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The Honorable Joseph Pitts
420 Cannon House Office Building
United States House of Representatives
Washington, DC 20515

RE: Written Testimony for the Record of the Hearing before the Committee on Energy and Commerce, Subcommittee on Health: "Examining the 340B Drug Pricing Program" Tuesday, March 24, 2015 at 10:00 AM

Submitted via email

Chairman Pitts and Members of the Committee on Energy and Commerce, Subcommittee on Health:

The Pharmaceutical Access for Community-based Service Providers (PACSP) respectfully submits the following testimony for the record for the hearing "Examining the 340B Drug Pricing Program" taking place March 24, 2015.

As the Committee considers the future direction of 340B, we ask that the program be strengthened and improved for the core safety net providers – its original beneficiaries – for the sake of vulnerable populations across the country.

PACSP's membership is primarily made up of AIDS Services Organizations (ASOs) that deliver medical services and social support to vulnerable populations across the nation. These providers are part of the original covered entities for which the 340B program was intended.

The 340B program is a critical life-line providing essential financial resources that enable ASOs and other safety net providers to maintain and expand services. For these original "covered-entities" 340B is working as it is intended. Without the resources available from the 340B discount program, many of these community-based providers would have to close their doors.

When Congress passed the 340B program in 1992, they were looking for ways to generate resources for safety net providers without having to outlay additional Federal monies. In the original Committee report after the legislation passed in 1992 (H.R. REP. 102-384(II)), Congress made its intent clear:

> "In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

The original intent of the program was not to give access to cheaper drugs to poor, underinsured or uninsured patients: it was to expand the capacity of providers to serve people who are poor, underinsured or uninsured. Opponents of 340B often misrepresent the original intent of the program to confuse the issue but the legislative history is quite clear.

Eligibility for participation in the 340B Program is strictly limited to the entities specified in the statutes and includes Federally Qualified Health Centers (FQHCs) and FQHC Look-Alikes, Native Hawaiian Health Centers, Tribal/Urban Indian Health Centers, Ryan White HIV/AIDS Program Grantees, Disproportionate Share Hospitals (DSH), children's hospitals, Critical Access Hospitals, free-standing cancer hospitals, Rural Referral Centers, Sole Community Hospitals, comprehensive hemophilia diagnostic treatment centers, black lung clinics, Title X Family Planning Clinics, Sexually Transmitted Disease Clinics and Tuberculosis Clinics.

The 340B program has enjoyed more than 20 years of broad support from Congress, safety net providers and the pharmaceutical industry. To ensure integrity in the program, certain safeguards have been put in place. Specifically, Section 340B(a)(5)(B) of the PHS Act prohibits entities from selling (or otherwise transferring) drugs purchased under the 340B Program to anyone who is not a patient of the covered entity. Congress did not define the term 'patient' in Section 340B, and initial HRSA guidelines implementing the 340B Program directed covered entities to "develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount" in order to prevent diversion. To accomplish this, entities were encouraged to utilize a separate purchasing account and separate dispensing records (See 59 FR 25110).

HRSA's guidance on how covered entities should define their patients is necessarily broad, accounting for the large number of covered entities and the wide diversity of eligible groups. In recent years it appears that certain covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program. Questions have also been raised about the types of services that should qualify as legitimate medical services for the purposes of defining a patient population.

Every day, ASOs provide a wide range of medical services, assistive services and supports, and other services necessary to patients with HIV/AIDS. These vulnerable patients are often dually diagnosed with mental or behavioral health challenges that demand intensive, individualized medical case management. As a result of a comprehensive bio-psycho-social assessment,

medical case management helps identify potential barriers to treatment – such as lack of resources for food, medication, clothing, shelter, transportation and child care, or active addictions, mental health issues and domestic violence. Medical case management serves as the coordinating function to ensure improved quality of life, adherence to drug and treatment protocols and better health outcomes by removing the barriers patients experience to scheduling and keeping medical appointments, as well as obtaining and administering medications.

Medical Case management is recognized as a legitimate health service, enabling patients to access and utilize necessary medical, social, educational and other services and as such are reimbursed under the Medicaid program. These services are based in recognized and established social work practice standards. Medical Case management does NOT include administrative functions such as prior authorization or referral services.

Providing the wide range of services and supports is expensive. While significant, contributions and fundraising cannot provide enough sustainable funding to meet the long-term needs of HIV/AIDS populations. Federal, state and local funds are available but in recent years, due to the economic situation, funds for HIV/AIDS service providers has decreased dramatically. Federal sequestration has further restricted funds available for direct service delivery. ASOs are feeling the pinch but remain committed to serving their patients. 340B funding allows ASOs to keep the doors open, expand services and provide medical and medical case management far beyond what they would otherwise be able to do. 340B is literally a lifesaver for these programs and the beneficiaries they serve.

The 340B program remains important even with the expansion of health coverage following the ACA. While the ACA guarantees a core set of essential health benefits, coverage for the specific and intensive services for patients living with HIV and AIDS - including medical case management, primary care, and pharmaceuticals - are not guaranteed. In the post-ACA world, ASOs and other providers serving at-risk populations will still be needed to fill in the gaps in coverage, serving as the primary points of service for these growing and complex populations.

PACSP appreciates the opportunity to submit this written testimony and looks forward to working with the Committee to improve this vital program. Please feel free to contact us as a resource.