AIR 340B Alliance for Integrity & Reform

Charity Care at 340B Hospitals is on a Downward Trend

October 2023

Executive Summary

The 340B Drug Pricing Program, established in 1992, aims to support certain hospitals and clinics that serve low-income and vulnerable patients by requiring pharmaceutical manufacturers to provide significant discounts for qualifying medicines purchased for those patients.[i] In exchange for these discounts – averaging nearly 60%[ii] – 340B providers are expected, based on the intent of the program,[iii] to help these patients access the outpatient medicines and care they need, including through charity care. As defined by the Centers for Medicare and Medicaid Services (CMS), charity care results from a hospital's policy to provide all or a portion of medically necessary health care services free of charge or at a discount to patients who meet the hospital's financial assistance policy.[iv]

At $54 billion in annual discounted sales,[v] the 340B program is now larger than Medicaid and Medicare Part B, making it the second largest U.S. federal prescription drug program. While the program was initially targeted to grantees and frontline safety-net hospitals, 340B has become concentrated among disproportionate share hospitals (DSHs), which comprise 80% of all 340B purchases.[vi] There is no requirement for 340B hospitals to use the discounts they receive to help low-income patients afford their medicines; consequently, growth in annual discounted 340B sales has not translated into higher charity care levels at hospitals in the 340B program.

To examine whether 340B hospitals are funding higher levels of free and reduced cost care for those unable to pay, the Alliance for Integrity and Reform of 340B (AIR340B) engaged Avalere to analyze the latest charity care data, from fiscal year (FY) 2021. A great deal of research shows that despite the program's continuous growth, many 340B DSH hospitals are not providing adequate levels of charity care.[vii]

The average national level of charity care for short-term acute care hospitals is 2.5%

In comparison, this analysis found:

- **69%** of 340B DSH hospitals provide charity care at rates lower than the national average.
- **36%** of 340B DSH hospitals provide charity care that represents less than **1%** of their total operating costs in FY 2021, and the number of hospitals at this rate is increasing
- A small share of 340B DSH hospitals account for most of the charity care provided by all 340B hospitals – with just **25%** of 340B DSH hospitals accounting for **80%** of all charity care provided by all 340B DSH hospitals in FY 2021

- Non-340B short-term acute care hospitals in the United States have higher average charity care **(2.6%)** than 340B DSH hospitals **(2.5%)**, on average

While the 340B program has grown by nearly every metric, there is still no guarantee that patients benefit from the significant discounts offered to certain hospitals. For these reasons, Congress must revise eligibility criteria for 340B hospitals to target true safety-net facilities – not hospitals that provide minimal charity care.

Background

Congress created the 340B program three decades ago to remedy an unforeseen problem created by the Medicaid Drug Rebate Program.[viii] Pharmaceutical manufacturers had historically provided these discounts voluntarily, but the 1990 enactment of the Medicaid drug rebate statute disincentivized doing so, because those discounts could trigger higher Medicaid rebates nationwide.[ix] Congress established the 340B program in response to this unintended consequence and restored deep discounts for true safety-net providers.

Today's 340B program bears little resemblance, both in character and size, when compared to the targeted program Congress designed. 340B has become a profit-driven program that often enriches large hospitals.

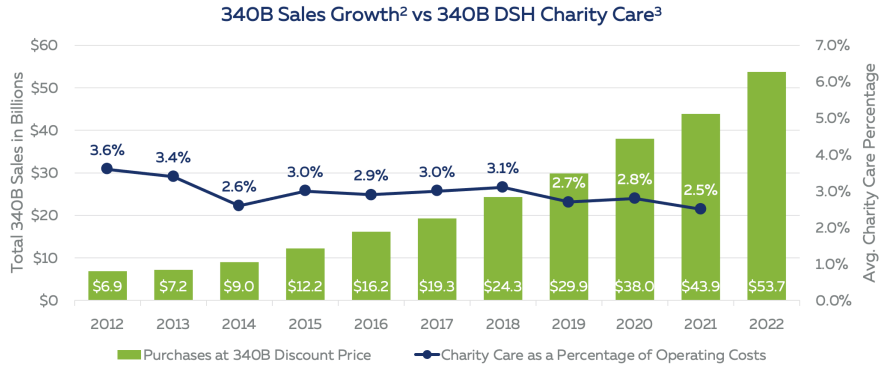
340B DSH Hospital Eligibility Is Not Linked To Charity Care

DSH hospitals become eligible for the 340B program based, in part, on the disproportionate share adjustment percentage – which is a proxy for safety-net hospitals treating a significant share of Medicaid and low-income Medicare inpatients.[x] The DSH hospital metric was not specifically designed for 340B eligibility purposes and does not measure the percentage of uninsured patients a hospital serves on an outpatient basis, or the level of charity care it provides to low-income and vulnerable populations.

As demonstrated in this paper, DSH hospital eligibility is not associated with high levels of charity care. In fact, rates of charity care have declined over the last decade due to more patients becoming Medicaid eligible under the Patient Protection and Affordable Care Act (ACA). More Medicaid patients means DSH hospital percentages have increased, making more hospitals eligible for 340B.[xi] This means more DSH hospitals are qualifying for the 340B program as charity care rates decline with more people becoming insured, highlighting the disconnect of the DSH metric for determining 340B eligibility.

340B DSH Charity Care is Again Trending Downwards

The 340B program has grown from $6.9 billion in discounted sales in 2012 to nearly $54 billion in discounted sales.[1] However, charity care for 340B DSH hospitals has decreased since 2018.



1. Fein AJ; Drug Channels Institute. EXCLUSIVE: The 340B Program Reached $54 Billion in 2022 – up 22% vs. 2021. Published September 2023. Accessed September 2023. https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html.
2. Drug Channels Institute analysis for PhRMA of data from the Health Resources and Services Administration (HRSA).
3. Avalere Health analysis for PhRMA of cost report data from the Centers for Medicare & Medicaid Services.

Nonprofit, Tax-Exempt 340B Hospitals Are Free Riding Their Favorable Status

Nearly two-thirds of all participating 340B hospitals are private, nonprofit hospitals.[xii] These hospitals qualify for the program, in part, based on having government contracts to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid.[xiii] Generally, nonprofit hospitals are required as a matter of federal law to have written and widely publicized financial assistance policies describing the free or discounted care available for eligible patients.[xiv] However, nonprofit hospitals often make the aid difficult to access,[xv] and as recent news stories highlight, nearly half of nonprofit hospitals (45%) routinely send medical bills to collect from patients with incomes low enough to qualify for charity care.[xvi]

Meanwhile, nonprofit hospitals continue to benefit from federal, state, and local tax exemptions – valued at over $28 billion in 2020.[xvii] Yet many nonprofit hospitals' charity care levels do not appear to align with their obligations as charitable organizations. A recent report found that 77% of nonprofit hospitals spend less on charity care and community investment than the estimated value of their tax breaks.[xviii] According to one study, for-profit hospitals provide 65% more charity care than nonprofit hospitals, which may in part be due to charity care expenses being tax deductible for for-profit hospitals.[xix] A separate report found even the most financially stable nonprofit hospitals provide disproportionately low levels of charity care.[xx]

Policymakers are reviewing potential abuse of the tax-exempt status by nonprofit hospitals.[xxi] A bipartisan group of U.S. Senators have questioned whether nonprofit hospitals provide sufficient community benefit and charity care to justify their generous tax-exempt status.[xxii] State policymakers are pursuing minimum charity care requirements for hospitals[xxiii] along with policies to protect low-income and uninsured patients from aggressive medical debt collection from hospitals.[xxiv]

IRS Regulations Make Charity Care Voluntary For 340B Hospitals

Overall, charity care practices can vary by hospital. Under Internal Revenue Service (IRS) regulations, hospitals can set their own eligibility standards for charity care. Neither the IRS regulations nor the 340B program provide specific guidance. And although the American Hospital Association's (AHA) voluntary guidelines for hospitals suggest that care should be provided free of charge to low-income patients and hospitals should ensure fair debt collection practices, there is no requirement that hospitals follow the AHA's guidelines.[xxv]

Given this flexibility, this paper analyzes levels of charity care at 340B DSH hospitals to inform whether charity care should be a requirement for 340B hospital eligibility.

Methodology

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.[xxvi]

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 with the 340B program's intent, which is to sustain care for low-income and vulnerable populations.

The analysis presented in this paper is based on data obtained from FY 2021 Medicare cost reports analyzed by 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). Average charity care across hospitals was calculated as a simple average.[xxvii]

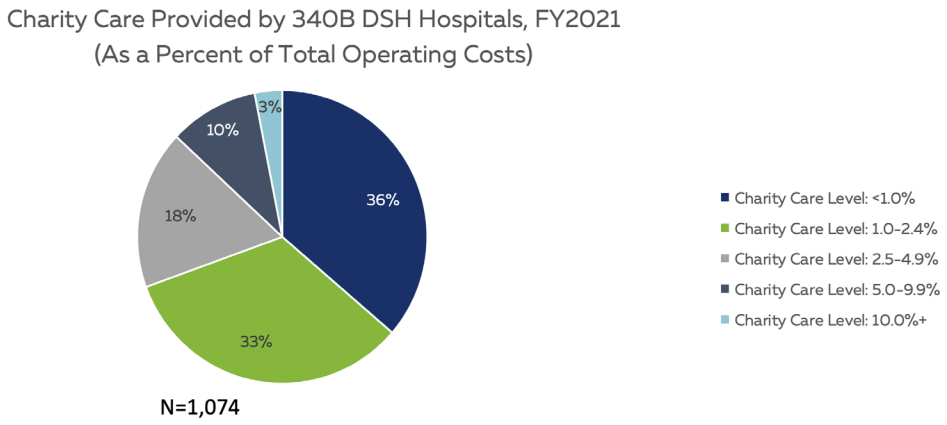
The analysis in this paper excludes Critical Access Hospitals because those small, often rural hospitals have very different cost structures than other hospitals and qualify for 340B based on different metrics (see Appendix B for more information on Critical Access Hospitals). Additionally, Freestanding Cancer Hospitals, Rural Referral Centers, Children's Hospitals, and Sole Community Hospitals were excluded from this analysis.

Results Of The Charity Care Analysis

The Majority Of 340B DSH Hospitals Provide Minimal, Below Average Levels Of Charity Care

The findings of this analysis indicate that many 340B DSH hospitals provide below average levels of charity care. Nearly seven in 10 (69%) 340B DSH hospitals provide less charity care than the national average (2.5%) for all short-term acute care hospitals (Figure 1). For over a third (36%) of the 340B hospitals studied, charity care represents less than 1% of hospital operating costs. An additional 33% of the studied 340B hospitals provide charity care that represents between 1% and 2.4% of total operating costs, which is below the national average for all short-term acute care hospitals.

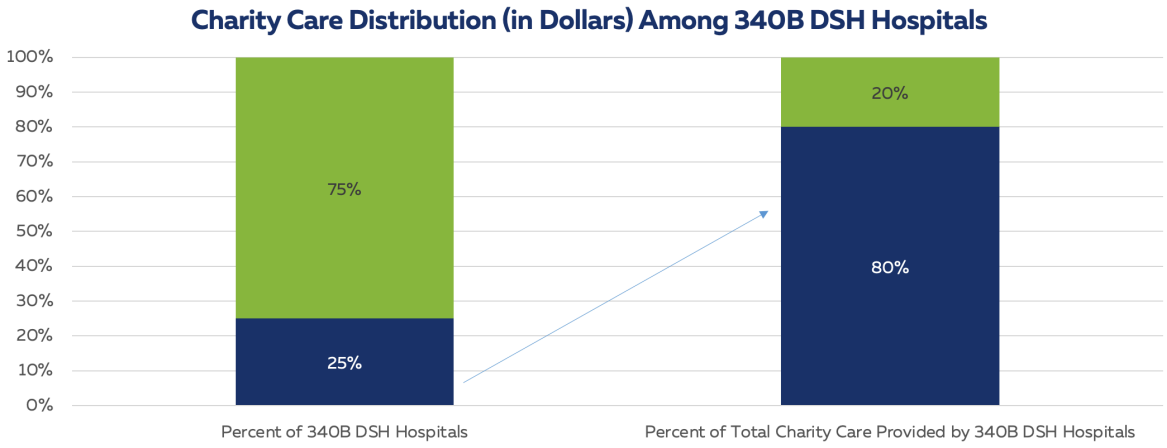
FIGURE 1: More Than Two-Thirds Of 340B Hospitals Provide Below Average Levels Of Charity Care



STACH: Short-Term Acute Care Hospital; DSH: Disproportionate Share Hospital
Source: Avalere analysis of FY2021 Medicare cost reports submitted by 3,218 STACHs. Of those, 1,074 hospitals were participating in 340B as a DSH entity for a full or a portion of their cost reporting period based on the enrollment and termination dates in the Office of Pharmacy Affairs (OPA) 340B database and submitted 2021 Medicare cost report data.

Overall, a small share of 340B hospitals provide most of the charity care provided by all 340B hospitals. Specifically, 25% of 340B hospitals provided 80% of the total charity care provided by all 340B hospitals, in FY 2021 (Figure 2).

FIGURE 2: 25% of Hospitals Account for 80% of Charity Care Provided by all 340B DSH Hospitals in FY2021



Source: Avalere analysis of FY2021 Medicare cost reports submitted by 1,074 hospitals that were participating in 340B as a DSH entity for a full or a portion of their cost reporting period based on the enrollment and termination dates in the Office of Pharmacy Affairs (OPA) 340B Database.

When comparing charity care across 340B and non-340B hospitals, the average charity care percentage for non-340B short-term acute care hospitals is higher than for 340B DSH hospitals (2.6% versus 2.5%).

Additional Government Funding Does Not Incentivize Hospitals To Provide Charity Care

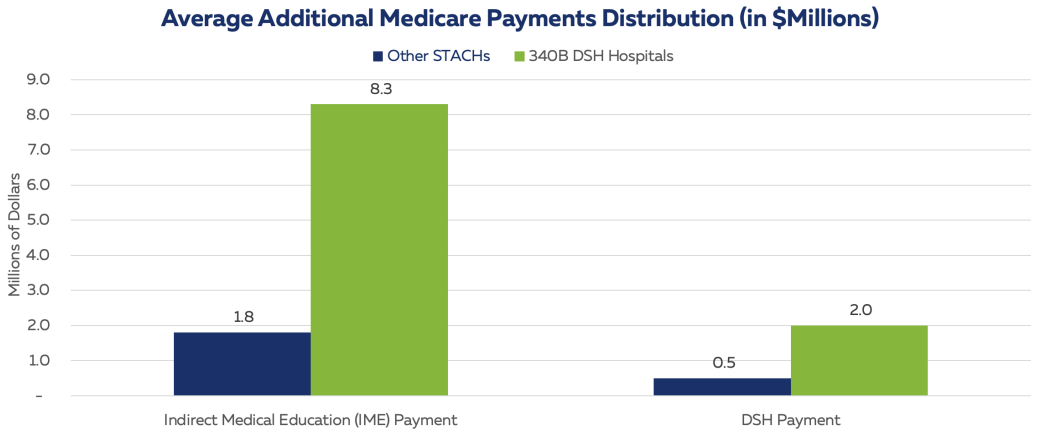
In addition to the tax benefits for nonprofit hospitals as mentioned above, hospitals (both 340B and non-340B) receive government funding from numerous sources to compensate them for the cost of charity care. Sources of government funding for charity care include Medicaid DSH payments, Medicare DSH payments, and Medicare uncompensated care payments.[xxviii] If hospitals prioritized charity care, the level of charity care would increase as the level of cash reserves increase, yet this is not the case.[xxix]

Some sources of government funding can be analyzed through the Medicare cost reports. Analysis of the FY 2021 data found 340B DSH hospitals receive over $10 billion in annual direct government funding. As mentioned, this includes DSH payments to offset hospitals' uncompensated care costs as well as indirect medical education payments to support teaching hospitals, many of which are 340B hospitals and therefore already receive discounts on medicines from the 340B program.[xxx] For these two sources of government

funding, payments made to 340B DSH hospitals are four times as large (Figure 3) as payments made to non-340B short-term acute care hospitals, on average.

Several 340B hospitals are also due to receive a share of the $10.5 billion in payments directed to hospitals after it was determined by the Supreme Court that 340B hospitals were underpaid.[xxxi] The 340B hospitals set to receive the highest repayments tend to be those providing lower than average charity care.[xxxii]

FIGURE 3: The Average Additional Medicare Payment for a 340B DSH Hospital is 4 Times that of Other STACHs in FY2021



Source: Avalere analysis of FY2021 Medicare cost reports submitted by 3,218 STACHs. Of those, 1,074 hospitals were participating in 340B as a DSH entity for a full or a portion of their cost reporting period based on the enrollment and termination dates in the Office of Pharmacy Affairs (OPA) 340B Database. Note that hospitals reporting zero payments are not included in this calculation.
Note: Inpatient Outlier Payments were unavailable for FY2021

Conclusion

The significant discounts pharmaceutical manufacturers provide under the 340B program should support access to outpatient medicines for uninsured or vulnerable patients through safety-net facilities. Yet, the 340B program's design allows eligible hospitals to benefit from steeply discounted prescription drug prices without meeting a certain threshold or standards for charity care. This is the fifth iteration of this report spanning nearly 10 years and the findings remain the same: Despite more hospitals generating more revenue from the 340B program, most 340B hospitals provide below average levels of charity care.

Hospital eligibility standards must be strengthened and aligned with the original intent of the program, ensuring only hospitals actually helping high numbers of low-income and vulnerable patients qualify for the program. This includes requiring 340B hospitals to provide charity care to uninsured, low-income and vulnerable patients. There should also be greater oversight and enforceable standards for private hospitals regarding the government contracts that allow them to qualify for the 340B program.[xxxiii]

Appendix A: Additional Information On Charity Care

Charity Care Background

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

- Establish written financial assistance and emergency medical care policies;
- Limit the amounts charged for emergency or other medically necessary care to individuals eligible for assistance under the hospital's financial assistance policy to not more than the amounts generally billed to individuals who have insurance covering such care;
- 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 at least once every three years and adopt an implementation strategy to meet the community health needs identified through such assessment.[xxxiv]

Each individual hospital develops its own policy regarding the specific financial criteria for an individual treated in the hospital to qualify for charity care. As mentioned, the American Hospital Association's voluntary policies and guidelines for hospitals suggest that care should be provided free of charge to certain low-income patients and hospitals should conduct fair debt collection practices, yet there is no requirement that hospitals follow these guidelines.[xxxv]

Charity Care Data

The charity care data analyzed in this report are taken from FY 2019-2021 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 non-public 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.

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 1 Provides An Overview Of The Number And Type Of Hospitals That Were Included In The Charity Care Analysis.

TYPE OF HOSPITAL	340B DSH Hospitals in analysis	Total STACHs (340B and non-340B) in analysis
Short-Term Acute Care Hospitals	1,074	3,218
Nonprofit	719	1,707
Government	222	493
Proprietary	34	663
Other (physician ownership, tribal, other)	99	355

Appendix B

[i] H.R. Rep. No. 102-384(II), at 12 (1992) (stating that the 340B statute is intended to apply "to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans").

[ii] Berkeley Research Group, 340B Program at a Glance, Dec. 2022, https://media.thinkbrg.com/wp-content/uploads/2022/12/06082105/340B-Program-at-aGlance-2022_clean.pdf.

[iii] H.R. Rep. No. 102–384(II), at 12 (1992).

[iv] CMS. Medicare Provider Reimbursement Manual, July 28, 2023, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/R21P240i.pdf.

[v] Fein, Adam, Exclusive: The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021, Sept. 24, 2023, https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html.

[vi] Fein, Adam, Exclusive: The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021, Sept. 24, 2023, https://

www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html.

[vii] Temple University Beasley School of Law, Patient Affordability and Debt Collection Policies at 340B Program Hospitals, May 2022, https://phlr.org/sites/default/files/uploaded_images/PatientAffordability340B_PolicyBrief_May2022.pdf (An analysis of patient financial assistance policies at 75 340B Hospitals found that only 13 of the 75 hospitals' policies include information to help low-income patients access their prescription medicines).; Anderson, Gerard, Bai, Ge, Eisenberg, Matthew, et al., Analysis Suggest Government and Nonprofit Hospitals' Charity Care is Not Aligned with Their Favorable Tax Treatment, Health Affairs, April 2021, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.01627.

[viii] H. Rep. No. 102-384 (II), at 11-13 (1992); Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 2967-71 (Nov. 4, 1992) (codified as amended at 42 U.S.C. § 256b).

[ix] 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.")

[x] Public Health Service Act § 340B(a)(4)(L)(ii).

[xi] Vandervelde, Aaron, "Growth of the 340b Program: Past Trends, Future Projections," Berkeley Research Group, December 2014.

[xii] GAO, Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements, Dec. 2019, https://www.gao.gov/assets/710/705854.pdf.

[xiii] GAO, "340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements," GAO-20-108, December 2019.

[xiv] 26 U.S.C. § 501(r).

[xv] Levey, Noam, Hundreds of Hospitals Sue Patients or Threaten Their Credit, a KHN Investigation Finds. Does Yours?, KFF Health News, Dec. 21 2022. https://kffhealthnews.org/news/article/medical-debt-hospitals-sue-patients-threaten-credit-khn-investigation/; Temple University Beasley School of Law, Patient Affordability and Debt Collection Policies at 340B Program Hospitals, May 2022, https://phlr.org/sites/default/files/uploaded_images/PatientAffordability340B_PolicyBrief_May2022.pdf (An analysis of patient financial assistance policies at 75 340B Hospitals found that only 13 of the 75 hospitals' policies include information to help low-income patients access their prescription medicines).

[xvi] Rau, Jordan, Patients Eligible for Charity Care Instead Get Big Bills, KFF Health News, Oct. 14, 2019, https://kffhealthnews.org/news/patients-eligible-for-charity-care-instead-get-big-bills.

[xvii] Goodwin, Jamie, et al., The Estimated Value of Tax Exemption for Nonprofit Hospitals Was About $28 Billion in 2020, KFF, Mar. 14, 2023, https://www.kff.org/health-costs/issue-brief/the-estimated-value-of-tax-exemption-for-nonprofit-hospitals-was-about-28-billion-in-2020.

[xviii] Lown Institute Hospitals Index, 2023 Fair Share Spending Report, https://lownhospitalsindex.org/2023-fair-share-spending.

[xix] Bai, Ge, et al., Analysis Suggests Government And Nonprofit Hospitals' Charity Care Is Not Aligned With Their Favorable Tax Treatment, Health Affairs, Apr. 5, 2021, https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01627.

[xx] Bai, Ge, et al., Charity Care Provision by US Nonprofit Hospitals, JAMA Internal Medicine, Feb. 17, 2020, https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2760774.

[xxi] House Ways and Means Committee Hearing on "Tax-Exempt Hospitals and the Community Benefit Standard," April, 2023, https://waysandmeans.house.gov/event/hearing-on-tax-exempt-hospitals-and-the-community-benefit-standard.

[xxii] https://www.warren.senate.gov/imo/media/doc/Letters%20on%20Nonprofit%20Hospitals.pdf.

[xxiii] Miller, Andy and Hawryluk, Markian, Nonprofit Hospitals Under Growing Scrutiny Over How they Justify Billions in Tax Breaks, KFF Health News, July 10, 2023, https://www.cnn.com/2023/07/10/health/nonprofit-hospitals-commu-

nity-benefits-kff-health-news/index.html.

[xxiv] States Move to Protect Hospital Patients from Heavy Medical Debt, The Wall Street Journal, Feb. 2022, https://www.wsj.com/articles/states-move-to-protect-hospital-patients-from-heavy-medical-debt-11644235200.

[xxv] American Hospital Association, "Patient Billing Guidelines," April 2020. Available at: https://www.aha. org/standardsguidelines/2020-10-15-patient-billing-guidelines.

[xxvi] CMS. Medicare Provider Reimbursement Manual, July 28, 2023, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/R21P240i.pdf.

[xxvii] The data from the Medicare cost reports, filed annually by hospitals, 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 that 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."

[xxviii] GAO, Hospital Uncompensated Care: Federal Action Needed to Better Align Payments with Costs, June 2016, https://www.gao.gov/assets/gao-16-568.pdf.; Coughlin, Teresa, et al., Sources of Payment for Uncompensated Care for the Uninsured, Apr. 6, 2021, https://www.kff.org/uninsured/issue-brief/sources-of-payment-for-uncompensated-care-for-the-uninsured.

[xxix] Jenkins, Derek, and Ho, Vivian, Nonprofit Hospitals: Profits and Cash Reserves Grow, Charity Care Does Not, Health Affairs, June 2023, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.01542.

[xxx] MedPAC, Report to Congress: Medicare Payment Policy, March 2020, https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_entirereport_sec.pdf.

[xxxi] 596 U.S. ___, Slip. Op. at 13.

[xxxii] CMS. Hospital Outpatient Prospective Payment Remedy for the 340B-Acquired Drug Payment Policy- Notice of Proposed Rulemaking with Comment Period Addendum "AAA." July 2023; Kacik, Alex, 340B Pay Remedy Favors Hospitals with the Least Uncompensated Care, July 24, 2023, https://www.modernhealthcare.com/politics-policy/cms-340b-remedy-hospitals-charity-care-analysis.

[xxxiii] GAO, Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements, Dec. 2019, https://www.gao.gov/assets/710/705854.pdf.

[xxxiv] 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.

[xxxv] American Hospital Association, "Patient Billing Guidelines," April 2020. Available at: https://www.aha. org/standardsguidelines/2020-10-15-patient-billing-guidelines.