340B HEALTH
The affordable prescription for healthy communities

February 16, 2018

The Honorable Bill Cassidy, M.D.
520 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Cassidy:

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 S.2312, the Helping Ensure Low-income Patients have Access to Care and Treatment (HELP) Act. We respectfully oppose S.2312 because it would significantly alter the 340B program, shrinking it in ways that would harm 340B hospitals' ability to serve their communities. Moreover, it would not increase transparency into how the 340B program serves low-income 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 HELP Act Limits Hospitals' Ability to Access 340B Savings and Provide Patient Care

We are concerned by the provisions in the 340B HELP Act that would call for regulations to create new eligibility requirements for DSH, children's, and cancer hospitals. The eligibility standards outlined in the bill would make it significantly more difficult for hospitals to qualify for 340B and could dramatically reduce the number of hospitals in the program. The bill would also place a freeze on enrollment of new 340B DSH hospitals.

In particular, the proposal to require private non-profit hospitals to provide a minimum level of care to low-income individuals who do not qualify for Medicare or Medicaid would fundamentally change the eligibility criteria that have been in place for DSH, children's, and cancer hospitals since the program's inception. The eligibility requirements laid out in the 340B statute focus on a hospital's provision of care to Medicaid and low-income Medicare patients. The HELP Act's proposal would focus on the level of care provided to

[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.*

patients who do not qualify for Medicare or Medicaid, missing out on the significant care that safety net hospitals provide to patients covered by public payers. Given that public payers, particularly Medicaid, chronically underpay hospitals for services provided to covered beneficiaries, it is critical to consider the care hospitals provide to these populations when evaluating a hospital's care. As such, this proposal would result in a major change to the program that could limit access to 340B savings for hospitals that treat high volumes of Medicaid and low-income Medicare patients.

Such dramatic changes to hospital eligibility rules are unwarranted, because data show that the current eligibility requirements in the 340B statute 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.[4]

The bill would also call for new rules regarding which outpatient locations of a DSH, children's, or cancer hospital are able to access 340B drugs as a child site and would place a freeze on registration of new child sites for DSH hospitals already enrolled in the program. These provisions would make it more difficult to register locations as child sites, thereby shrinking the program. Moreover, placing limits on child site eligibility could prevent hospitals from using 340B discounts 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 are 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 program for current participants.

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

Sen. Cassidy has described the HELP Act as a means to "…increase transparency and strengthen reporting requirements to prevent abuse and ensure 340B discounts are used efficiently and to lower drug costs.[5] 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 the difference between their 340B drug acquisition costs and their reimbursements from payers for 340B drugs. This information is not reflective of how much hospitals save through the 340B program, as a 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 demonstrate what 340B hospitals are doing with their program savings to serve low-income and rural patients. The legislation would require

[4] 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.
[5] Press Release, January 16, 2018, https://www.cassidy.senate.gov/newsroom/press-releases/cassidy-introduces-legislation-to-increase-accountability-in-340b-program-ensure-drug-discounts-are-passed-on-to-patients.

hospitals to report payer mix and charity care costs. Charity care is merely one portion of care provided by safety net hospitals and does not fully capture the high level of services hospitals provide to low-income patients. A more complete picture of the financial pressures hospitals face treating low-income patients requires a broader review of uncompensated and unreimbursed care.

For example, charity care typically refers to the cost of providing financial assistance to patients who qualify for a hospital's financial assistance policy and covers services for which a hospital did not receive or expect to receive payment because the hospital determined a patient could not pay for the services. In addition to charity care, hospitals also incur bad debt costs when they provide services to low-income patients that they expected to be paid for but were not reimbursed. In addition, hospitals also incur shortfalls in reimbursement from Medicaid and other state and local indigent care programs that do not cover hospital costs. A hospital's level of care to low-income patients can also be measured by looking at the hospital's caseload of low-income patients in conjunction with the types of specialized services it provides, such as labor and delivery and trauma care services, that are critical to low-income patients but for which hospitals are typically underreimbursed.

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 legislation would also require DSH, children's, and cancer hospitals to use modifiers to identify 340B drug claims when billing public and private payers as well as require all covered entities to use modifiers to identify 340B drugs when billing Medicaid, Medicare Advantage, and Medicare Part D. We are very concerned that identifying 340B drugs for payers would provide information to insurers that could be used to reduce reimbursement rates for 340B drugs which would undermine the very purpose of the 340B program to stretch scarce federal resources to provide more care to more patients. Sharing 340B claim information with non-Medicaid payers would do nothing to support compliance with program requirements. Moreover, such modifier requirements would be administratively and financially burdensome for providers to implement.

The HELP Act Does Not Address Manufacturer Transparency

In addition, the HELP 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 HELP 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 186 bipartisan cosponsors. 340B Health strongly supports this bill and urges Congress to swiftly enact it into law.

For these reasons, 340B Health opposes S.2312. We welcome and support the Senate's work identifying ways to strengthen the 340B drug pricing program and look forward to a constructive dialogue. If you have questions, please contact me at 202-552-5851 or susan.pilch@340bhealth.org or Kathryn DiBitetto at 202-552-5855 or kathryn.dibitetto@340bhealth.org.

Sincerely,

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