



Alerts

OPA Program Update 2020 Highlights Changes to 340B Program Registration and Recertification Requirements

August 13, 2020
Health Care Alert

On July 20, 2020, the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA) issued the [OPA Program Update 2020](#). In addition to adopting new Covered Entity registration and recertification requirements, the Program Update outlines enhancements to the 340B Office of Pharmacy Affairs Information System (OPAIS). It also addresses documentation required for covered entities to demonstrate compliance with 340B Program registration and recertification requirements. The Program Update will become effective in the registration component of [340B OPAIS](#) beginning August 17, 2020. A user guide and a variety of educational resources regarding 340B program registration and recertification are available on the [OPA website](#).

General 340B OPAIS Registration and Recertification Requirements

Registration

HRSA requires registration and approval for covered entities to participate in the 340B Program. Facilities that meet the criteria of a Covered Entity apply to participate in the 340B Program by completing the online registration process during one of four quarterly registration windows. In addition to the online registration, Covered Entity registrants must submit any required supporting documentation on the same day that they complete their online registration.

New registrants must identify their Authorizing Official and Primary Contact. The Authorizing Official must be an individual who can bind the organization to a contract, such as a CEO, COO, CFO, clinic administrator, or program manager. The Primary Contact should be an employee of the organization. Notably, the Primary Contact may not be the same as the Authorizing Official, and cannot be a consultant or contractor.

Attorneys

Michael A. Dowell



Recertification

Covered Entities must recertify their eligibility annually to remain in the 340B Program and continue purchasing covered outpatient drugs at discounted 340B prices. Emails with preliminary information about the recertification process are sent to the Covered Entity's Primary Contact and Authorizing Official. Once the recertification period begins, the Authorizing Official only has access via their user accounts to perform recertification. Then, the Authorizing Official will be required to log into the 340B OPAIS, update information as needed, and attest to the Covered Entity's compliance with the following 340B Program requirements:

- Covered Entity meets 340B Program eligibility requirements and will notify OPAIS if there are any changes in 340B eligibility.
- Covered Entity will comply with the prohibition against duplicate discounts and diversion, and acknowledges that if there is a material breach pertaining to duplicate discounts or diversion, the Covered Entity might be liable to drug manufacturers and may be subject to removal from the 340B Program.
- Contract pharmacy arrangements comply with 340B program requirements, including all OPAIS requirements, if applicable.
- The Covered Entity will maintain adequate records that demonstrate compliance with the 340B pharmacy program.
- The Covered Entity will comply with Section 340B of the Public Health Services Act and notify OPAIS if there is a material breach by the Covered Entity.
- All information listed on the 340B database is complete and accurate.

The Covered Entity must ensure the contacts listed in the 340B database are accurate at all times to receive all recertification notifications.

New 340B OPAIS Registration and Recertification Requirements

All Covered Entities

When registering new locations, all Covered Entity sites must disclose whether or not they will bill Medicaid fee-for-service for drugs, and respond to the following question: "At this site, will the Covered Entity bill Medicaid fee-for-service for drugs purchased at 340B prices?" If the Covered Entity answers "yes" for a particular location, it must also list each Medicaid state and the state Medicaid billing number that will be used to bill the state for Medicaid fee-for-service drugs at that location. Information for new locations must be provided during initial registration, while information for currently active locations must be updated in OPAIS by the end of the Covered Entity's next annual recertification period.

Hospitals

Eligible hospitals must fall within one of three classifications: (1) ownership or operation by a state or local government; (2) nonprofit corporations with state or local governmental powers; or (3) private, nonprofit hospitals that have contracts with state or local governments to provide healthcare services to low-income individuals who are not eligible for Medicaid or Medicare.

When registering new locations, a hospital must submit supporting documentation for the "hospital classification" selected at the time of registration of the parent hospital. Similarly, hospitals changing classifications during recertification will be required to submit supporting documents. Hospitals contracted with state or local governments will need to provide documentation showing that the hospitals are private non-profits and have contracts to provide health care services for low-income individuals who are not entitled to benefits under Medicaid or Medicare or eligible for the state plans under Medicare or Medicaid. As for hospitals owned or operated by state or local governments, some form of official documentation describing hospital ownership is required. Such supporting documentation may include IRS forms or letters, state letters, and copies of contracts with state or local governments.



Clinics for Sexually Transmitted Diseases, Tuberculosis, and Ryan White HIV/AIDS

For new registrations, STD/TB/RW entities will be required to enter information regarding their Notice of Funding Opportunity (NOFO) Number, the data range of their NOFO funding, and, if applicable, the type of in-kind support they are receiving from the federal grant recipient or sub-recipient. Any currently active STD/TB/RW entity will be required to update the required registration information during their next recertification submission.

Implications for 340B Covered Entities

The Program Update was issued by HRSA in response to two recent General Accounting Organization (GAO) reports. The reports concluded that HRSA's processes do not provide reasonable assurance that participating nongovernmental hospitals meet 340B Program eligibility requirements and that HRSA had not implemented processes, policies, or procedures to prevent Medicaid duplicate discounts. Covered Entities should familiarize themselves with the Program Update in order to reduce the risks of HRSA sanctions for noncompliance, registration or recertification denials—or delays in the processing thereof—due to failure to comply with the new registration and certification requirements.

Duplicate Discounts

Covered Entities should also ensure that Medicaid duplicate discount policies and procedures include monitoring and auditing processes that will identify and submit repayment for Medicaid duplicate discounts on a timely basis.

Policies and Procedures

Covered Entities should make sure that general 340B pharmacy program policies and procedures are in place. Additionally, they should update the policies and procedures to include annual confirmation of consistency of state Medicaid enrollment documentation by location and location-specific 340B program OPAIS information.

340B Site Eligibility

Covered Entities are required to inform OPA if there are any changes to their 340B sites—such as site address or authorized contact—by completing the 340B Participant Change form. According to OPA, all health care delivery and contract pharmacy sites must be registered on OPAIS prior to participation in the 340B program.

Thus, Covered Entities should review their sites registered on OPAIS and compare the listed sites with internal eligibility documents. Hospitals should ensure all locations on the OPAIS are eligible, and health centers should review their EHB handbook 5B and the OPAIS to ensure the site names and addresses match, and that all active sites are listed on OPAIS. Finally, grantees should make sure the grant number and site IDs on their Notice of Grant award is listed correctly on OPAIS.

Hinshaw has a team of pharmacy law attorneys and paralegals that assist clients with 340B pharmacy program compliance and regulatory issues, including participation requirements, registration and recertification, patient eligibility determinations, contract pharmacy requirements, and Medicaid duplicative discount compliance, HRSA and manufacturer audits, manufacturer and wholesale distributor contracting, policies and procedures, and transactions. Please contact your [Hinshaw attorney](#) with any questions and for additional guidance on 340B pharmacy program or federally qualified health center matters.