

July 8, 2019

VIA ELECTRONIC SUBMISSION

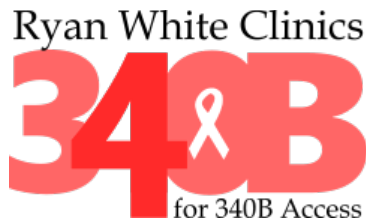
Information Collection Clearance Officer
Health Resources and Services Administration
5600 Fishers Lane
Room 14N136B
Rockville, MD 20857

RE: Information Collection Request – Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB Number 0915-0327

Ryan White Clinics for 340B Access (RWC-340B) is a coalition of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act, either through a primary grant or subgrant, and participate as “covered entities” in the federal 340B drug discount program (340B program). Many of our members also receive funding as a Section 318 sexually transmitted disease (STD) subgrantee or through a Section 318 in-kind grant. RWC-340B appreciates the opportunity to submit the following comments in response to the Information Collection Request (ICR), issued by the Health Resources and Services Administration (HRSA), entitled Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and published in the Federal Register on May 9, 2019 (84 Fed. Reg. 20373).

To determine eligibility for the 340B program, HRSA requires entities to submit administrative information, certifying information, and attestation from appropriate grantee level or entity level authorizing officials and primary contacts. Registration and annual recertification information is entered into the 340B Office of Pharmacy Affairs Information System (OPAIS) by covered entities and is verified by HRSA staff. In the May 9 ICR, HRSA announced that it intends to revise the registration form for Ryan White Clinics (RWCs) to require a clinic to provide “its” Notice of Funding Opportunity (NOFO) number, as well as the time period of such assistance. In addition, HRSA also proposes to require an STD clinic to provide “its” NOFO number at the time of registration, the type of in-kind funding it receives, and the time period of funding. HRSA’s stated reason for collecting this information is that it will “assist HRSA to accurately determine the eligibility of the covered entity registration.”¹ RWC-340B is concerned that requiring RWCs and STD clinics to report a NOFO number when registering for 340B eligibility would impose significant, additional operational and administrative burden on these covered entities.

¹ Information Collection Request – Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB Number 0915-0327, 84 Fed. Reg. 30373 (May 9, 2019).



The complications of including NOFOs as part of the registration process are compounded by HRSA's unwritten policy to require RWCs and STD clinics with multiple locations to register each location separately. Requiring a NOFO for each RWC or STD location adds to the administrative burden imposed by HRSA's multisite registration policy.

HRSA's 340B Program Registration Requirements for RWCs and STD/TB Clinics Imposes Undue Operational and Administrative Burdens

The new NOFO reporting requirement would require RWCs and STD clinics to input information that the entity may not have readily available. The HRSA grant process begins when the agency issues a NOFO that contains the grant or cooperative agreement, as well as the start and end dates of the project period.² Entities respond to the NOFO, which HRSA reviews and later issues a Notice of Award for each applicant selected for funding.³ However, the Notice of Award that HRSA ultimately provided to the grantee does not contain the NOFO number.⁴ While information such as the general grant number and the Catalog of Federal Domestic Assistance (CFDA) number are listed on the NOA, these are not synonymous with the NOFO number.

HRSA's new reporting requirement is particularly concerning for clinics that receive subgrants or Section 318 in-kind contributions. HRSA's ICR characterizes each RWC or STD clinic as having "its" NOFO, but a subgrantee or recipient of in-kind funding would have had no involvement with the NOFO. In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.⁵ Entities that receive subgrants or in-kind contributions are eligible for the 340B program by virtue of receiving these awards, and are currently subject to detailed reporting requirements as a condition of receiving such funds. In many instances, the recipient of the subgrant or in-kind contribution may not have access to the NOFO for the primary grant, making registration more difficult for these covered entities.

Our members who receive subgrants or in-kind contributions are concerned that it may be very difficult to coordinate with the primary grantee to get this information in a timely manner. If entities are not able to retrieve this information in a timely manner, a delay in 340B registration may result. RWCs and STD clinics rely on 340B savings to "stretch scarce federal resources as far as possible,"⁶ and delaying access to 340B drugs would put further strain on

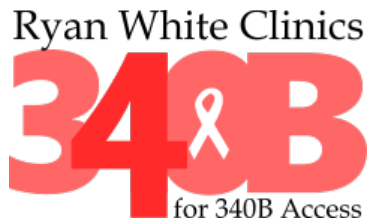
² HRSA, Understanding the Grant Process, <https://www.hrsa.gov/grants/apply/understanding-grant-process.html> (last reviewed March, 2019).

³ *Id.*

⁴ HRSA, How to Read Your Notice of Award, <https://bphc.hrsa.gov/programopportunities/fundingopportunities/continuation/how-to-read-noa-update.pdf> (last viewed July 2, 2019).

⁵ HRSA, FAQ, 340B Program Eligibility, <https://www.hrsa.gov/opa/faqs/index.html> (last viewed July 2, 2019).

⁶ H.R. REP. 102-384(II), at 12 (1992).



already tight budgets and threaten the ability of these RWCs and STD clinics to provide quality services to patients.

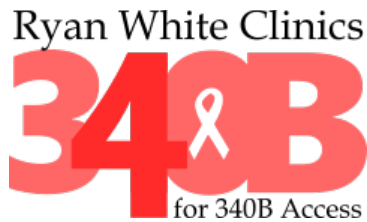
RWCs and STD clinics, like other federal grantees and sub-grantees, are subject to detailed reporting requirements as a condition of receiving such funds. HRSA's new reporting requirement will impose an administrative burden on RWCs and STD clinics that could hinder the clinics' core mission of meeting the health needs of their patients for no reason. While RWC-340B members inherently support transparency in government programs, it is vitally important that such methods do not impede the work of providing important comprehensive services to patients or strain financial reserves that are intended for patient care. For these reasons, we believe it would be in the best interest of RWCs, STD clinics, and their patients, to forgo implementing the requirement to provide the NOFO number and time period of funding at the time of registration.

RWC-340B also questions the proposed requirement to require a description of a STD in-kind grant and time period for the funding. RWC-340B is concerned that this requirement is a precursor to a policy that would allow HRSA to reject or deny registration in the 340B program based on the type of STD in-kind funding that an entity receives. RWC-340B believes that State and local governments are in the best position to determine and provide the type of in-kind grants that would meet the needs of their communities.

Moreover, Apexus recently communicated to us that, according to HRSA, grantees other than FQHCs must register each location operating under a single grant as a separate covered entity with a unique 340B identification number on the OPAIS. By letter dated June 14, 2019, RWC-340B contested this unwritten policy and asked HRSA to reverse it. RWC-340B objected to the unwritten policy for various reasons, including the complexity of maintaining separate 340B inventories and contract pharmacy arrangements, the lack of written notice of the policy and the fact that the policy is at odds with this Administration's goal to reduce administrative burden. HRSA's proposed policy to require a NOFO at the time of registration adds to the complexities and the undue administrative burdens that were described in our June 14 letter because a NOFO will be required for each site. RWC-340B members believe that HRSA's policy creates undue operational and administrative burdens on both grantees and HRSA.

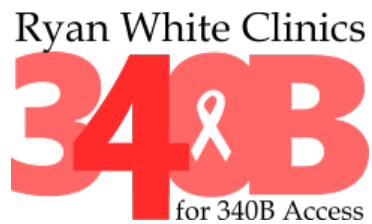
As you know, RWCs, STD clinics, and other safety-net providers are at the front lines of caring for low-income and vulnerable patients suffering from HIV/AIDS. We rely on the 340B program to support the complex array of health care and social services needed by this vulnerable population. We appreciate your attention to this important matter. Please contact our President, Shannon Stephenson, with any questions. Shannon can be reached at ceo@cempa.org or (423) 648-9911.

Sincerely,



RWC-340B Members

Action Wellness – *Philadelphia, Pennsylvania*
AID Atlanta – *Atlanta, Georgia*
AIDS Care Group – *Philadelphia, Pennsylvania*
AIDS Center of Queens County – *Queens, New York*
AIDS Healthcare Foundation – *Los Angeles, California*
AIDS Outreach Center – *Fort Worth, Texas*
AIDS Project of the Ozarks – *Springfield, Missouri*
AIDS Resource Center of Wisconsin – *Milwaukee, Wisconsin*
AIDS Taskforce of Greater Cleveland – *Cleveland, Ohio*
Alamo Area Resources Center – *San Antonio, Texas*
Allies for Health + Wellbeing – *Pittsburgh, Pennsylvania*
Aniz, Inc. – *Atlanta, Georgia*
Big Bend Cares – *Tallahassee, Florida*
Buddies of NJ – *Hackensack, New Jersey*
CAN Community Health – *Sarasota, Florida*
Cempa Community Care – *Chattanooga, Tennessee*
Chicago House and Social Service Agency – *Chicago, Illinois*
Christie's Place – *San Diego, California*
Community AIDS Resource and Education Services –
Kalamazoo, Michigan
Conemaugh Health System – *Johnstown, Pennsylvania*
Damien Cares – *Indianapolis, Indiana*
Equitas Health – *Columbus, Ohio*
Evergreen Health Services – *Buffalo, New York*
Fenway Health – *Boston, Massachusetts*
Foothill AIDS Project – *Claremont, California*
Heartland CARES – *Paducah, Kentucky*
HIV Alliance – *Eugene, Oregon*
Hyacinth AIDS Foundation – *Elizabeth, New Jersey*
Men's Health Foundation – *Los Angeles, California*
MetroHealth – *Washington, DC*
North Jersey Community Research Initiative – *Newark, New Jersey*
Northern Nevada HOPES – *Reno, Nevada*
Northland Cares – *Prescott, Arizona*
Nuestra Clinica – *Lancaster, Pennsylvania*
One Community Health – *Sacramento, California*
Open Door Health Center – *Elgin, Illinois*
Positive Health Clinic – *Pittsburgh, Pennsylvania*
Positively U – *Davenport, Florida*
Prism Health North Texas – *Dallas, Texas*
Project Response – *Melbourne, Florida*
South Carolina HIV/AIDS Council – *Columbia, South Carolina*



Southwest CARE Center – *Santa Fe, New Mexico*
Thrive Alabama – *Huntsville, Alabama*
Trillium Health – *Rochester, New York*
Urban Solutions Inc. – *Philadelphia, Pennsylvania*
Virginia Commonwealth University – *Richmond, Virginia*
Whole Family Health Center – *Vero Beach, Florida*