

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.

The proposed changes are to strengthen language and provide additional clarity regarding a specific 340B program requirement – the GPO prohibition. HRSA released a policy statement on February 7, 2013 to provide additional clarity on the existing requirement for certain 340B covered entities. In order to include the information that was clarified on February 7, HRSA wants to clarify its forms to reflect this policy statement to ensure 340B covered entities are complying with the most up to date requirements related to the GPO prohibition. 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. HRSA requests that the following forms are updated to reflect the changes regarding the GPO prohibition:

- 340B Program registration form for disproportionate share hospitals (DSH)
- 340B Program registration form for children's hospitals and free-standing cancer hospitals
- Certification form regarding non-participation by a covered entity hospital in a GPO
- Annual recertification attestation form

The specific changes to each form are attached.