Ryan White Clinics for 340B Access

August 15, 2022

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

Via electronic submission: Paperwork@hrsa.gov

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

Ryan White Clinics for 340B Access (RWC-340B) appreciates the opportunity to submit 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 Tuesday, June 14, 2022.[1] 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 (RWCs) 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 (FQHCs), FQHC look-alikes, sexually transmitted disease clinics, family planning clinics and/or safety net hospitals.

RWC-340B Supports HRSA's Proposal to Eliminate Notice of Funding Opportunity Information for RWCs

RWC-340B members support HRSA's proposal to no longer require that RWCs submit the Notice of Funding Opportunity (NOFO) number associated with their grants as part of the 340B program registration and recertification process. RWC-340B agrees with HRSA's justification for removing the NOFO submission requirement:

> The NOFO number is an unnecessary component to determine the eligibility of a Ryan White entity's registration. Since the NOFO number correlates to the Ryan White entity's Federal Grant Number, which is already required to be entered in 340B OPAIS during registration, the NOFO number is not needed.[2]

RWC-340B applauds HRSA for recognizing that the NOFO number is not a necessary component to determine the eligibility of an RWC in the 340B program and for proposing to eliminate this unnecessary requirement in the RWC registration and recertification process.

[1] 87 Fed. Reg. 35,983.
[2] *Id*. at 35,984.

HRSA Should Make Clear that Covered Entities are Required to Report "Material" Breaches to HRSA

The draft recertification document proposed by HRSA includes an attestation that lists several 340B program requirements and states that "the covered entity acknowledges its responsibility to contact OPA as soon as possible if there is any change in 340B eligibility and/or breach by the covered entity of any of the foregoing…" RWC-340B respectfully suggests that this statement be amended to state that the covered entity will notify HRSA if the covered entity is responsible for a "material" breach of the 340B program requirements listed. This change would conform the proposed attestation statement with longstanding HRSA policy, which only requires that covered entities report material breaches to HRSA.[3] Under HRSA policy, covered entities are responsible for repayment to manufacturers for breaches that involve an overpayment and are not material, but they are not required to report those breaches to HRSA. Again, RWC-340B requests that the attestation statement in the draft recertification document be amended to clarify that covered entities only have to report "material" breaches to HRSA.

HRSA Must Comply with the Notice Requirements of the Paperwork Reduction Act

The first change discussed above, regarding elimination of the NOFO requirement, was clearly stated in the ICR notice and the second change, to clarify that covered entities are required to report to HRSA only "material" breaches, was not proposed by HRSA but is needed to conform the recertification attestation to HRSA policy. RWC-340B is concerned, however, that other aspects of HRSA's notice do not comply with the notice requirements of the Paperwork Reduction Act (PRA), 44 U.S.C. § 3501 *et seq*. RWC-340B is particularly concerned that HRSA failed to provide proper notice of its new policy for listing pharmacies as shipping addresses.

All federal agencies are required to give sixty (60) days' notice of any ICR request that they plan to submit to the Office of Management and Budget (OMB). Specifically, the regulations implementing the PRA state:

> **(d)(1)** Before an agency submits a collection of information to OMB for approval, and except as provided in paragraphs (d)(3) and (d)(4) of this section, the agency shall provide 60-day notice in the FEDERAL REGISTER, and otherwise consult with members of the public and affected agencies concerning each proposed collection of information, to solicit comment to:
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> **(i)** Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
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> **(ii)** Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
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> **(iii)** Enhance the quality, utility, and clarity of the information to be collected; and
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> **(iv)** Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.[4]

[3] *See* Apexus Prime Vendor Program, Establishing Material Breach Threshold, https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.340bpvp.com%2FDocuments%2FPublic%2F340B%2520Tools%2Festablishing-material-breach-threshold.docx&wdOrigin=BROWSELINK (July 20, 2020).
[4] 5 C.F.R. § 1320.8(d).

The PRA also makes clear that the agency notice must be adequate.[5] Inherent in the notice requirement is the agency's obligation to clearly explain the changes that it plans to make in the ICR notice and to ensure that any procedural or paperwork modifications not make substantive changes to current agency requirements. In this regard, the HRSA ICR notice fails. The ICR notice states:

> HRSA is providing additional clarification for covered entities to complete the shipping address section in 340B OPAIS to assist in determining the exact shipping address location and relationship to the covered entity. This clarification will not change the burden on entities.[6]

The "additional clarification" that HRSA proposes to add to the registration, recertification and change request process for listing pharmacies as shipping addresses, however, is not simply a clarification. Rather, the proposal makes substantive changes to current HRSA policy. Review of the draft registration, recertification and change request documents shows that HRSA proposes to require covered entities to provide documentation to demonstrate that the covered entity owns a retail pharmacy in order to register the pharmacy as a shipping address at the time that the covered entity registers, adds the shipping address through a change request, and at recertification. 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 are problematic for at least three reasons. First, these changes are not clearly stated in the ICR notice. HRSA's statement in the ICR notice is that covered entities will be required to provide "additional clarification" regarding shipping addresses. It says nothing about requiring documentation of ownership by the covered entity of pharmacies that are registering as shipping addresses of the covered entity. Nor does the ICR notice state that a covered entity must enter into a contract pharmacy agreement with a pharmacy that it does not own directly. Those additional requirements are only clear from HRSA's draft documents, which were available to interested parties only if the party requested them from HRSA. Interested parties, however, would have had no reason to believe that they should have requested draft documents because the ICR notice does not provide any indication of the substantive changes that HRSA proposes regarding shipping addresses.[7]

Second, HRSA's draft documents would implement a policy regarding ownership of pharmacies that is a departure from its current policy. HRSA's current policy is set forth in an Apexus FAQ, which states 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. That FAQ states:

> **Q:** How must we register our in-house pharmacy that is a separate legal entity under our 340B covered entity?
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> **A:** An in-house pharmacy is not eligible to register as a child site. The in-house pharmacy could be listed as a shipping address. If the covered entity has a contract with the in-house pharmacy because it is a separate legal entity, then it must be registered as a contract pharmacy and may

[5] *See* 44 U.S.C. § 3506(d)(3) ("With respect to information dissemination, each agency shall…provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products.").
[6] 87 Fed. Reg. at 35,984.
[7] *See McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317, 1323 (D. C. Cir.1988) (an agency notice must be "clear and to the point" and the agency may not implement changes in a "crabwise" fashion).

not dispense any 340B drugs until a written contract is in place and the pharmacy is listed as a contract pharmacy for the covered entity on 340B OPAIS.[8]

This FAQ asks whether an in-house pharmacy that *is a separate legal entity* may be registered as a shipping address and Apexus states that the pharmacy may be a shipping address. Apexus also states that, alternatively, the covered entity and pharmacy may enter into a contract pharmacy agreement. Therefore, Apexus' answer, which represents HRSA's currently policy, is that covered entities have flexibility to determine whether a pharmacy that is within a health care system may be listed as a shipping address or contract pharmacy. Accordingly, the statement in HRSA's draft documents – that a pharmacy must be owned by a covered entity to be listed as a shipping address of the covered entity – is a significant change from its current policy. HRSA has historically provided covered entities with flexibility to register a pharmacy that is owned within the covered entity's health care system as either a shipping address or to register the pharmacy as a contract pharmacy and HRSA should continue to provide that flexibility.

Third, implicit in HRSA's new pharmacy listing policy is an assumption that may not be true. HRSA's policy assumes that a pharmacy cannot properly perform the role of receiving and dispensing drugs on a covered entity's behalf if it is in a separate legal entity and not operating under a contract pharmacy arrangement. Many covered entities rely on pharmacies that are organized as separate corporations but are under common ownership with the covered entity's health system. There is support under state law that such pharmacies can act as a receiving and dispensing agent of the covered entity without them being contract pharmacies. 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.

For the above reasons, HRSA's new shipping address policy is problematic. Requiring covered entities to register pharmacies that are within their health care system but not directly owned by the covered entity as contract pharmacies is particularly problematic given the restrictions that manufacturers are currently placing on obtaining 340B pricing at contract pharmacies. Implementation of the proposed change by HRSA will mean that covered entities that have previously listed system-owned pharmacies as shipping addresses will have to enter into contract pharmacy agreements with those pharmacies. Consequently, under the policies of some drug manufacturers, those covered entities will lose access to 340B pricing at those pharmacies.

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RWC-340B respectfully requests that HRSA: 1) implement its proposal to no longer require a NOFO number for registration or recertification of RWCs, which proposal was clearly stated in the ICR notice; 2) clarify that covered entities are required to notify HRSA of "material" breaches in the attestation statement, which is consistent with current HRSA policy; and 3) continue its current policy of allowing covered entities the flexibility

[8] Apexus FAQ 1184, available at: https://www.340bpvp.com/hrsa-faqs/faq-search?Ntt=1184.

to list a pharmacy that is owned within a covered entity's health system as either a shipping address or to register the pharmacy as a contract pharmacy.

We appreciate your attention to this important matter. Please contact me with any questions at ceo@cempa.org or (423) 648-9911.

Sincerely,

Shannon Stephenson
President, RWC-340B