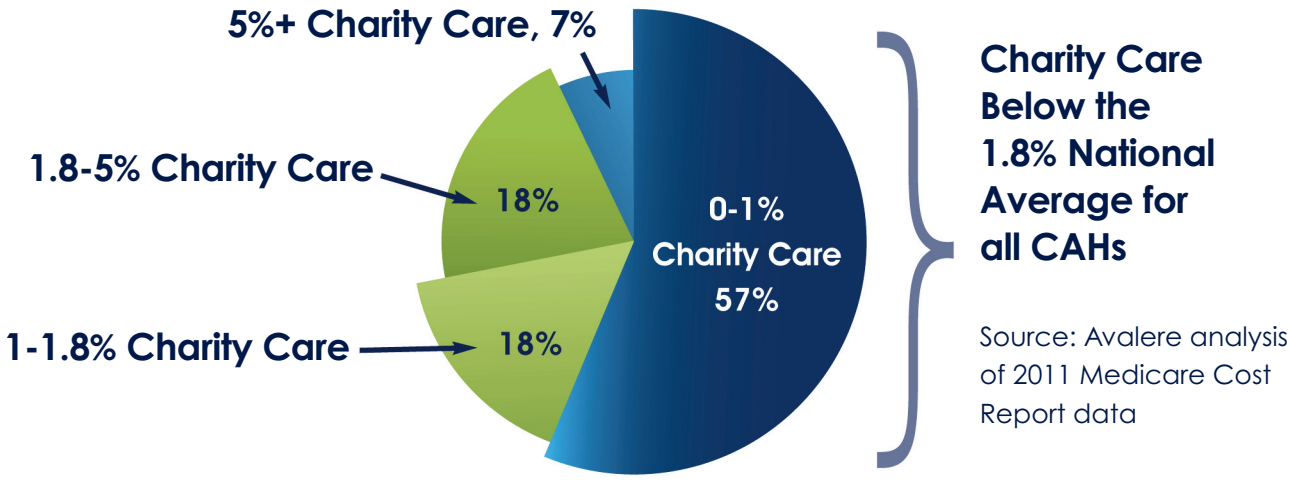
For the bulk of the analyses in this report, the data for Critical Access Hospitals (CAH) are excluded or presented separately than the data for Short-term Acute-Care Hospitals (STACH). CAHs have a different operating structure than most STACHs given the statutory requirements for CAH approval. According to the original requirements set out in the Balanced Budget Act of 1997, a CAH must have no more than 25 beds, be at least 15 miles by secondary road and 35 miles by primary road from the nearest hospital, or be declared a "necessary provider" by the state (although the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 eliminated a state's ability to declare a hospital as a necessary provider). Once qualified as a CAH, the Medicare program reimburses the facility on a cost-plus basis rather than under the IPPS that is used for all STACHs.[29]

In addition to meeting the statutory requirements, most CAHs are located in rural areas where the mix of patients is likely to be quite different than it is for STACHs. For example, a recent report from the Department of Health and Human Services Office of the Inspector General (OIG) found that the average CAH had an inpatient utilization rate of only 21%, whereas STACHs ranged from 37% to 65% inpatient utilization rates, depending on their size.[30] Likewise, the OIG found that Medicare beneficiaries represented over 60% of all inpatient utilization for CAHs, while the STACH rates ranged from approximately 35% to 45%.[31] CAH admissions were also less likely to come from the emergency room (ER): less than 40% of all CAH admissions came from the ER, while the STACH rate ranged from approximately 55% to 65%.[32]

Due to these differences in size, location, patient mix, and other factors, co-mingling the operating statistics between CAHs and STACHs tends to inappropriately skew the results. Instead, the operating statistics for STACHs were compared only to other STACHs, while the operating statistics for CAHs were compared only to other CAHs. Notably, the same pattern for 340B DSH hospitals also holds for 340B CAHs–about three-quarters of the 340B CAHs provide less charity care than the average for all CAHs. Analysis of the provision of charity care by CAHs is shown below in figure 4.

Figure 4:

Charity Care as a Percent of Patient Costs for 340B CAHs Compared to National Average for All CAHs



Source: Avalere analysis of 2011 Medicare Cost Report data

[1]See 42 U.S.C. § 256b (the "340B statute").

[2]Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (Sept. 2011); Alexander A, Garloch K, "Hospitals probed on use of drug discounts," Charlotte Observer (Oct. 3, 2012) available at http://www.charlotteobserver.com/2012/09/29/3566421/hospitals-probed-on-use-of-drug.html; Rena M. Conti and Peter B. Bach, Cost Consequences of the 340B Drug Discount Program, 309 J. Am. Med. Ass'n 1995 (May 2013).

[3]See, e.g., Hearing Before the Committee on Labor and Human Resources, U.S. Senate (Oct. 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.")

[4]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).

[5]See 42 U.S.C. § 256b(a)(4)(e)

[6]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).

[7]See, e.g., HRSA, "Black Lung Clinics Program," available at 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," available at 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.")

[8]See 42 U.S.C. § 256b(a)(4)(L)-(O).

[9]U.S. House of Representatives Report accompanying H.R. Rep. 102-384 (II) (1992).

[10]See 42 U.S.C. § 1395ww(d)(5)(F).

[11]See Department of Health and Human Services, "Medicare Disproportionate Share Hospital," ICN 006741 (Jan. 2013), available at http://www.hrsa.gov/opa/eligibilityandregistration/hospitals/disproportionatesharehospitals/index.html.

[12]Health Resources and Services Administration, "Clarification of Eligibility for Hospitals That Are Not Publicly Owned or Operated," pp. 1-2 (Mar. 7, 2013).

[13]The 2,048 hospitals include disproportionate share hospitals, critical access hospitals, children's hospitals, sole community hospitals, rural referral centers, and cancer hospitals.

[14]Avalere analysis of HRSA 340B database and FY2011 cost reports. Avalere estimated outpatient drug costs using reported charges. For facilities currently in the program but who did not participate during FY2011, Avalere reduced their outpatient drug costs to estimate what cost would have been under the 340B program.

[15]AIR 340B Analysis of MEPSnet data for entire U.S. population.

[16]Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (Sept. 23, 2011).

[17]Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (Washington, DC: MedPAC, March 2007).

[18]Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (Sept. 23, 2011).

[19]See Patient Protection and Affordable Care Act, Disproportionate Share Hospital, Pub. L. No. 111-148, § 2551 (2011).

[20]American Hospital Association, "AHA Policies & Guidelines on Billing, Collections, Tax-Exempt Status, and Community Health," available at http://www.aha.org/content/00-10/07nov-billingpolicyguidelines.pdf.

[21]Patient Protection and Affordable Care Act, Disproportionate Share Hospital, Pub. L. No. 111-148, § 9007 (2011).

[22]IRS, "Exempt Organizations Hospital Study Executive Summary of Final Report" (Feb. 2009), available at http://www.irs.gov/pub/irs-tege/execsum_hospprojrept.pdf

[23]Hadley, J., Holahan, J, Coughlin, C., and Miller, D, "Covering the Uninsured in 2008: A Detailed Examination of Current Costs and Sources of Payment, and Incremental Costs of Expanding Coverage," Kaiser Commission on Medicaid and the Uninsured (Aug. 2008).

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