Statement of 340B Health

United States House of Representatives Energy and Commerce Committee
Subcommittee on Health

Hearing: *Opportunities to Improve the 340B Drug Pricing Program*
July 11, 2018

340B Health appreciates the opportunity to provide these comments as the Committee seeks to gather additional perspectives on the 340B program and to consider proposals that would alter the program. 340B Health represents more than 1,300 nonprofit and public hospitals that participate in the 340B program. Our membership consists of a broad spectrum of hospitals, including academic medical centers, community hospitals, children's hospitals, and rural facilities.

The 340B program was enacted in 1992 with broad bipartisan support and Congress clearly stated that the program is intended to provide additional resources to safety net providers so they can "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] This goal is still of critical importance today.

The 340B Program Helps Preserve the Health Care Safety Net in the United States

The 340B program is a critically important program that allows participating entities to serve the needs of low-income and/or rural patients in their communities. Some hospitals use their 340B savings to provide free community clinics or discounted drugs while others may rely on the program to offset the provision of high levels of uncompensated care or a high volume of

[1] H.R. Rep. 102-384, Pt. 2 (1992).

Medicaid patients. A recent report found that 340B hospitals provide significantly more care to low-income patients than other hospitals, including uncompensated care and unreimbursed care.[2] They also provide more specialized and community-based health services that are critical for low-income patients but are often underpaid (i.e., labor and delivery and trauma services).[3] Researchers from the Pew Charitable Trusts recently noted that curtailing or scaling back the 340B program would simply transfer money from 340B safety net providers to pharmaceutical manufacturers.[4]

Hospitals Providing Data and Information About 340B

There have been a number of questions raised by policymakers about how hospitals are using savings realized through the 340B program to assist low-income patients. 340B Health encourages hospital members to share information about the benefits that the hospital realizes through participation in the program as well as details about the myriad of services that those savings then allow the hospital to provide in support of low-income patients. 340B Health has created a resource document for hospitals to use as a template to prepare and share this information.[5]

Conversations about data review and disclosure should take into account the wide array of services that 340B hospitals provide to support low-income and rural patients as well as the reporting requirements with which these hospitals currently comply that gather information related to services provided to low-income patients through Medicare Cost Reports and IRS filings (Form 990). Discussions on the topic should also consider the extensive services that hospitals provide over and above those specifically captured in these reporting structures.

[2] L&M Policy Research, Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients (March 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf.
[3] *Id.*
[4] Coukell AJ, Dickson S. Reforming the 340B Drug Pricing Program Tradeoffs Between Hospital and Manufacturer Revenues. *JAMA Intern Med*. Published online May 21, 2018. Doi:10.1001/jamainternmed.2018.2007
[5] 340B Health, *Impact Profile Guide*, available at https://www.340bhealth.org/files/340B_ImpactProfileGuidebook_.pdf

Discussion on this issue must also consider manufacturer data disclosure obligations. Congress required that manufacturer 340B prices be disclosed to covered entities after receiving reports of widespread manufacturer overcharging. After eight years, these provisions have yet to be implemented. HHS should proceed immediately with publishing the government-verified pricing list.

340B Health believes there should be balanced oversight, including proper oversight of manufacturers. H.R. 6071, The Stretching Entity Resources and Vulnerable (SERV) Communities Act, would ensure balanced oversight of both 340B covered entities and manufacturers. In particular, the bill highlights evidence of manufacturers overcharging providers and recognizes that HHS has not implemented civil monetary penalties (CMPs) to address these overcharges as required by law. The bill would also require HHS to share 340B prices with providers, which will help them verify that manufacturers are charging the correct prices.

340B Health also supports legislative efforts to reverse the Medicare payment reduction affecting certain 340B hospitals. H.R. 4392 and H.R. 6071 would provide relief to 340B hospitals subject to a nearly 30 percent reduction in Medicare Part B drug payments that went into effect January 1, 2018, as part of the FY2018 Outpatient Prospective Payment System (OPPS) payment rule. Reversing the cuts is critical to ensuring safety net hospitals have the resources needed to serve their low-income and rural patients.

Several Legislative Proposals Seek to Significantly Scale Back the Program or Require Data from Hospitals That Goes Beyond Evaluating Whether the Program Meets its Purpose

A number of the legislative proposals go well beyond promoting transparency and reporting requirements and would significantly scale back the program, resulting in fewer low-income and rural patients having access to care in their communities. The discussion draft offered by Representative Barton would raise the minimum disproportionate share (DSH) adjustment percentage for certain hospitals to qualify for the 340B program and would significantly scale

back the number of hospitals in the program. Based on an analysis by 340B Health, this proposal would eliminate 573 safety-net providers that treat high volumes of low-income patients from the program.

The discussion draft put forward by Representative Collins to re-define the term "patient" would limit the number of eligible patients and H.R. 4710, The 340B Protecting Access for the Underserved and Safety-Net Entities (PAUSE) Act would freeze enrollment of disproportionate share/safety-net hospitals and their "child sites" into the 340B program and seek to obtain information solely about charity care levels alone—which comprise only a portion of the services that hospitals provide to low-income patients. 340B Health strongly opposes these provisions.

It is important to recognize that any attempt to evaluate the amount of care that hospitals provide to low-income patients must look at a variety of factors; not just charity care. Charity care refers only to the costs of covering the care provided to patients who apply to participate in a hospital's financial assistance program prior to care being provided and complete the necessary paperwork. Safety net hospitals are also responsible for bad debt costs and under-reimbursed care. Bad debt refers to care provided by the hospital for which the hospital expects to be paid but is ultimately not reimbursed. This typically occurs when a patient's insurance does not cover certain services and the patient is unable to pay for these services themselves. Hospitals also incur significant shortfalls due to chronic under-reimbursement from Medicaid and other state and local indigent care programs that do not cover hospital costs.

In creating the 340B program, Congress intentionally targeted hospitals for the program that treat a high volume of Medicaid and low-income Medicare patients or are located in rural areas—specifically recognizing that these entities treat patients with complex medical conditions or face other unique challenges ensuring access to care, and yet are under-reimbursed for these services. Hospitals participating in the 340B program are also

distinguished by the types of specialized services they provide that are critical to low-income patients—such as labor and delivery, trauma care and substance abuse/addiction treatment – for which they are frequently underpaid.

Legislative Proposals that Seek to Require Reporting on a Hospital's 340B Savings Target Extraneous Data Points

We also have concerns with several legislative proposals that seek to gather information on the benefit or savings that participating hospitals obtain through the 340B program but miss the mark in terms of the specific data points they target. Hospitals accrue a financial benefit through participation in the 340B program by acquiring outpatient drugs at discounted prices, resulting in savings as compared to what hospitals would have paid for those drugs outside the 340B program. 340B transparency or disclosure of savings should not focus on reimbursement that hospitals receive from payers for 340B drugs, as that information is not applicable to how much hospitals save through participation in the program. Focusing on payer reimbursement information may in fact present an inflated and misleading picture of a hospital's savings obtained through 340B participation.

Physician-Hospital Consolidation In Oncology Is Part of a Larger Trend—Not Specifically Attributable to the 340B Program

Critics of the 340B program have claimed that 340B hospitals are consolidating with oncology practices in wealthy areas. If this were true, one would expect those hospitals to be treating fewer low-income people with oncology drugs. However, Medicare data shows that the share of low-income Medicare Part B cancer drug recipients in 340B hospitals (those dually eligible for Medicaid) increased from 2013 to 2014, and in both years was significantly higher than the share of low-income Medicare cancer drug recipients treated at non-340B hospitals and private physician clinics. In fact, 340B hospitals treat over 60 percent more low-income Medicare cancer patients than non-340B providers.[6] This Medicare data is consistent with other data

[6] http://www.340bhealth.org/files/LowIncomeOncology.pdf

indicating that community oncologists do not serve commensurate levels of low-income patients as 340B hospitals. Only 4 percent of patients treated by community oncologists were uninsured, and only 4 percent were Medicaid, according to information reported by insurers related to community oncology practices.[7]

It is important to realize that consolidation and mergers in the area of health care are an industry-wide occurrence due to a variety of market forces. A recent article published in Health Affairs noted that hospital integration with specialty practices is slower than has been reported in the media, with hospitals acquiring "only one or two more specialty practices, such as oncology practices, over the decade."[8] The authors specifically noted that their data calls into question immediate legislation to slow vertical integration around the 340B program and recommended that more research be conducted.[9] Another Health Affairs article noted that "the health care industry has experienced massive consolidation over the past decade."[10] Other recent studies link increased consolidation in the market for cancer care as part of a broader trend toward integrated health care systems and a shift to value-based care.[11]

The 340B Program is Intended to Provide Safety Net Providers With Additional Resources to be Used in a Variety of Ways and was Never Intended to be Limited to Specific Purpose or Prescription Drug Program.

The 340B program was intended to provide hospitals with additional resources to increase access to care in the safety net, which may include making medicines more affordable or providing preventative care services or specific programs to meet the unique needs of the low-income or underserved community. The program was never intended to be limited to offering discounts on medications. Providing discounts on drugs to low-income patients is one way entities can use 340B savings to support their low-income populations, but it is not the only

[7] https://pdfs.semanticscholar.org/5935/93e63b3a8322a3485e63815c707caf5255c1.pdf
[8] https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1520
[9] *Id.*
[10] https://doi.org/10.1377/hlthaff.2016.0830
[11] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2016.0830

way. The discussion draft put forward by Representative Burgess would require covered entities to establish certain fee amounts charged to certain low-income patients for 340B drugs. In response to a recent 340B Health survey of members, hospitals unanimously reported using their program savings to support low-income and rural patients, consistent with the program's purpose. Both disproportionate share (DSH) and rural hospitals reported using those savings to maintain or increase uncompensated care (95%) and increase the type of services provided (89%). DSH hospitals were particularly likely to report using their savings to provide direct services and support for low-income patients, with 80 percent of DSH hospitals reporting they used 340B discount savings to offset low Medicaid reimbursement rates in their state. Rural hospitals, however, were more likely to report using program savings to ensure access to care in remote areas, with three-quarters of rural hospitals (74%) reporting they used 340B savings to keep their doors open and preserve access to care for their patients and communities. As such, it may be premature for Congress to limit the mechanisms by which hospitals may use program savings to support care for low-income patients and there may be value in further exploring data on the services hospitals are currently providing to low-income populations.

The 340B Program Does Not Contribute to Manufacturers' Decision to Set High List Prices

Researchers have concluded that 340B discounts are such a small share of the overall drug market that they cannot plausibly be causing manufacturers to increase drug prices.[12] In a report released in May 2018, the Pew Charitable Trusts also noted that in 2015, 340B discounts amounted to a net reduction in total manufacturer revenue of approximately 1.9%.[13]

In addition, there is no evidence that reducing the level of discounts that manufacturers provide to hospitals would result in manufacturers voluntarily lowering list prices rather than simply returning those amounts to their respective companies and shareholders. We believe that the program as a whole is such a small share of the drug market, that any proposed

[12] Dobson DaVanzo, Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers (July 2017), https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf

[13] Coukell AJ, Dickson S. Reforming the 340B Drug Pricing Program Tradeoffs Between Hospital and Manufacturer Revenues. *JAMA Intern Med*. Published online May 21, 2018. Doi:10.1001/jamainternmed.2018.2007

changes to shrink the program would not reduce list prices for drugs but may limit the extent to which 340B hospitals are currently able to provide care to underserved patients. It is clear, however, that drug prices are at an all-time high, and it is drug manufacturers that set list prices.

Conclusion

340B Health appreciates this opportunity to provide our viewpoint and suggestions regarding the 340B program. If there are any questions about the information presented in this statement please contact Maureen Testoni, Interim CEO, at maureen.testoni@340health.org or 202-552-5860.