September 18, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
Hubert H Humphrey Building
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Azar,

I am writing today on behalf of the National Infusion Center Association (NICA) regarding a letter you recently received from several members of Congress that expressed concerns on potential disruptions to the 340B Program. We appreciate the time and attention your office has given to the issue of drug pricing and lowering Americans’ out-of-pocket costs, as well as your acknowledgement of the perverse effects of the 340B Program and the need for greater transparency.

As you know, the 340B Drug Discount Program was designed to maintain and optimize population health for some of our nation’s most vulnerable communities. However, as you have previously alluded to in your remarks at the 340B Coalition Summer Meeting, the program is fraught with fundamental oversights and deficiencies that not only cloud our ability to objectively evaluate its performance, but also provide both opportunity and incentive for bad actors to exploit the program's flaws for financial gain.

A report from the New England Journal of Medicine found there is no evidence that 340B savings are being used to expand care for low-income patients. Additionally, a 2020 Government Accountability Office report stated “[the Department of Health and Human Services] does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts”. Both reports point to two major issues with the program that NICA believes need to be addressed:

- HRSA lacks sufficient authority to clarify program requirements and adequately oversee the program. Consequently, key aspects of the program have remained vague, resulting in harmful variation in the way covered entities use the 340B program.

Congress did not clearly identify its intent for the program or the program's parameters, leaving the statute silent on many important program requirements (e.g., patient eligibility).

Before issuing directives aimed at managing the downstream consequences of the program’s design flaws, we urge you to instead push for a long overdue approach to identify the underlying problem(s)—establishing transparency within the 340B program to ensure it aligns with its original intent.

The attached report expounds upon our concerns and our ask to increase transparency, evaluate to what extent the program is actually serving patients, refocus the program where needed, and mitigate abuse.

We sincerely appreciate your thoughtful consideration of this very important matter and would welcome the opportunity for further discussion at your convenience. Thank you for your time and commitment to public service.

Sincerely,

Brian Nyquist, MPH  |  Executive Director
NATIONAL INFUSION CENTER ASSOCIATION