

340B Program Update: Upcoming 340B OPAIS Updates

HRSA's Office of Pharmacy Affairs (OPA) will implement updates to the 340B Office of Pharmacy Affairs Information System (OPAIS) effective October 1, 2026.

These updates support program integrity, transparency, and operational efficiency by enhancing several registration, recertification, and change request processes. The updates were approved through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) review process.

The updates include:

- Additional shipping address information to assist HRSA in determining whether a location should be maintained as a shipping address or registered separately as a covered entity, child site, or contract pharmacy.
- New documentation requirements for Sexually Transmitted Disease (STD) and Tuberculosis (TB) covered entities to verify eligibility. Covered entities must submit their federal Notice of Award (NoA), including the grantor, grant number, funding period, and recipient. Subrecipients must provide documentation that includes the 318 Notice of Funding Opportunity (NOFO)/grant number, site name, site address, and funding period.
- Collection of assistance period information for Family Planning covered entities.
- Additional questions related to street address changes to assist HRSA in evaluating continued eligibility and facilitating efficient review.
- Collection of Tribal Agreement numbers for Tribal Contract/Compact (FQHC 638) covered entities.
- Hospital terminology updates that align OPAIS with Centers for Medicare & Medicaid Services (CMS) Medicare Cost Report terminology, including updates from “File Date” to “Date/Time Prepared” and from “Medicare Provider Number” to “CMS Certification Number.”
- Clarification of hospital registration instructions related to Worksheet S submissions and trial balance documentation.

These updates do not change the underlying statutory eligibility requirements for participation in the 340B Program.

OPA has also developed a [340B OPAIS OMB Forms Updates PowerPoint Presentation](#) to help stakeholders prepare for these changes. The presentation provides an overview of the implementation timeline, explains the new and updated requirements, highlights what is

staying the same, and provides additional resources to assist stakeholders with the transition.

Covered entities are encouraged to review the updated 340B OPAS user guide instructions and ensure applicable documentation is readily available before submitting registrations, recertifications, or change requests.