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SUBMITTED ELECTRONICALLY VIA PAPERWORK@HRSA.GOV

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HRSA Information Collection Clearance Officer
5600 Fishers Lane
Room 14NWH04
Rockville, MD 20857

Re: Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Enrollment and Re-Certification of Covered Entities in the 340B Drug Pricing Program, OMB Number 0915–0327—Revision

Ms. Miller:

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). Ryan White clinics are at the front lines of caring for low-income and vulnerable patients living with HIV/AIDS. Although a core characteristic of RWC-340B membership is receipt of Ryan White grant funding, most members also qualify for and participate in the 340B program as federally-qualified health centers, FQHC look-alikes, sexually transmitted disease (STD) clinics, family planning clinics and/or safety net hospitals.

RWC-340B appreciates the opportunity to respond to the above-captioned Federal Register Notice (FRN) issued by the Health Resources and Services Administration (HRSA) published on August 7, 2025.[1] RWC-340B supports HRSA's stated goals in the FRN for 340B covered entity registration to maintain "efficiency, transparency, and integrity" while administering the 340B program. However, RWC-340B is concerned that those goals will not be achieved if HRSA enacts its proposed changes. The additional information HRSA proposes to collect during enrollment and recertification would undermine the 340B program's efficiency because covered entities would be subject to increased administrative burdens. More importantly, HRSA's proposal lacks transparency, exceeds the agency's statutory authority and would violate the Paperwork Reduction Act (PRA) and Administrative Procedures Act (APA).

[1] 90 Fed. Reg. 38167 (Aug. 6, 2025).

HRSA's Additional Requirements for STD Clinics are Unclear, Untenable, and Exceed the Agency's Authority

The FRN states that: "HRSA is requesting that STD grantees provide supporting documentation to demonstrate 340B eligibility…during initial registration as well as during recertification if requested…." The FRN clarifies that "documentation" will include a copy of the federal grant notice of award or a copy of the executed written subrecipient agreement for grant subrecipients. HRSA does not state how often covered entities will need to provide such documentation.

STD clinics are eligible for the 340B program via a federal grant program established under section 318 of the Public Health Service Act and administered by the Centers for Disease Control and Prevention (CDC). The CDC typically issues 318 grant awards to the clinics' state and the state makes a subaward to the clinic. Sometimes STD clinics receive their subawards from a county or city because local governments can qualify for 318 funding directly from the CDC or indirectly from the state. Either way, the CDC grant is not directly awarded STD clinics. Therefore, as a general matter, do not possess the CDC notice of award or are privy to its contents. It is unclear how STD clinics can submit their federal grant notice of awards to HRSA when they do not possess such documentation in the first place.

If an STD clinic participates in the 340B program based on a subrecipient agreement, obtaining a copy of a subrecipient agreement to share with HRSA is similarly challenging. Many subgrantees participating in the 340B program do not have written agreements that include the information required under the proposal. Moreover, the subrecipient agreements are not uniform and use formats that vary widely by state, county, and city. Requesting changes to these documents to reflect HRSA's new requirements would likely be time-consuming. Some STD clinics qualify for the 340B program not only by receiving subgrant funding but also by receiving in-kind services or supplies like lab testing, test kits and educational material. Amending the agreements describing these in-kind services or supplies may be even more difficult. Neither the FRN nor the draft instruments referenced in the FRN anticipate the need to make amendments to subrecipient agreements, creating uncertainty about how STD clinics must comply.

It is inherently unfair to impose on STD clinics documentation requirements that they cannot satisfy without government assistance. Access to a federal grant notice of award or a copy of the executed written subrecipient agreement is dependent on government entities' willingness to provide this information to the clinics. And their responsiveness may be slow, especially because many state and local governments are not aware of these new requirements and may lack the capacity and training to provide the needed assistance.

HRSA's request for additional documentation greatly impacts RWC-340B members. Ryan White clinics (RWCs) often provide preventive services such as administering PrEP to non-HIV patients as part of their effort to eradicate the spread of the HIV virus in the U.S. Because RWCs are not permitted to use the 340B program for their non-HIV patient population, many are

registered in OPAIS as both RWCs and STD clinics. Based on a recent RWC-340B member survey, 71 percent of RWC-340B's members are registered in OPAIS as STD clinics. RWC-340B membership is concerned about the level of effort required to comply with this mandate. Accordingly, the clinics often do not have access to the notice of award issued to the state, county or city health departments by the CDC.

RWC-340B is also concerned that the additional documentation requested by HRSA exceeds the agency's statutory authority. The 340B statute does not list a state, county, or city notice of award or subrecipient agreement as a relevant factor in the certification process for STD clinics.[2] Nor does section 318 of the Public Health Service Act or any statute give HRSA the authority to define what must be included in the subgrants issued by a state, county, or city. Should HRSA move forward with its proposed requirements, it is putting itself at risk of litigation for acting outside of its authority.

HRSA's Shipping Address Requirements Lack Clarity and Will Disrupt Covered Entity Operations

The FRN states that "HRSA is providing additional clarification for covered entities to complete the shipping address section." RWC-340B welcomes clarification of existing 340B program policies, but the FRN fails to mention that the proposed clarification would limit many covered entities' participation in the 340B program, and reduce their 340B savings and ability to meet patient needs. The critical language is in HRSA's draft instruments, not the FRN. HRSA's draft instruments prohibit covered entities from registering their retail pharmacies as shipping addresses unless they provide documentation demonstrating that they own the pharmacies. The draft documents also state that, if the pharmacy is not directly owned by the covered entity, "The pharmacy must be registered as a contract pharmacy."

The proposed changes in HRSA's instruments are problematic for at least two reasons. First, they would significantly disrupt covered entity operations. Retail pharmacies are often separately incorporated from covered entities for tax, licensure and other reasons governed under state law. Yet they operate no differently than entity-owned pharmacies. By forcing covered entities to reregister these pharmacies as contract pharmacies, HRSA would effectively reduce covered entities' access to 340B medications. This is because nearly 50 manufacturers prohibit covered entities from dispensing 340B drugs through contract pharmacies while no such restrictions apply to shipping addresses.

The proposed shipping address policy would be especially harmful for health systems that include multiple covered entities. Covered entities within a common health system often rely on the same pharmacy to meet their patients' pharmacy needs. A single specialty pharmacy, for example, is better able to serve patients requiring specialty medications than multiple pharmacies. Because the pharmacy is owned and controlled at the health system level, it

[2] 42 U.S.C. § 256b(a)(7).

operates as an in-house pharmacy for each covered entity within the system and is registered as a shipping address for each. Such an arrangement would be prohibited under HRSA's proposed change. The change would disrupt covered entity operations, rather than streamlining the process as the FRN suggests it does. It would reduce flexibility and impose significant burdens on covered entities due to the increased number of contract pharmacy restrictions adopted by manufacturers over the past five years.

Many covered entities rely on pharmacies that are organized as separate corporations but are under common ownership with the covered entity's health system. An agency relationship can exist between two parties even though there is no contractual relationship between them. An agency relationship does not necessarily require a contract, written or unwritten. The key factor is that the principal has control over the agent and the agent acts for the principal's benefit. Application of this analysis to the 340B program means a covered entity is not limited to using the contract pharmacy model for relying on a system-owned pharmacy to receive and dispense 340B drugs on its behalf. As an agent, the system-owned pharmacy can be directed by the health system both to receive the covered entity's 340B drugs and to dispense such drugs to the covered entity's patients.

A second reason that HRSA's shipping address proposal is problematic is that it lacks clarity. HRSA instruments do not specify whether HRSA will require additional documentation from covered entities about their pharmacies routinely or only if requested. In an October 2022 information collection request, HRSA proposed similar restrictions applicable to covered entities' use of retail pharmacies.[3] HRSA declined to implement the changes in response to strong and stated that it would release guidance about shipping addresses in the future. HRSA has not released such guidance or provided any other notice to the public that the agency intends to modify its policy. Given that HRSA failed to discuss this new requirement in any detail, it is unclear how HRSA expects covered entities to comply with this ambiguous requirement without the promised guidance.

Contributing to this lack of clarity is the widely held view by covered entities that their registration of system-owned pharmacies as shipping addresses complies with current HRSA policy. Consistent with an Apexus FAQ, [4] HRSA currently affords covered entities flexibility in determining whether a pharmacy within a health care system is listed as a shipping address or a contract pharmacy. The FAQ strongly suggests that a pharmacy that is a separate legal entity from a covered entity may be either listed as a shipping address or registered as a contract pharmacy.

[3] Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, 87 Fed. Reg. 35983, 35984.
[4] Apexus FAQ 1184, available at: https://www.340bpvp.com/hrsa-faqs/faq-search?Ntt=1184.

HRSA Promulgated the Shipping Address Requirements in Violation of the PRA and APA

HRSA violated the PRA and APA by promulgating its new requirements for covered entity shipping addresses without complying with the applicable procedures. The PRA requires "adequate notice" when an agency "substantially modif[ies] . . . significant dissemination products."[5] PRA regulation establishes that notice must be provided in a manner that is reasonably calculated to inform the public with specific implementation methods.[6] This FRN does not meet the PRA's notice requirement.

HRSA did not clearly state in the FRN that it was proposing to change how covered entities register in-house pharmacies in the FRN. The FRN simply states that covered entities will be required to provide "additional clarification" regarding shipping addresses. It says nothing about requiring ownership documentation of pharmacies that are being registered as shipping addresses of the covered entity. Nor does the FRN state that a covered entity must enter into a contract pharmacy agreement with a pharmacy that it does not own directly. Those additional requirements were only clear from HRSA's draft documents, which were only available upon request. Interested parties would have had no reason to believe that they should have requested draft documents because the FRN does not provide any indication of the substantive changes that HRSA proposes regarding shipping addresses.

The FRN also violates the APA. The APA requires that federal agencies promulgate substantive rules using notice-and-comment rulemaking. HRSA's proposed shipping address policy is a substantive rule. Yet it was set forth in a draft instrument that falls outside of the notice-and-comment rulemaking process. In *American Mining Congress v. Mine Safety & Health Administration*, 995 F.2d 1106, 1112 (D.C. Cir. 2015), the D.C. Circuit established a three-part test for determining whether an agency has promulgated a substantive rule. A rule is a substantive rule if any of the three factors are met. The change to how covered entities list in-house pharmacies meet two out of the three factors.

The first factor is "whether in the absence of the rule there would be an adequate legislative basis for enforcement action or other agency action to…ensure the performance of duties." Many system-owned pharmacies are registered as shipping addresses rather than as contract pharmacies. This proposed change would effectively terminate the pharmacies from the program because most manufacturers will not ship 340B products to them if they are registered as contract pharmacies. The 340B statute does not grant HRSA the legal authority to exclude system-owned pharmacies from the program. This proposed change therefore meets the first factor of the *American Mining* test.

A second factor in *American Mining* is "whether the rule effectively amends a prior legislative rule." The revised shipping address requirements meet this standard. HRSA has not previously

[5] 44 U.S.C. § 3506(d)(3).
[6] 5 CFR 1320.5(b).

enforced the proposed restriction on covered entity shipping addresses. Accordingly, HRSA had established a de facto rule that it would not act against covered entities that have registered their separately incorporated pharmacies as shipping addresses. The new shipping address requirement would amend this prior rule.

In short, the FRN reflects an attempt by HRSA to impose a substantive rule on covered entities. Yet it failed to adopt the change in accordance with well-established through notice-and-comment procedures, which violates the APA.

HRSA's FRN Burden Estimation Is Inaccurate

The PRA defines "burden" to include "time, effort, or financial resources expended…to… provide information to or for a Federal agency, including the resources expended for… completing and reviewing the collection of information…."[7] The PRA requires that each agency provide a "specific and objectively supported estimate of burden" for each collection.[8] HRSA's FRN does not provide an objective estimate for completing the collection tasks described in the notice.

The FRN characterizes the changes to the forms, including the additional shipping address documents, as "minor revisions" and states that it should not increase the burden on members of the public responding to the forms. As mentioned above, HRSA's pharmacy shipping requirements listed on the draft instruments would significantly alter covered entity operations. The coordination required to comply with the additional requirements would likely take a significant amount of additional time. So HRSA's burden estimate does not accurately predict the "time, effort, or financial resources expended" to respond to the revised collection policy. HRSA's characterization of the anticipated burden is also inconsistent with the statutory definition of "burden" under PRA.

In the FRN, HRSA increased its burden estimate from 60 to 75 minutes to complete the registration for STD and TB clinics. As mentioned above, requiring that covered entities coordinate with state, county, and local government to obtain and alter subrecipient agreements to comply with HRSA requirements is more time-consuming than the additional 15 minutes HRSA estimated. The burden that HRSA estimated for this collection does not meet the PRA requirement to be "specific and objectively supported."

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For the aforementioned reasons, RWC-340B respectfully requests that HRSA reconsider and/or withdraw its plan for implementing its proposed changes to STD documentation and shipping

[7] 44 USC 3502(2).
[8] 44 USC 3506(c)(1)(A).

address requirements. We appreciate HRSA's consideration of our comments. For further information, please contact Peggy.Tighe@PowersLaw.com, Legislative Counsel to RWC-340B.

Sincerely,

Shannon Burger, MBA, CPA
President
Ryan White Clinics for 340B Access