**HRSA Office of Pharmacy Affairs 340B Recertification Frequently Asked Questions**

**Where do I go for more information on the 340B Program and recertification?**

Please direct inquiries to the 340B recertification email inbox at 340brecertification@hrsa.gov or phone calls to Prime Vendor Program at 888-340-2787 or visit the 340B web page at <http://www.hrsa.gov/opa/index.html>

**Am I required to fill out a change request form for recertification if my covered entity has no necessary changes to be made in the 340B database prior to recertification?**

No change request form will be required.

**My Covered entity submitted a change request form, does this mean we are recertified?**

No - a change request form only updates the covered entity’s information in the 340B database. Recertification is a separate process that will require the covered entity’s Authorizing Official to update covered entity information if necessary and certify to compliance with program requirements during a specified time period.The hospital’s Authorizing Official is responsible for ensuring program compliance for the covered entity.  Recertification will cover the organization (parent) and all registered outpatient/sub-grantee (child) sites in the program database. OPA, however strongly recommends that you update the database using the change request form prior to recertification to ensure a smooth recertification process. It is the covered entity’s responsibility to keep all information in the 340B Program database up to date at all times.  The program database is the sole source for covered entity and manufacturer information.

**During recertification will the Authorizing Official and Primary Contact receive emails?**

The Authorizing Official and Primary Contact will receive an email from OPA with the date that recertification will begin, advanced notifications, and for all webinar and training events.  On the recertification start date, only the Authorizing Official will receive the required User name and Password to perform recertification.

**Who Can or should be listed as the Authorizing Official?**

Each entity type runs their 340B programs slightly different based upon several factors of grantee status/sub-grantees/Federal funding distribution.  The Authorizing Official is someone who represents and confirms that they are fully authorized to legally bind the covered entity into a relationship with the Federal Government and has knowledge of the practices and eligible programs at that site.  This would be the person responsible and whom the Federal Government would reach out to for requests of compliance, integrity evaluations, and audits.  So for many entities this is the grantee of record or the Clinic Director based upon Federal funding streams.  For hospitals it is required that someone of the CEO/CFO/COO/President/Vice President level perform this role.

**I was told that we cannot list our in-house pharmacy as a child site.  Is that correct?**

Pharmacies are not eligible 340B covered entities and therefore, should not be listed as a child site with a 340B ID in the database.  If the site is only a pharmacy and is listed as a covered entity with a 340B ID, this pharmacy must be terminated from the database.  It should then be determined whether it is appropriate for the pharmacy to be added as a “ship to” address for the actual covered entity in the database.

If the pharmacy is located within an offsite outpatient facility that also provides healthcare services and provides 340B drugs to its patients, the outpatient facility must be registered as a child site with the pharmacy listed as a “ship to” of that outpatient facility.  When a pharmacy is supporting multiple child sites of a parent entity, the pharmacy should be listed as a “ship to” address under the parent’s 340B ID.

**Is my covered Entity required to submit our Medicaid/NPI number to the database?**

If a covered entity bills 340B drugs to Medicaid it must provide that Medicaid billing number to the Office of Pharmacy Affairs to ensure against duplicate discounts. For further clarification on whether to submit your Medicaid/NPI number please review the Medicaid Exclusion Tutorial at:

<http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html>

If a child site bills under a different Medicaid Provider Number or NPI than the parent site, those need to be appropriately listed with the child sites.