340B HEALTH
The affordable prescription for healthy communities

January 18, 2018

The Honorable Larry Bucshon
United States House of Representatives
1005 Longworth House Office Building
Washington, DC 20515

The Honorable Scott Peters
United States House of Representatives
1122 Longworth House Office Building
Washington, DC 20515

Dear Congressman Bucshon and Congressman Peters:

We are writing on behalf of 340B Health, a non-profit organization of more than 1,300 public and private nonprofit hospitals and health systems participating in the 340B drug pricing program, to express our deep concerns regarding H.R. 4710, the 340B Protecting Access for the Underserved and Safety-net Entities (PAUSE) Act. While we appreciate your concern for underserved populations as well as your acknowledgement that 340B is critical in helping hospitals meet the needs of their patients, we respectfully oppose H.R. 4710 because it would not accomplish its intended purpose of adding transparency into how the 340B program serves low-income patients. Moreover, it would limit the ability of hospitals to access 340B savings and subject hospitals to burdensome requirements that would harm their ability to treat low-income and rural patients.

The 340B program was enacted with strong bipartisan support more than 25 years ago to reduce drug costs for those providers that care for vulnerable populations. Congress clearly stated the program's purpose during debate over the program's creation: "To stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] The savings created by the 340B program do not come from taxpayers; rather they are the result of a requirement that pharmaceutical manufacturers reduce their drug prices for safety net providers. In 2015, these reductions saved providers $6.1 billion,[2] which was reinvested in care for patients and communities. While these dollars represent only 1.3 percent of total U.S. drug sales,[3] their benefits to patients are far-reaching and substantial.

The Information Collected Under the 340B PAUSE Act Does Not Address How Hospitals Use 340B Savings to Support Patient Care

Rep. Buchson has described the 340B PAUSE Act as calling for 340B hospitals to report data to ensure that the program is "adequately serving low-income and uninsured patients."[4] However, the information that would be collected from hospitals under the bill would not shed light on how much hospitals save through 340B. For example, the bill would require hospitals to report their 340B drug acquisition costs and their reimbursements from payers for 340B drugs. This information would not indicate how much a hospital saves through 340B, as a

[1] H. R. No. 102-384, Part II, Pg. 12, 102nd Congress, Second Session.
[2] Dobson DaVanzo, Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers 4 (July 2017), http://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf.
[3] *Id.*
[4] Press Release (Dec. 21, 2017), https://bucshon.house.gov/news/documentsingle.aspx?DocumentID=629.

hospital's 340B savings are the difference between what a hospital spends on 340B drugs and what a hospital would have spent on those drugs outside the 340B program.

In addition, the information collected under the legislation would not indicate what 340B hospitals are doing with their program savings to serve low-income and rural patients. The legislation would require hospitals to report payer mix and charity care costs. Evaluating charity care alone does not measure the full array of services hospitals provide to low-income patients. Hospitals use their 340B savings to provide services to patients who are uninsured as well as Medicaid patients, low-income Medicare patients, underinsured patients, and patients with limited access to care. Discussion about 340B transparency should include consideration of the services hospitals provide to all of these populations. We support having a thoughtful conversation about 340B transparency, but such a discussion should involve a comprehensive evaluation of the services hospitals provide to their low-income patients. This must comprise all uncompensated care, including not only charity care, but also bad debt, underpayments from Medicaid and other public payers, and other services that hospitals provide at a loss.

The 340B PAUSE Act Does Not Address Manufacturer Transparency

The 340B PAUSE Act fails to address transparency and oversight of drug manufacturers related to their 340B obligations. For example, 340B covered entities are unable to determine whether manufacturers are charging them the correct price because they do not have access to 340B ceiling prices, even though, in 2010, Congress directed the Department of Health and Human Services (HHS) to create a ceiling price website for 340B covered entities.

The 340B PAUSE Act Limits the Ability of Hospitals to Access 340B Savings and Provide Patient Care

We are also concerned by the provisions in the 340B PAUSE Act that would place a freeze on enrollment of new 340B DSH hospitals and registration of new child sites for existing DSH hospitals. Data shows that the current eligibility requirements in the 340B statute for 340B DSH hospitals are working properly to target hospitals that provide a high level of services to low-income patients. Compared to non-340B hospitals, 340B DSH hospitals treat significantly more Medicaid and low-income Medicare patients. While these hospitals comprise only 36 percent of all acute-care hospitals, they provide 60 percent of the nation's uncompensated care, and are more likely to provide specialized services that are critical to low-income patients but are often underpaid, such as HIV/AIDS, trauma, and neonatal services.[5]

Placing limits on child site registrations for DSH hospitals currently in the 340B program could prevent hospitals from using 340B in locations that are clearly part of the hospital. The Health Resources and Services Administration (HRSA), the agency that administers the 340B program, allows hospitals to use 340B drugs in outpatient locations only if they listed on a reimbursable line of the hospital's Medicare cost report, which means they are an integral part of the hospital and are subject to the same compliance requirements as the main hospital building. As such, child site restrictions would affect the ability of hospitals currently in the 340B program to continue accessing 340B savings and could, therefore, reduce the scope of the 340B program for current participants.

[5] Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals (Nov. 15, 2016), http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf.

The 340B PAUSE Act Does Not Address Medicare Payment Cuts to 340B Hospitals

Lastly, any conversation about maintaining the viability of the 340B program and ensuring it helps low-income patients must address the drastic reduction in Medicare Part B drug payments to certain 340B hospitals that went into effect January 1, 2018. As part of the 2018 Outpatient Prospective Payment System (OPPS) payment rates, Medicare reduced Part B drug reimbursement to certain 340B hospitals by 28.5 percent, taking $1.6 billion from these hospitals in 2018 alone. Without Congressional action to reverse the policy, the payment cuts will cause long-term damage, forcing hospitals to reduce services, close service sites, and layoff thousands of employees. The cuts will do nothing to lower drug prices, will not save Medicare a single dollar, and will not save the vast majority of beneficiaries a penny in cost-sharing. Legislation to reverse these cuts, H.R. 4392, has been introduced by Representative David McKinley (R-WV) and currently has 176 bipartisan cosponsors. 340B Health strongly supports this bill and urges Congress to swiftly enact it into law.

For these reasons, 340B Health opposes H.R. 4710. We welcome and support the Energy and Commerce Committee's work identifying ways to strengthen the 340B drug pricing program and look forward to a constructive dialogue. If you have questions, please contact Jeff Davis at 202-552-5867 or Jeff.Davis@340bhealth.org.

Sincerely,

Samuel L. Ross, MD, MS
Chief Executive Officer
Bon Secours Baltimore Health System
Chair, 340B Health Board of Directors

Ted Slafsky, MPP
President and Chief Executive Officer
340B Health