

August 27, 2020

PRESS STATEMENT: FOR IMMEDIATE RELEASE Contact: Peggy.Tighe@PowersLaw.com

Ryan White Clinics Call on Congress, HHS, & HRSA to Stop Drug Manufacturers from Undermining Our Use of the 340B Program to Care for People with HIV

Washington, D.C. – Below is a statement from Shannon Stephenson, president of RWC-340B, on recent manufacturer actions to limit distribution of 340B drugs to safety net providers and their patients.

In just the last few months, several drug manufacturers have set themselves up as "the fox in charge of the henhouse." If left unchecked by Congress and the Department of Health and Humans Services (HHS), these manufacturer's actions will cripple the ability of HIV clinics and other safety net providers to care for vulnerable patients while we are in the midst of the worst public health crisis to ever hit the globe.

The 340B program's stated intent is for safety net providers to use their 340B savings to serve more patients and to provide more comprehensive services. But recently several drug manufacturers have sent letters either announcing their new self-serving policy of only selling 340B drugs to in-house pharmacies or demanding submission to new on-line portals of sensitive claims data to which the manufacturers are not entitled. Implementation of these one-sided policies will quickly decrease access to both pharmaceuticals and quality of care for patients and their communities and only serve to line the pockets of drug manufacturers.

It is particularly concerning that manufacturers have taken these steps during the COVID-19 public health emergency. Ryan White clinics are not only answering the call to protect their communities from COVID-19, they are simultaneously continuing to fight the HIV/AIDS epidemic. Our member organizations are skilled at caring for patients with infectious diseases and, for this reason, are on the front lines of fighting against both epidemics. Manufacturer actions are thwarting our members' public health efforts which, in turn, will exacerbate the current public health emergency.

Adding insult to injury, the Health Resources and Services Administration (HRSA), the agency under HHS charged with overseeing the 340B drug discount program, announced its perceived lack of authority to prevent manufacturers from taking these actions, reversing 24 years of asserting that it possesses such authority. Congress, in establishing the 340B program in 1992 and expanding it in 2010, never intended that for-profit manufacturers be given free rein to decide how they will participate.

One manufacturer-supported model is described by its authors as turning the 340B drug discount program into a rebate program. The 340B program was written to provide an "up-

front" discount to the safety net, not to allow manufacturers and their vendors to rewrite the rules on a whim to deny savings rightfully owed to the safety net at the point of sale. We are also concerned that the new on-line claims submission platforms present serious legal privacy and contracting issues for safety net providers across the country. Without formal and transparent government oversight of the 340B program, we simply don't know what these manufacturers will require of us next, if they will change the rules midstream, or if they will even provide us with the discount.

Ryan White clinics are highly dependent on the 340B program to advance the program's twin goals of providing more comprehensive care and serving more patients. Without access to the up-front discounted pricing available through the 340B program, our members would be forced to provide fewer services and/or serve fewer patients. Some clinics may be forced to close altogether. There is no question in our minds that these manufacturer actions would seriously undercut our ability to fight COVID-19 and HIV/AIDS.

RWC-340B calls on Congress, HHS, and HRSA to stop these manufacturers from restricting access to 340B savings, actions that thwart Congress' and the agencies' oversight responsibility, undermine the integrity of the 340B program, and directly threaten access to the care we provide to our vulnerable patient populations.

Ryan White Clinics for 340B Access (RWC-340B) is a national organization of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act and participate as "covered entities" in the federal 340B drug discount program.