

340B Program Hospital Registration Instructions

The purpose of these instructions is to describe the hospital requirements to register for the 340B Program. In order to participate in the 340B Program, eligible hospitals must first register in the 340B Office of Pharmacy Affairs Information System (OPAIS) during one of the quarterly registration periods. Registrations must be approved and submitted by the Authorizing Official (AO) by the end of the open registration period. Hospitals may participate in the 340B Program as only one hospital type; benefits in the program are dependent on the participating entity type. Hospitals will receive alerts during the registration period if information is needed to verify the eligibility of an entity. Please read the alerts closely and follow the instructions carefully. Upload all requested documents into the registration. Registrations submitted without the documentation will be rejected without being reviewed.

Statutory Requirements

Disproportionate share adjustment percentage (DSH)

| Hospital Type | DSH Requirement | When registering for the 340B Program |
|--|-----------------|--|
| Disproportionate share hospital (DSH) Free-standing cancer hospital (CAN) Children’s Hospital** (PEDS) | > 11.75% | Have the hospital’s latest filed Medicare cost report with you during registration. You will refer to it several times during the registration session. Hospitals registering with the 340B Program for the first time may need their Worksheet E Part A (line 33) to verify their latest DSH percentage. |
| Sole Community Hospital (SCH) Rural Referral Center (RRC) | ≥ 8% | |
| Critical Access Hospital (CAH) | N/A | Children’s hospitals that file a cost report may use Worksheet S-3 for the data to calculate a DSH% for the hospital. You may receive alerts during registration that you must send documentation to the 340B Program on the same day as the registration. The 340B Program will review this information at registration and reserves the right to ask for clarification or more information is necessary. *If the requested documents are not uploaded to the registration, it will not be reviewed and will be rejected. |

* If a children’s hospital does not file a Medicare cost report, the hospital must obtain an independent audit indicating a disproportionate share adjustment percentage that meet the requirement. More information can be found at [Guidelines for Children's Hospitals](#).

**Instructions for submitting documentation are below.

Hospital Classification

Section 340B(L)(i) of the Public Health Service Act defines the hospital classifications that are eligible for the 340B Program. The hospital must meet one of the classifications below. Please know which classification you will choose during the registration process and have the supporting documentation with you when you register. All documents must be in place at the time of registration and must be available

upon request as part of annual recertification and as part of the hospital's 340B Program auditable records.

| Classification | Required Supporting Documentation |
|---|---|
| <p>1) Owned or operated by a State or local government</p> | <p>Official documentation must indicate that the hospital is owned or operated by a unit of State or Local government. The following are examples of documentation: copy of the law that created the hospital, documentation from the state or local government that clearly demonstrates ownership, Hospital's charter, Bylaws, documentation from the IRS describing the hospital.</p> <p>More than one document may be necessary to demonstrate eligibility. Any documentation provided should clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital.</p> |
| <p>2) Private nonprofit with a contract with a unit of State or local government</p> | <p>Hospitals must be able to demonstrate through official documentation that it is both private nonprofit and that it has a contract as set forth in the statute. Please have a copy of the following:</p> <ol style="list-style-type: none"> 1. Nonprofit status: documentation that shows the hospital is private non-profit. The following are examples of documentation: Hospital's charter, Articles of Incorporation, Bylaws, other documents from the State that may certify the hospital is non-profit, a copy of the hospital's latest filed IRS-990 form, or other official IRS documentation. More than one document may be necessary to demonstrate eligibility. 2. Contract: copy of the contract that is in place between the hospital and the unit of State or local government. The contract must provide for health care services to low income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan under this title. In addition, the contract should include the following: <ol style="list-style-type: none"> 1) Names of the hospital and the government agency; 2) Signatures of hospital and government agency representatives; and 3) Dates clearly indicating effective dates of the contract. |
| <p>*The contract must be to provide health care services to low income individuals who are not entitled to benefits under Medicare or eligible for assistance under Medicaid.</p> | |

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|---|--|
| <p>3) A public corporation which is formally granted governmental powers by a unit of State or local government</p> <p>OR</p> <p>Private non-profit corporation, which is formally granted governmental powers by a unit of State or local government.</p> | <p>**Examples of documentation include: copy of the law that created the hospital, documentation from the State or Local government that clearly demonstrates ownership, Hospital’s charter, Bylaws, documentation from the IRS describing the hospital. Documents should clearly state the hospital’s ownership, the date the ownership was established, and the name of the hospital. More than one document may be necessary to demonstrate eligibility.</p> <p>**Examples of documentation include: Hospital’s charter, Articles of Incorporation, Bylaws, other documents from the State that may certify the hospital is non-profit, a copy of the 501(c)(3) certification, the latest filed IRS-990 Form, or other official IRS documentation. Documents should clearly state the hospital’s ownership, the date the ownership was established, and the name of the hospital. More than one document may be necessary to demonstrate eligibility.</p> |
| <p>AND</p> | |
| <p>In addition, the hospital must have in place documentation that confers governmental powers. A hospital is “formally granted governmental powers” when a state or local government formally delegates to the hospital a power usually exercised by the state or local government. The delegation may be granted through state or local statute or regulation; a contract with a state/local government; creation of a public corporation; or development of a hospital authority or district to provide healthcare to a community on behalf of the government. Examples of governmental powers include, but are not limited to, the power to tax, issue government bonds, act on behalf of the government, etc. Without one of the aforementioned, powers generally granted to private persons or corporations upon meeting of licensure requirements, such as a license to practice medicine or provide healthcare services commercially, do not by themselves constitute governmental powers. Documentation submitted to HRSA should contain <u>all</u> of the following elements:</p> <ol style="list-style-type: none"> 1) Identity of the government entity granting the governmental powers; 2) Description of the governmental power that has been granted to the hospital and a brief explanation as to why the power is considered to be governmental; and 3) A copy of any official documents issued by the government to the hospital that reflect the formal grant of governmental power. | |

Hospitals must be granted governmental powers by the unit of State or local government, prior to registration in the 340B Program.

Parent hospital registration requirements

The 340B Program uses the Centers for Medicare and Medicaid Services (CMS) Hospital Cost Report

Information System (HCRIS) data to verify eligibility. Hospitals registering for the first time are encouraged to have their latest filed Medicare care cost report with them when registering to confirm that the data received from CMS is current and complete. Hospitals will specifically need:

- Signed and digitally stamped Worksheet S;
- Worksheet S-2; and
- Worksheet E Part A.

Hospital off-site outpatient facility (child sites) registration requirements

All off-site outpatient clinics and services located outside the four walls of the hospital that intend to use or purchase 340B drugs for its patients must register and be listed in the 340B OPAIS. HRSA verifies eligibility of offsite outpatient facilities using the hospitals most recently filed Medicare cost report as outlined in the 1994 Outpatient Hospital Facilities Federal Register Notice. The off-site facilities must be listed as reimbursable on the hospital's most recently filed Medicare cost report and have associated outpatient costs and charges.

Hospitals registering outpatient facilities will also be asked to enter several figures from Worksheet A, Worksheet C from the latest filed Medicare cost report and the associated trial balance. These include:

- Total costs from the cost center/line associated with the site being registered (Worksheet A, column 7);
- Outpatient charges associated with the cost center/line being registered (Worksheet C, column 7); and
- If the costs and charges from more than one clinic, service or facility are rolled up to a single cost center, you will need the specific costs and charges from the working trial balance. For cost centers/lines that reflect only a single outpatient clinic, service or facility, these figures will come directly from Worksheet A, Column 7 and Worksheet C column 7.

HRSA and CMS work closely to ensure that the most recent cost report and provider enrollment data are available to facilitate 340B Program registration. HRSA's Office of Pharmacy Affairs (OPA) verifies information on net costs and outpatient charges with CMS data. If the data entered during registration does not match the latest CMS data, hospitals will receive an alert notifying them to upload the documentation into the registration. If the documentation is not uploaded with the registration, the registration will not be reviewed and will be rejected. OPA will contact the hospital if clarification is needed to complete the registration review. HRSA reserves the right to ask for more information in order to fully verify eligibility of the registering entity.

Uploading documentation

Hospitals will be alerted during the registration process when it is necessary to upload documentation. For instructions on how to upload documentation, click on the "[help](#)" in the upper right hand corner of the registration. You can find more information on the uploading process at <https://www.hrsa.gov/opa/340b-opais/index.html>.

340B drugs for Medicaid patients

Hospitals planning to bill Medicaid for 340B drugs for Medicaid patients will need to provide the Medicaid billing number and/or National Provider Identifier. These numbers will be entered onto the Medicaid Exclusion File (MEF) posted each quarter on the 340B OPAIS. The MEF is the official data source to facilitate the prevention of duplicate discounts. Please refer to the December 2014 Policy Release No. 2014-01, "Clarification on Use of the Medicaid Exclusion File" for additional information.

Changing hospital entity types

There are six hospital types eligible to participate in the 340B Program: DSH, SCH, RRC, CAH, PEDS and CAN. When entering the program, hospitals must choose one type under which to participate in the 340B Program and comply with the associated requirements. Hospitals must meet the definition of the hospital type at the time of registration. It is the responsibility of the hospital to understand the prohibitions applicable to the different hospital types. Hospital types are described in [Section 340B\(a\)\(4\)\(L-O\) of the Public Health Service Act](#).

If you are considering changing hospital types, please contact the [340B Prime Vendor Program](#) for technical assistance as soon as possible. A seamless transition from one hospital type to another MAY be possible only if the hospital is proactive and acts prior to any of the program requirements changing for the hospital. When changing hospital entity types, the main hospital, all child sites, as well as contract pharmacies must be reregistered in order for OPA to verify eligibility. The regular quarterly registration periods apply and hospitals are required to remain 340B eligible during the transition from one hospital type to another. Hospitals can participate in the 340B Program only after their qualifications have been approved by the OPA.

Program prohibitions

| GPO Prohibition | Orphan Drug prohibition |
|------------------------|--------------------------------|
| DSH, CAN, PEDS | CAN, RRC,SCH, CAH |

For more information on about the GPO and orphan drug prohibitions, visit the following:

- [Statutory Prohibition on Group Purchasing Organization Participation](#)
- <https://www.hrsa.gov/opa/faqs/index.html>
- <https://www.340bvp.com/faqs/>