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February 9, 2026

Russell Vought
Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

RE: OMB No. 0915-0327; Information Collection Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program

Dear Mr. Vought:

The Healthcare Association of New York State, on behalf of our member nonprofit and public hospitals, nursing homes, home health agencies and other healthcare providers, welcomes the opportunity to comment on this Information Collection Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program.

The Health Resources and Services Administration, via a prior *Federal Register* notice and this ICR, proposed changes that, if implemented, would require 340B hospitals and other covered entities to make significant updates to their existing 340B Office of Pharmacy Affairs Information System registrations.

HANYS' utmost concern is that these new or clarified documentation requirements could cause temporary or inadvertent loss of 340B "child" sites or even the termination of a covered entity's 340B participation simply because a 340B hospital is in the process of updating financial documentation to comply.

As explained in detail below, HANYS recommends a non-punitive approach to address these concerns.

HANYS urges HRSA to allow for a transition to these new requirements or, short of a full and clear transition timeframe, allow 340B hospitals to maintain uninterrupted 340B eligibility while documentation updates, address changes or cost-center clarifications under these new policies are under HRSA review.

HANYS' comments focus on HRSA's clarifications that 340B hospitals registering a child site must submit a trial balance with "unique and separate" reimbursable outpatient costs and charges for each service being registered.

Hospital trial balances are not uniform instruments. They are tailored to internal accounting, not federal program requirements. Requiring unique and separate reimbursable outpatient costs for each service may force hospitals to create new accounting layers or manual reports — generating potential compliance issues along with a workload and audit exposure that may not be captured in HRSA's burden estimates.

The proposed clarifications may require 340B hospitals to remap cost centers; reconcile cost reports with internal ledgers; produce location-specific documentation; and coordinate across reimbursement, finance, compliance and clinical departments. These resource-intensive steps require substantial ramp-up time and demand an appropriate transition or non-punitive correction period/process. Many 340B hospitals already struggle with limited resources and staffing challenges and the ramp-up to meet these new compliance standards may be felt even more acutely in rural and urban underserved areas.

For example, many 340B hospitals operate multidisciplinary specialty clinics at a single physical address, where services such as cardiology, endocrinology and immunology are offered in one shared location. However, on the Medicare cost report, each specialty is assigned its own cost center and trial balance because the financials are maintained separately. Under HRSA's clarified documentation requirements, hospitals may be expected to register each specialty as a separate child site to match these cost-center distinctions. For hospitals that currently register such clinics as a single location, this would represent a major operational change, creating significant workload and increasing the risk of delayed approvals or temporary loss of 340B eligibility while hospitals adjust their registration practices.

Another example is when a 340B hospital operates multiple clinics at different addresses but reports them under a single cost center and trial balance on the Medicare cost report. Under HRSA's proposal, it is unclear how hospitals should register multiple child sites under one cost center, and many hospitals lack the systems to quickly separate financial data by location. This makes compliance difficult and costly and increases the risk of delays in approval or temporary loss of 340B eligibility.

To address these concerns, **HANYS urges HRSA to implement a minimum 12-month transition period before enforcing the revised documentation requirements.** During this period, 340B hospitals and other covered entities should be permitted to continue participating in the 340B program while adapting their financial reporting and trial balance structures to HRSA's clarified expectations.

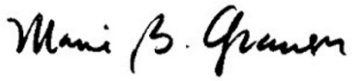
Short of a transition, **HANYS urges HRSA to allow 340B hospitals and outpatient sites to maintain 340B eligibility without disruption** while documentation updates, address changes or cost center clarifications are under HRSA review to prevent financial harm.

Lastly, to avoid inconsistent interpretation and enforcement of HRSA's clarified documentation requirements, **HANYS suggests HRSA develop a frequently asked questions resource and consider developing examples of acceptable trial balance formats and/or other resources to support 340B hospital compliance.**

Bottom line: HANYS urges HRSA to be flexible and not subject hospitals to non-compliance under 340B for purely technical reasons unrelated to statutory eligibility.

Thank you for the opportunity to comment. If you have questions, please contact Kevin Krawiecki, vice president, fiscal policy, at kkrawiec@hanys.org or 518.431.7634.

Sincerely,



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