

**Health Resources and Services Administration
340B Drug Pricing Program**

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

This is a request for a non-material or non-substantive change to a currently approved OMB approval for the Health Resources and Services Administration's 340B Drug Pricing Program Forms, for entities who are enrolling or re-certifying to participate in the 340B Drug Pricing Program. The current OMB approval under OMB No. 0915-0327 expires in 8/31/2012.

Public Law 111-148 (P.L. 111-148), Section 7101 of the Patient Protection and Affordable Care Act allows a group of newly eligible covered entities to participate in the 340B Program including Critical Access Hospitals (CAH), Sole Community Hospitals (SCH), Rural Referral Centers (RRC), and Cancer Hospitals. This is a request for approval for a non-substantive change to the 340B Drug Pricing Program Forms to increase the estimated number of respondents and reflect the covered entities that are newly eligible to participate in the 340B Program due to P.L. 111-148. The content of registration and certification forms remains the same as those already approved for Disproportionate Share Hospitals under OMB #0915-0327. The only change is a non-substantive one to change the currently approved number of respondents and burden hours to permit an increase in the respondents applying for this program.

This non-substantive change will impose an estimated annual average total burden of an additional 1,306 hours. This would bring the total currently approved burden under this clearance to 2,812 hours for this annual data collection. The current total burden hours in the OMB inventory for the 340B Drug Pricing Programs (OMB No. 0915-0327) is 1,505 hours. There will be an additional 1536 respondents submitting 340B Registrations for Hospitals; an additional 1859 respondents submitting Certifications to Enroll Hospital Outpatient Facilities; and an additional 1536 respondents submitting Hospital Annual Recertification. The following table outlines the additional numbers of respondents and burden hours due to the Patient Protection and Affordable Care Act.

Number of:	Currently approved number	Additional	Total
<u>RESPONDENTS:</u> IC # 3 Certifications to Enroll DSH & Children's Hospitals Outpatient Facilities to 340B Program	180	1,859	2,039
<u>RESPONDENTS:</u> IC # 4 Hospital Annual Recertification	937	1,536	2,473
<u>RESPONDENTS:</u> IC # 10 340B Registrations & Certifications for Disproportionate Share Hospitals	70	1,536	1,606
<u>RESPONSES</u>	26,226	4,931	31,157
<u>BURDEN HOURS</u>	1,505	1,306	2,812