Health Resources and Services Administration
340B Drug Pricing Program

Subject: Request for a non-substantive change to existing program data collection activity approved by OMB under number 0915-0327

This is a request for a non-material or non-substantive change to currently approved OMB data collection forms for the Health Resources and Service Administration's 340B Drug Pricing Program (340B Program). The current OMB approval is under OMB Control Number 0915-0327.

Section 7101 of the Patient Protection and Affordable Care Act (Pub. L. 111-148) expanded the types of covered entities eligible to participate in the 340B Program under the PHS Act to include certain free-standing cancer hospitals, rural referral centers, sole community hospitals, critical access hospitals, and children's hospitals. Of these entities, children's hospitals were already eligible to participate in the 340B Program under the Deficit Reduction Act of 2005 (Pub. L. 109-171). Section 2302 of the Health Care and Education Reconciliation Act (Pub. L. 111-152) (HCERA) (the Patient Protection and Affordable Care Act and HCERA collectively hereinafter will be referred to as the "Affordable Care Act") added section 340B (e) to the PHS Act, which contains a provision that limits the types of drugs that free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals can obtain through the 340B Program. Section 204 of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111-309), amended section 340B (e) and removed children's hospitals from the entity types affected by the orphan drug exclusion. Under the changes made by section 2302, orphan drugs, when used for the rare condition or disease for which that orphan drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act, are excluded from the definition of covered outpatient drug for the specified newly-eligible covered entity types for purposes of the 340B Program.

340B registration and change request forms for the newly eligible covered entity types were approved under OMB 0915-0327 on October 10, 2012. Due to the orphan drug exclusion, the new forms will require newly-eligible covered entity types to notify OPA of their intention to purchase orphan drugs inside or outside of the 340B Program. If this request is approved, OPA will make a non-substantive changes to the forms the newly-eligible covered entity types are required to complete to participate in the 340B Program. The addition of this proposed language to the forms is not expected to add increased burden by the applicants but will improve the integrity of the 340B Program. These non-substantive changes are being submitted for OMB approval to ensure OPA compliance with the Paperwork Reduction Act and Affordable Care Act.

HRSA requests that the following forms are updated to reflect the changes regarding the GPO prohibition:

- 340B program registration for Critical Access Hospital (CAH)

- 340B program registration for Free-Standing Cancer Hospital
- 340B program registration for Rural Referral Centers and Sole community Hospitals
- 340B annual recertification for Critical Access, Rural-Referral Centers and Sole Community Hospitals
- 340B annual recertification for Free-Standing Cancer Hospitals
- 340B Participant change request forms