340B HEALTH

September 30, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
7500 Security Blvd
Baltimore, MD 21244

Re: CMS-1736-P: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems

Dear Administrator Verma:

340B Health submits these comments in response to the payment policy proposals for 340B drugs included in the Notice of Proposed Rulemaking (Proposed Rule) published in the Federal Register on August 12, 2020, setting payment rates under the outpatient prospective payment system (OPPS) for calendar year (CY) 2021.[1] 340B Health represents more than 1,400 public and nonprofit hospitals that participate in the federal 340B drug pricing program. Under 340B, Congress requires drug manufacturers to discount drugs for safety-net hospitals to help them fund care for patients with low incomes or who live in rural areas, and overwhelming evidence shows that 340B hospitals meet this goal.[2] Starting in 2018, CMS has diverted the benefit of the mandatory drug discounts away from the safety net, instead increasing payments to providers that do not meet 340B's requirements to provide high levels of care to patients in need, thereby increasing Medicare beneficiary copayments for other services. This proposed rule would further undermine the safety net by diverting even more of the 340B discounts that finance care for patients with low incomes or who live in rural areas. **340B Health strongly opposes CMS's proposal to cut payments to 340B hospitals down to Average Sales Price (ASP) minus 34.7% plus an add-on payment of 6%, and its alternative proposal to continue payment at ASP minus 22.5% with no add-on. Both proposals would deepen the damage done to the safety net and the millions of patients who rely on these hospitals for their care at a time when our hospitals are caring for those afflicted with COVID-19. We urge CMS to restore Medicare Part B payments to the statutory level established by Congress of ASP + 6%.**

Additional concerns we have about the proposal include that it would pay less than cost in many instances, is based on a premise that has been thoroughly rebutted with published research, and is contrary to law. We also believe that 340B hospitals should receive the same 6% add-on payment to cover drug handling costs that is provided to other hospitals.

While we strongly oppose CMS's proposals to pay 340B hospitals less than non-340B hospitals, 340B Health fully supports CMS's decision to continue exempting from the payment reduction children's hospitals, PPS-exempt cancer hospitals, and hospitals with a rural sole community hospital designation from Medicare given the unique patient populations these hospitals serve and how they are paid under the OPPS.[3]

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[1] *See* Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 85 Fed. Reg. 48772 (Aug. 12, 2020) (CMS-1736-P).
[2] Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106, Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b; see also H Rpt. No. 102-384, Part II, Pg. 12, 102nd Congress, Second Session.
[3] 85 Fed. Reg. 48772, 48890 (Aug. 12, 2020) (noting that children's and PPS-exempt cancer hospitals are "held harmless" under the OPPS and must receive outpatient payments from Medicare in the current year that are no less than the estimated amount they would have received prior to implementation of the OPPS and recognizing particularly unique needs of rural communities and the financial challenges rural hospital face).

I. CMS's 340B Payment Reduction Harms Hospitals' Ability to Finance Care for Low-Income Patients, and Proposals to Deepen the Cuts Would Worsen the Impact

A. 340B hospitals treat high volumes of low-income patients and increasing the cuts would further harm hospitals' ability to treat these populations

Since the 340B payment reduction took effect in 2018, hospitals have reported that the reduced payments limit their ability to finance care for patients with low incomes. For example, Medical University of South Carolina Health (MUSC), a 340B DSH hospital located in South Carolina, reports that reduced Medicare Part B payments for 340B drugs threaten the hospital's ability to sustain telemedicine services the hospital provides to patients with sickle cell disease and patients in need of psychiatric services.[4] MUSC relies on its 340B savings to provide these telemedicine services to patients who may be otherwise unable to travel extreme distances to receive treatment.[5][6]

In a recent survey of 340B Health members, hospitals reported the following:

- **A deeper payment reduction would further limit hospitals' ability to provide uncompensated and unreimbursed care (74%) and community service initiatives (72%). Other potential impacts on patient care include:**
    - **Reduced provision of discounted and/or free drugs at pharmacy locations**
    - **Reduced provision of services in underserved areas**
    - **Reduced provision of targeted programs to serve vulnerable populations**
    - **Cuts to pharmacy services (e.g., medication therapy management, meds to beds)**
    - **Cuts to patient care services (e.g., primary care, specialty care)**

- **A deeper payment reduction would also harm certain clinical services and outcomes. The most common responses were impacts to cancer care and other infusion services (75%) and utilization management (e.g., reducing readmissions and emergency department use (74%)). Other clinical areas likely harmed include medication adherence, diabetes, mental health and substance abuse, and pulmonary services**

- **100% of hospitals reported that they are concerned by the proposal to deepen the payment reduction, with 85% of hospitals reporting that they are very concerned**

340B hospitals have a documented record of providing high levels of care to low-income individuals, and additional Medicare payment cuts will further harm hospitals' ability to serve patients living with low incomes and those living in rural communities. Although 340B disproportionate share (DSH) hospitals represent 43% of hospitals, they provide 75% of all hospital services to Medicaid patients,[7] who have a higher burden of illness and have payment rates below cost, thus creating special challenges for these hospitals.[8] 340B DSH hospitals

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[4] L. Endriukaitis, G. Hayes, and J. Mills, Economic Evaluation of Changes in Reimbursement for Medications Purchased Through the 340B Drug Pricing Program, Hospital Pharmacy Journal, (Nov. 2019), https://journals.sagepub.com/doi/10.1177/0018578719888907

[5] *Id.*

[6] Since the 340B payment reduction took effect on Jan. 1, 2018, 340B hospitals have collectively lost hundreds of millions of dollars, thereby threatening critical services that hospitals may be unable to fund with lower reimbursement amounts. *See* American Hospital Association v. Azar, 348 F. Supp. 3d 62, 69 (D.D.C. 2018), Plaintiffs' Motion for a Firm Date By Which Defendants Must Propose a Remedy for Violations of the Medicare Act, (filed May 10, 2019) (stating that 340B hospitals as a group have been losing $25 million per week since Jan. 1, 2018).

[7] Dobson DaVanzo. The Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients. 2020. https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf (included as an attachment to this comment letter).

[8] Medicaid and CHIP Payment and Access Commission (MACPAC) and Medicare Payment Advisory Commission (MedPAC). Data Book: Beneficiaries Dually Eligible for Medicare and Medicaid. 2018. https://www.macpac.gov/publication/data-book-beneficiaries-dually-eligible-for-medicare-and-medicaid-3/#:~:text=Dually%20eligible%20beneficiaries%20receive%20both,or%20disability%20and%20low%20income.&text=This%20data%20book%20was%20jointly,Payment%20Advisory%20Commission%20(MedPAC). American Hospital

are much more likely than non-340B hospitals to provide essential health care services that are vital to low-income patients, but are often under-reimbursed, including HIV/AIDS services, trauma and burn care, and outpatient alcohol/drug abuse services.[9] 340B DSH hospitals are also more likely to serve racial and ethnic minorities.[10]

The crucial role of 340B hospitals in the safety net is accompanied by substantially lower—negative on average—operating margins than those of non-340B hospitals.[11] Further, focusing just on Medicare, outpatient Medicare margins *before* CMS cut payments to 340B hospitals were 22% and 21% less than those of non-340B DSH hospitals and other non-340B hospitals, respectively.[12] Lower Medicare margins for 340B hospitals indicate that Medicare was not inappropriately subsidizing safety-net hospitals through Medicare drug payments, and it is no surprise that safety-net hospitals report significant impacts on their ability to serve their patients as a result of the targeted cuts to 340B hospitals.

B. CMS's data confirm that CMS's proposal to cut payments targets 340B hospitals with the highest volumes of low-income patients for the deepest cuts

CMS's own data confirm that its proposal to further cut payments to 340B hospitals would reduce overall reimbursement to hospitals treating high volumes of low-income patients. The Proposed Rule estimates that hospitals with lower DSH patient percentages, reflecting lower levels of care to Medicaid patients and low-income Medicare patients, as well as non-teaching hospitals, will see overall payment increases.[13] Hospitals with higher DSH patient percentages and "major" teaching hospitals, which are much more likely to be 340B hospitals, will see payment decreases.[14] More specifically, CMS estimated that the 340B drug payment reduction combined with enhanced payments for other services under the corresponding budget neutrality adjustment would result in a 0.8% payment increase for hospitals that have a DSH patient percentage of 10 or less and therefore do not qualify for 340B, whereas hospitals with a DSH patient percentage of 35 or greater, a category which includes many 340B DSH hospitals, are estimated to see a 0.6% decrease in payment.[15] These estimates demonstrate that the proposal targets safety-net hospitals for the most financial harm. The resulting harm contravenes the purpose of the 340B program, which is to support providers that meet 340B's rigorous standards of providing significant care to Medicaid and low-income Medicare populations.

II. CMS's Proposal to Pay 340B Hospitals Based on Average Acquisition Cost Would Harm Patient Care Without Reducing Patient Costs or Medicare Spending

Though clearly undermining care for low-income populations, CMS's proposal to further cut payments would not reduce overall patient costs or reduce Medicare spending. CMS estimates that Medicare will pay 340B hospitals $427 million less under this new proposal, which it proposes to redistribute under budget neutrality principles by raising payments by 0.85% for other services.[16] As a result, pharmaceutical companies would be subsidizing enhanced Medicare payments to providers that are not required to meet any criteria for providing care to low-income populations. 340B Health fundamentally disagrees with a policy of transferring the 340B

Association. Underpayment by Medicare and Medicaid Factsheets. 2016-2020. https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid

[9] Dobson DaVanzo. The Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients, *supra.*

[10] L&M Policy Research. A Comparison of Characteristics of Patients Treated by 340B Hospitals (2019), https://www.340bhealth.org/files/340B_Patient_Characteristics_Report_FINAL_04-10-19.pdf

[11] Dobson DaVanzo. The Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients, *supra*.

[12] Government Accountability Office (GAO), Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals 20 (June 2015), https://www.gao.gov/assets/680/670676.pdf.

[13] 85. Fed. Reg. 48772, 49048 (Aug. 12, 2020).

[14] *Id.*

[15] *Id.*

[16] 340B Health believes this is a significant underestimate. We note that in its final rule setting OPPS payment rates for CY 2018, CMS acknowledged that it underestimated the financial impact of the cuts by nearly 78%, or $700 million (82 Fed. Reg. 52356, 52623) (Nov. 13, 2017)). Moreover, CMS's revised estimate of the financial impact of the CY 2018 cuts was also an underestimate. *See* MedPAC Report to Congress: Medicare and the Health Care Delivery System (June 2020), http://www.medpac.gov/docs/default-source/reports/jun20_reporttocongress_sec.pdf?sfvrsn=0 (estimating the impact of the CY 2018 payment reduction to be $1.9 billion, which is $300 million more than CMS's estimate of $1.6 billion).

benefit from the safety net to providers that do not meet 340B's strict eligibility requirements of treating patients with low incomes.

Nor would CMS's proposal reduce copayments for Medicare beneficiaries. In fact, by implementing the payment reduction in a budget neutral manner, CMS is ensuring that any reduction in Medicare payment amounts for 340B drugs would be offset by increased Medicare payment amounts, and therefore, increased patient copayments for other services.[17] Moreover, by targeting safety-net hospitals for reduced payments that must be implemented in a budget neutral manner, CMS's proposal could actually increase costs for patients by limiting 340B hospitals' ability to continue providing the same level of assistance to low-income beneficiaries and the uninsured that the 340B program currently helps them provide.

III. CMS's Proposal to Pay 340B Hospitals Based on Average Acquisition Cost Does Not Represent a Conservative Estimate of the Average 340B Discount and Would Underpay 340B Hospitals for Certain Drugs

Based on analysis of the data it collected via a survey of 340B hospitals from April 24 through May 15, 2020, CMS used "statistical methodologies" to determine "an appropriate average or typical amount by which to reduce ASP that would approximate hospital acquisition costs for 340B drugs."[18] CMS says that "[i]n fairness to hospitals, [CMS] generally chose methodologies that yield the most conservative reduction to ASP when establishing the payment rate, and thus would be most generous to hospitals."[19] Yet, according to a recent 340B Health survey, half of the hospitals that analyzed the financial impact of CMS's proposal to set payment for 340B drugs based on average acquisition cost reported that they would lose money on Medicare Part B drugs overall if the proposal is finalized. There are additional steps that CMS could have taken that would have yielded a more conservative and accurate estimate of the average 340B discount relative to ASP, consistent with CMS's stated approach.

A. CMS should exclude from its calculation of the average 340B discount any drug that is subject to an inflationary penalty to avoid excessive losses on some drugs

CMS is seeking comment on whether excluding "penny-priced" drugs from its calculation of the average 340B discount accurately represents 340B drug acquisition costs. As stated in the Proposed Rule, CMS is concerned that including a discount of a penny-priced drug from the two quarters of 340B survey data may inappropriately increase the average discount. Penny pricing occurs because the formula used to determine the 340B price imposes a penalty when a manufacturer increases the average price of a drug faster than inflation.[20] If the increase is big enough, the resulting 340B price can be zero, whereupon manufacturers are required to charge $0.01 for the drug.[21] CMS proposes to exclude penny-priced drugs because of price variation from quarter to quarter and a recognition that these prices may distort the average discount. We agree that CMS should exclude penny-priced drugs to avoid inappropriately increasing the average 340B discount.

A more conservative and fairer estimate of the average 340B discount would also exclude any drug that is subject to an inflationary penalty to avoid setting average payment rates that fall significantly below acquisition costs for some drugs. CMS is proposing to cut payment for all 340B drugs by the same percentage regardless of the actual discount for a drug. Under CMS's proposal, however, the calculation of the average 340B discount would remain distorted by substantial 340B discounts for drugs that, although not penny-priced, are still subject to significant inflationary penalties. Because of this distortion in the average 340B discount, the resulting percentage reduction from ASP will cause significant losses on some drugs. This will disadvantage hospitals with a service mix skewed toward use of drugs subject to the minimum 340B discount and may have

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[17] *See* MedPAC Report to Congress: Medicare and the Health Care Delivery System, (June 2017), http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf, (noting that Medicare fee-for-service beneficiaries without supplemental insurance coverage are typically responsible for 20% of the Medicare-approved payment amount for Part B services).
[18] 85 Fed. Reg. 48772, 48886 (Aug. 12, 2020).
[19] *Id.*
[20] Section 1927(c)(2)(A) of the Social Security Act provides that if the Average Manufacturer Price (AMP) increases faster than the rate of inflation, the manufacturer pays an additional rebate amount which is reflected in an increased Unit Rebate Amount (URA). 42 U.S.C. § 1396r-8(c)(2)(A).
[21] Health Resources and Services Administration, 340B Drug Pricing Program Notice: Clarification of Penny Pricing Policy, (Nov. 21, 2011).

unintended consequences for the delivery of services. Large academic medical centers, for example, are more likely to use new, high cost drugs that have yet to be affected by inflationary penalties. We recommend that CMS eliminate all drugs with inflationary penalties from its calculations to avoid the potential for losses that are unevenly distributed across types of drugs and across hospitals.

Eliminating drugs with inflationary penalties could also reduce situations where payment amounts would be insufficient to cover acquisition costs for expensive drugs, such as cancer drugs. Hospitals have reported that CMS's proposal to pay 340B hospitals based on an average reduction from ASP would result in reimbursement at amounts less than cost for many expensive cancer drugs, including drugs among the highest in terms of spending like Neulasta, Herceptin and Opdivio.[22] 340B hospitals are a significant source of care for patients with cancer, evidenced by the fact that a majority of National Cancer Institute (NCI)-designated cancer centers (75%) are affiliated with 340B hospitals. 340B hospitals also serve as the safety net for cancer patients. MedPAC found that 340B hospitals serve a disproportionate share of low-income and disabled Medicare cancer patients relative to non-340B hospitals and physician offices.[23] In a recent 340B Health survey, 340B hospitals report that cancer care and other infusion services are the most likely clinical services to be negatively impacted by CMS's proposal.

B. CMS's methodology for volume-weighting the survey data is flawed

CMS says that in calculating the average discount that 340B drugs receive relative to ASP, it should account for how often those drugs were billed by all hospitals under the OPPS for 2018 and 2019 to better reflect each drug's overall utilization under the OPPS. Therefore, CMS says it volume-weighted the drug discounts determined from the survey to mirror overall drug utilization under the OPPS. However, non-340B hospitals' drug utilization is irrelevant for setting reimbursement rates under the OPPS for drugs acquired under the 340B program based on survey data provided by 340B hospitals only.

In addition, weighting individual percentage discounts by utilization without considering the price of each drug is a methodological error that results in an inaccurate and potentially inflated average discount rate. Not considering both the dollar discount and volume underweights the discounts associated with higher cost drugs and overweights the discounts associated with lower priced drugs. Given the ever higher launch prices of new drugs, particularly cancer drugs, and the fact that newer drugs have lower inflationary penalties because they have been subject to the penalty for less time, we believe this methodological error underweights drugs with lower discounts and overweights drugs with higher discounts. A correctly calculated average discount would consider both the dollar size of the discount and the utilization of each drug, resulting in a more accurate and conservative estimate of the average 340B discount.

C. CMS did not account for costs hospitals incur in participating in the 340B program

CMS also failed to account for various costs that hospitals incur participating in the 340B program. DSH hospitals incur costs to be in the 340B program due to the 340B statute's group purchasing organization (GPO) prohibition.[24] The Health Resources and Services Administration (HRSA) effectively requires these hospitals to make their initial purchase of any drug at a non-340B, non-GPO price, typically wholesale acquisition cost (WAC).[25] The GPO prohibition also requires hospitals to use WAC drugs for 340B-ineligible outpatients, as well as Medicaid patients (including dually eligible beneficiaries) if a hospital has elected not to use 340B drugs for Medicaid beneficiaries in accordance with the 340B statute's prohibition against duplicate discounts. Even if a hospital is not subject to the GPO prohibition, the hospital still must buy drugs for 340B-ineligible and carved-out Medicaid patients at non-340B prices that are likely higher than 340B prices. CMS failed to take these significant costs, unique to participation in the 340B program, into account, which is problematic given that the payment reductions affect some 340B hospitals' reimbursement for non-340B drugs. According to a recent 340B Health survey, 39% of respondents reported that their organizations use the "JG" modifier on non-340B

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[22] 340B hospitals report that of the 10 drugs that comprised the highest Medicare Part B drug spending amounts in 2018, 8 of those drugs (Neulasta, Herceptin, Opdivio, Avastin, Keytruda, Prolia, Remicade, and Rituximab) will be reimbursed at amounts less than cost if CMS finalizes its proposal to pay 340B hospitals at average acquisition cost.
[23] *See* MedPAC Report to Congress: Medicare Payment Policy (March 2020), http://medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf
[24] 42 U.S.C. § 256b(a)(4)(L)(iii)-(M).
[25] Health Resources and Services Administration, 340B Drug Pricing Program Notice: Statutory Prohibition on Group Purchasing Organization Participation, (Feb. 7, 2013).

drugs due to billing system limitations and compliance concerns, which triggers reduced Medicare reimbursement for drugs acquired at non-340B prices.

IV. CMS's Alternative Proposal Is Not an Appropriate Payment Rate for 340B Drugs

A. CMS should pay 340B hospitals the same drug add-on payment that non-340B hospitals receive for drug overhead and related expenses

CMS should not continue with the alternative proposed reimbursement rate of ASP minus 22.5%. The current 340B drug payment policy under the OPPS pays separately payable drugs at ASP minus 22.5% with no add-on payment to account for drug overhead and related costs. CMS says that hospitals receive a significant margin on 340B drugs under its current payment policy and an additional add-on payment is therefore not necessary. Yet, CMS also acknowledges that there should be an overhead payment whether a drug is paid at a 340B price or a non-340B price.[26]

Like non-340B hospitals, 340B hospitals should also receive an add-on payment of 6% of a drug's ASP. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 required MedPAC to determine whether the OPPS should have a payment adjustment to cover services provided by hospital pharmacies related to drug handling and overhead costs.[27] After speaking with stakeholders and analyzing Medicare hospital cost report data, MedPAC concluded that drug handling costs are not negligible, and MedPAC noted that some hospitals such as hospitals that specialize in cancer care or teaching hospitals that provide newer services have higher drug handling costs and would be unfairly penalized if CMS set payment at acquisition cost without accounting for drug handling costs.[28] MedPAC determined that the payment system dictated by the MMA should include an adjustment for handling products when Medicare pays for the products at acquisition cost and recommended that the Secretary establish separate, budget neutral payments to cover the costs that hospitals incur for handling separately paid drugs.[29]

340B hospitals, many of which specialize in cancer care and include large academic medical centers, are precisely the kinds of hospitals that MedPAC identified as having higher handling costs. ASP minus 22.5% is not an appropriate payment amount for separately payable Part B drugs acquired under 340B in part because that rate does not include a 6% add-on payment.

V. CMS's 340B Payment Proposals Rely on a Faulty Premise That Part B Drug Spending Increases Are Caused by 340B Hospitals

CMS's proposal to deepen the payment cuts is based on a faulty premise that 340B hospitals are responsible for increases in Medicare Part B drug spending. Citing to MedPAC's March 2019 report to Congress, CMS says that MedPAC noted that outpatient payments increased in part due to rapid growth in Part B drug spending, and that MedPAC stated that this rapid growth in OPPS specifically was largely driven by the margins for drugs obtained through the 340B program.[30] This is a mischaracterization of MedPAC's report, as MedPAC did not say or even suggest that 340B discounts contribute to increases in Part B drug spending. Rather, MedPAC said that growth in spending reflects price increases for existing drugs and the introduction of new, expensive drugs.[31]

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[26] *See* 85 Fed. Reg. 48772, 48889 (Aug. 12, 2020) (stating that "it is reasonable to assume that a given drug will have similar overhead and other administrative costs regardless of whether the drug was purchased under the 340B Program or by a non-340B entity.").
[27] Pub. L. No. 108-173; 42 U.S.C. § 1395(l)(t)(14)(E).
[28] *See* MedPAC Report to Congress: Payment for Pharmacy Handling Costs in Hospital Outpatient Departments, (June 2005), http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0
[29] *Id.*
[30] 85 Fed. Reg. 48772, 48885 (Aug. 12, 2020).
[31] *See* MedPAC Report to Congress: Medicare Payment Policy (March 2019), http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf (stating that "[t]he growth in combined program spending and cost sharing for drugs has accelerated in recent years (2016 to 2017) … [e]ven though drug spending has increased under the OPPS, drugs are profitable overall in the outpatient setting because hospitals' revenue exceed their costs for drugs, largely driven by [340B margins] … [t]he growth in spending on Part B drugs reflects both price increases in existing drugs and the introduction of new, expensive cancer drugs.").

CMS also relied on a similar faulty premise when it first proposed the 340B payment cut for CY 2018. CMS cited to a 2015 Government Accountability Office (GAO) report that 340B DSH hospitals may be using more drugs or more expensive drugs than necessary.[32] MedPAC recently published a report that wholly refutes the GAO's finding. In examining five cancer types, MedPAC concluded that if there is any link between hospitals' 340B participation and higher Medicare spending on cancer medications, that link has a modest effect, is dwarfed by rising prices on cancer drugs in general, and potentially can be attributed to differences in patient characteristics.[33] CMS now does not cite to the GAO report in the CY 2021 Proposed Rule to support CMS's 340B payment policy proposals.

Moreover, the 340B program plays an important role in deterring manufacturers from raising drug prices generally and not just to providers that participate in the program. A new independent study in the Journal of the American Medical Association (JAMA) shows that inflation penalties built into 340B discounts have restrained the rate of drug price increases.[34] The JAMA study found that increases in the percentage of drug sales subject to inflation penalties included in the 340B discounts were associated with lower annual price increases for drugs.[35] Researchers with the Pew Charitable Trusts note that the 340B statute's inflationary penalty may be particularly impactful in the Medicare Part B program, where there are no inflation adjustments or rebates to offset price increases.[36] CMS should recognize the important role that the 340B discount plays in lowering drug prices for all Americans, even when the drugs are not purchased through 340B, and stop penalizing 340B hospitals with lower Medicare payment rates based on a faulty premise that they have increased Medicare Part B drug spending.

VI. CMS's 340B Payment Proposals are Contrary to Law

A. CMS does not have the authority to vary payment to 340B hospitals without drug acquisition cost survey data

We continue to believe that the payment reduction of ASP minus 22.5% that was finalized by CMS as part of the final rule setting OPPS payment rates for CY 2018 was made without statutory authority. The OPPS is established at 42 U.S.C. § 1395l(t). Subparagraph (14) addresses payment for certain "specified covered outpatient drugs" that are furnished as part of covered outpatient department services and separately payable. Payment for such drugs shall be equal:

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(o) of this title, section 1395w–3a of this title, or section 1395w–

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[32] Government Accountability Office (GAO), Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals 20 (June 2015), https://www.gao.gov/assets/680/670676.pdf.
[33] *See* MedPAC Report to Congress: Medicare Payment Policy (March 2020), http://medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf (of the five cancer types MedPAC examined, its regression analysis for two cancer types (lung and prostate cancers) found that "340B market share had statistically significant effects of just over $300 per patient per month. Those 340B effects, however, were much smaller than the effects of the general trend in oncology spending, which reflects both the effect of rising prices and shifts in the mix of drugs, including the launch of new products with higher prices. For example, between 2009 and 2017, cancer drug spending per month grew by more than $2,000 for patients with breast cancer, lung cancer, and leukemia/lymphoma. Given the relative size of the potential 340B effect, the overall effect on beneficiary cost sharing is likely to be modest and vary by beneficiaries' supplemental coverage.").
[34] Dickson, Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases, *JAMA Network Open,* 2020;3(9):e2016388, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770540
[35] *Id.*
[36] The Pew Charitable Trusts, Comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, (July 13, 2018), https://www.regulations.gov/document?D=CMS-2018-0075-2649

> 3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.[37]

CMS relied on subclause (II) for its authority to reduce payment to 340B hospitals beginning in CY 2018.[38] As we explained in our comments to CMS on its CY 2018 proposal, only subclause (I) permits CMS to vary payment by hospital group, and only if drug acquisition cost data are collected and considered in setting payment under subclause (I). Judge Pillard, a Circuit Judge on the U.S. Court of Appeals for the D.C. Circuit, agreed with this interpretation in her dissenting opinion in *Am. Hosp. Assn. v. Azar* (D.C. Cir. July 31, 2020). She explained that the payment reduction could not be upheld under Chevron deference because the statute is clear:

> *"Only subclause (I), not subclause (II), authorizes HHS to set different reimbursement rates for distinct hospital groups" and it provides that authority only if HHS "tak[es] into account the different acquisition costs identified in the robust, hospital-specific data that Congress required."*[39]

Judge Pillard said she would affirm the district court's conclusion that HHS "cannot fundamentally rework the statutory scheme-by applying a different methodology than the provision requires-to achieve under subclause (II) what it could not do under subclause (I) for lack of adequate data."[40] In addition, we agree with Judge Pillard's determination that the majority's decision conflicts with D.C. Circuit precedent because it allows HHS to use its "adjustment" authority under subclause (II) to work "basic and fundamental changes" to the statutory scheme.[41]

Moreover, CMS should not continue the payment cuts while the litigation is ongoing. After CMS issued its CY 2021 proposed OPPS rule, a petition for an en banc rehearing was filed with the D.C. Circuit. The petition argues that an en banc rehearing is warranted because the panel decision conflicts with D.C. Circuit precedent and because upholding the payment reduction would threaten 340B hospitals' ability to care for patients who need it most.

B. The survey did not generate a statistically significant estimate of hospitals' average acquisition costs in violation of the Medicare statute's requirements

In order to set Medicare reimbursement for specified covered outpatient drugs (SCODs) at average acquisition cost, the law requires that such reimbursement rates are established using a survey of hospital acquisition costs.[42] The survey of hospital acquisition costs must have a "**large sample of hospitals** that is sufficient to generate a **statistically significant estimate** of the average hospital acquisition cost for each SCOD."[43] A study that is "statistically significant" has results that are unlikely to be the result of random error.[44] Statistical significance is determined, in part, by the number of observations in a dataset, with smaller groups likely to be different from the population than larger ones, and therefore, have more sampling error.[45]

We are concerned that CMS did not obtain an adequate survey response rate, raising concerns that the data from those who did respond are insufficient to generate a statistically significant estimate of hospitals' average acquisition costs. 340B Health is not surprised to learn that 542 hospitals, representing 38% of surveyed

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[37] 42 U.S.C. § 1395l(t)(14)(A)(iii).
[38] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82. Fed. Reg. 33558, 33634 (July 20, 2017) (CMS-1678-P).
[39] *Am. Hosp. Ass'n v. Azar*, 2020 U.S. App. LEXIS 24220 *46 (D.C. Cir. July 31, 2020) (Pillard, C, dissenting).
[40] *Id.* at *48 (citing *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 82 (D.D.C. 2018).
[41] *Id.* at *51 (stating that "[t]he Hospitals' limited reading of the adjustment authority that subclause (II) confers is supported by [the appellate court's] previous caution that the term 'adjustment' in this statute—like the term 'modify' at issue in *MCI Telecommunications Corp. v. AT&T Co.,* 512 U.S. 218, 225 (1994), which the Court held 'means to change moderately or in minor fashion'—cannot permit 'basic and fundamental changes in the scheme'." (citing *Amgen Inc. v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004) (quoting *MCI,* 512 U.S. at 225)).
[42] 42 U.S.C. § 1395(l)(t)(14)(A)(iii)(I).
[43] 42 U.S.C. § 1395(l)(t)(14)(A)(D)(iii) (emphasis added).
[44] *Matrixx Initiatives, Inc., v. Siracusano*, 563 U.S. 27 (2011).
[45] The National Academies Press, Reference Manual on Scientific Evidence, Third Edition, https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf; *Moussouris v. Microsoft Corp*., 311 F. Supp. 3d 1223 (W.D. Wash., Mar. 7, 2016).

hospitals, did not respond to CMS's survey, as many hospitals reported to us that they did not receive it or that they did not have time, during the COVID pandemic, to complete it.[46] Moreover, as part of its "terms of clearance," OMB said that CMS must clearly describe "the scope and characteristics" of the hospitals that responded to the survey as well as "any limitations in the generalizability of the information collected" in any documents or regulations that CMS produces using the data. The proposed rule did not address whether CMS satisfied OMB's terms of clearance which is particularly concerning given that over one third of surveyed hospitals did not respond.[47] For these reasons, CMS cannot use the survey data to establish reimbursement rates for SCODs.

C. The survey collected acquisition cost data from 340B hospitals, and excluded other hospitals, in violation of the Medicare statute's requirements for setting payment for hospital outpatient drugs at average acquisition cost

CMS does not have the authority under the Medicare statute to conduct a survey of only 340B hospitals to determine drug acquisition costs. Section 1395l(t)(14)(D)(ii) of the Social Security Act allows CMS to survey hospitals to determine "the hospital acquisition cost for each specified covered outpatient drug." There is no indication in the statute that the survey can be for only a subset of hospitals, such as 340B hospitals, or only a subset of drugs, such as 340B drugs. Moreover, the Medicare statute's reference to a "large sample of hospitals" indicates that the survey must reflect acquisition costs across all hospitals, not just a subset of hospitals such as 340B hospitals.[48] Thus, CMS did not have the authority to survey only 340B hospitals, should disregard the survey results, and not finalize its proposal to pay 340B hospital at average acquisition cost.

* * * *

340B Health requests that CMS not finalize its proposal to deepen the payment cuts to 340B hospitals using flawed drug acquisition cost data. Finalizing such a proposal would further harm 340B hospitals' ability to serve low-income patients at a critical time for safety-net hospitals serving as the front line of defense against COVID-19. CMS's proposal would not reduce overall costs for the Medicare program or beneficiaries and would increase Medicare payments to OPPS providers that do not meet strict 340B eligibility criteria. We urge CMS to abandon the payment cuts and pay 340B hospitals at the same rate paid to non-340B hospitals.

Sincerely,

Maureen Testoni
President & Chief Executive Officer

Amanda Nagrotsky
Legal Counsel

[46] 85 Fed. Reg. 48772, 48886 (Aug. 12, 2020).
[47] *See id.* at 48898 (stating without explanation or detail that the characteristics CMS analyzed included hospital bed count, teaching hospital status, hospital type, and geographic classification as a rural or urban hospital and that the survey respondent hospitals were generally similar to the general 340B survey population).
[48] Though CMS may set payment rates that vary by hospital group based on relevant hospital characteristics such as volume of outpatient services, (42 U.S.C. § 1395(t)(14)(A)(iii)(I)), CMS is not permitted to survey the acquisition costs of only one group of hospitals for purposes of setting the payment rates under the OPPS.

340B HEALTH

The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients

Submitted to:
340B Health

Submitted by:

Dobson | DaVanzo
HEALTH ECONOMICS CONSULTING

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Wednesday, September 30, 2020

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Dobson | DaVanzo
HEALTH ECONOMICS CONSULTING

Executive Summary

340B Health commissioned Dobson DaVanzo & Associates to perform a descriptive analysis comparing disproportionate share (DSH) hospitals participating in the 340B program to non-participating acute care hospitals in the delivery of services to Medicaid and low-income Medicare patients (SSI recipients) as well as their offering of essential community and other services important to underserved populations. We also looked at the financial performance of hospitals in both groups, which may be reflective of their role in providing services to Medicaid patients, as Medicaid significantly underpays providers for their services. This study has four central findings:

1. **340B DSH hospitals deliver disproportionately more hospital services to Medicaid and low-income Medicare patients than non-340B acute care hospitals.**

We found that 340B DSH hospitals treat significantly more Medicaid and low-income Medicare patients than non-340B hospitals. The average Medicaid/Medicare SSI patient load for 340B DSH hospitals was 40.6 percent in 2018, compared with 26.3 percent for non-340B hospitals.

2. **Medicaid makes up a greater share of operating revenue for 340B hospitals.**

We found that Medicaid revenue as a percent of total operating revenue is twice as high at 340B DSH hospitals than non-340B hospitals (16.9 percent versus 8.5 percent in 2018). Additionally, this percentage was higher for smaller hospitals. 340B DSH hospitals make up 42.9 percent of hospitals in our analysis, but account for 75.2 percent of Medicaid revenue. Medicaid patients have a higher burden of illness, are more racially and ethnically diverse, and have lower payment rates creating special challenges for 340B hospitals.

3. **Operating margins for 340B DSH hospitals are significantly lower than those of non-340B hospitals, which may be reflective of their dedication of resources to serve patients with low income.**

An examination of operating margins among 340B DSH and non-340B hospitals in 2018 revealed that 340B DSH hospitals consistently have lower average margins than their non-340B counterparts across size groupings, and that average operating margins were negative for 340B DSH hospitals overall. This is an indication that the vital services provided by 340B DSH hospitals to patients with Medicaid, for which they are often undercompensated, create financial challenges.

4. **340B DSH hospitals are more likely to provide un-and under-reimbursed "essential community services," specialized services, and community health and wellness services than non-340B hospitals. These services are often financially unprofitable for the hospital and contribute to low operating margins.**

This analysis revealed that 340B hospitals represent a large proportion of the hospitals providing highly specialized services such as burn and trauma care. Also, the percentage of hospitals providing services targeting vulnerable patients like HIV/AIDS and behavioral health services, as well as a range of services to promote community health and access and/or address social determinants of health, was higher among 340B DSH hospitals than among hospitals that were not in the program. Many of the services provided disproportionately by 340B DSH hospitals have been deemed "essential community services" by the Medicaid and CHIP Payment and Access Commission (Medicaid and CHIP Payment and Access Commission, 2020). In summary, this study finds that 340B DSH hospitals treat higher levels of Medicaid and low-income Medicare patients than their non-340B counterparts, provide three-quarters of hospital care received by Medicaid patients, have lower margins, and are more likely to provide highly specialized services, essential community services, behavioral health services, and services to promote community health, wellness, and access. The 340B program inherently recognizes the special challenges that these hospitals face in providing care to Medicaid and Medicare patients with low income and is critical to the continued existence of many eligible entities.

Introduction

The 340B Drug Pricing Program, administered by the Health Resources & Services Administration (HRSA), requires drug manufacturers to provide outpatient drugs to eligible health care organizations, or covered entities, at reduced prices. Covered entities under the 340B program include providers that are critical to treating low-income and rural populations, such as Federally Qualified Health Centers, AIDS Drug Assistance Programs, and certain public and non-profit hospitals, including disproportionate share (DSH) hospitals.[49] The 340B program was established to provide these providers with an avenue for purchasing outpatient drugs at a reduced cost. Congress intended for the savings from these discounted prices to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" (H.R. No. 102-384, Part II, Pg. 12, 102nd Congress, Second Session, 1992).[50] This suggests that congressional

> *"The purpose of the 340B program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."*
> *- 102nd Congress, Second Session, 1992*

[49] Eligible entities include federally qualified health centers, urban Indian organizations, family planning clinics, sexually transmitted disease grantees, Native Hawaiian Health Centers, state-operated Ryan White AIDS Drug Assistance Programs, other Ryan White grantees, hemophilia treatment centers, and black lung clinics. Eligible hospitals include certain DSH hospitals, critical access hospitals (CAHs), sole com-munity hospitals (SCHs), rural referral centers (RRCs), freestanding cancer hospitals, and children's hospitals. Depending upon hospital type, these hospitals must meet the requirements of 42 USC 256b(a)(4)(L). Additionally, providers that meet all of the requirements for the federally qualified health centers program, but do not receive federal grants—referred to as federally qualified health center look-alikes—are eligible to participate in the 340B Program.

[50] 102nd Congress, Second Session. (1992). *H.R. No. 102-384, Part II.*

intent was for resources to be targeted toward specific hospitals and toward patients with low income and the services they require to maintain or improve their health.

More specifically, when Congress first enacted the 340B program in 1992, it targeted DSH hospitals that provide high levels of care to Medicaid and low-income Medicare beneficiaries. Thus, the 340B program inherently recognizes the special challenges that these hospitals face in providing care to these patients. Medicaid enrollees are approximately three times more likely to report being in fair or poor health than people with private insurance, and they are significantly more likely to have chronic diseases like diabetes, heart disease, and arthritis. The population covered by Medicaid is also more ethnically and racially diverse than are the privately insured (Medicaid and CHIP Payment and Access Commission, 2019). Importantly, Medicaid payments do not typically cover the cost of care, with hospitals receiving direct payments of 89 cents for every dollar spent providing care to Medicaid patients (American Hospital Association, 2020). As a result, the 340B program is critical to the continued existence of these eligible entities.

Given this context, 340B Health commissioned Dobson DaVanzo & Associates, LLC to perform a descriptive analysis comparing DSH hospitals participating in the 340B program with non-participating acute care hospitals on several metrics indicative of their level of service to Medicaid and Medicare patients with low income. These metrics include:

1) Medicaid/Medicare SSI patient load, defined as the hospital's proportion of Medicaid days to total inpatient days plus Medicare SSI days to total Medicare days;
2) Medicaid revenue as a percent of hospital operating revenue;
3) Hospital operating margins; and
4) Provision of highly specialized services, services targeting underserved populations, and services promoting community health and access.

Analyses such as these are critical to confirming that 340B DSH hospitals are meeting the mission of serving the populations intended by the legislation.

Methodology in Brief

The research team at Dobson | DaVanzo used the fiscal year (FY) 2020 Medicare Inpatient Prospective Payment System (IPPS) final rule and correction notice impact file (Centers for Medicare & Medicaid Services, 2019)[51] to identify the universe of eligible hospitals to be included in the study. The team then used the HRSA Office of Pharmacy Affairs Information System (OPAIS) Covered Entity Daily Report as of January 6, 2020 (Health Resources & Services Administration Office of Pharmacy Affairs, 2020) to divide these hospitals into two groups: (1) those participating in the 340B program between October 1, 2017 and December 31, 2018; and (2) all other IPPS acute care hospitals.

Once hospitals were initially identified and separated into the 340B and non-340B categories, the research team applied a number of exclusions to the universe of potentially study-eligible hospitals. First, because the Medicare hospital cost reports serve as the primary analytic data source, only those hospitals with a Medicare hospital cost report for FY 2018 were retained. We also excluded hospitals when required data elements were missing or when data showed a high degree of variation from the mean. In all, 1,127 340B DSH hospitals and 1,503 non-340B hospitals were retained for analysis.

Metrics for comparison taken from Medicare hospital cost reports include Medicaid/Medicare SSI patient load, Medicaid revenue as a percent of hospital operating revenue, and operating margins. The research team stratified hospitals by size when comparing 340B DSH and non-340B hospitals on these key metrics to account for the different scope of operations reflected in hospitals of varying sizes. Total patient care costs were used as a proxy for hospital size, and data are presented on key metrics for "comparably sized" hospitals.[52]

Data on service offerings came from the American Hospital Association (AHA) Annual Survey for 2018 (Health Forum, LLC, 2019). We excluded hospitals with missing AHA survey data, as well as

[51] The FY 2020 IPPS impact file contains data from the March 2019 update of the FY 2018 Medicare Provider Analysis and Review dataset, the March 2019 Provider Specific File, and Medicare Hospital Cost Reports from FYs 2016 and 2017 (Centers for Medicare & Medicaid Services, 2019).

[52] While the number of hospitals in each quartile is the same, the distribution between 340B DSH and non-340B hospitals is different within each quartile, as each group has a different number of hospitals overall and in each quartile. Based on the measure of patient care costs, 340B DSH hospitals tend to be larger than non-340B hospitals. See Appendix A for additional details.

non-responding hospitals with estimated data only.[53] We adjusted the groupings to include 340B and non-340B hospitals identified in the AHA survey as primarily providing general medical and surgical care to children (i.e., children's hospitals).[54]
A detailed methodology of hospital selection and metric definition can be found in Appendix A.

[53] The AHA survey data contained estimates for key utilization variables for some non-responding hospitals. Hospitals with no reported data (i.e., nonresponding hospitals) – which did not have data regarding the provision of public health and specialized services - were excluded from the analyses of service offerings.
[54] Identification of children's general medical and surgical hospitals was based upon the variable PRIMARY_SERVICE in the AHA data, which provides the category best describing the hospital's type of service provided to the majority of admissions.

Study Findings

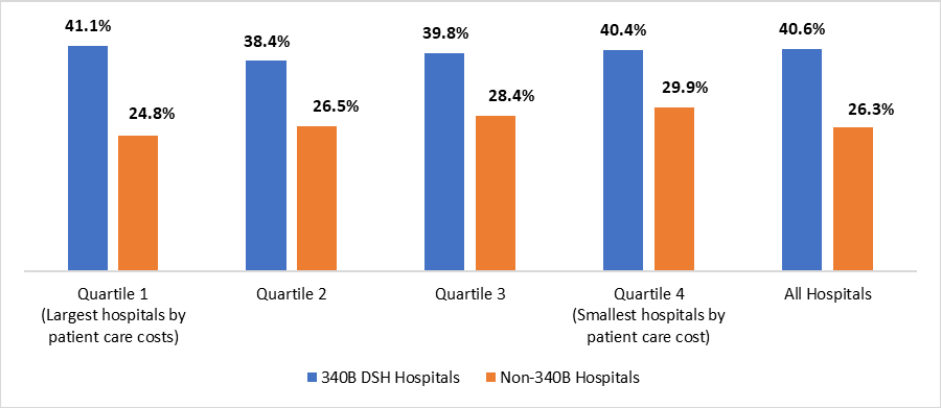
In the following sections, we present the results of our comparison between 340B DSH and non-340B hospitals on the four analytic metrics outlined above: Medicaid/Medicare SSI patient load, a measure reflecting service to Medicaid patients and Medicare patients with low income; Medicaid revenue; hospital operating margins; and the provision of services.

Medicaid/Medicare SSI Patient Load

340B DSH hospitals have a 54 percent higher Medicaid/Medicare SSI patient load than non-340B hospitals.

340B DSH hospitals serve a disproportionate share of Medicaid and low-income Medicare patients. The Medicaid/Medicare SSI patient load is measured as the sum of Medicaid inpatient days as a percent of total inpatient days plus Medicare SSI days as a percent of total Medicare days, as compared to non-340B hospitals. Medicare SSI recipients are dually eligible for Medicare and Medicaid. Figure 1 contains a comparison of the Medicaid/Medicare SSI patient load for the hospital cohorts overall and by quartile. It shows that 340B DSH hospitals had a higher Medicaid/Medicare SSI patient load in 2018 than non-340B hospitals. In each quartile, the Medicaid/Medicare SSI patient load was at least ten percentage points higher in 340B DSH hospitals than in non-340B hospitals. Overall, the Medicaid/Medicare SSI patient load for 340B DSH hospitals in 2018 was 54.4 percent higher than the Medicaid/Medicare SSI patient load for non-340B hospitals (40.6 percent versus 26.3 percent respectively). This finding indicates that 340B DSH hospitals serve as an important community safety net.

Figure 1: Average Medicaid/Medicare SSI Patient Load for 340B DSH and Non-340B Hospitals by Quartile of Total Patient Care Costs, FY 2018



Source: Dobson | DaVanzo analysis of FY 2018 Medicare hospital cost reports

Figure 1 also demonstrates consistency in the Medicaid/Medicare SSI patient load across 340B DSH hospitals of all sizes, as measured by patient care costs. Whereas the Medicaid/Medicare SSI patient loads rise with decreasing hospital size in non-340B hospitals, the Medicaid/Medicare SSI loads among 340B DSH hospitals are generally stable at approximately 40 percent. This is an indication of the importance of 340B DSH hospitals to Medicaid and low-income Medicare patients, traditionally underserved populations, across a wide range of hospital sizes.

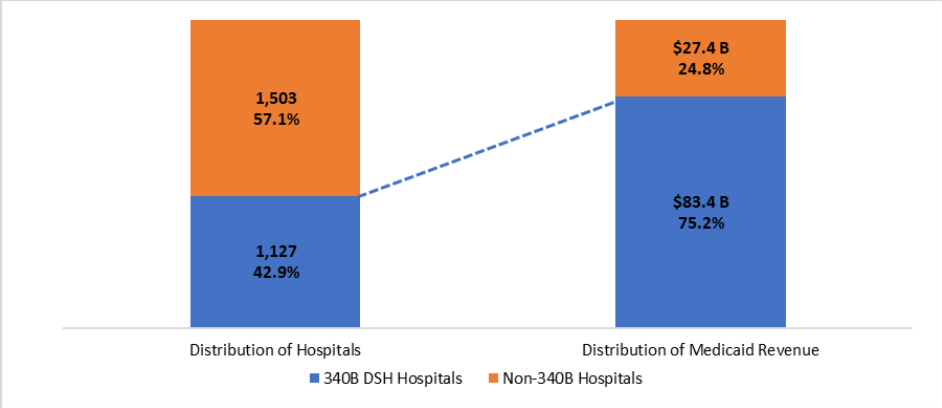
Medicaid Revenue

The analysis of Medicaid/Medicare SSI patient load presented above indicates that 340B DSH hospitals treat a higher proportion of Medicaid and low-income Medicare patients. We also examined hospital revenues to determine what share of overall Medicaid revenue is generated by 340B hospitals, and whether this share is disproportionate to the share of hospitals that 340B DSH hospitals represent. As shown in Figure 2, we found that 340B hospitals represent 42.9 percent of hospitals in the analysis, but account for 75.2 percent of Medicaid services as measured by net Medicaid revenue.

340B DSH hospitals represent 43 percent of hospitals in the analysis but account for 75 percent of Medicaid revenues.

Figure 2: Distribution of 340B DSH and Non-340B Hospitals and Medicaid Revenue, FY 2018

Medicaid revenue as a percent of operating revenue is two times higher at 340B DSH hospitals than at non-340B hospitals.



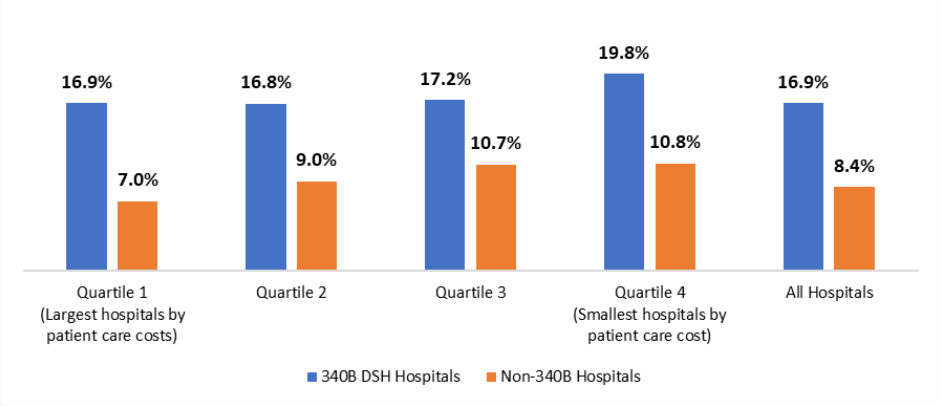
Source: Dobson | DaVanzo analysis of FY 2018 Medicare hospital cost reports

Another way to look at whether 340B DSH hospitals provide more care to Medicaid patients is to examine whether the portion of hospital revenue that comes from Medicaid patients is higher in 340B DSH hospitals than in non-340B hospitals. As demonstrated in Figure 3, the percentage of revenue from Medicaid is six to ten percentage points higher in 340B DSH hospitals than in non-340B hospitals, regardless of hospital size. Overall, 16.9 percent of

revenue from 340B DSH hospitals comes from Medicaid, double that of non-340B hospitals (8.4 percent).

This metric is an indication that the larger size of 340B DSH hospitals relative to non-340B hospitals is not driving the finding that 340B DSH hospitals provide more Medicaid services as measured by revenue. In fact, the percentage of revenue from Medicaid generally increases as hospital size decreases. That is, the smallest hospitals receive the highest percentage of revenue from Medicaid, thus bearing a relatively higher burden of Medicaid under-reimbursement.

Figure 3: Medicaid Revenue as a Percent of Total Hospital Operating Revenue for 340B DSH and Non-340B Hospitals by Quartile of Total Patient Care Costs, FY 2018



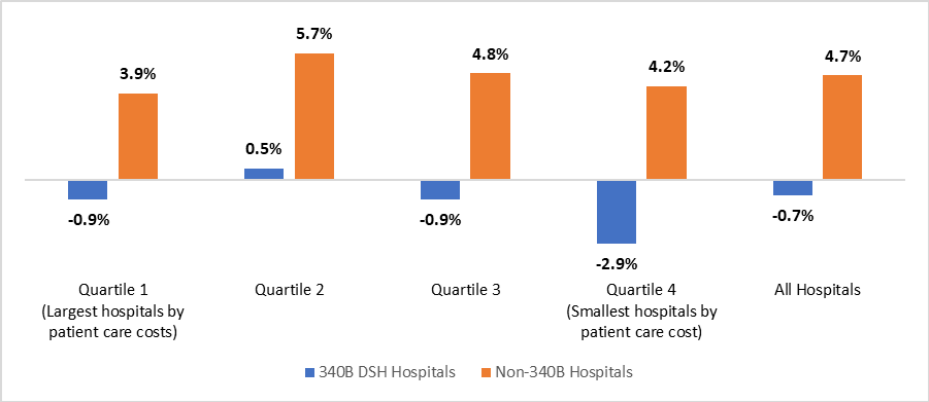
Source: Dobson | DaVanzo analysis of FY 2018 Medicare hospital cost reports

Hospital Operating Margins

Figure 4 demonstrates that, on average, 340B DSH hospitals have negative operating margins (-0.7 percent for 340B DSH hospitals overall). This stands in contrast to the operating margins of non-340B hospitals, which were 4.7 percent overall in 2018. 340B DSH hospitals, and in particular the smallest hospitals, are losing money providing patient care, due in part to the higher proportion of Medicaid revenue and resulting public payer shortfalls, and the provision of typically unprofitable services (discussed below). Hospitals cannot consistently incur financial losses and continue to provide essential services, making the 340B program critical to the continued existence of eligible entities.

The crucial role of 340B hospitals in the safety net is accompanied by substantially lower operating margins than those of non-340B hospitals.

Figure 4: Hospital Operating Margins for 340B DSH and Non-340B Hospitals by Quartile of Total Patient Care Costs, FY 2018



Source: Dobson | DaVanzo analysis of FY 2018 Medicare hospital cost reports

Provision of Services

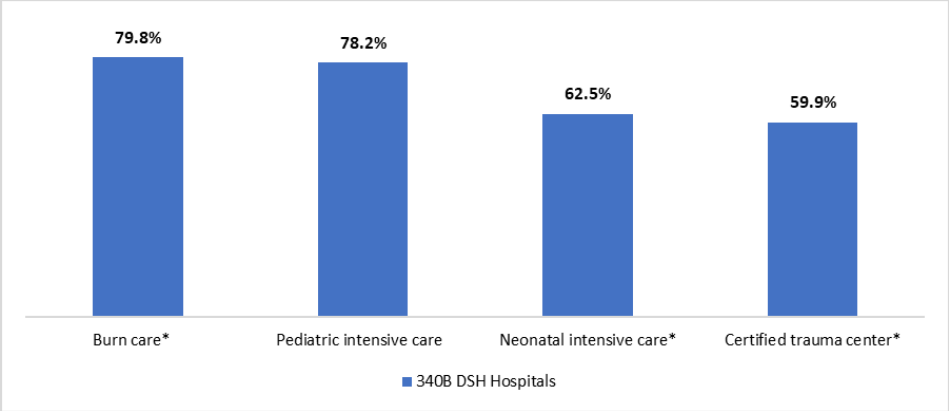
We used AHA annual survey data to examine the service offerings of 340B versus non-340B hospitals to gauge whether 340B hospitals are more likely to offer "essential community services," highly specialized services, and/or services targeted to underserved populations or geared toward community health or wellness. Certain services have been deemed "essential community services" by the Medicaid and CHIP Payment and Access Commission (MACPAC) because of their importance to underserved populations (Medicaid and CHIP Payment and Access Commission, 2020). We found that highly specialized services are concentrated in 340B hospitals. Additionally, the percentage of hospitals providing services targeted to underserved patients and community health or wellness services was higher among 340B DSH hospitals than among those that were not in the program.

Provision of Highly Specialized Services

Highly specialized services are concentrated in 340B DSH hospitals.

As illustrated in Figure 5, 340B DSH hospitals represent the majority of hospitals providing highly specialized services, including burn care, pediatric and neonatal intensive care, and care in certified trauma centers. Nearly 80 percent of hospitals that provide burn care and pediatric care participate in the 340B program, as do approximately 60 percent of hospitals that provide neonatal intensive care or are certified trauma centers. Three of these services – burn care, neonatal intensive care, and certified trauma centers - have been deemed "essential community services" by MACPAC.

Figure 5: 340B Hospitals as Percent of All Hospitals Offering Highly Specialized Services



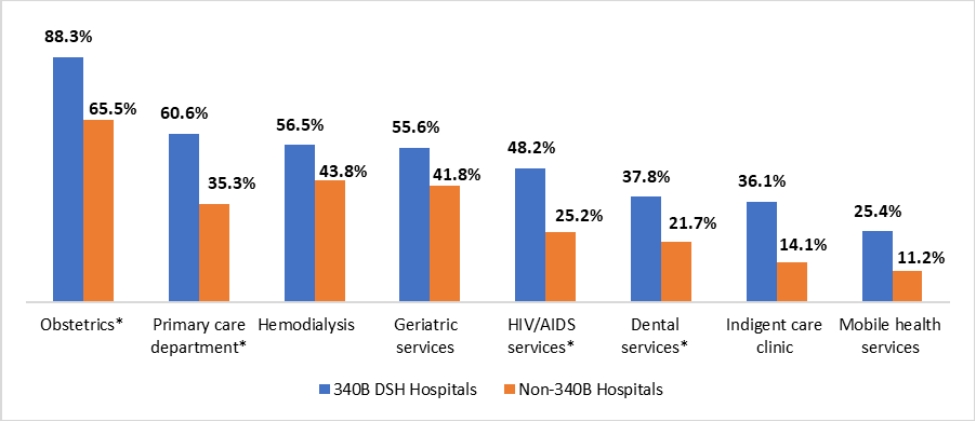
Source: Dobson | DaVanzo analysis of the 2018 American Hospital Association Annual Survey
* Defined as essential community services by the Medicaid and CHIP Payment Access Commission (Medicaid and CHIP Payment and Access Commission, 2020)

Essential Community and Other Critical Services

340B DSH hospitals provide an important access point to care for underserved populations. As shown in Figure 6, 340B hospitals are substantially more likely to offer essential community services such as obstetrics, primary care, HIV/AIDS services, and dental care. The same is true for other critical services like indigent care clinics and geriatric services. Many of these services have a challenging payer mix and must be subsidized to remain operational (Chen, Bazzoli, & Hsieh, 2009; Horowitz, 2005).

340B DSH hospitals are more likely to offer services critical to underserved populations than are non-340B hospitals.

Figure 6: Percentage of 340B DSH and Non-340B Hospitals Providing Essential Community and Other Health Services



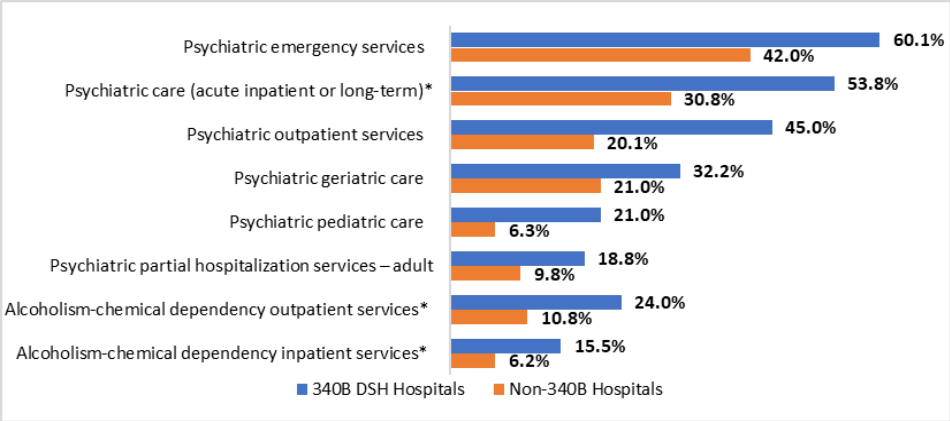
Source: Dobson | DaVanzo analysis of the 2018 American Hospital Association Annual Survey
* Defined as essential community services by the Medicaid and CHIP Payment Access Commission (Medicaid and CHIP Payment and Access Commission, 2020)

Behavioral Health

Figure 7 presents the percentage of 340B and non-340B hospitals in the analysis providing behavioral health services. It demonstrates that the provision of these vital services, which face challenges such as lack of coverage and inadequate reimbursement (American Hospital Association, 2019), is done proportionally more often in 340B DSH hospitals than in non-340B hospitals. Some types of behavioral health services, such as psychiatric outpatient services and alcoholism-chemical dependency outpatient services, are more than twice as likely to be provided in 340B DSH hospitals as in non-340B hospitals.

340B DSH hospitals are more likely provide behavioral health services than are non-340B hospitals.

Figure 7: Percentage of 340B DSH and Non-340B Hospitals Providing Behavioral Health Services



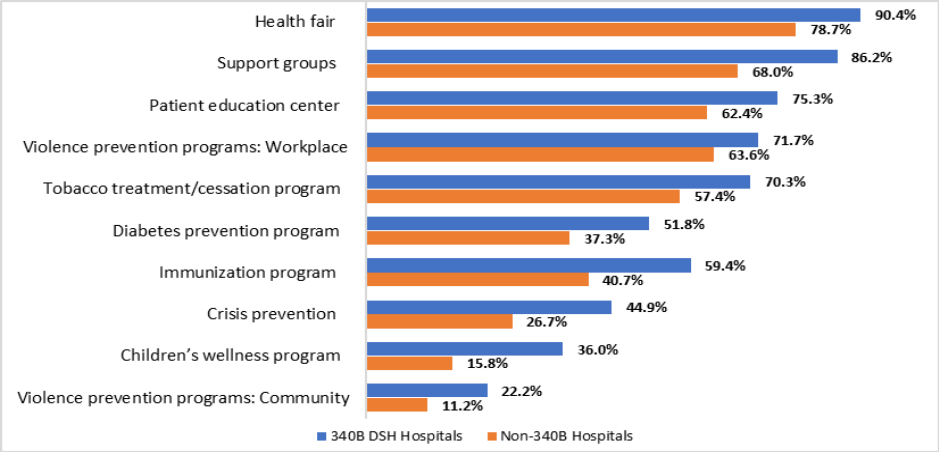
Source: Dobson | DaVanzo analysis of the 2018 American Hospital Association Annual Survey
* Defined as essential community services by the Medicaid and CHIP Payment Access Commission (Medicaid and CHIP Payment and Access Commission, 2020)

Community Health and Wellness

Underserved populations often have special challenges in terms of health and wellness. 340B DSH hospitals are more likely to provide a host of services from health fairs to smoking cessation to violence prevention that help people prevent disease and achieve better health (Figure 8).

340B DSH hospitals are more likely than non-340B hospitals to offer services addressing community health and wellness.

Figure 8: Percentage of 340B DSH and Non-340B Hospitals Providing Community Health and Wellness Services



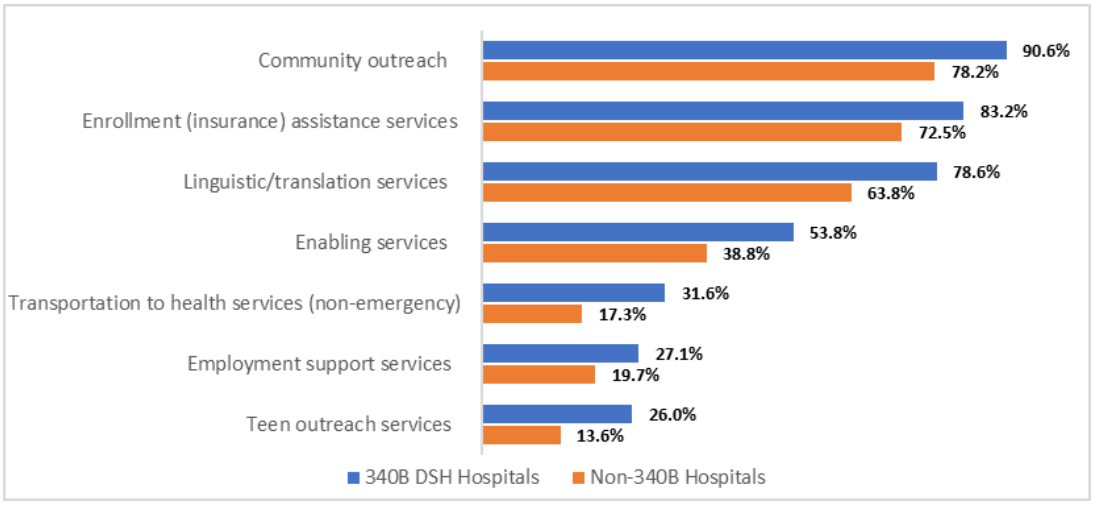
Source: Dobson | DaVanzo analysis of the 2018 American Hospital Association Annual Survey

Addressing Social Determinants of Health

340B hospitals are more likely than non-340B hospitals to provide services that go beyond health and wellness and begin to address some of the barriers underserved populations face in obtaining health care. These services, which help people better access services and improve their experience of care, include outreach services, enrollment assistance, translation, and transportation, among others. See Figure 9.

340B DSH hospitals are more likely than non-340B hospitals to provide services addressing social determinants of health.

Figure 9: Percentage of 340B DSH and Non-340B Hospitals Providing Services Targeting Social Determinants of Health



Source: Dobson | DaVanzo analysis of the 2018 American Hospital Association Annual Survey

Discussion

This study finds that 340B DSH hospitals treat higher levels of Medicaid and low-income Medicare patients than their non-340B counterparts, provide three-quarters of hospital care received by Medicaid patients, have lower margins, and are more likely to provide highly specialized services, essential community services, behavioral health services, and services to promote community health, wellness, and access. The 340B program inherently recognizes the special challenges that these hospitals face in providing care to Medicaid patients, and is critical to the continued existence of many eligible entities.

Overall, the Medicaid/Medicare SSI load for 340B DSH hospitals in 2018 was 40.6 percent, versus 26.3 percent for non-340B hospitals. Medicaid revenues represented 16.9 percent of total operating revenues at 340B DSH hospitals, versus 8.4 percent at non-340B hospitals. These results are consistent for hospitals in all size quartiles. Thus, economies of scale and scope are not protective of a hospital's ability to perform mission-related and community services. Furthermore, despite representing just 42.9 percent of hospitals in the analysis, 340B DSH hospitals accounted for 75.2 percent of all Medicaid revenue ($83.4 billion versus $27.4 billion).

An examination of operating margins found that 340B DSH hospitals consistently have lower average margins than their non-340B counterparts, regardless of size. Average operating margins were negative for 340B DSH hospitals overall, negative for three of four size quartiles and low for the other, an indication that the vital services provided by 340B DSH hospitals, which are often undercompensated or uncompensated, cause hospitals to lose money from the primary business of providing patient care, despite the discounts received on 340B drugs.

Still, 340B DSH hospitals continue to be more likely than non-340B hospitals to provide specialized services that are critical to low-income and underserved populations, such as pediatric and neonatal intensive care, burn care, trauma services, behavioral health, HIV/AIDS services, transportation, and translation services. This finding may explain, in part, the low operating margins of 340B DSH hospitals, which meet community service objectives at the cost of operating margins, despite the benefits of participation in the 340B program.

Taken together, the results of these analyses show that 340B DSH hospitals continue to provide higher levels of care to low-income and underserved populations, serving higher levels of Medicaid and low-income Medicare patients and offering a variety of services targeted to underserved populations.

Appendix A: Methodology

In this study, we compare 340B DSH hospitals with acute care hospitals not participating in the 340B program. The data source for the analyses of Medicaid/Medicare SSI patient load, Medicaid revenue, and hospital financial data, is the FY 2018 Medicare hospital cost reports (Centers for Medicare & Medicaid Services, 2020). The analysis of the public health and/or specialized services uses the 2018 American Hospital Association (AHA) annual survey (Health Forum, LLC, 2019). Our methodologies for identifying eligible hospitals to be included in the analysis, as well as other methodological considerations, are presented below.

Identification of Eligible Hospitals

Data Sources Used for Hospital Identification

The research team at Dobson | DaVanzo used the fiscal year (FY) 2020 Medicare Inpatient Prospective Payment System (IPPS) final rule and correction notice impact file (Centers for Medicare & Medicaid Services, 2019)[55] to identify the universe of eligible hospitals to be included in the study. The FY 2020 IPPS impact file, designed to be used in estimating the payment impacts of various policy changes to the IPPS final rule, allowed the research team to identify 3,315 acute care hospitals initially eligible for our analysis based solely upon their inclusion in this file as hospitals that are paid under the IPPS.

Next, the research team divided these 3,315 acute care hospitals into two groups: (1) those participating in the 340B program between October 1, 2017 and December 31, 2018; and (2) all other IPPS acute care hospitals. To make this division, the team used the HRSA Office of Pharmacy Affairs Information System (OPAIS) Covered Entity Daily Report as of January 6, 2020 (Health Resources & Services Administration Office of Pharmacy Affairs, 2020), which provides

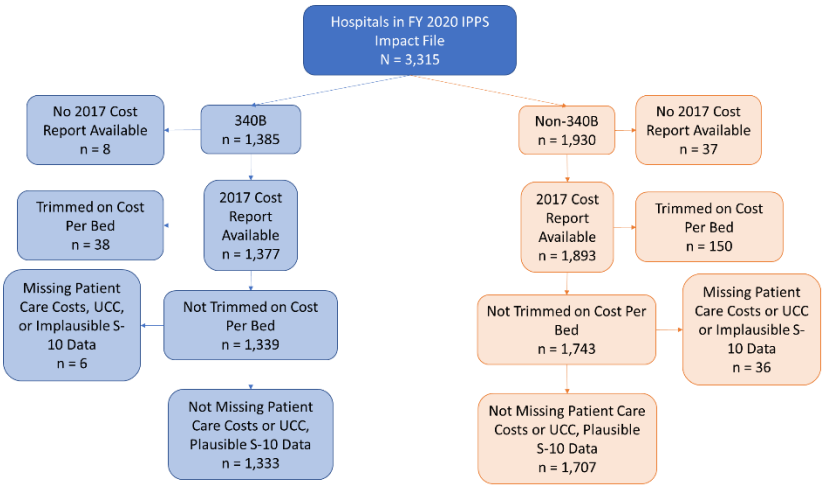
[55] The FY 2020 IPPS impact file contains data from the March 2019 update of the FY 2018 Medicare Provider Analysis and Review dataset, the March 2019 Provider Specific File, and Medicare Hospital Cost Reports from FYs 2016 and 2017.

up-to-date information on all active and inactive covered entities in the 340B program. Based on these data, the research team determined that 1,385 hospitals were 340B program participants and 1,930 hospitals were not.

Hospital Inclusion and Exclusion Criteria

Once hospitals were initially identified and separated into the 340B and non-340B categories, the research team applied a number of exclusions to the universe of potentially study-eligible hospitals. First, because the Medicare hospital cost reports serve as the analytic data source, only those hospitals with a Medicare hospital cost report for FY 2018 were retained.[56] Next, hospitals with a total patient care cost per bed[57] value that was above or below two standard deviations from the log of the mean value were excluded from the analysis. Finally, hospitals not reporting patient care costs, uncompensated or unreimbursed care costs, and hospitals with implausible Worksheet S-10 data were excluded.[58] As shown in Figure A-1 below, after these exclusion criteria were applied, 1,333 340B DSH hospitals and 1,707 non-340B hospitals remained for potential inclusion in the analysis.

Figure A-1: Exclusion Criteria Applied to Hospitals in the FY 2019 IPPS Impact File



Source: Dobson | DaVanzo analysis of FY 2018 Medicare hospital cost reports, FY 2020 IPPS impact file, and OPAIS Covered Entity Daily Report

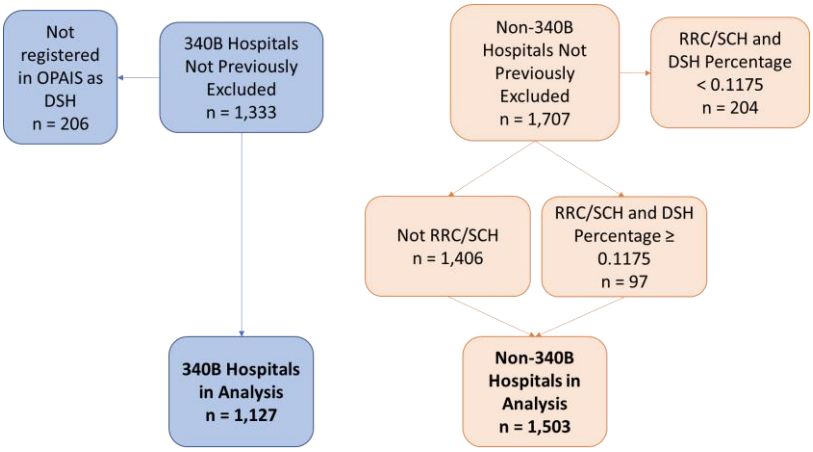
[56] If more than one FY 2018 Medicare hospital cost report existed for a single facility, the report covering the longest period of time was used for analysis.

[57] Total patient care costs were defined from Medicare cost report (Worksheet A, line 118, col 7). Patient care costs exclude costs for Medicare non-reimbursable cost centers (i.e., gift shop, research, physician private offices and non-paid workers) from hospital operating costs since these are not related to patient care. Number of beds was defined as the total number of facility beds available for use by patients at the end of the cost reporting period (Worksheet S-3, line 27, col 2).

[58] Hospitals with total costs reported on Worksheet S-10 (lines 7, 11, 15, 21 and 29) plus Medicare costs greater than total hospital costs (Worksheet C, Part I, line 202, col 3) were excluded.

From this dataset, we included only 340B participating hospitals that were categorized as a DSH in the HRSA Office of Pharmacy Affairs Information System (OPAIS) database, which resulted in 1,127 340B DSH hospitals being included in our final analysis file. For the comparison group of non-340B hospitals, we excluded hospitals with a provider type of rural referral center (RRC) or sole community hospital (SCH) from the FY 2020 IPPS impact file. We then examined the excluded RRCs and SCHs and found hospitals for which the DSH adjustment percentage[59] was over 11.75 percent. These hospitals were added back to the file, which resulted in 1,503 hospitals being included in the non-340B hospital comparison group. See Figure A-2.

Figure A-2: Final Criteria for Identification of Eligible Hospitals



Source: Dobson | DaVanzo analysis of FY 2018 Medicare hospital cost reports, FY 2020 IPPS impact file, and OPAIS Covered Entity Daily Report

Stratifying Hospitals by Quartile

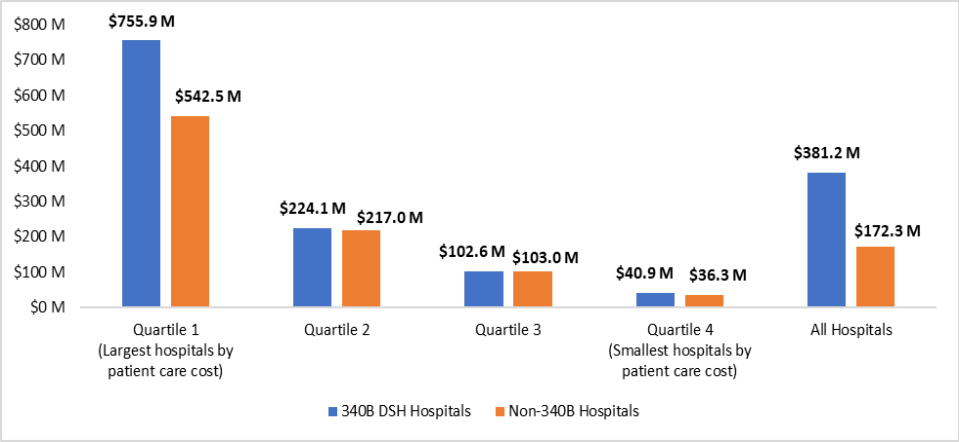
This study compares 340B DSH to non-340B hospitals on the basis of financial and care delivery characteristics. In this context, it is important to compare hospitals of like size to one another because simple aggregate comparisons do not take into account the different scope of operations reflected in hospitals of varying sizes. These operational differences could affect results. Therefore, using patient care costs as a proxy for hospital size, the research team stratified the final list of hospitals based on total patient care costs[60] in order to determine how various subsets of 340B DSH hospitals are performing relative to other "comparably sized" hospitals not in the 340B program. That is, the 2,630 hospitals in our analysis were divided into quartiles based on total patient care costs. Hospitals with the highest patient care costs comprised Quartile 1, and hospitals with the lowest patient care costs comprised Quartile 4. Therefore, the largest 340B DSH hospitals were compared to the largest non-340B hospitals,

[59] The DSH adjustment percentage refers to additional Medicare payments to hospitals serving a significantly disproportionate number of low-income patients as mandated by Social Security Act (SSA) § 1886(d)(5)(F).
[60] Total patient care costs were defined from Medicare cost report (Worksheet A, line 118, col 7).

and so on. Note that while the number of hospitals in each quartile is the same (657 or 658 in each), the distribution between 340B DSH and non-340B hospitals is different within each quartile, as each group has a different number of hospitals overall and in each size quartile. Based on the measure of patient care costs, 340B DSH hospitals tend to be larger than non-340B hospitals, with 39.6 percent (n = 446) of 340B DSH hospitals falling into Quartile 1, the quartile comprising hospitals with the highest total patient care costs, and only 14.0 percent (n = 211) of non-340B hospitals in this quartile. Conversely, 15.5 percent of 340B DSH hospitals are in Quartile 4, the quartile comprising hospitals with the lowest total patient care costs, while 32.1 percent of non-340B hospitals are in this quartile.

The division of hospitals into quartiles allows for the comparison of hospitals that are more similar in terms of size, although in general 340B DSH hospitals have higher average patient care costs than their non-340B counterparts.

Figure A-3: Average Patient Care Costs for 340B DSH and Non-340B Hospitals by Quartile of Total Patient Care Costs, FY 2018



Source: Dobson | DaVanzo analysis of FY 2018 Medicare hospital cost reports

Definition of Analytic Metrics

As described below, the research team extracted a number of elements from the Medicare hospital cost reports to quantify the metrics of interest: Medicaid/Medicare SSI patient load; Medicaid revenue in total and as a percent of hospital operating revenue; and operating margins. These metrics are defined below.

Medicaid/Medicare SSI Patient Load

When comparing 340B DSH hospitals to non-340B DSH hospitals on their provision of services to low-income patient populations, we looked at the relative size of the hospital's caseload of patients eligible for both Medicaid and Medicare Supplemental Security Income (SSI) benefits (Medicaid/Medicare SSI patient load). Medicare SSI beneficiaries are dually eligible for

Medicaid. We used this population because Congress chose to include only hospitals treating these patients with low income in the 340B statute for DSH eligibility. In addition, the legislative history behind the 340B program shows that Congress intended to provide lower drug pricing to hospitals that treat high levels of low-income patients, for whom the hospitals' provision of care is not typically fully compensated. To create this metric, we obtained the percent of total inpatient days which were attributable to Medicaid[61] as well as the percent of Medicare days devoted to patients with SSI.[62] We then combined these percentages into one metric, Medicaid/Medicare SSI patient load.

Medicaid Revenue as a Percent of Operating Revenue

Similar to Medicaid/Medicare SSI patient load, this metric is designed to evaluate the size of a hospital's Medicaid services relative to all hospital services. The measure of Medicaid revenue for this metric combined net Medicaid revenue with Medicaid DSH and supplemental payments.[63]

Operating Margins

In health care, operating margins are frequently used as a measure of a hospital's profitability related to its primary business of providing patient care. Operating margins express the difference between patient care revenue and operating costs as a proportion of patient care revenue.[64] Lower operating margins are an indication that hospitals treat higher levels of Medicaid and other low-income patients whose care costs are not typically fully compensated.

Service Offerings

We evaluated the service offerings of hospitals using the 2018 AHA annual survey (Health Forum, LLC, 2019). This survey queries respondent hospitals on whether they provided various medical and mission-type services. Published literature presents examples of traditionally "unprofitable" services provided by hospitals dedicated to the health and well-being of the individual and the community, including burn care, inpatient psychiatric care, psychiatric emergency services, maternity care, AIDS services, substance abuse services, and trauma care (Chen, Bazzoli, & Hsieh, 2009; Horowitz, 2005). In many communities, hospitals are the primary

[61] Total hospital days were defined as the sum of Lines 14, 30, and 32 from Worksheet S3, Part 1, Column 8, minus Lines 5 and 6. The proportion of total hospital days attributable to Medicaid was taken from Worksheet E, Part A, Column 1, Line 31.

[62] Medicare days was defined as the sum of Lines 2 and 6 from Worksheet S3, Part 1, Column 6. The proportion of Medicare days devoted to patients with SSI was taken from Worksheet E, Part A, Line 30, Column 1.

[63] Net Medicaid revenue and DSH and supplemental payments came from Worksheet S-10, Column 1, Lines 2 and 5. Operating revenue is from Worksheet G-3, Column 1, Line 3.

[64] Operating revenue is taken from Worksheet G3, Column 1, Line 3 and operating costs are taken from Worksheet G3, Column 1, Line 4.

resources for these services. These hospitals also tend to offer services that attract potentially difficult to treat patient populations, including psychiatric inpatient and outpatient care and alcoholism inpatient treatment. Examining the extent to which 340B DSH hospitals provide these services is therefore essential to evaluating their status as safety nets in the community. We note that the list of hospitals included in the analysis of public health and specialized services was slightly different than that used in the other analyses presented in this report. Starting with the hospitals identified for inclusion in the study, as outlined above, those hospitals identified in the AHA survey data as primarily providing general medical and surgical care to children[65] were added to the analysis in both the 340B DSH and non-340B cohorts. Hospitals without AHA survey data were excluded from this analysis of public health and specialized services, as were non-responding hospitals with estimated data only.[66] In all, 2,129 hospitals were included in this portion of the analysis, of which 1,000 were in the 340B DSH cohort and 1,129 were non-340B.

[65] Identification of children's general medical and surgical hospitals was based upon the variable PRIMARY_SERVICE in the AHA data, which provides the category best describing the hospital's type of service provided to the majority of admissions.

[66] The AHA survey data contained estimates for key utilization variables for some non-responding hospitals. Hospitals with no reported data – which did not have data regarding the provision of public health and specialized services - were excluded from the analysis.

References

American Hospital Association. (2019, May). *Increasing Access to Behavioral Health Care Advances Value for Patients, Providers and Communities.* Retrieved from AHA.org: https://www.aha.org/system/files/media/file/2019/05/aha-trendwatch-behavioral-health-2019.pdf

American Hospital Association. (2020, January). *Fact Sheet: Underpayment by Medicare and Medicaid.* Retrieved from AHA.org: https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid

Centers for Medicare & Medicaid Services. (2019). *FY 2020 Final Rule and Correction Notice Data Files*. Retrieved from CMS.gov: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Data-Files

Centers for Medicare & Medicaid Services. (2020). *Hospital 2552-2010 Form*. Retrieved from CMS.gov: https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Hospital-2010-form

Chen, H.-F., Bazzoli, G. J., & Hsieh, H.-M. (2009). Hospital Financial Conditions and the Provision of Unprofitable Services. *Atl Econ J., 37*(3), 259-277.

Health Forum, LLC. (2019, December 19). All U.S. Hospitals with Selected Data Fields, AHA Data Query, FY2018/Current Data. (R. Wedeward, Compiler)

Health Resources & Services Administration Office of Pharmacy Affairs. (2020, February 24). *340B OPAIS Reports/Files.* Retrieved from 340BOPAIS.HRSA.gov: https://340bopais.hrsa.gov/Reports

Horowitz, J. R. (2005). Making Profits and Providing Care: Comparing Nonprofit, For-Profit, and Government Hospitals. *Health Affairs, 24*(3), 790-801.

Medicaid and CHIP Payment and Access Commission. (2019). *MACStats: Medicaid and CHIP Data Book.* Retrieved from https://www.macpac.gov/wp-content/uploads/2020/01/MACStats-Medicaid-and-CHIP-Data-Book-December-2019.pdf

Medicaid and CHIP Payment and Access Commission. (2020). *March 2020 Report to Congress on Medicaid and CHIP.* Retrieved from https://www.macpac.gov/wp-content/uploads/2020/03/March-2020-Report-to-Congress-on-Medicaid-and-CHIP.pdf