Ryan White Clinics for 340B Access

March 28, 2018

Representative Scott Peters
U.S. House of Representatives
1122 Longworth House Office Building
Washington, DC 20515

We write to respond to your February "Open Letter to Grantees" regarding your sponsorship of H.R. 4710, the 340B PAUSE Act. We strongly agree that the 340B program is "one of Congress' significant bipartisan achievements" and that it should be "preserved, strengthened, and protected." However, we are compelled to address several points made in the letter that are not reflective of the facts of the 340B program as we know them.

We disagree with the contention that your legislation does not affect Ryan White HIV clinics. Patients of Ryan White clinics (RWCs) depend on many types of organizations, including hospitals, to provide a continuum of care for people living with HIV. RWCs have referral relationships with hospitals to facilitate and support the transition of care from one setting to the other. If your legislation becomes law, it would restrict otherwise legitimately eligible non-profit providers from using the program that financially supports the broader infrastructure of health care services needed by this vulnerable and complex patient population. Freezing enrollment of new hospitals and sites would shrink hospital resources, shifting the burden of care from hospitals to RWCs.

H.R. 4710 would establish onerous and unnecessarily intrusive reporting requirements that stand in stark contrast to the lack of transparency into the pricing practices utilized by manufacturers. Even though most of H.R. 4710's transparency requirements do not apply directly to RWCs, they would set a troubling precedent of extracting and publicizing private information that goes well beyond the reporting requirements applicable to RWCs under their grants and subgrants. RWC-340B supports transparency within the 340B program but the proposed reporting requirements are intrusive and unfair compared to the meager disclosure requirements applicable to manufacturers. Your legislation's requirements stand in stark contrast to manufacturers' complete freedom to hide their pricing information from the public. In 1990, Congress acquiesced to manufacturer demands to adopt an industry-specific law that keeps their drugs' average price and best price in the marketplace completely hidden from public scrutiny. The blatant imbalance in transparency requirements applicable to covered entities versus manufacturers would be exacerbated by H.R. 4710, even though such lack of parity is patently unfair and must be rectified.

H.R. 4710 reflects a misunderstanding of the 340B program's purpose which could result in a narrowing of the 340B program's size and scope. The 340B program is critically important to RWCs because it gives them the resources to fill the gaps in care that otherwise prevent people diagnosed with HIV from achieving viral suppression. RWCs deserve to participate in the 340B program because they offer patient-focused comprehensive care and specialized services for people living with HIV that are not otherwise available in their communities. Many of the services provided by RWCs – including testing, linkage to care, retention in care, medication adherence, case management, and arranging for transportation and housing – are unreimbursed or under-reimbursed by payers, though these are the services that most directly reduce viral loads and control the epidemic from spreading. RWCs also help patients navigate the complexities of the health insurance system, providing assistance to help patients with insurance afford their high copays. RWC-340B is concerned that H.R. 4710's reporting requirements – by focusing on charity care and demanding reimbursement data that overstates the benefit of the 340B program – reflect a much narrower understanding of how providers should qualify for the program and how the program should be used. We are fearful that, if charity care data is used to assess covered entity eligibility, many RWCs would be disqualified from the program. If it used to limit the patients eligible to receive 340B drugs, the bill would shrink program savings, drive up costs and threaten patient care.

We have not seen evidence of "bad actors" using the 340B program, nor explosive growth in 340B. Our experience is that the 340B provider community is doing its best to comply with a program that is complex and requires enormous resources to implement. Program participants, whether they are hospitals or clinics, are following the intent, spirit and letter of the law as best they can. The program has expanded, but not because of any misuse by covered entities. Rather, Congress increased the number of qualifying entities on three separate occasions -- in 2003, 2005 and 2010. The expansion was limited to certain children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals – all critically important safety net institutions. HRSA estimates that the newly eligible hospitals account for only 10% of total 340B purchasing volume. The greatest increase in use of the 340B program therefore was not only intentional and expected but the direct result of Congressional action and with minimal volume impact. In addition, the Department of Health and Human Services (HHS) started requiring separate registration of every address where covered entity facilities are located, giving the illusion of program growth. We respectfully assert that the motives of those who claim the program is being expanded inappropriately really want to put a halt, or as your bill states, a "pause" on one of the few federal programs that is actually helping to address the high cost of drugs in the U.S.

Pausing the 340B program does not indicate support for the program. 340B is working as intended for safety net providers and should be protected rather than paused. Preventing newly-eligible non-profit hospitals from accessing the 340B program is inconsistent with legislation that would repeal HHS's regulation slashing hospital reimbursement for 340B drugs. We are also concerned with the use of the *New England Journal of Medicine* "published study" as a basis for the PAUSE Act's halting of otherwise eligible hospitals from applying to use the 340B program for their patients. The article you cited was an opinion piece reflecting the drug industry's policy agenda, not a peer reviewed research study.

The 340B program benefits patients and their non-profit safety net providers. The 340B program costs taxpayers and the government nothing. It seems obvious to us that pharmaceutical industry is trying to dismantle 340B for two reasons – to lessen their responsibility to assist the safety net and to avoid having a real conversation on increasing drug prices. We ask that you reconsider your approach to the 340B program and work with RWCs, other safety net providers and the patients they serve to protect the program.

Sincerely,

MEMBERS OF RWC-340B

AIDS Center of Queens County
AID Atlanta
AIDS Care Group
AIDS Healthcare Foundation
AIDS Outreach Center
AIDS Project of the Ozarks
AIDS Resource Center of Wisconsin
AIDS Taskforce of Greater Cleveland
Alamo Area Resource Center
Allies for Health + Wellbeing
Big Bend Cares
CAN Community Health
Chattanooga CARES
Christie's Place
Conemaugh Health System
Damien Cares
Equitas Health
Evergreen Health Services
Fenway Health
Foothill AIDS Project
Heartland CARES, Inc.
Hyacinth AIDS Foundation
MetroHealth
Northern Nevada HOPES
North Jersey Community Research Initiative
Northland Cares
Nuestra Clinica
One Community Health
Open Door Health Center of Illinois
Positive Health Clinic
Positively U
Prism Health North Texas
South Carolina HIV/AIDS Council
Southwest CARE Center
Thrive Alabama
Trillium Health
Urban Solutions Inc.
Whole Family Health Center