

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.

HRSA maintains an online 340B registration database to allow drug manufacturers and wholesalers to verify that an organization claiming to be eligible for 340B discounts is indeed an active participant in the 340B program. New registrations from eligible organizations are accepted at published intervals; we would like to begin collecting each registrant's Employer Identification Number (EIN) in addition to the currently approved data elements. Collecting EINs will allow us to more effectively identify related entities and will enhance program integrity without significantly impacting reporting burden.

Once accepted into the program, participants recertify their eligibility each year and can request decertification (termination from the program) as part of that process or at any time via a separate change request form. Entities requesting decertification/termination are asked to select their reason for leaving the program from a list of acceptable options; we are requesting approval to begin collecting three additional data points:

- 1) The precise date the terminating entity became ineligible (e.g., loss of grant) or otherwise intends to withdraw from the program.
- 2) The last day that 340B-discounted drugs were or will be purchased under the program ID requested for termination.
- 3) An optional brief statement describing the facts surrounding the reason for termination and how the effective date was determined (e.g. "qualifying grant expiring on 9/30/2013")

We believe the requested elements will similarly enhance program integrity without any substantial increase in reporting burden, as they only apply to entities that have already lost eligibility or made the decision to voluntarily withdraw (i.e., reporting readily available facts versus synthesizing new information).

Screen shots and paper form equivalents are attached for review; registration is a primarily online process and recertification is completed entirely online, but change requests are currently accepted both online and on paper.