January 13, 2016

Francis J. Crosson, M.D.
Chairman, Medicare Payment and Advisory Commission
425 I Street, NW Suite 701
Washington, DC  20001

RE:  Draft Recommendation Related to the 340B Drug Discount Program

Dear Dr. Crosson:

On behalf of the more than 1,100 hospitals we represent that participate in the 340B drug discount program, we are writing to express our concerns with the draft recommendation related to the 340B program, which we understand will be considered and voted on by the Medicare Payment and Advisory Commission (MedPAC) in its meeting later this week. We believe the proposed policy change would fundamentally change the 340B program and that there is strong reason to believe that the proposed changes would harm 340B hospitals and their low-income patients. In addition, the Health Resources and Services Administration (HRSA), the agency that administers 340B, is in the process of changing the program rules in a way that could significantly limit hospitals’ use of 340B and require hospitals to implement burdensome and costly systems to maintain compliance. Now is not the time for MedPAC to consider fundamental changes to the program, especially as 340B hospitals struggle to meet the needs of their low-income and underserved populations in an era of rapidly increasing drug costs.

In December, MedPAC evaluated a draft recommendation to reduce Medicare Part B payments to 340B hospitals from the current rate of average sales price (ASP) to ASP minus 10 percent, which would effectively reduce 340B hospitals’ 340B savings by roughly 30%. The draft recommendation also proposed to redirect the savings to the Medicare uncompensated care pool to be redistributed to hospitals based on their provision of uncompensated care (defined as charity care and bad debt). The draft recommendation reflected two key changes from the policy options the Commission considered during its November meeting, including reducing 340B savings by 30% instead of 50%, and redistributing that 30% back to certain hospitals rather than having it remain with the federal government. Several Commissioners had noted in prior meetings that 340B hospitals rely on their program savings to treat their vulnerable patients. These changes seem intended to at least partly recognize the vital role 340B savings play in allowing 340B hospitals to meet their safety net missions.

Nevertheless, we have grave concerns about the impact the draft recommendation would have on the 340B safety net hospitals that Congress intended to benefit from 340B. Although 340B DSH hospitals account for only one third of hospitals, they provide nearly 60% of hospital uncompensated care. In addition, 340B Health will be releasing a report in the coming weeks demonstrating that compared to Medicare Part B patients treated by non-340B providers, 340B DSH hospital Part B patients are twice as likely to be disabled or dually eligible

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for Medicare and Medicaid. We are also concerned that MedPAC has not made publicly available detailed information about how hospitals would be impacted by the proposed redistribution of 340B savings. In particular, we are concerned that the sole focus on uncompensated care levels discriminates against hospitals that have high volumes of Medicaid patients. Congress set the 340B eligibility criteria to explicitly include high-volume Medicaid hospitals in the 340B program, and did not focus solely on uncompensated care levels.

MedPAC has suggested that there is a role for the Commission to play in making recommendations about the 340B program to the extent that they are related to how Medicare reimburses hospitals for 340B drugs. However, the changes proposed by the draft recommendation would do more than address the reimbursement of 340B drugs. The revisions would fundamentally change the scope of the 340B program by making changes to the criteria for determining which hospitals can access the full amount of the 340B benefit. Reducing payments to hospitals that meet the eligibility criteria included in the 340B statute and redistributing the savings on the basis of a different set of criteria would create separate levels of the 340B benefit, with some eligible 340B hospitals accessing a reduced 340B benefit, others accessing a higher benefit, and some hospitals that do not meet the 340B eligibility criteria now also benefitting from 340B savings. We do not believe it would be appropriate for MedPAC to recommend making such a fundamental change to the scope of the 340B program, especially given the lack of information on how hospitals would be impacted by the proposed changes and which would be harmed.

In addition to the fundamental concerns we have with the draft recommendation, we are also concerned that hospitals would face significant operational challenges implementing the changes MedPAC is considering. A number of the drugs billed to Medicare Part B by 340B hospitals are purchased at non-340B prices due to program rules that prevent the use of 340B for certain drugs or patients. We understand that under the proposed changes, hospitals would be expected to identify which drugs billed to Medicare Part B are purchased at 340B prices. However, hospitals have reported to us that their systems do not currently allow them to know at the time a drug is billed to Medicare whether it was a 340B-eligible purchase. Implementing systems to allow for this type of claim identification would require more than simply taking additional time before submitting a bill; it would require developing new costly and complex software systems, which currently do not exist.

Thank you for your consideration of these comments. Please contact me at 202-552-5851 or maureen.testoni@340bhealth.org if you have any questions.

Sincerely,

Maureen Testoni
Senior Vice President and General Counsel