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Setting the Record Straight on 340B

Congress created the 340B program in 1992 under the Public Health Service Act to protect safety net providers from escalating drug prices. The program was designed to allow certain safety net hospitals and other covered entities to purchase outpatient drugs at a discount from drug manufacturers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] Since the savings are derived from drug manufacturer discounts, the program provides patients and communities critical access and services at no cost to taxpayers. Initially, public and not-for-profit general acute care disproportionate share hospitals (DSH) that served a significant share of low-income patients as well certain federal grantees were eligible to participate. The success of the program prompted Congress to expand the program to include more rural and small urban hospitals, as well as critical access hospitals, into the program.[2]

Since its inception 25 years ago, 340B program benefits have been far-reaching, and lawmaker support is bipartisan. Yet, the program has recently come under some unfounded criticism. A *New England Journal of Medicine* study by Desai and McWilliams, "Consequences of the 340B Drug Pricing Program," asserts that the 340B program incentivizes physician-hospital consolidation and the use of more drugs at 340B hospital outpatient departments, with no evidence of enhanced access or improved quality for low-income populations. As others have also pointed out, however, the study methodology is deeply flawed.[3,4,5]

As discussed below, study flaws result in incorrect conclusions about the effectiveness of the 340B program. Further, the authors fail to recognize that the vertical integration of cancer care and the related drug prescribing shifts are driven by multifaceted factors other than the 340B program.

Study flaws result in incorrect conclusions about the effectiveness of the 340B program.

Improving health for their communities and caring for the sick, regardless of socioeconomic status, are clearly stated missions at 340B hospitals and embraced as core values by doctors, nurses, and staff who serve in these organizations. Drug discounts from the 340B program are used to sustain the mission and support care for low-income populations, including Medicaid enrollees, the uninsured, and the underinsured. 340B hospitals comprise 34% of short term general hospitals but incur 70% of charity care costs, 57% of bad debt costs, and account for 61% of all Medicaid shortfalls, based on the AAMC's analysis of the FY2015 Medicare cost report data.

In addition to subsidizing the costs of care for vulnerable population, hospitals use savings from the 340B program to enhance care through a wide range of patient services that improve health. Programs range from offering free or discounted drugs, establishing and improving neighborhood clinics, bringing mobile units to communities with no local primary care providers, and creating multidisciplinary clinics to treat substance use and mental health disorders. The diversity of these programs reflects the unique needs of the patients and communities served by 340B hospitals.

The authors of the *NEJM* article failed to find evidence of enhanced access for low-income populations at 340B-eligible hospitals because they based their results on a limited set of data that does not represent the

low-income populations served by 340B hospitals or the universe of hospitals that participate in the 340B hospital.

The study was based solely on data from Medicare beneficiaries, most of whom have adequate insurance coverage. While a portion of Medicare beneficiaries are low-income, especially those who are dual eligible, this population on its own is not sufficient to represent of the number and array of low-income patients served by 340B hospitals, including the uninsured and Medicaid.

The authors should have examined additional proxies of care for low-income patients, which would have affected their conclusions. For example, an AAMC analysis using the same study definition of 340B-eligible hospitals that the authors used, but using charity care costs and bad debt as the proxy for low-income care, shows that these hospitals, on average, provided $11.6 million in charity care costs and $6.1 million in bad debt costs per hospital in FY 2015, which is more than 40% higher than 340B-ineligible hospitals (Table 1).

Table 1: Comparison of Charity Care and Bad Debt Costs, FY 2015

Not-for-Profit & Public Hospitals	340B-Ineligible (DSH: 1.75-10.75%)	340B-Eligible (DSH: 12.75-21.75%)	Percent Difference
Average Charity Care Costs ($ Million)	$ 8.0	$ 11.6	44%
Average Charity Care Costs per Bed	$ 36,228	$ 39,177	8%
Average Bad Debt Costs ($ Million)	$ 4.2	$ 6.1	47%
Average Bad Debt Costs per Bed	$ 18,860	$ 20,719	10%

Source: Charity care and bad debt costs are from FY 2015 Medicare cost report data. We used the authors' hospital exclusion criteria.

This analysis demonstrates it is inappropriate and misleading to draw conclusions about the effectiveness of the 340B program based on narrowly defined criteria.

Another flaw is that the 340B hospitals included in the study are not a representative sample of the 340B hospital universe. Under the statute, the 340B eligibility threshold is established based on the share of low-income patients served at a hospital. 340B hospitals closer to the eligibility threshold have lower shares of low-income patients compared to those far above the threshold. The study only includes hospitals within a narrow band of the eligibility threshold, therefore excluding hospitals with a higher share of low-income patients. As a result, the study can only draw conclusions about hospitals near the threshold and is not equipped to make any inferences about the consequences of the 340B program more broadly.

The vertical integration of cancer care and the related drug prescribing shifts are driven by multifaceted factors other than the 340B program.

Critics, including the authors, have asserted that the 340B program incentivizes physician-hospital consolidation. However, the increase in hospital ownership of physician practices is a relatively recent phenomenon compared to the 25-year history of the 340B program and is explained by other factors. Alpert et al analyzed vertical integration in the cancer care market during the period 2003–2015 and found that "(hospital) ownership (of physicians) was relatively flat from 2003 to 2009" but "increased markedly" after the passage of ACA in 2010.[6] The Alpert study found little evidence that 340B expansion

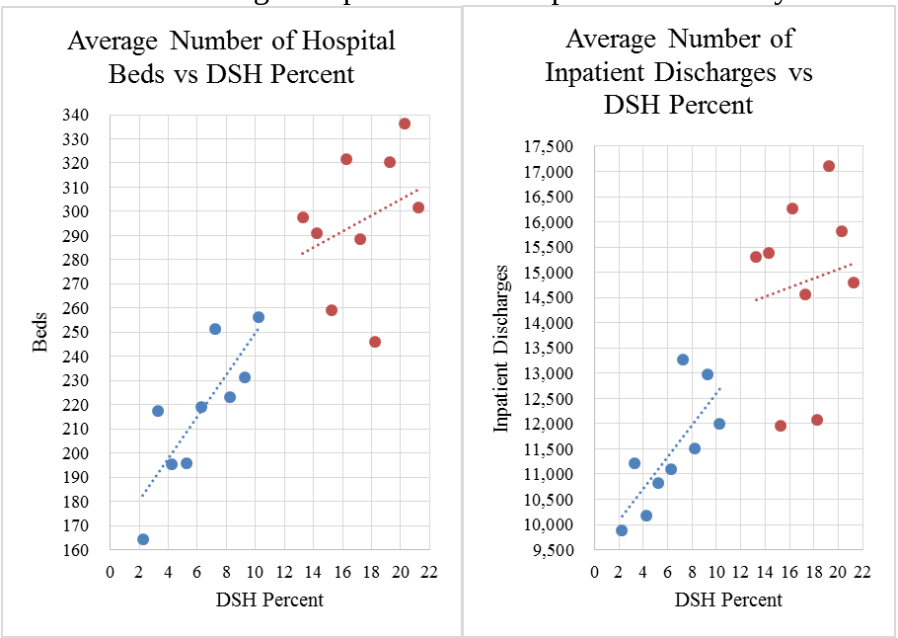
authorized under ACA contributed to vertical integration. Rather, the increased consolidation reflected "a broader post-ACA trend toward integrated health care systems."[7]

For many years, the most cited driver of consolidation was payment reform under the Medicare Modernization Act of 2003 (MMA) that significantly reduced physician reimbursements for cancer drugs beginning in 2005.[8,9] According to a 2007 study, drug reimbursement accounted for 77% of oncology practice revenue.[10] The revenue loss on cancer drugs as a result of the MMA contributed to dwindling operating margins for oncology practices between 2007 and 2010.[11] As recently as 2012, David Eagle, MD, past president of the Community Oncology Alliance (COA)—an organization representing community oncologists—noted "the key driver of consolidation in oncology is financial strain."[12]

Other factors have also contributed to the dramatic increase in the number of cancer clinics that have either closed, struggled financially, merged, or been acquired since 2008.[13] For some cancer clinics, rising bad debt and tightened lending standards during the recession were the "last straw" on their post-MMA financial struggles.[14] To others, the evolution of cancer care to integrate services like genetic testing, specialty pharmacies, and nutritional support also played a role in making solo practice less economically viable.[15,16] Finally, the appeal of economies of scale for activities such as billing and general technology infrastructure provided strong incentives to consolidate.[17]

Desai and McWilliams' assertion that the 340B program drives vertical integration in cancer care is based on their finding that the 340B-eligible hospitals included in the study have 2.3 more cancer doctors per hospital than 340B-ineligible hospitals. However, as shown in Figure 1, the study fails to control for the fact that the 340B-eligible hospitals (shown in red to the right) have more beds and volume on the inpatient side.

Figure 1: Trend of Average Hospital Size and Inpatient Volume by DSH Percent



Source: Bed size & DSH percentages are from the FY2018 Medicare IPPS Final Rule Impact File. Inpatient discharges from all payors are extracted from 2015 Medicare Cost Report. We recomputed DSH percent for hospitals whose DSH percent is capped at 12%. We used the authors' hospital exclusion criteria. Dots are means of 1-percentage point bins; red reflect 340B-eligible hospitals and blue reflects 340B ineligible. For illustrative purposes, a linear trend line is shown on either side of the 340B eligibility threshold, an illustration approach used by the authors.

As a matter of scale, therefore, these hospitals would be expected to have more doctors, more visits, and more drugs administered on the outpatient side.

Desai and McWilliams' suggestion that there has a been a shift in parenteral drug prescribing from community oncology practices to hospital outpatient departments is not surprising given the MMA payment reductions among other factors.

For example, the Medicare Payment Advisory Commission (MedPAC) found that after the MMA was implemented, oncology practices in some markets stopped treating Medicare beneficiaries without supplemental coverage and referred them to hospital outpatient departments or safety net facilities[18]. MedPAC also found that after MMA, some private practices were reluctant to use expensive new therapies for fear of coverage disputes with insurers.

In many communities, 340B hospitals are now the last resort of cancer care for uninsured, underinsured, and patients who need high-cost therapies. These safety net facilities rely on the 340B program not only to ensure access for cancer patients, but also to support the wide range of services they provide to the vulnerable patients in their communities.

For more information, visit www.aamc.org/340b.

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