



August 15, 2022

HRSA Information Collection Clearance Officer
Room 14N136B
5600 Fishers Lane
Rockville, MD 20857

Re: Proposed Changes to Information Collection Request: Enrollment and Re-certification of Entities in the 340B Drug Pricing Program (OMB Number 0915-0327-Revision), 87 Fed. Reg. 35983 (June 14, 2022)

Dear HRSA Information Collection Clearance Officer:

Sanford is a non-profit integrated health system headquartered in the Dakotas. We are one of the largest health systems in the nation with 46 hospitals, 1,525 physicians, and more than 200 Good Samaritan Society senior care locations in 26 states and ten countries. Sanford's 48,000 employees make it the largest employer in the Dakotas.

Sanford Health appreciates the opportunity to comment on the proposed collection of information by the Health Resources and Services Administration (HRSA). HRSA is requesting approval for existing information collections related to covered entity enrollment/registration/certification, outpatient facility and contract pharmacy registration, and change request forms. The notice says that the previously approved collections are mostly unchanged and that some form changes were made to increase program efficiency and integrity. Several changes proposed by HRSA are significant because they impact long-standing HRSA guidance, and in some cases, conflict with Federal Register notices that HRSA finalized after soliciting and responding to comments from program stakeholders. If finalized as proposed, these changes are likely to create confusion for covered entity stakeholders and could fail to advance HRSA's efforts to promote 340B program integrity and transparency. After reviewing the proposed changes, we have comments as outlined below:

1. **Proposed Change:** HRSA proposes changes on the forms to make clear that if the pharmacy is not "owned by the covered entity," it must be registered as a contract pharmacy. HRSA states that upon registration, pharmacies that do not have evidence of being owned by the covered entity cannot be listed as shipping addresses in OPAIS.

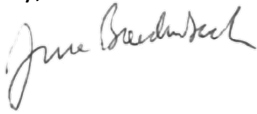
Sanford Health feels that the listing of wholly owned pharmacies under common ownership and control should be permitted to be listed as shipping addresses for CE under that same umbrella ownership structure for the following reasons:

- a) This simplifies the management of these pharmacies in the current environment where manufacturers are placing restrictions on access to pricing in contract pharmacies.
- b) **Not all manufacturers have the wholly owned exception policy** so entities that are forced to register retail pharmacies that are wholly owned by a parent or sister corporation introduces risk that the entities will **lose access to 340B pricing** in these pharmacies.

- c) It also places **unnecessary burden on the covered entities** to ensure that pricing is restored and maintained in these pharmacies for those manufacturers that do have an exception in place for wholly owned pharmacies.
- d) In 2020 Apexus Level II Support advised Sanford that “Pharmacies owned by the umbrella company (IDN) can be entity owned pharmacies and do not need to be registered as a CP on OPAIS. The ship to address being added to OPAIS is needed for wholesalers to be able to ship 340B drugs to that location.”

For the reasons highlighted above Sanford would advise HRSA and HHS to allow covered entities to list the commonly owned pharmacies as shipping addresses on the HRSA OPAIS database. We appreciate HRSA’s consideration of these comments and look forward to HRSA’s responses in the final guidance.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jesse Breidenbach".

Jesse Breidenbach
System Executive Director, Pharmacy
Sanford Health