November 27, 2019

Rep. Danny Davis
2159 Rayburn House Office Building
Washington, DC 20515

Rep. Brad Wenstrup
2149 Rayburn House Office Building
Washington, DC 20515

Rep. Terri Sewell
2201 Rayburn House Office Building
Washington, DC 20515

Rep. Jodey Arrington
1029 Longworth House Office Building
Washington, DC 20515

RE: Rural and Underserved Communities Health Task Force Request for Information

Dear Reps. Davis, Sewell, Wenstrup, and Arrington:

340B Health appreciates the opportunity to respond to the Rural and Underserved Communities Task Force (Task Force) request for information (RFI) on policy options to improve care delivery and health outcomes within rural and underserved communities. 340B Health represents more than 1,400 public and nonprofit hospitals that participate in the federal 340B drug pricing program. Our membership spans a broad spectrum of hospitals including academic medical centers, community hospitals, children's, free-standing cancer hospitals and rural facilities. The 340B program provides resources to hospitals serving high volumes of low-income and rural patients to enable those hospitals to provide more comprehensive services and treat more patients.[1]

Question #2 of the RFI asks for feedback on successful models that show a positive impact on health outcomes within rural or underserved communities. As the Task Force considers policies to improve health care for underserved individuals, we encourage the Task Force to consider how the 340B program supports access to care for underserved patients. Since its enactment in 1992, the 340B program has helped safety net providers meet the needs of low-income and other underserved patients in both urban and rural communities.

340B Allows Hospitals to Support Care for Low-Income and Rural Patients

The 340B program requires drug manufacturers to offer outpatient drugs to qualifying providers entities at discounted prices as a condition of participation in the Medicaid and Medicare Part B programs. Through access to discounted drug prices, 340B helps safety net hospitals stretch their resources, allowing them to support care for low-income and rural patients. This care is not funded by taxpayer dollars as resources come from the price discounts.

Hospitals must provide a high volume of care to low-income patients or be located in remote, rural areas to qualify for the 340B program.[2] In particular, 340B disproportionate share (DSH)

[1] 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.
[2] 42 U.S.C. § 256b(a)(4)(L).

hospitals must treat a high volume of Medicaid and low-income Medicare patients to qualify for 340B.[3] Although 340B DSH hospitals are 38 percent of hospitals, they provide 60 percent of all uncompensated care.[4] They also treat significantly more Medicaid and low-income Medicare patients than non-340B hospitals. They are significantly more likely to offer vital health care services that are critical to low-income patients but are often unreimbursed, including trauma centers, HIV/AIDS services, and immunizations.[5] Compared to non-340B providers, 340B DSH hospitals treat many more Medicare Part B beneficiaries who are low-income cancer patients, dually eligible for Medicaid, disabled, or are racial or ethnic minorities.[6] 340B DSH hospitals have 31 percent lower median total facility margins than non-340B acute care hospitals.[7] Researchers have confirmed that 340B DSH hospitals incur financial challenges due to the nature of the patients they treat, who tend to be sicker, lower income, and more likely to suffer from chronic conditions and therefore more expensive to treat.[8]

Several categories of hospitals located in rural areas participate in 340B, including critical access hospitals (CAHs), sole community hospitals (SCHs), and rural referral centers (RRCs). Many DSH hospitals are also located in rural areas. Since its expansion to rural providers in 2010, over 1,000 rural hospitals participate in the program, allowing them to meet the needs of their rural patients.[9]

340B hospitals use their program savings to support patient care in a variety of ways. One way that hospitals use 340B savings is to provide free or discounted drugs to low-income patients. These hospitals also use 340B savings to provide other vital services to support low-income and rural patients, such as maintaining and supporting uncompensated care and offsetting low Medicaid reimbursement.[10] For example, hospitals report relying on their 340B savings to support the implementation and operation of programs and services to treat opioid dependency, such as changes to opioid prescribing patterns; community education programs; distribution of free naloxone and suboxone to first responders; clinical care teams to manage, treat, and prevent cases of opioid use; medication-assisted treatment programs; and drug take-back days in coordination with local law enforcement.[11]

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[3] *Id.*
[4] 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.
[5] *Id.*
[6] Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Provider (2017), http://www.340bhealth.org/files/LowIncomeOncology.pdf; L&M Policy Research, A Comparison of Characteristics of Patients Treated by 340B and Non-340B Providers (April 8, 2019), https://www.340bhealth.org/files/340B_Patient_Characteristics_Report_FINAL_04-10-19.pdf.
[7] Government Accountability Office (GAO), Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program (June 2018), https://www.gao.gov/assets/700/692587.pdf.
[8] Dobson DaVanzo, Financial Challenges Faced by 340B Disproportionate Share Hospitals In Treating Low-Income Patients, https://www.340bhealth.org/files/Financial_Challenges_Final_Report_08.04.17.pdf.
[9] Office of Pharmacy Affairs Information System (OPAIS), https://340bopais.hrsa.gov/coveredentitysearch.
[10] 340B Health, Evaluating 340B Hospital Savings and Their Use in Serving Low-Income and Rural Patients: Results From a Survey of 340B Health Members (June 2018), https://www.340bhealth.org/files/2017_Annual_Survey_Report_final.pdf.
[11] 340B Health, 340B Hospitals on the Front Lines of Addressing the U.S. Opioid Epidemic (Jan. 2019), https://www.340bhealth.org/files/OpioidReport_FINAL_1_23_19.pdf.

Hospitals report that a loss of 340B savings would affect their ability to provide patient services, including the provision of primary care, oncology, and diabetes services as well as their provision of free or discounted drugs to patients in need.[12]

340B Supports Access to Care in Rural America

Among rural hospitals in 340B, more than 90 percent report relying on 340B savings to keep their doors open.[13] More than half of rural hospitals report that if they lost all or a portion of their 340B savings, they would likely have to close their doors or would face significant financial challenges that would force them to cut certain services.[14] At a time of record closures of rural hospitals, 340B savings play a critical role in stemming the tide of such closures.

Rural hospitals also report using their 340B savings to maintain or expand their level of uncompensated and unreimbursed care.[15] As such, these hospitals are able to care for more rural patients, even if it means they provide that care at a net financial loss to the hospital. Most rural hospitals also report using savings to offer free or discounted drugs to their patients, many of whom are unable to afford their medications.[16] By providing certain drugs for free or at steep discounts, rural hospitals are able to better ensure that their patients are accessing the medications they need in order to improve their overall health.

Sanford Health is an integrated health system headquartered in the Dakotas, and it is the largest employer in the Dakotas. Many of its hospitals and clinics are located in rural areas and face financial challenges. The savings from the 340B program allow Sanford Health to serve the uninsured and the growing number of patients with high deductible plans who cannot afford to pay for services only partially covered by insurance. 340B savings also allow Sanford health to implement charity care programs for high-cost services, so patients are then able to focus on their recovery instead of paying bills. The loss of 340B savings in Sanford Health's rural facilities would limit their ability to provide outreach to rural communities, impair their ability to provide charity care for the uninsured, and restrict the ability to expand access to patients in need of care.

Johnson County Hospital is a critical access hospital that participates in the 340B program. It serves a high Medicare population located in a rural area, 45-60 miles from a tertiary hospital. Johnson County Hospital brings in several specialty doctors each month to allow patients to receive treatment closer to home. The savings from the 340B program help Johnson County provide services in the region that would otherwise not be available, including home health, chemotherapy, and free blood pressure checks. Without the savings from the 340B program, Johnson county would have to consider scaling back or eliminating these critical services.

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[12] 340B Health, Evaluating 340B Hospital Savings and Their Use in Serving Low-Income and Rural Patients: Results From a Survey of 340B Health Members (June 2018), https://www.340bhealth.org/files/2017_Annual_Survey_Report_final.pdf.
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*

Congress Can Improve Access to Care in Rural America By Closing the 340B Orphan Drug Loophole

Although Congress sought to make it easier for rural hospitals and free-standing cancer hospitals to participate in the 340B program in 2010, CAHs, SCHs, RRCs and cancer hospitals are largely being deprived of program benefits due to court decisions broadly interpreting a provision of the 340B law that excludes drugs with an orphan designation from the program's discount requirements. Under that reading of current law, drug manufacturers are not required to provide discounts on orphan drugs to rural and cancer hospitals, even when the medications are used for common purposes. We urge Congress to take action to close this loophole and make discounted orphan drugs available to these hospitals when they are used to treat non-orphan diseases and conditions. Legislation introduced earlier this year, H.R. 4538, the Closing Loopholes for Orphan Drugs Act, would address this issue by clarifying the 340B program's orphan drug exclusion and ensuring that rural and cancer hospitals can fully access the 340B benefit, as Congress intended, to help maintain and improve access to care for rural and underserved populations.

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We thank the Task Force for the opportunity to submit these comments. We hope that the Task Force will consider the important role the 340B program plays in supporting and maintaining access to care for low-income and rural patients in underserved communities across the country. We would welcome the opportunity to provide additional information if there are any questions. Please contact Kathryn DiBitetto, Vice President of Government Relations at kathryn.dibitetto@340bhealth.org or 202-552-5855.

Sincerely,

Maureen Testoni
President and CEO
340B Health

CC: Chairman Richard Neal, Ranking Member Kevin Brady