Ryan White Clinics for 340B Access

340B STATEMENT OF PRINCIPLES

RWC-340B is a national association of HIV/AIDS clinics and service providers that receive support under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act and participate in the 340B program. The 340B program is essential to assist Ryan White clinics (RWCs) to achieve their mission of caring for low-income and vulnerable patients living with HIV/AIDS and to stop transmission of HIV.

RWCs are on the frontlines of the battle against the HIV/AIDS epidemic, supporting patients by providing primary care, case management, dental and behavioral health, and other support services. Data shows that RWCs are extremely successful in helping patients achieve sufficient viral suppression so that they cannot transmit HIV.

RWCs use 340B savings for services that are typically not covered by a grant or insurance and, importantly, as the 340B program intended: to provide more comprehensive services to HIV/AIDs patients and to reach more HIV/AIDS patients. The key to controlling and ultimately ending the AIDS epidemic is testing people who don't know they have the virus, getting them into treatment if they test positive, and retaining them in treatment – none of which is covered or adequately reimbursed by insurance and none of which is achieved by lowering the cost of medications.

RWC-340B strongly opposes any attempts to change the reach of the 340B program because the program is working as it was intended for RWCs. RWC-340B asks policymakers to consider that shrinking of the 340B program means that drug manufacturers increase their already astronomical profits at the expense of safety net providers.

1. **Legislative Intent.** The legislative intent of the 340B program should not be reinterpreted, re-envisioned, or stated any differently than it already is: "The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

2. **Flexibility in Use of 340B Savings**. RWCs use savings from providing 340B drugs to any patient (some with drug coverage) to provide more comprehensive services to more patients at no taxpayer expense. The 340B program should not be restructured as only a patient drug assistance program or focus only on low-income and uninsured patients because doing so would mean that RWCs no longer have the resources to provide more comprehensive care to all patients. RWC grant requirements currently require RWCs to provide care to low-income patients and RWCs already ensure that each of their patients receive the drugs that they need often at no cost to the patient.

3. **Grant-specific limitations on service.** Any proposals that create narrowly defined limits on access to 340B drugs, by disease state or condition, would seriously undermine the ability of safety net providers to use 340B savings to care for patients' comprehensive needs and threaten our efforts to end the HIV epidemic. Medical best practices and the terms of our grants require that we provide comprehensive, holistic care.

4. **Contract pharmacy.** Policymakers and/or the courts must stop manufacturers from dictating the rules for the 340B contract pharmacy program. Contract pharmacy arrangements must not be limited in number, by geography or to certain service areas or populations. Many RWC patients need drugs that are only available through specialty pharmacies located far from the RWC, but also need other drugs that they can pick up from their local pharmacy. Arbitrary limitations set by drug manufacturers on access to 340B drugs only benefit the manufacturers and deny access to life saving medications to patients.

5. **Regulatory Requirements.** As a condition of receiving a federal grant, RWCs must report on their uses of grant funds and funds that are generated from the grant. Proposals that would require additional, onerous reporting requirements are unnecessary and will force RWCs to take time away from patient care and community service.

6. **Pharmaceutical Benefit Managers (PBMs).** PBMs must be prohibited from siphoning off 340B savings by making reduced payments for 340B drugs or creating network requirements that funnel RWCs to pharmacies in the PBM system. In contrast, covered entities should be permitted to continue to contract with for-profit vendors because those vendors help covered entities comply with the requirements of the 340B program.

7. **Accountability.** Compliance with the prohibition on diversion and duplicate discount prevention should not be a condition of eligibility for the 340B program. Covered entities are already required to make repayments to manufacturers if they discover any issue of non-compliance, which often result from a simple error or misunderstanding of complex guidance from HRSA. A national clearinghouse should be established to reduce duplicate discounts, but the clearinghouse should be narrowly targeted to prohibit duplicate discounts on Medicaid claims only, as prohibited in the 340B statute, not expanded to commercial claims.

8. **340B Eligibility.** HRSA and OPA should be supported in ensuring program integrity through proper monitoring of 340B eligibility. Any proposals to limit 340B eligibility should be weighed carefully against the detrimental impact on underserved communities that will result from reducing resources to these safety net providers. The Ryan White program is divided into various parts, some for grantees and others for subgrantees through the states. Any proposals seeking to limit 340B access to only grantees and not subgrantees could create severe limitations with enormous negative impacts on HIV care nationwide.

9. **Nullification of State Law.** In no instance should Congress nullify state laws on 340B. More than 25 states have passed laws to prevent discriminatory reimbursement and one state passed a law to regulate manufacturers' distribution within state boundaries.