October 27, 2015

Krista Pedley
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Submitted via: http:/www.regulations.gov

Re: Regulatory Information Number (RIN) 0906-AB08

Dear Captain Pedley:

We are writing on behalf of the HIV Medicine Association (HIVMA) and the Ryan White Medical Providers Coalition (RWMPC) with comments regarding the 340B Drug Pricing Program Omnibus Guidance (RIN 0906-AB08). HIVMA represents nearly 5,000 physicians, scientists, and other health care professionals working on the frontlines of the HIV epidemic across the U.S. The RWMPC is a national coalition of medical providers and administrators who work in clinics supported by the Ryan White HIV/AIDS Program.

The 340B program plays a critical role in supporting access to and the delivery of high quality comprehensive HIV care to low income, uninsured and underinsured patients receiving services through Ryan White funded programs. Many Ryan White clinics could not sustain the patient centered medical home care that they provide without the 340B program. We appreciate that additional 340B guidance and oversight is needed given the recent growth in the 340B program; however, we urge HRSA to not unduly harm long-standing 340B entities and the patients that they serve in the process.

Individuals who receive Ryan White services have better health outcomes, including higher viral suppression rates – the clinical goal of HIV treatment. The complexities of health care financing and health care coverage in the U.S. requires HIV clinics serving low income and vulnerable patient populations to cobble together multiple and diverse funding and programming mechanisms, including the 340B program, to help patients achieve and sustain viral suppression. A number of factors contribute to the financial solvency challenges that HIV clinics face – including the high cost of HIV medications and (increasingly medications generally); high rates of serious co-occurring conditions among HIV patients, such as mental illness and hepatitis C; the range of supportive services that many HIV patients require to access care and treatment; poor Medicaid reimbursement rates, and the high out-of-pocket costs imposed by health insurers.

In order to meet the goals of the updated National HIV/AIDS Strategy – which include increasing the percentage of people with HIV retained in care to 90% and the number of diagnosed individuals with HIV who are virally suppressed to 80%, among other goals -- it will be critical to sustain the systems of care supported by the Ryan White Program and Ryan White Program grantee eligibility for 340B participation. We strongly urge HRSA to proceed cautiously in implementing changes to the 340B program that may have unintended consequences, such as disrupting Ryan White systems of care and interrupting HIV care and treatment for patients. With this in mind, we offer the following comments regarding the proposed guidance.

We strongly support HRSA's recognition that in their role as essential providers, many 340B entities manage care for patients via telemedicine in rural and medically underserved areas. Many Ryan White clinics draw patients from a large geographic radius and telemedicine plays an important role in helping to keep patients in care and on HIV treatment. Key issues that are barriers to keeping people with HIV in care can be addressed through telemedicine, including travel time and costs, crowding of specialty clinics, and lost patient work time. **We urge HRSA to retain the provision allowing patients managed via telemedicine to meet the qualified patient definition.**

However, in general, the proposed patient definition that would change patient eligibility from three to six criteria is overly restrictive and would result in an unprecedented level of administrative complexity. Implementation of this definition would result in significant policy shifts that would harm 340B entities, including Ryan White funded clinics, and could limit their ability to provide outpatient HIV primary care (or primary care in the case of Federally Qualified Community Health Centers). Ryan White clinics often serve as the medical home (or primary care provider) for their patients. In addition to providing comprehensive primary HIV care, these clinics also coordinate care, provide specialty care, and provide and support a range of other services. The ability to provide such comprehensive services is a critical factor in achieving the high viral suppression rates reported by many Ryan White clinics. However, many of these clinics are unable to contract with specialists, and instead often have established referral relationships. HRSA's proposal to require a contracted provider to prescribe eligible 340B medications is without justification given the role Ryan White clinics play in managing the ongoing care of patients with HIV. Such a change would weaken a Ryan White clinic's ability to effectively provide the level of coordination necessary for non-HIV care and services. We strongly urge HRSA to reconsider this significant policy shift that would limit the ability of safety-net providers to meet the complex medical needs of the patients they serve.

The proposed changes to qualified AIDS Drug Assistance Program (ADAP) payments would severely hamper the ability of many state ADAPs to maximize the value of scarce resources through health insurance purchasing and/or cost sharing assistance. Without assistance from ADAP, many insured Ryan White clinic patients would be unable to afford their health insurance premiums or the cost sharing required to obtain medications because of the intensity of their medication needs and the high cost sharing often required for HIV medications. To

illustrate the potential impact of these changes, the National Alliance of State and Territorial AIDS Directors (NASTAD) estimates that the proposed policy change would result in a drop of 45 to 55 percent of ADAP rebate revenue. At a time of escalating costs for HIV medications and diminished funding for federal discretionary programs, this slashing of ADAP funds would lead to dramatic changes in the services and support available to our patients living with HIV/AIDS.

Since the expansion of insurance purchasing by ADAPs, restrictions on program eligibility, including waiting lists for HIV medications, have been significantly reduced or eliminated. A retreat in ADAP payments eligible for the 340B rebate places these programs at serious risk at a time when the Patient Protection and Affordable Care Act (PPACA) has contributed to significant progress in obtaining insurance coverage for patients living with HIV/AIDS. Access to health insurance coverage, often for the first time, has provided these patients with critical access to non-HIV services as well as health coverage stability.

We also strongly urge HRSA to reject the position of some manufacturers who recommend disqualifying premium payments for patients who receive other subsidies. Congress recognized in the PPACA the unique role that ADAPs play in providing cost sharing support by allowing ADAP payments to count toward the true out of pocket costs or "TrOOP" incurred by Medicare Part D beneficiaries. A new interpretation of this role would disqualify more than 80 percent of existing insured ADAP clients from the qualified payment definition, according to estimates by NASTAD, and would jeopardize the health coverage and health stability of many patients.

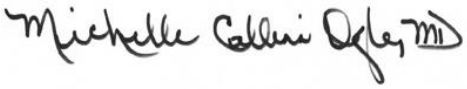
Additionally, we are concerned that the proposed change may disproportionately impact ADAPs in states with the highest rates of HIV-related health disparities and highest rates of new HIV cases. These states are less likely to have in place the necessary infrastructure to pay insurance premiums and/or cost sharing; so the proposed policy would hinder the ability of these states to provide the limited assistance that they are able to support, and therefore leave patients without this critical support.

The proposed changes to the treatment of qualified ADAP payments would represent a major shift in policy and would be a setback to the intent of the 340B program – to stretch scarce federal resources to help meet the health needs of underserved populations, including patients with HIV/AIDS. If HRSA elects to advance these harmful changes, we strongly recommend delaying implementation by more than the proposed one year to avoid serious disruptions in the delivery of HIV care and treatment, and to allow for adequate time for policies, systems and any necessary legislation to be implemented.

The 340B program has been a lifeline for HIV clinics and the medically underserved patients they serve, and we are very supportive of efforts to strengthen the integrity of the program and to ensure its sustainability. However, we are concerned that the proposed guidance would be a significant retreat from the intended purpose of the program, as well as the cause for substantial disruption and harm to the comprehensive, effective system of care for people

living with HIV/AIDS. We urge HRSA to reconsider the proposed changes to the 340B patient definition and to the definition of qualified ADAP payments in light of the program's intent and the potential harmful impact on access to HIV care and treatment nationwide. We also urge HRSA to continue to seek input from Ryan White providers and other 340B entities to develop solutions that ensure the 340B program's longevity while also fulfilling its mission of supporting essential community providers in meeting the health care needs of their patients. Please contact HIVMA executive director Andrea Weddle at aweddle@hivma.org or RWMPC convener Jenny Collier at jennycollierjd@yahoo.com.

Sincerely,



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