



Office of Pharmacy Affairs
340B Database

OPA Database Guide

For

Public Users – Registration

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Covered Entities Guide for Public Users

Registering a Covered Entity into 340B

This guide describes how to register a covered entity into the 340B Drug Pricing Program. Once an entity has registered and is approved to participate in the 340B Program, it is the entity's responsibility to notify drug manufacturers and wholesalers that it will now begin purchasing outpatient drugs at 340B prices once the new quarter begins.

Registering an entity in the 340B program is an online process. The entire registration process must be completed in a single browser session or any data entered will be lost. Partially completed registrations cannot be saved.

Major Sections in This Guide:

To jump to a specific section in this guide, click one of these links:

- [Registering a Hospital](#) (page 2)
- [Registering an Outpatient Facility](#) (page 10)
- [Change Entity Type \(New Registration\)](#) (page 16)
- [Reinstating Hospitals and Outpatient Facilities](#) (page 22)
- [Authorize and Submit a Hospital or Outpatient Facility](#) (page 30)
- [Registering a Non-Hospital Entity](#) (page 34)

Follow these steps to register a covered entity. The starting point is the same for both hospital and non-hospital entities.

- 1) On the 340B Database home page, click the **Register** icon under **“What Would You Like to Do?”**.



Note: You can also select **Register Covered Entity and/or Outpatient Facility** from the **Register** tab the top of the home page.

- 2) On the **Register** screen, click **Covered Entities**.



- 3) **What type of Covered Entity Registration do you wish to submit?** Identify whether you are registering a hospital or a non-hospital. Registration requirements vary depending on the entity type. If you are registering a non-hospital entity, skip to the [Registering a Non-Hospital Entity](#) section in this guide.

Registering a Hospital

This section describes how to register a hospital in the 340B Program. The screens you see when registering a hospital will vary depending on your hospital type. Only sections pertinent to your hospital type will be displayed.

The first screen asks you to select to register a hospital or non-hospital.

- 1) Click **A Hospital** to begin the registration process for all hospital types.



Note: Current [Hospital Registration Instructions](#) are available by clicking the link under the **"A Hospital" icon** (<http://www.hrsa.gov/opa/files/HospitalRegInfo.pdf>).

- 2) Enter the hospital's **Medicare Provider Number** and click the **Search** button.

Search For Hospital

Medicare Provider Number 010038

Search

Cancel

The **Register Hospital** page displays the Medicare Provider Number, the hospital's name and location, the hospital type and its current 340B status.

Register Hospital

Medicare Provider Number	010038
Hospital Name	STRINGFELLOW MEMORIAL HOSPITAL
Street Address	301 EAST 18TH STREET ANNISTON, AL 36207
Entity Type	Disproportionate Share Hospital
Current 340B Status	Unregistered

Caution: Only government-owned/operated or otherwise non-profit facilities with appropriate government contracts or that have formally granted governmental powers are eligible for the 340B program. The most recent cost report data received from CMS indicate that your hospital is a for-profit organization; you may proceed with registration but you must submit evidence that the CMS classification is incorrect.

IMPORTANT: If you are changing your hospital classification from For-Profit to Private, Non-Profit Hospital with state/Local Government Contract or Owned/Operated by State/Local Government, then you will need to submit the supporting documentation to OPA on the same day as this registration:

What would you like to do?

Register for the 340B program as the entity type listed above

Register as a different entity type

This is not me. Search again by entering a new Medicare Provider Number

What would you like to do?: The options offered in this section will depend on the 340B status of the hospital you are registering:

- **Register a new hospital** (for unregistered hospitals)
 - **Reinstate a hospital** (see [Reinstating a Terminated Hospital](#), page 22)
 - **Register an Outpatient Facility** (see [Registering an Outpatient Facility](#), page 10). This option is for active hospitals that are already participating in the 340B program or that have already submitted a registration for the parent hospital.
 - **Reinstate an Outpatient Facility** (see [Reinstating Terminated Outpatient Facilities](#), page 25)
 - **Register as a different hospital type** (see [Change Entity Type / New Registration](#), page 16).
 - **This is not me. Search again** (see [Search Again / Not Me](#), page 29).
- 3) Select **Register for the 340B program as the hospital type listed above**.

The **Pre-Qualification Question(s)** section displays.

Pre-Qualification Question(s)

Pre-Qualification Question(s)

Are you the Authorizing Official of the covered entity? (The authorizing official may be the President, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, or Program Director. Registrations that are electronically signed and submitted by an individual that OPA determines is NOT an acceptable Authorizing Official will not be processed. If you are in doubt regarding who the correct Authorizing Official is, please contact the Apexus Answers prior to submitting the registration.) Yes No

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 2.0 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C-24, Rockville, Maryland, 20857.

Cancel

- 4) Select **Yes** if you are the hospital's Authorizing Official who can sign and submit the new hospital registration form. If you select **No**, the system will not allow you to proceed .
- 5) Click the button.

The **Covered Entities Details** section displays.

Covered Entity Details

Covered Entity Details

Name STRINGFELLOW MEMORIAL HOSPITAL
Type Disproportionate Share Hospital

Employer Identification Number (EIN)
(As assigned by the IRS)

Medicare Provider Number 010038

Street Address 301 EAST 18TH STREET
ANNISTON, AL 36207

Billing Address Same as Street Address
 Shipping Address Same as Street Address
(PO Boxes Are Not Allowed)

Shipping Address 1

Address Line 2

- 6) If the billing and/or shipping addresses are different from the main address, uncheck one or both checkboxes. The section expands to allow you to enter the address information. Add multiple shipping addresses by clicking the button for each shipping address as needed.

Note: A shipping address can be any location to which drugs may be lawfully delivered and that is **not already registered as a contract pharmacy**. The listing of shipping addresses is to give covered entities flexibility in where they wish drugs to be shipped, while also increasing transparency of how the covered entity utilizes the 340B Drug Pricing Program.

Covered entities should be aware that designating a location as a shipping address does not make that location eligible to use 340B drugs for individuals treated there.

Qualification Information

This section will vary according to the hospital type. All Hospitals must meet eligibility requirements, which vary by hospital type.

Note: Most registrants are no longer required to submit Medicare cost report worksheets and trial balances to OPA for review. During registration, the 340B database will use the most recent data available from CMS data sources. The database will display the hospital's cost reporting period from which that data came. However, registrants will be able to make changes if the data shown is not the most current or is incorrect. If any of the data is changed, the registrants are required to submit Medicare cost report worksheets and a working trial balance to OPA for review on the same day as the registration is submitted. Instructions and a list of the specific worksheets to send to OPA are available in the Hospital Registration Instructions at <http://www.hrsa.gov/opa/files/HospitalRegInfo.pdf>.

- 7) Select the checkbox to confirm that the hospital meets the qualifications defined by the Social Security Act and recognized by CMS.
- 8) **Disproportionate Share Adjustment Percentage:** Edit this percentage if a more recent figure is available. If the percentage entered is below the minimum DSH percentage requirement, you will not be able to proceed with the registration. Please see the Hospital Registration Instructions for acceptable DSH percentages based on entity type.

Note: If you change the **Disproportionate Share Adjustment Percentage** or the **Cost Reporting Period** dates, the system will display the message *“WARNING: The qualifying information entered is different from what CMS has on file. You must submit the appropriate documents the same day you submit the registration, or your registration will be deleted without being reviewed. Instructions for submitting documents are displayed after you “Authorize & Submit” the registration.”*

- 9) **Cost Reporting Period:** Edit the cost period begin and end dates if you have a more recent period. The end date must be at least 12 months after the start date.

Note: A warning message appears if the Cost Reporting Period is less than 12 months or if you are registering a critical access hospital or one of its outpatient clinics for which the cost report is more than 18 months old.

WARNING: The most recent cost report available from CMS for your organization is more than 18 months old. Please update the values below and submit all required cost report worksheets as per the instructions provided at the end of the registration process.

Cost Reporting Period: 7/1/2012

6/30/2013

Filing Date: 11/27/2013

Registration Based On: Select One
 Official Determination from HHS Contractor
Medicare Cost Report Data
 Independent Auditor

ⓘ If the cost report does not have sufficient information to calculate the DSH adjustment percentage, see Section D (Process for Admission of Children's Hospitals to the 340B Program) of the 340B program guidance [here](#).

- 10) **Filing Date:** Date when the Cost Report was filed (must be greater than the Cost Reporting Period end date and not more than a year in the past).
- 11) **Registration Based On:** CAN and PED entities only – How the Cost Report was filed. Select the applicable control type from the drop-down list if the value shown is not correct.
- 12) **Control Type per HCRIS:** Select the applicable control type from the drop-down list if the value shown is not correct.

Cost Reporting Period: 7/1/2012

6/30/2013

Filing Date:

Control Type per HCRIS: 0 - Undetermined
 1 - Voluntary Nonprofit, Church
2 - Voluntary Nonprofit, Other
 3 - Proprietary, Individual
 4 - Proprietary, Corporation
 5 - Proprietary, Partnership
 6 - Proprietary, Other
 7 - Governmental, Federal
 8 - Governmental, City-County
 9 - Governmental, County
 10 - Governmental, State
 11 - Governmental, Hospital District
 12 - Governmental, City
 13 - Governmental, Other

Hospital Classification

Contract Number or Identifier, if applicable

The Cost Reporting Period end date suggests that the hospital may have filed a more recent Medicare Cost Report. Please provide the cost reporting period dates from your latest filed cost report.

Filing Date is required.

If a for-profit entity type (3–6) is selected, the system will display the message “The control type you entered suggests that the hospital is a for-profit entity, which makes the hospital ineligible to participate in the 340B Program. You must submit appropriate documents that show governmental or nonprofit status the same day you submit the registration, or the registration will be deleted.”

- 13) **Hospital Classification:** Select the type of hospital classification from the drop-down list. If your hospital is a for-profit organization, it is ineligible to participate in the 340B program.

- 14) **Contract Number or Identifier:** Type the contract ID number if applicable and available.

- 15) **Contract Date:** These fields only appear if the Hospital Classification is “*Private, Non-Profit Hospital with State/Local Govt Contract.*” Enter the contract begin and end dates.

Note: The contract end date may not be prior to the first day of the upcoming quarter (participation start date).

- 16) **Entity’s contract is valid until cancelled:** Selecting this check box overrides the contract end date.

- 17) **Has the Provider changed ownership since the end of the above cost reporting period?** Answer **Yes** or **No**. If you answer **Yes**, click the calendar icon to select the effective date of the ownership change, which must fall within the Cost Reporting Period dates.

If a change in ownership date is entered that is after the Cost Reporting Period end date, the system will display the message “*If the hospital has had a change in ownership since the filing of its last Medicare Cost Report, please contact Apexus at 1-888-340-2787 to determine which documents you will need to submit.*”

- 18) The **Government Ownership/Operation Certifying Official** section only appears if the hospital is owned or operated by a state or local government. Government Contract Certifying Official section appears if the hospital is private, non-profit with a state or local government contract. Identify and provide contact information for a government official who is authorized to attest the relationship with the hospital.

Government Contract Certifying Official	
Name	<input type="text"/> <small>Name is required.</small>
Title	<input type="text"/> <small>Title is required.</small>
Government Organization	<input type="text"/> <small>Government Organization is required.</small>
Phone	<input type="text"/> Ext. <input type="text"/> <small>Phone Number is required.</small>
Email	<input type="text"/> <small>Email Address is required.</small>

Warning: The Government official must be able to certify that the hospital organization is owned or operated by a unit of state or local government, or that the hospital organization has a valid contract to provide 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 of Title XIX of the Social Security Act, as appropriate.

The specified official will receive an e-mail from the Office of Pharmacy Affairs requesting this certification; he or she must respond with the next five calendar days. If the government official does not confirm the hospital's status by the deadline, the registration will be deleted. It is the hospital's responsibility to ensure that the government official's email address is correct, and that he or she is available to respond within 5 calendar days.

Important: Government ownership/operation or contractual arrangements will be verified electronically. Paper certifications with actual ink signatures are no longer required. The registrant must ensure that their Government Official will be available to respond the electronic request for certification within the allotted time frame (5 calendar days).

Statutory Prohibition on Group Purchasing Organization Participation

- 19) If you are registering a Disproportionate Share Hospital (DSH), Children's Hospital (PED), or Free Standing Cancer Hospital (CAN), select the checkbox to confirm that your hospital will not obtain covered outpatient drugs through a group purchasing organization (GPO).

Statutory Prohibition on Group Purchasing Organization Participation
<p>Section 340B(a)(4)(L)(iii) of the Public Health Service Act, which is reiterated in the Statutory Prohibition on Group Purchasing Organization Participation Policy Release (2013-1), requires that the hospital not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. This is a requirement for Disproportionate Share Hospitals, Children's Hospitals, and Free Standing Cancer Hospitals.</p> <p>The authorizing official must certify that this hospital will not participate in a group purchasing organization or group purchasing arrangement for covered outpatient drugs as of the date of this listing on the OPA database. If drugs are purchased using a GPO for covered outpatient drugs while participating in the 340B Program, the covered entity understands that this violates program eligibility requirements and that the covered entity is obligated to inform OPA and may be required to repay manufacturers for the 340B discount received.</p>
<input checked="" type="checkbox"/> Yes, I Confirm* <small>Required</small>

Note: This section will not appear for a Critical Access Hospital (CAH), Rural Referral Center (RRC), or Sole Community Hospital (SCH).

Medicaid Billing

- 20) Answer whether you will bill Medicaid at 340B prices. If you select **Yes**, the **Medicaid Billing** section expands for entry of at least one **MPN/State** or **NPI Number** (required).

Medicaid Billing

Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs? Yes No

If "Yes", please provide the entity's Medicaid Provider Number(s) (MPN) and/or National Provider Identifier(s) (NPI) for each applicable entity location that bills Medicaid for 340B drugs. If you are unsure of the entity's MPN and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status and appropriate provider identifier number(s) are accurate in the OPA database and align with your billing practices in order to prevent Medicaid rebates on drugs that were purchased at the 340B discounted price.

All covered entities should notify OPA prior to any change in Medicaid billing status. For more information, please visit the [HRSA website](#).

Medicaid Provider Number(s)			NPI Number(s)	
Medicaid Provider Number	State	Delete	NPI Number	Delete
<input type="text" value="500348"/>	VA <input type="button" value="v"/>	<input type="button" value="Delete"/>	<input type="text" value="0123456789"/> <small>NPI Number is Required</small>	<input type="button" value="Delete"/>
<input type="button" value="Add"/>			<input type="button" value="Add"/>	

- 21) Click the appropriate button under **Medicaid Number(s)** or **NPI Number(s)** and enter the **MPN/State** or **NPI Number** information.
- 22) Click the button if you want to delete the associated number.
- 23) Click the button when finished.

Note: If one or more of the required fields are not completed or in error, the system will take you back to where the first error occurred and display the validation message for that field. After you correct the error, if there are any more errors, the system will display the next field for correction until all errors are resolved.

You will now affirm that you are the Authorizing Official and can submit the registration. Refer to [Authorize and Submit](#) for instructions.

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Registering an Outpatient Facility

This section outlines how to register an outpatient facility for all hospital types.

The screenshot shows a form titled "Register Hospital" with the following details:

Medicare Provider Number	010038
Hospital Name	STRINGFELLOW MEMORIAL HOSPITAL
Street Address	301 EAST 18TH STREET ANNISTON, AL 36207
Entity Type	Disproportionate Share Hospital
Current 340B Status	Pending

Below the form is a yellow alert box: **Alert:** There is a pending registration for this hospital.

Underneath the alert is a section titled "What would you like to do?" with two radio button options:

- Register Outpatient Facilities
- This is not me. Search again by entering a new Medicare Provider Number

- 1) **Registering Outpatient Facilities:** When you select this option, the **Pre-Qualification Questions** section displays.

The screenshot shows a "Pre-Qualification Question(s)" form with the following content:

Are you the Authorizing Official of the covered entity? Yes No

The Authorizing Official on file is: **Dave Tester, Tester**

The authorizing official must submit any additional outpatient facility registrations. If the listed authorizing official is incorrect, please cancel this registration and submit an [online change request](#).

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 2.0 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C-24, Rockville, Maryland, 20857.

At the bottom are "Cancel" and "Continue" buttons.

- 2) Select **Yes** if you are an Authorizing Official who can sign and submit the new hospital registration form. If you select **No**, the system will not allow you to proceed.
Note: If the Authorizing Official has changed, click the **“online change request”** link to initiate an online change request to update Authorizing Official on file. (Refer to [Submitting a Change or Termination Request](#) for instructions.)
- 3) Click the **Continue** button.

Covered Entity – Outpatient Facility Search Results

The **Covered Entity Outpatient Facility Search Results** lists available outpatient facilities for the covered entity.

Covered Entity

Medicare Provider Number: 010038
 Hospital Name: STRINGFELLOW MEMORIAL HOSPITAL
 Location: 301 EAST 18TH STREET
 Entity Type: Disproportionate Share Hospital
 Current 340B Status: Pending

Covered Entity Outpatient Facility Search Results

Instructions -Please select your outpatient facility and click Continue. If you cannot find the facility you are registering in the search results below, use the text boxes above each column to narrow the results. If the facility is not listed, click the button next to "Not found, add a facility," then click Continue.

Selection	Entity Name	Address	City	State
<input checked="" type="radio"/>	ANNISTON HMA INC	1717 LEIGHTON AVE	ANNISTON	AL
<input type="radio"/>	ANNISTON HMA INC	301 EAST 18TH ST	ANNISTON	AL
<input type="radio"/>	WOUND CARE CENTER	1900 LEIGHTON AVE	ANNISTON	AL
<input type="radio"/>	SLEEP DIAGNOSTIC CENTER	1900 LEIGHTON AVE STE 206	ANNISTON	AL
<input type="radio"/>	PHYSICAL THERAPY	1900 LEIGHTON AVE STE 102	ANNISTON	AL
<input type="radio"/>	STRINGFELLOW IMAGING	1612 HAMRIC DR E	OXFORD	AL
<input type="radio"/>	Not Found. Add a Facility.			

- 4) Select the outpatient facility you want to register. If the outpatient facility you want to register is not listed, select **Not Found. Add a Facility** to add it.
- 5) Click the button.

The **Covered Entity Details** section allows you to record any addition information for the outpatient facility.

Covered Entity Details

Name	STRINGFELLOW MEMORIAL HOSPITAL
Sub-Division Name	ANNISTON HMA INC
Does this location house multiple clinics or services?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Type	Disproportionate Share Hospital
Employer Identification Number (EIN) (As assigned by the IRS)	72-1346819
Outpatient EIN (if different from parent)	<input type="text"/>
Medicare Provider Number	010038
Outpatient Facility Provider Number (if different)	<input type="text"/>
Street Address	1717 LEIGHTON AVE ANNISTON, AL 36207-3832

Note: If you are adding a new outpatient facility (by using the ***Not Found. Add a Facility option***) you will be required to enter the ***Sub-Division Name*** and address information.

- 6) ***Does this location house multiple clinics or services?:*** Choose **Yes** or **No** depending on whether the hospital has multiple outpatient facilities at a single location. If you answer **Yes**, the page expands for you to identify the specific clinic or service you are registering.
- 7) ***Outpatient EIN (only populated if different from parent hospital):*** Enter the facility's nine-digit taxpayer ID, if different from parent. Otherwise, leave blank.
- 8) ***Outpatient Facility Provider Number (only populated if different from parent hospital):*** Enter the facility's Medicare Provider Number, if different from parent. Otherwise, leave blank.

The next section is for the outpatient facility's address.

The screenshot shows a form for adding a shipping address. At the top, the 'Street Address' is pre-filled with '1717 LEIGHTON AVE ANNISTON, AL 36207-3832'. Below this, there are two checkboxes: 'Billing Address Same as Street Address' (checked) and 'Shipping Address Same as Street Address' (unchecked). Under the 'Billing Address' section, there are three text input fields: 'ANNISTON HMA INC', '1717 LEIGHTON AVE', and 'Address Line 2'. Below these are fields for 'ANNISTON', a state dropdown menu set to 'AL', a zip code field with '36207', and a 'Zip+4' field. A blue button labeled 'Add a Shipping Address' is located at the bottom right. A red note below the shipping address checkbox states '(PO Boxes Are Not Allowed)'.

If the billing and/or shipping addresses are different from the main address of the outpatient facility, uncheck one or both checkboxes. The page expands to include address fields for you to complete. Add multiple shipping addresses by clicking the **Add a Shipping Address** button for each shipping address, as needed.

Note: A shipping address can be any location to which drugs may be lawfully delivered and that is **not already registered as a contract pharmacy**. The listing of shipping addresses is to give covered entities flexibility in where they wish drugs to be shipped, while also increasing transparency of how the covered entity utilizes the 340B Drug Pricing Program.

Designating a location as a shipping address does not make that location eligible to use 340B drugs for any individuals treated there.

- 11) **Net Expenses:** Enter the net expenses for the cost center. This figure will come from Worksheet A, Column 7.
- 12) **Outpatient Charges:** Enter the associated outpatient charges for the cost center. This figure will come from Worksheet C, Column 7.
- 13) **Specific Service/Clinic Cost:** Record the outpatient expenses for the clinic/service being registered. If more than one clinic, service or facility is rolled up to a single cost center, these figures will come 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 will be the same as those provided above under the first bullet.
- 14) **Specific Service/Clinic Revenue:** Enter the outpatient revenue for the clinic/service being registered. These figures will come from the working trial balance as well.

Statutory Prohibition on Group Purchasing Organization Participation

Three hospital types—Disproportionate Share Hospitals (DSH), Children’s Hospitals (PED), and Free-Standing Cancer Hospitals (CAN)—are required to confirm that they will not obtain covered outpatient drugs through a group purchasing organization (GPO) or arrangement. The confirmation box is deactivated for outpatient facilities if the confirmation has already been made for the parent covered entity.

Statutory Prohibition on Group Purchasing Organization Participation

Section 340B(a)(4)(L)(iii) of the Public Health Service Act, which is reiterated in the Statutory Prohibition on Group Purchasing Organization Participation Policy Release (2013-1), requires that the hospital not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. This is a requirement for Disproportionate Share Hospitals, Children’s Hospitals, and Free Standing Cancer Hospitals.

The authorizing official must certify that this hospital will not participate in a group purchasing organization or group purchasing arrangement for covered outpatient drugs as of the date of this listing on the OPA database. If drugs are purchased using a GPO for covered outpatient drugs while participating in the 340B Program, the covered entity understands that this violates program eligibility requirements and that the covered entity is obligated to inform OPA and may be required to repay manufacturers for the 340B discount received.

Yes, I Confirm*
Required

Note: This section will not appear for a Critical Access Hospital (CAH), Rural Referral Center (RRC), or Sole Community Hospital (SCH).

Medicaid Billing Information

- 15) Answer whether you will bill Medicaid at 340B prices. If you select **Yes**, the **Medicaid Billing** section expands for entry of at least one **MPN/State** or **NPI Number** (required).

Medicaid Billing

Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs? Yes No

If "Yes", please provide the entity's Medicaid Provider Number(s) (MPN) and/or National Provider Identifier(s) (NPI) for each applicable entity location that bills Medicaid for 340B drugs. If you are unsure of the entity's MPN and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status and appropriate provider identifier number(s) are accurate in the OPA database and align with your billing practices in order to prevent Medicaid rebates on drugs that were purchased at the 340B discounted price.

All covered entities should notify OPA prior to any change in Medicaid billing status. For more information, please visit the [HRSA website](#).

Medicaid Provider Number(s)			NPI Number(s)	
Medicaid Provider Number	State	Delete	NPI Number	Delete
<input type="text" value="500348"/>	VA <input type="button" value="v"/>	<input type="button" value="Delete"/>	<input type="text" value="0123456789"/> <small>NPI Number is Required</small>	<input type="button" value="Delete"/>
<input type="button" value="Add"/>			<input type="button" value="Add"/>	

- 16) Click the appropriate button under **Medicaid Number(s)** or **NPI Number(s)** and enter the **MPN/State** or **NPI Number** information.

- 17) Click the button if you want to delete the associated number.

- 18) Click the button.

Note: If one or more of the required fields are not completed or in error, the system will take you back to where the first error occurred and display the validation message for that field. After you correct the error, if there are any more errors, the system will display the next field for correction until all errors are resolved.

You will now affirm that you are the Authorizing Official and can submit your registration. Refer to [Authorize and Submit](#) for instructions.

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Change Entity Type (New Registration)

This section applies to registering a hospital as different type than what appears in the **Register Hospital** section.

- 1) Select the **Register as a Different Entity Type** option and begin a new registration.

The screenshot shows a form titled "Register Hospital" with the following details:

Medicare Provider Number	461309
Hospital Name	KANE COUNTY HOSPITAL
Street Address	355 NORTH MAIN KANAB, UT 84741
Entity Type	Critical Access Hospital
Current 340B Status	Unregistered

Below the details, the question "What would you like to do?" is followed by three radio button options:

- Register for the 340B program as the entity type listed above
- Register as a different entity type
- This is not me. Search again by entering a new Medicare Provider Number

Note: A screen message will display if a previous or pending registration exists to warn you that it will be deleted by the new registration if you change the entity type. The deletion will not occur until the new registration is approved.

Pre-Qualification Questions

The **Pre-Qualification Questions** section asks you to affirm that you are the Authorizing Official and select the new type of hospital that you would like to register as.

The screenshot shows a form titled "Pre-Qualification Question(s)" with the following content:

Are you the Authorizing Official of the covered entity? (The authorizing official may be the President, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, or Program Director. Registrations that are electronically signed and submitted by an individual that OPA determines is NOT an acceptable Authorizing Official will not be processed. If you are in doubt regarding who the correct Authorizing Official is, please contact the Apexus Answers prior to submitting the registration.)

Yes No

Change Entity Type

Existing Type
Critical Access Hospital

New Type

Please select new Entity type

- Please select new Entity type
- Free Standing Cancer Hospital
- Disproportionate Share Hospital
- Children's Hospital

Buttons: Cancel, Continue

- 2) Select **Yes** if you are an Authorizing Official who can sign and submit the registration form. If you select **No**, the system will not allow you to proceed.
- 3) **New Type:** Click the drop-down list of hospital types to select from a list of appropriate entity types for the current hospital.
- 4) Click the **Continue** button.

Covered Entity Details

The **Covered Entity Details** section displays a message to inform you that the hospital is not currently registered under the new entity type and information from the cost report may need to be updated.

Register Disproportionate Share Hospital - This hospital is not currently registered as a 340B Covered Entity of this type. The information displayed below is from the most recently filed cost report available from CMS. Please review each section. If there is more up-to-date information please make revisions as necessary.

Covered Entity Details

Name	KANE COUNTY HOSPITAL
Type	Children's Hospital
Employer Identification Number (EIN) <small>(As assigned by the IRS)</small>	87-0467930
Medicare Provider Number	461309
Street Address	355 NORTH MAIN KANAB, UT 84741

Billing Address Same as Street Address

Shipping Address Same as Street Address

- 5) **Employer Identification Number (EIN):** Enter or update the entity's taxpayer ID if necessary.

Qualification Information

The **Qualification Information** section displays, prompting you to confirm that the entity qualifies as the new hospital type.

Qualification Information

Entity is a Disproportionate Share Hospital defined by section 1886(d)(1)(B) of the Social Security Act, and this status is recognized by CMS.

Disproportionate Share Adjustment Percentage 13.0

WARNING: The qualifying information entered is different from what CMS has on file. You must submit the appropriate documents the same day you submit the registration, or your registration will be deleted without being reviewed. Instructions for submitting documents are displayed after you "Authorize & Submit" the registration.

Cost Reporting Period: 1/1/2013

12/31/2013 The Cost Reporting Period and date suggests that the hospital may have filed a more recent Medicare Cost Report. Please provide the cost reporting period dates from your latest filed cost report.

Control Type per HCRIS: 5 - Proprietary, Partnership

The control type you entered suggests that the hospital is a for-profit entity, which makes the hospital ineligible to participate in the 340B Program. You must submit appropriate documents that show governmental or nonprofit status the same day you submit the registration, or the registration will be deleted.

Hospital Classification: Ineligible for-profit organization

For-profit organizations are ineligible for registration

- 6) Select the checkbox if your entity qualifies as the hospital type you selected in Step 3.
- 7) The **Disproportionate Share Adjustment Percentage** must meet eligibility requirements, which vary by hospital type. If the percentage is below the minimum requirement, an error message displays. The registration cannot proceed if the hospital does not meet the DSH adjustment percentage eligibility requirement. This field does not apply for CAH hospital types.

Note: If you change the **Disproportionate Share Adjustment Percentage** or the **Cost Reporting Period** dates, the system will display the message “**WARNING: The qualifying information entered is different from what CMS has on file. You must submit the appropriate documents the same day you submit the registration, or your registration will be deleted without being reviewed. Instructions for submitting documents are displayed after you “Authorize & Submit” the registration.**”

- 8) **Cost Reporting Period:** Edit the cost period begin and end dates if you have a more recent period. The end date must be at least 12 months after the start date.

Note: A warning message appears if the Cost Reporting Period is less than 12 months.

WARNING: The most recent cost report available from CMS for your organization is more than 18 months old. Please update the values below and submit all required cost report worksheets as per the instructions provided at the end of the registration process.

Cost Reporting Period: 7/1/2012

6/30/2013

Filing Date: 11/27/2013

Registration Based On: Select One
Official Determination from HHS Contractor
Medicare Cost Report Data
Independent Auditor

ⓘ If the cost report does not have sufficient information to calculate the DSH adjustment percentage, see Section D (Process for Admission of Children’s Hospitals to the 340B Program) of the 340B program guidance [here](#).

- 9) **Filing Date:** *CAN and PED entities only* – Date when the Cost Report was filed (must be greater than the Cost Reporting Period End Date not more than a year in the past).
- 10) **Registration Based On:** *CAN and PED entities* – How the Cost Report was filed. Select the applicable description from the drop-down list.
- 11) **Control Type per HCRIS:** Select the applicable control type from the drop-down list if the value shown is not correct.

Cost Reporting Period: 1/1/2014

12/31/2014

Control Type per HCRIS: 9 - Governmental, County

Hospital Classification

Contract Date

- 0 - Undetermined
- 1 - Voluntary Nonprofit, Church
- 2 - Voluntary Nonprofit, Other
- 3 - Proprietary, Individual
- 4 - Proprietary, Corporation
- 5 - Proprietary, Partnership
- 6 - Proprietary, Other
- 7 - Governmental, Federal
- 8 - Governmental, City-County
- 9 - Governmental, County**
- 10 - Governmental, State
- 11 - Governmental, Hospital District
- 12 - Governmental, City
- 13 - Governmental, Other

If a for-profit entity type (3–6) is selected, the system will display the message “*The control type you entered suggests that the hospital is a for-profit entity, which makes the hospital ineligible to participate in the 340B Program. You must submit appropriate documents that*”

show governmental or nonprofit status the same day you submit the registration, or the registration will be deleted.”

- 12) **Hospital Classification:** Select the type of hospital classification from the drop-down list. If your hospital is a for-profit organization, it is ineligible to participate in the 340B program.

The screenshot shows a form with the following elements:

- Control Type per HCRIS:** A dropdown menu with the selected value "9 - Governmental, County".
- Hospital Classification:** A dropdown menu with the selected value "Owned or Operated by State or Local Government". The dropdown is open, showing the following options:
 - Select One
 - Owned or Operated by State or Local Government
 - Private, Non-Profit Hospital with State/Local Govt Contract
 - Public or Private Non-Profit Hospital Granted Governmental Powers
 - Ineligible for-profit organization
- Has the provider changed ownership during or since the end of the above cost reporting period?:** Radio buttons for "Yes" and "No".

- 13) **Contract Number or Identifier:** Type the contract ID number if applicable and available.

The screenshot shows a form with the following elements:

- Hospital Classification:** A dropdown menu with the selected value "Private, Non-Profit Hospital with State/Local Govt Contract".
- Contract Number or Identifier, if applicable:** An empty text input field.
- Contract Date:** Two date pickers. The first is set to "01/01/2014" and the second to "12/31/2015". A red error message next to the second date picker reads: "The contract end date cannot be prior to the participation date."
- Entity's contract is valid until cancelled:** An unchecked checkbox.
- Has the provider changed ownership during or since the end of the above cost reporting period?:** Radio buttons for "Yes" (selected) and "No".
- When was the effective date of this change?:** A date picker set to "01/01/2015". A red error message below it reads: "If the hospital has had a change in ownership since the filing of its last Medicare Cost Report, please contact Apexus at 1-888-340-2787 to determine which documents you will need to submit."

- 14) **Contract Date:** These fields only appear if the Hospital Classification is “Private, Non-Profit Hospital with State/Local Govt Contract.” Enter the contract begin and end dates.

Note: The contract end date may not be prior to the first day of the upcoming quarter (participation start date).

- 15) Select **Yes** or **No** if the entity has recently changed ownership. If **Yes**, you will be required to provide the effective date of the change and to submit supporting documents to OPA.

If a change in ownership date is entered that is after the Cost Reporting Period end date, the system will display the message “If the hospital has had a change in ownership since the filing of its last Medicare Cost Report, please contact Apexus at 1-888-340-2787 to determine which documents you will need to submit.”

- 16) Complete the required fields in the **Government Ownership/Operation Certifying Official** or Government Contract Certifying Official (depending on hospital classification type) section. All fields are required.

Government Contract Certifying Official

Name	<input type="text"/>	
	<small>Name is required.</small>	
Title	<input type="text"/>	
	<small>Title is required.</small>	
Government Organization	<input type="text"/>	
	<small>Government Organization is required.</small>	
Phone	<input type="text"/>	Ext. <input type="text"/>
	<small>Phone Number is required.</small>	
Email	<input type="text"/>	
	<small>Email Address is required.</small>	

Warning: The Government official must be able to certify that the hospital organization is owned or operated by a unit of state or local government, or that the hospital organization has a valid contract to provide 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 of Title XIX of the Social Security Act, as appropriate.

The specified official will receive an e-mail from the Office of Pharmacy Affairs requesting this certification; he or she must respond with the next five calendar days. If the government official does not confirm the hospital's status by the deadline, the registration will be deleted. It is the hospital's responsibility to ensure that the government official's email address is correct, and that he or she is available to respond within 5 calendar days.

Statutory Prohibition on Group Purchasing Organization Participation

Important: Government ownership/operation or contractual arrangements will be verified electronically. The registrant must identify an appropriate government official who will receive an e-mail from HRSA's Office of Pharmacy Affairs requesting that they confirm the hospital's status within the next 5 calendar days.

The Government Official must be able to certify that the hospital organization is owned or operated by a unit of state or local government, or that the hospital organization has a valid contract to provide 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 of Title XIX of the Social Security act, as appropriate.

The registrant is responsible for conducting proper follow-up and ensures that their government official will be available to respond the electronic request for certification in the allotted time frame. You will be notified by e-mail once the government official has confirmed the hospital's status. If the Government Official does not confirm by the deadline, the registration will be deleted and must be re-submitted.

Statutory Prohibition on Group Purchasing Organization Participation

Three hospital types—disproportionate share hospitals (DSH), children’s hospitals (PED), and free-standing cancer hospitals (CAN)—are required to confirm that they will not obtain covered outpatient drugs through a group purchasing organization or arrangement. The confirmation box is deactivated for outpatient facilities if the confirmation has already been made for the parent covered entity.

Statutory Prohibition on Group Purchasing Organization Participation

Section 340B(a)(4)(L)(iii) of the Public Health Service Act, which is reiterated in the Statutory Prohibition on Group Purchasing Organization Participation Policy Release (2013-1), requires that the hospital not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. This is a requirement for Disproportionate Share Hospitals, Children’s Hospitals, and Free Standing Cancer Hospitals.

The authorizing official must certify that this hospital will not participate in a group purchasing organization or group purchasing arrangement for covered outpatient drugs as of the date of this listing on the OPA database. If drugs are purchased using a GPO for covered outpatient drugs while participating in the 340B Program, the covered entity understands that this violates program eligibility requirements and that the covered entity is obligated to inform OPA and may be required to repay manufacturers for the 340B discount received.

Yes, I Confirm

Note: This section will not appear for a Critical Access Hospital (CAH), Rural Referral Center (RRC), or Sole Community Hospital (SCH).

Medicaid Billing

17) Answer whether you will bill Medicaid at 340B prices. If you select **Yes**, the **Medicaid Billing** section expands for entry of at least one **MPN/State** or **NPI Number** (required).

Medicaid Billing

Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs? Yes No

If "Yes", please provide the entity’s Medicaid Provider Number(s) (MPN) and/or National Provider Identifier(s) (NPI) for each applicable entity location that bills Medicaid for 340B drugs. If you are unsure of the entity’s MPN and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status and appropriate provider identifier number(s) are accurate in the OPA database and align with your billing practices in order to prevent Medicaid rebates on drugs that were purchased at the 340B discounted price.

All covered entities should notify OPA prior to any change in Medicaid billing status. For more information, please visit the [HRSA website](#).

Medicaid Provider Number(s)			NPI Number(s)	
Medicaid Provider Number	State	Delete	NPI Number	Delete
<input type="text" value="010150600"/>	UT <input type="button" value="v"/>	<input type="button" value="Delete"/>	<input type="text" value="1427114099"/>	<input type="button" value="Delete"/>
<input type="button" value="Add"/>			<input type="button" value="Add"/>	

18) Click the appropriate **Add** button under **Medicaid Number(s)** or **NPI Number(s)** and enter the **MPN/State** or **NPI Number** information.

19) Click the **Delete** button if you want to delete the associated number.

20) Click the **Continue** button.

Note: If one or more of the required fields are not completed or in error, the system will take you back to where the first error occurred and display the validation message for that field. After you correct the error, if there are any more errors, the system will display the next field for correction until all errors are resolved.

You will now affirm that you are the Authorizing Official and can submit your registration. Refer to [Authorize and Submit](#) on page 30 for instructions.

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Reinstating Hospitals and Outpatient Facilities

Reinstating a Terminated Hospital

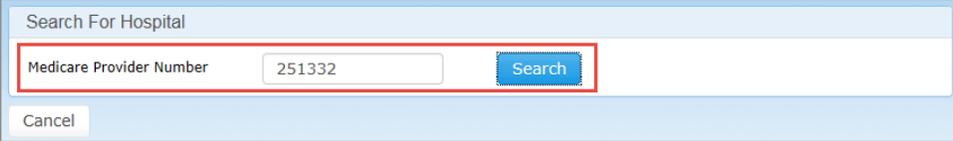
Follow these steps to reinstate a terminated hospital and its outpatient facilities.

- 1) After selecting **Register > Covered Entities**, click **A Hospital** under “*What type of Covered Entity Registration do you wish to submit?*”



The screenshot shows a web interface titled "REGISTER" with a clipboard icon. Below the title is a question: "What type of Covered Entity Registration do you wish to submit?". There are two main options: "A Hospital" (represented by a blue hospital icon) and "A Non-Hospital" (represented by a green first aid kit icon). The "A Hospital" option is highlighted with a red border. Below each option is a note: "Note: Before beginning the registration process, please review the Hospital Registration Instructions" and "Note: Hospitals that are registering grant-supported clinics (e.g., Title X Family Planning projects) should choose this option." The word "OR" is placed between the two options.

- 2) Enter the **Medicare Provider Number** for the terminated hospital you want to reinstate and click the **Search** button.



The screenshot shows a search form titled "Search For Hospital". It has a text input field labeled "Medicare Provider Number" with the value "251332" entered. To the right of the input field is a blue "Search" button. Below the input field is a "Cancel" button.

- 3) When the **Register Hospital** page displays, select the option to reinstate the selected entity in the **“What would you like to do?”** section.

Register Hospital

Medicare Provider Number	251332
Hospital Name	PIONEER COMMUNITY HOSP OF NEWTON CO
Street Address	9421 EAST SIDE DRIVE EXTENSION NEWTON, MS 39345
Entity Type	Critical Access Hospital
Current 340B Status	Terminated

Caution: Only government-owned/operated or otherwise non-profit facilities with appropriate government contracts or that have formally granted governmental powers are eligible for the 340B program. The most recent cost report data received from CMS indicate that your hospital is a for-profit organization; you may proceed with registration but you must submit evidence that the CMS classification is incorrect.

IMPORTANT: If you are changing your hospital classification from For-Profit to Private, Non-Profit Hospital with state/Local Government Contract or Owned/Operated by State/Local Government, then you will need to submit the supporting documentation to OPA on the same day as this registration:

Alert: This hospital is Terminated.

What would you like to do?

Reinstatement the selected entity

Register as a different entity type

This is not me. Search again by entering a new Medicare Provider Number

The **Pre-Qualification Question(s)** section displays.

Pre-Qualification Question(s)

Are you the Authorizing Official of the covered entity? (The authorizing official may be the President, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, or Program Director. Registrations that are electronically signed and submitted by an individual that OPA determines is NOT an acceptable Authorizing Official will not be processed. If you are in doubt regarding who the correct Authorizing Official is, please contact the Apexus Answers prior to submitting the registration.) Yes No

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 2.0 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C-24, Rockville, Maryland, 20857.

Cancel

- 4) Select **Yes** to indicate you can sign and submit the reinstatement. If you select **No**, the system will not allow you to proceed.
- 5) Click the button.
- Proceed as if you were [Registering a New Hospital](#) (page 2).
 - When finished, affirm that you are the Authorizing Official and can submit the reinstatement, and provide the most up-to-date Authorizing Official and Primary Contact information (see [Authorize and Submit](#), page 30).

- 6) The next page notifies you that your registration/reinstatement has been submitted and asks if you want to register or reinstate an outpatient facility. Follow the instructions if additional supporting documents need to be submitted. Once the registration/reinstatement is approved, it can be accessed and viewed, but it cannot be changed until the upcoming quarter begins.

3 Your Electronic Registration Request Has Been Submitted to the Office Of Pharmacy Affairs!

Your 340B registration has been successfully submitted and will be reviewed for eligibility. You will be contacted by OPA Staff if any additional information is required.

If the hospital's eligibility is based on government ownership/operation or on having an appropriate contract with a unit of state or local government, the government official you identified will receive an email from HRSA's Office of Pharmacy Affairs (340BDrugPricingProgram@hrsa.gov) requesting that they confirm the hospital's status. The government official **MUST** respond within 5 calendar days. You will be notified by e-mail once the government official has confirmed the hospital's status; **if the government official does not confirm by the deadline, the registration will be deleted and must be re-submitted.** If the current registration period has ended, the hospital will not be able to submit another registration until the next open registration period

If the government official contact information provided during the registration was incorrect, e-mail HRSA immediately with the correct contact information. Please remember to include the hospital's Medicare provider number in the subject of the e-mail, which should be sent to the appropriate address listed below based on the hospital type.

If the hospital's eligibility is based on the formal granting of government powers, you must submit evidence of the identity of the government entity granting those powers, a description of the governmental powers that have been granted to the hospital and a brief explanation as to why the powers are considered to be governmental, and a copy of any official document of the granting of those powers. This information must be submitted to OPA the same day as the registration, or the registration will be deleted without being reviewed.

If you made changes to any of the Medicare cost report information provided by CMS, or the information was unavailable from CMS, the hospital MUST submit copies of all necessary documents from the hospital's latest filed Medicare cost report, as shown in the table below, to the appropriate email address or fax number below. If required documents are not submitted the same day as the registration, the registration will be deleted without being reviewed.

Hospital Type	Cost Report Worksheets			
	S	S-2	S-3	E (Part A)
Disproportionate Share (DSH)	Yes	Yes	No	Yes
Critical Access (CAH)	Yes	Yes	No	No
Freestanding Cancer (CAN)	Yes	Yes	No	Yes
Pediatric (PED)	Yes	Yes	Yes	No
Rural Referral Center (RRC)	Yes	Yes	No	Yes
Sole Community (SCH)	Yes	Yes	No	Yes

Please send these documents to the email address or fax number for your hospital type as described below.

Registration Type	E-mail address	Fax
Disproportionate Share Hospitals	340BRegistrationDSH@hrsa.gov	301-443-6571
Critical Access Hospitals	340BRegistrationCAH@hrsa.gov	301-443-6572
Sole Community Hospitals	340BRegistrationSCH@hrsa.gov	301-443-6573
Rural Referral Centers	340BRegistrationRRC@hrsa.gov	301-443-6574
Freestanding Cancer Hospitals	340BRegistrationCAN@hrsa.gov	301-443-6575
Pediatric Hospitals	340BRegistrationPED@hrsa.gov	301-443-6576

Additional assistance may be obtained through the 340B Prime Vendor Program: 888-340-2787 or ApexusAnswers@340bpvp.com. If you have any questions, please contact us at: Office of Pharmacy Affairs, Mail Stop 8W05A, 5600 Fishers Lane, Rockville, MD 20857.

Outpatient Facilities

Would you like to register an outpatient facility? Register Outpatient Facility

Would you like to reinstate a previously terminated outpatient facility? Reinstate Outpatient Facility

Return Home

- To register an outpatient facility for the same hospital, click the Register Outpatient Facility button (see [Registering an Outpatient Facility](#), page 10).
- To reinstate an outpatient facility for the same hospital, click the Reinstate Outpatient Facility button.

The **Covered Entity** page displays. The **Covered Entity Outpatient Facility Search Results** section displays a list of terminated outpatient facilities that may be reinstated.

Covered Entity				
Medicare Provider Number	251332			
Hospital Name	PIONEER COMMUNITY HOSP OF NEWTON CO			
Location	9421 EAST SIDE DRIVE EXTENSION			
Entity Type	Critical Access Hospital			
Current 340B Status	Pending			

Covered Entity Outpatient Facility Search Results				
Instructions -Please select your terminated outpatient facility to reinstate and click Continue. If you cannot find the facility you are reinstating in the search results below, use the text boxes above each column to narrow the results.				
Selection	Entity Name	Address	City	State
<input type="radio"/>	NEWTON FAMILY AND SPECIALTY CLINIC	9421 EASTSIDE DRIVE EXT	NEWTON	MS

- 7) Select the outpatient facility you want to reinstate and click the button.

Proceed as you normally would to register an outpatient facility (see [Registering an Outpatient Facility](#), page 10).

Reinstating Terminated Outpatient Facilities

Follow these steps to reinstate a terminated outpatient facilities for an active or pending hospital.

- 1) After selecting **Register > Covered Entities**, click **A Hospital** under “**What type of Covered Entity Registration do you wish to submit?**”



REGISTER

What type of Covered Entity Registration do you wish to submit?



A Hospital

Note: Before beginning the registration process, please review the [Hospital Registration Instructions](#).

OR



A Non-Hospital

Note: Hospitals that are registering grant-supported clinics (e.g., Title X Family Planning projects) should choose this option.

- 2) Enter the **Medicare Provider Number** for the parent hospital of the outpatient facility you want to reinstate and click the **Search** button.

Search For Hospital

Medicare Provider Number **Search**

Cancel

The **Register Hospital** page displays. For an active or pending hospital with terminated outpatient facilities, the **“What would you like to do?”** section will include an option to reinstate terminated outpatient facilities.

Register Hospital

Medicare Provider Number	051317
Hospital Name	St Helena Hospital Clearlake
Street Address	15630 18th Ave - Hwy 53 Clearlake, CA 95422
Entity Type	Critical Access Hospital
Current 340B Status	Active

What would you like to do?

Register Outpatient Facilities

Reinstate Terminated Outpatient Facilities

Register as a different entity type

This is not me. Search again by entering a new Medicare Provider Number

- 3) Select the **Reinstate Terminated Outpatient Facilities** option.

The **Pre-Qualification Question(s)** section displays.

Pre-Qualification Question(s)

Are you the Authorizing Official of the covered entity? Yes No

The Authorizing Official on file is: **CARLTON JACOBSON, CFO**

The authorizing official must submit any additional outpatient facility registrations. If the listed authorizing official is incorrect, please cancel this registration and submit an [online change request](#).

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 2.0 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C-24, Rockville, Maryland, 20857.

Cancel **Continue**

- 4) Select **Yes** to indicate you can sign and submit the reinstatement. If you select **No**, the system will not allow you to proceed.
- 5) Click the **Continue** button.

The **Covered Entity** page displays. The **Covered Entity Outpatient Facility Search Results** section displays a list of the hospital’s terminated outpatient facilities that may be reinstated.

Covered Entity

Medicare Provider Number	051317
Hospital Name	ST. HELENA HOSPITAL CLEARLAKE
Location	18TH AVENUE & HI-WAY 53
Entity Type	Critical Access Hospital
Current 340B Status	Active

Covered Entity Outpatient Facility Search Results

Instructions -Please select your terminated outpatient facility to reinstate and click Continue. If you cannot find the facility you are reinstating in the search results below, use the text boxes above each column to narrow the results.

Selection	Entity Name	Address	City	State
<input checked="" type="radio"/>	St. Helena Medical Specialties Family Practice	15322 Lakeshore Drive Suite 201	Clearlake	CA

- 6) Select the outpatient facility to be reinstated and click the button.

The **Covered Entity Details** page displays. The messages at the top of the page indicate that the outpatient facility is currently inactive and must be reinstated as a 340B Covered Entity, and that you must submit the applicable Medicare cost report worksheets from the facility’s most-recently filed cost report.

Register Critical Access Hospital - This Outpatient Facility is not currently registered in the 340B Program. Displayed below is a combination of information from 340B program and CMS databases. Please review each section. If there is more current information available, please update the fields as necessary.

Covered Entity Details

Entity name and address are shown per the organization's cost report and may be different from that on the prior registration.

Name	St Helena Hospital Clearlake
Sub-Division Name	St. Helena Medical Specialties Family Practice
Does this location house multiple clinics or services?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Type	Critical Access Hospital
Employer Identification Number (EIN) (As assigned by the IRS)	68-0395149
Outpatient EIN (if different from parent)	<input type="text"/>
Medicare Provider Number	051317
Outpatient Facility Provider Number (if different)	<input type="text"/>
Street Address	15322 Lakeshore Drive Suite 201 Clearlake, CA 95422
<input checked="" type="checkbox"/> Billing Address Same as Street Address	
<input checked="" type="checkbox"/> Shipping Address Same as Street Address	

- 7) Proceed as you normally would to register an outpatient facility (see [Registering an Outpatient Facility](#), page 10).
- 8) When finished, affirm that you are the Authorizing Official and can submit the reinstatement (see [Authorize and Submit](#), page 30).
- 9) After you authorize and submit the reinstatement, the next page notifies you that your reinstatement has been submitted and asks if you want to register an outpatient facility or reinstate another terminated outpatient facility. Follow the instructions if additional

supporting documents need to be submitted to OPA. Once the reinstatement is approved, it can be accessed and viewed, but it cannot be changed until the upcoming quarter begins.

Your Electronic Registration Request Has Been Submitted to the Office Of Pharmacy Affairs!

Your 340B registration has been successfully submitted and will be reviewed for eligibility. You will be contacted by OPA Staff if any additional information is required.

If you made changes to any of the Medicare cost report information provided by CMS, or the information was unavailable from CMS, the hospital MUST submit copies of all necessary documents from the hospital's latest filed Medicare cost report, as shown in the table below, to the appropriate email address or fax number below. If required documents are not submitted the same day as the registration, the registration will be deleted without being reviewed.

Hospital Type	Cost Report Worksheets			
	S	S-2	S-3	E (Part A)
Disproportionate Share (DSH)	Yes	Yes	No	Yes
Critical Access (CAH)	Yes	Yes	No	No
Freestanding Cancer (CAN)	Yes	Yes	No	Yes
Pediatric (PED)	Yes	Yes	Yes	No
Rural Referral Center (RRC)	Yes	Yes	No	Yes
Sole Community (SCH)	Yes	Yes	No	Yes

If the hospital is registering one or more outpatient facilities, and you made changes to the auto-populated cost reporting period or other qualifying information, the hospital must also submit copies of Worksheet A, Worksheet C, and a trial balance corresponding to the latest filed cost report that shows revenue and expenses for the specific site, clinic or service being registered. [\(Example working trial balance\)](#)

Please send these documents to the email address or fax number for your hospital type as described below.

Registration Type	E-mail address	Fax
Disproportionate Share Hospitals	340BRegistrationDSH@hrsa.gov	301-443-6571
Critical Access Hospitals	340BRegistrationCAH@hrsa.gov	301-443-6572
Sole Community Hospitals	340BRegistrationSCH@hrsa.gov	301-443-6573
Rural Referral Centers	340BRegistrationRRC@hrsa.gov	301-443-6574
Freestanding Cancer Hospitals	340BRegistrationCAN@hrsa.gov	301-443-6575
Pediatric Hospitals	340BRegistrationPED@hrsa.gov	301-443-6576

Additional assistance may be obtained through the 340B Prime Vendor Program: 888-340-2787 or ApexusAnswers@340bpvp.com. If you have any questions, please contact us at: Office of Pharmacy Affairs, Mail Stop 8W05A, 5600 Fishers Lane, Rockville, MD 20857.

Outpatient Facilities

Would you like to register another outpatient facility? [Register Outpatient Facility](#)

Would you like to reinstate another previously terminated outpatient facility? [Reinstate Outpatient Facility](#)

[Return Home](#)

- To register an outpatient facility for the same hospital, click the [Register Outpatient Facility](#) button.
- To reinstate another outpatient facility for the same hospital, click the [Reinstate Outpatient Facility](#) button.

[\[Back to the top\]](#)

Search Again / Not Me

- 1) **What would you like to do?:** If you choose ***This is not me. Search again by entering a new Medicare Provider Number*** and click the **Continue** button, you will be returned to the **Search for Hospital** page.

Register Hospital

Medicare Provider Number	041306
Hospital Name	COMM MEDICAL CENTER OF CALICO ROCK
Street Address	PARK ST CALICO ROCK, AR 72519
Entity Type	Critical Access Hospital
Current 340B Status	Terminated

Alert: This hospital is Terminated.

What would you like to do?

Reinstate the selected entity

Register as a different entity type

This is not me. Search again by entering a new Medicare Provider Number

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 2.0 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C-24, Rockville, Maryland, 20857.

- 2) **Medicare Provider Number:** Re-enter the Medicare Provider Number. The correct number should bring up your hospital's information.

Search For Hospital

Medicare Provider Number

Refer to registration instructions for [Registering a Hospital](#).

[\[Back to the top\]](#)

Authorize and Submit a Hospital or Outpatient Facility

This section is for the affirmation and confirmation of the listed obligations that the Authorizing Official assumes on behalf of the covered entity. t

Authorize and Submit

- 1) Select the checkbox to affirm that you are authorized to legally bind the entity and certify that the information provided is accurate.

The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. The undersigned further acknowledges the 340B covered entity's responsibility to abide by the following:

As an Authorized Official, I certify on behalf of the covered entity that:

- (1) all information listed on the 340B Program database for the covered entity will be complete, accurate, and correct;
- (2) the covered entity will meet all 340B Program eligibility requirements, including section 340B(a)(4)(L)(iii) and the Statutory Prohibition on Group Purchasing Organization Participation Policy Release 2013-1 which ensures that the covered entity hospital does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement;
- (3) the covered entity will comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity;
- (4) the covered entity will maintain auditable records demonstrating compliance with the requirements described above;
- (5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described above;
- (6) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);
- (7) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and
- (8) the covered entity acknowledges that if there is a breach of the requirements described above that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.

In addition, I have read all applicable registration instructions and I am aware that my registration will not be reviewed if the required supporting documents are not submitted today. Please provide any additional information that may be helpful in reviewing this registration for 340B eligibility:

Required By checking this box, I confirm that I have read the above statements and fully understand my obligations.

Authorizing Official

This section is for the name and contact information for the Authorizing Official who can legally bind the hospital into a contract with the federal government and for a primary contact if different from the Authorizing Official. It is preferable to have different individuals listed as the Authorizing Official and Primary Contact.

Contact Information

Authorizing Official

Name
Name is required.

Title
Title is required.

Phone Ext.
Phone Number is required.

Fax

Email
Email Address is required.

Make Primary Contact information the same as Authorizing Official

Primary Contact

Name
Name is required.

Title
Title is required.

Phone Ext.
Phone Number is required.

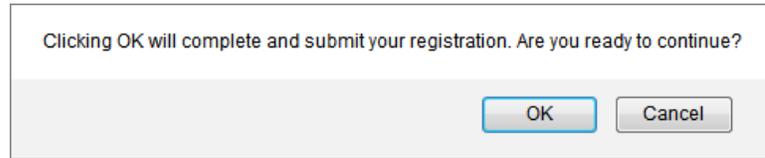
Fax

Email
Email Address is required.

- 2) **Authorizing Official:** Enter the name and contact information of the Authorizing Official.
- 3) **Make Primary Contact Information the same as Authorizing Official:** Enter the name and contact information for the Primary Contact. If the Authorizing Official and the Primary Contact are the same, select the checkbox to fill the **Primary Contact** fields with the Authorizing Official's information.
- 4) **Primary Contact:** If the primary contact is different from the Authorizing Official, enter contact data for that individual.
- 5) Click the button.

**Covered Entities Guide for Public Users
Authorize and Submit a Hospital or Outpatient Facility**

- 6) A confirmation message appears. Click **OK**.



- 7) The next page notifies you that your registration has been submitted. Follow the instructions on this page to provide OPA with additional supporting documents, if needed. Once OPA approves the registration, you will be able to access and view the registration but will not be able to make changes to the information until the quarter begins.

For hospital registrations, the page will look like this:

Your Electronic Registration Request Has Been Submitted to the Office Of Pharmacy Affairs!

Your 340B registration has been successfully submitted and will be reviewed for eligibility. You will be contacted by OPA Staff if any additional information is required.

If the hospital's eligibility is based on government ownership/operation or on having an appropriate contract with a unit of state or local government, the government official you identified will receive an email from HRSA's Office of Pharmacy Affairs (340BDrugPricingProgram@hrsa.gov) requesting that they confirm the hospital's status. The government official MUST respond within 5 calendar days. You will be notified by e-mail once the government official has confirmed the hospital's status; **if the government official does not confirm by the deadline, the registration will be deleted and must be re-submitted.** If the current registration period has ended, the hospital will not be able to submit another registration until the next open registration period.

If the government official contact information provided during the registration was incorrect, e-mail HRSA immediately with the correct contact information. Please remember to include the hospital's Medicare provider number in the subject of the e-mail, which should be sent to the appropriate address listed below based on the hospital type.

If the hospital's eligibility is based on the formal granting of government powers, you must submit evidence of the identity of the government entity granting those powers, a description of the governmental powers that have been granted to the hospital and a brief explanation as to why the powers are considered to be governmental, and a copy of any official document of the granting of those powers. This information must be submitted to OPA the same day as the registration, or the registration will be deleted without being reviewed.

If you made changes to any of the Medicare cost report information provided by CMS, or the information was unavailable from CMS, The hospital MUST submit copies of all necessary documents from the hospital's latest filed Medicare cost report, as shown in the table below, to the appropriate email address or fax number below. If required documents are not submitted the same day as the registration, the registration will be deleted without being reviewed.

Hospital Type	Cost Report Worksheets			
	S	S-2	S-3	E (Part A)
Disproportionate Share (DSH)	Yes	Yes	No	Yes
Critical Access (CAH)	Yes	Yes	No	No
Freestanding Cancer (CAN)	Yes	Yes	No	Yes
Pediatric (PED)	Yes	Yes	Yes	No
Rural Referral Center (RRC)	Yes	Yes	No	Yes
Sole Community (SCH)	Yes	Yes	No	Yes

Please send these documents to the email address or fax number for your hospital type as described below.

Registration Type	E-mail address	Fax
Disproportionate Share Hospitals	340BRegistrationDSH@hrsa.gov	301-443-6571
Critical Access Hospitals	340BRegistrationCAH@hrsa.gov	301-443-6572
Sole Community Hospitals	340BRegistrationSCH@hrsa.gov	301-443-6573
Rural Referral Centers	340BRegistrationRRC@hrsa.gov	301-443-6574
Freestanding Cancer Hospitals	340BRegistrationCAN@hrsa.gov	301-443-6575
Pediatric Hospitals	340BRegistrationPED@hrsa.gov	301-443-6576

Additional assistance may be obtained through the 340B Prime Vendor Program: 888-340-2787 or ApexusAnswers@340bvpvp.com. If you have any questions, please contact us at: Office of Pharmacy Affairs, Mail Stop 8W05A, 5600 Fishers Lane, Rockville, MD 20857.

Outpatient Facilities

Would you like to register an outpatient facility? [Register Outpatient Facility](#)

[Return Home](#)

For outpatient registrations, the page will look like this:

Your Electronic Registration Request Has Been Submitted to the Office Of Pharmacy Affairs!

Your 340B registration has been successfully submitted and will be reviewed for eligibility. You will be contacted by OPA Staff if any additional information is required.

If you made changes to any of the Medicare cost report information provided by CMS, or the information was unavailable from CMS, the hospital MUST submit copies of all necessary documents from the hospital's latest filed Medicare cost report, as shown in the table below, to the appropriate email address or fax number below. If required documents are not submitted the same day as the registration, the registration will be deleted without being reviewed.

Hospital Type	Cost Report Worksheets			
	S	S-2	S-3	E (Part A)
Disproportionate Share (DSH)	Yes	Yes	No	Yes
Critical Access (CAH)	Yes	Yes	No	No
Freestanding Cancer (CAN)	Yes	Yes	No	Yes
Pediatric (PED)	Yes	Yes	Yes	No
Rural Referral Center (RRC)	Yes	Yes	No	Yes
Sole Community (SCH)	Yes	Yes	No	Yes

If the hospital is registering one or more outpatient facilities, and you made changes to the auto-populated cost reporting period or other qualifying information, the hospital must also submit copies of Worksheet A, Worksheet C, and a trial balance corresponding to the latest filed cost report that shows revenue and expenses for the specific site, clinic or service being registered. (Example working trial balance)

Please send these documents to the email address or fax number for your hospital type as described below.

Registration Type	E-mail address	Fax
Disproportionate Share Hospitals	340BRegistrationDSH@hrsa.gov	301-443-6571
Critical Access Hospitals	340BRegistrationCAH@hrsa.gov	301-443-6572
Sole Community Hospitals	340BRegistrationSCH@hrsa.gov	301-443-6573
Rural Referral Centers	340BRegistrationRRC@hrsa.gov	301-443-6574
Freestanding Cancer Hospitals	340BRegistrationCAN@hrsa.gov	301-443-6575
Pediatric Hospitals	340BRegistrationPED@hrsa.gov	301-443-6576

Additional assistance may be obtained through the 340B Prime Vendor Program: 888-340-2787 or ApexusAnswers@340bpvp.com. If you have any questions, please contact us at: Office of Pharmacy Affairs, Mail Stop 8W05A, 5600 Fishers Lane, Rockville, MD 20857.

Outpatient Facilities

Would you like to register another outpatient facility? [Register Outpatient Facility](#)

[Return Home](#)

- 8) If you want to register an outpatient facility, click the [Register Outpatient Facility](#) button (see [Registering an Outpatient Facility](#)), or click the [Return Home](#) button to return to the home page.

Once an online registration is submitted, it will be reviewed by OPA. If approved, the Authorizing Official and Primacy Contact will receive a registration confirmation email notifying them of the effective date for participation in the 340B Program, a unique 340B ID for the covered entity, and links to the covered entity's detailed record, OPA contact information, and other relevant information.

[\[Back to the top\]](#)

Registering or Reinstating a Non-Hospital Entity

The following instructions apply when you are registering a non-hospital covered entity:

Note: Occasionally, Federally Qualified Health Center Look-Alike entities will receive Section 330 grant funding and become a full-fledged grantee. In this event, the entity must submit a new registration by selecting the “Consolidated Health Center Program” from the “Covered Entity Type” drop-down box to begin the process.

- 1) On the **Register** screen, click **Covered Entities**.



- 2) The next page you see asks you to identify the type of entity you are registering. Click **A Non-Hospital**.



- 3) The next page asks you to identify the type of non-hospital entity you are registering. Click the drop-down arrow to highlight the applicable entity type.

Important! Registrations instructions and pre-qualification questions will vary based on the type of entity you select. The following example describes a Tuberculosis entity type registration.

- 4) Click the button.

The **Register [entity type abbreviation] Online** page lists important pre-qualification questions.

Pre-Qualification Questions

- 5) Answer **Yes** or **No** to the questions. If your answers make your entity ineligible for participation in the 340B program you will be unable to proceed with registration. If you are not authorized to sign for the entity, OPA will not process your registration.

In the **Entity Reinstatement** section, select **Yes** if you want to reinstate a terminated entity under a previous 340B ID number, or select **No** to register a new facility.

For TB and STD entity types only, a second question, “Do you know whether your organization receives direct grant funding and/or “in-kind” products or services purchased with grant funds under Section 317(j)(2) (42 USCS§247b(j)(2)) of the Public Health Service Act?” appears. Select **Yes** if that is the case.

Register TB Online

This registration form must be completed and submitted according to the established deadlines that are published on the OPA website (www.hrsa.gov/opa). The registration process is not complete unless the registration form has been completed in its entirety.

Pre-Qualification Questions

IMPORTANT: This information is required in order to complete the HRSA OPA Registration process. Should you answer No to any of these questions, you are returned to the HRSA OPA homepage, and unable to complete the Registration form.

1. Are you the Authorizing Official of the covered entity? (The authorizing official may be the President, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, or Program Director. Forms that are signed by an individual that OPA determines is not an acceptable representative will not be processed. If you are in doubt regarding the acceptability of a signature, please contact OPA prior to submission of your registration.) Yes No

2. Do you know whether your organization receives direct grant funding and/or “in-kind” products or services purchased with grant funds under Section 317(j)(2) (42 USC§247b(j)(2)) of the Public Health Service Act? Yes No

Entity Reinstatement

Would you like to reinstate a previously terminated 340B ID? Yes No

For CH and FQHCLA entity types only, the Authorizing Official question is preceded by another question, “Is the site you wish to register active in HRSA’s EHB system?” appears. Select **Yes** if that is the case.

Register CH Online

This registration form must be completed and submitted according to the established deadlines that are published on the OPA website (www.hrsa.gov/opa). The registration process is not complete unless the registration form has been completed in its entirety.

Registration for the 340B drug pricing program is limited to sites that are active in HRSA’s Electronic Handbooks (EHBs). After entering your grant number, you will be asked to select from a list of sites associated with your grant. If the site you wish to register is not on the list or its information is incorrect, you may need to request changes to your approved scope of project. In addition, sites with approved changes cannot be registered until verified within the EHB system. Contact your health center’s assigned Bureau of Primary Health Care (BPHC) Project Officer for further assistance in any of these cases; you will not be able to proceed with 340B registration at this time.

Pre-Qualification Questions

IMPORTANT: This information is required in order to complete the HRSA OPA Registration process. Should you answer No to any of these questions, you are returned to the HRSA OPA homepage, and unable to complete the Registration form.

1. Is the site you wish to register active in HRSA’s EHB system? Yes No

2. Are you the Authorizing Official of the covered entity? (The authorizing official may be the President, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, Executive Director or comparable. Forms that are signed by an individual that OPA determines is not an acceptable representative will not be processed. If you are in doubt regarding the acceptability of a signature, please contact the 340B Prime Vendor Program at 1-888-340-2787 or via email at ApexusAnswers@340bpvp.com prior to submission of your registration form.) Yes No

Entity Reinstatement

Would you like to reinstate a previously terminated 340B ID? (Reinstatements only apply in cases where the BPHC Site ID is unchanged. If the site has relocated or otherwise has a new Site ID, please answer ‘No’ and complete a new registration instead.) Yes No

6) Click the button.

If you selected **No** to the question about reinstating a facility, skip to [Instructions for Completing the 340B Registration Process](#) on page 38.

- 7) **For CH entity types only**, enter the Grant Number when prompted and click the button.

Register CH Online

Please enter your qualifying grant number in the field below. If you do not know your grant number, contact the HRSA Bureau of Primary Health Care (BPHC) Help Line at bphchelpine@hrsa.gov or 1-877-974-BPHC for assistance.

EHB Search Criteria

Grant Number:

- For FQHCLA entity types**, enter the FQHCLA Designation Number when prompted and click the button.

Register FQHCLA Online

Please enter your qualifying FQHC look-alike designation number in the field below. If you do not know your designation number, contact the HRSA Bureau of Primary Health Care (BPHC) Help Line at bphchelpine@hrsa.gov or 1-877-974-BPHC for assistance.

EHB Search Criteria

FQHCLA Designation Number:

- 8) **For CH and FQHCLA entity types**, the EHB Search Results page displays. Select an entity with 340B Status of "Available" and the button.

Register CH Online

Select the site you wish to register for the 340B program from the list below:

EHB Search Results

The number of rows returned: 36 Rows/Page:

	340B Status	Grant Number	Organization Name	Site Name	Address	City	State	Zip Code	Site ID
<input type="radio"/>	Approved	H80CS00663	PRIMARY HEALTH NETWORK, INC.	FARRELL HEALTH CENTER	602 Roemer Blvd	Farrell	PA	16121-1902	BPS-H80-000105
<input checked="" type="radio"/>	Available	H80CS00663	PRIMARY HEALTH NETWORK, INC.	Primary Health Network Administration	100 Shenango Ave	Sharon	PA	16146-1503	BPS-H80-000361
<input type="radio"/>	Approved	H80CS00663	PRIMARY HEALTH NETWORK, INC.	SHEAKLEYVILLE HEALTH CENTER	3339 PERRY HIGHWAY	SHEAKLEYVILLE	PA	16151-2315	BPS-H80-000686
<input type="radio"/>	Available	H80CS00663	PRIMARY HEALTH NETWORK, INC.	PHN Wellness	1000 S Mercer St	New Castle	PA	16101-4672	BPS-H80-002764

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1 2 3 4

Note: Sites in 'Approved' status are currently or will soon become active program participants; sites in 'Pending OPA' status have been submitted for registration and are awaiting review by OPA. Sites in 'Pending EHB Verification' status cannot be registered in the 340B database until EHB verification is complete; grantees should contact the HRSA Bureau of Primary Health Care (BPHC) Help Line at bphchelpine@hrsa.gov or 1-877-974-BPHC if additional assistance is needed.

If you selected **No** to the question about reinstating a non-hospital, skip to [Instructions for Completing the 340B Registration Process](#) on page 38.

Search Criteria for Reinstating a Non-Hospital Entity

If you selected **Yes** to reinstate a terminated entity under a previous 340B ID number, the **Search Criteria** page displays.

- 9) **Search Criteria:** Complete one or more search criteria fields to locate your entity in the 340B database. ([Searching, Viewing, and Exporting Covered Entity Data](#)).
- 10) Click the button. The **Search Results** screen displays the results of your search.

- 11) Select the desired entity and click the button.

Instructions for Completing the 340B Registration Process

The “**Instructions for Completing the 340B Registration Process**” section displays.

- Registration must be started and completed within the same browser session. You cannot save your data entries. If you quit before submitting registration forms, your data will be lost.
- Registration must be signed by an Authorizing Official or someone who can bind the organization to a contract.
- The entity’s primary contact must be an employee, not a contractor or other non-employee.

Register TB Online
Instructions for Completing the 340B Registration Process

Registration Information

NOTE: The Registration Process must be started and completed within the same browser session. Incomplete Registration Forms cannot be saved for later submission.

Registrations must be signed electronically by an Authorizing Official, which is someone who can bind the organization to a contract, such as the CEO, CFO, COO, Executive Director, President or Vice President of the hospital). In addition, the primary contact person may not be a non-employee of the covered entity (i.e. consultants). If you are in doubt regarding the acceptability of a signature, please contact the 340B Prime Vendor Program at 1-888-340-2787 or via email at ApexusAnswers@340bpvp.com prior to submission of your registration form.

Covered Entity Details

***Entity Name:** LOS ANGELES COUNTY DHS

Entity Sub-Division Name: YVONNE BURKE HEALTH CENTER

Entity Type: Tuberculosis

***Employer Identification Number:** 11-1111111 (Enter the registrant's EIN if a sub-grantee/sub-recipient)

Grant Number: (Contact Federal grantee if unknown)

*** Nature of Support:**

- Direct Funding (dollars received from CDC or an intermediate organization)
- In-Kind products or services (see note below; must have been purchased with section 317 funds)
- None

Note: In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.

Continue Undo

Continue Cancel

- 12) **Employer Identification Number:** The entity's nine-digit taxpayer ID is required.
- 13) **Nature of Support:** These check boxes only appear for Tuberculosis (TB) and Sexually Transmitted Diseases (STD) entities only. As appropriate, select the check boxes for the nature of Section 317 funding—either Direct Funding or “In-Kind” products or services purchased with Section 317 funds (or both). Selecting “None” will uncheck the other check boxes if selected and makes an entity ineligible to proceed with registration.
- 14) Click the button.

The next section requires the entity's street address.

Covered Entity Details / Address

The next section, **Covered Entity Address**, is for recording the entity's address. If the billing and/or shipping addresses are different, the section expands to include another address section(s).

Note: A shipping address can be any location to which drugs may be lawfully delivered and that is **not already registered as a contract pharmacy**. The listing of shipping addresses is to give covered entities flexibility in where they wish drugs to be shipped, while also increasing transparency of how the covered entity utilizes the 340B Drug Pricing Program.

Covered entities should be aware that a location being listed as a shipping address does not make that location eligible to use 340B drugs for any individuals treated there.

Once you have advanced to the next registration section, data entered in the previous section becomes read-only unless you click **Edit** to change the data in the previous section. Click **Undo** on the current section to delete the data you have entered and start over.

The screenshot shows a web form titled "Register TB Online". It is divided into two main sections: "Covered Entity Details" and "Covered Entity Address".

Covered Entity Details: This section contains the following information:

- Entity Name: LOS ANGELES COUNTY DHS
- Entity Sub-Division Name: YVONNE BURKE HEALTH CENTE
- Entity Type: Tuberculosis
- Employer Identification Number: 11-1111111
- Grant Number:
- Nature of Support: Direct Funding (dollars received from CDC or an intermediate organization), In-Kind products or services (see note below; must have been purchased with section 317 funds), None.

A red-bordered "Edit" button is located in the top right corner of this section.

Covered Entity Address: This section is divided into two sub-sections:

- Street Address (PO Box Not Allowed):** Contains input fields for Address Line 1 (2509 PICO BLVD), Address Line 2 (2ND FLOOR), City (SANTA MONICA), State (California), and Zip (90405). A red-bordered "Continue Undo" button is in the top right.
- Billing Address:** Contains input fields for Organization Name, Address Line 1, Address Line 2, City, State (Select a State), and Zip. A red-bordered "Continue Undo" button is in the top right.

At the bottom of the form, there are "Continue" and "Cancel" buttons. Two checkboxes are present: "Billing Address Same as Street Address" (unchecked) and "Billing Address Same as Street Address" (checked).

15) Click the **Continue** button.

The registration page expands to display the **Medicaid Billing Information** section.

Medicaid Billing Information

- 16) **Will you bill Medicaid for drugs purchased at 340B drug price?** If you answer **Yes**, the screen expands for entry of the Medicaid Number and/or NPI to be used for the billing.
- 17) If you answer **Yes**, click **Add**. Two fields, **Medicaid Number** and **State**, appear for you to complete. At least one Medicaid or NPI number is required.

Medicaid Billing Continue Undo

Medicaid Billing Information

Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs? Yes No

If "Yes", please provide the entity's Medicaid Provider Number(s) (MPN) and/or National Provider Identifier(s) (NPI) for each applicable entity location that bills Medicaid for 340B drugs. If you are unsure of the entity's MPN and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status and appropriate provider identifier number(s) are accurate in the OPA database and align with your billing practices in order to prevent Medicaid rebates on drugs that were purchased at the 340B discounted price.

All covered entities should notify OPA prior to any change in Medicaid billing status. For more information, please visit the [HRSA website](#).

Medicaid Exclusion Tutorial

Medicaid Number(s): Add

Medicaid Number	State	
3198461667	Maryland	Insert Cancel

NPI Number(s): Add

NPI Number	

Continue Cancel

- 18) Click the **Insert** button to add the Medicaid number to the registration form. The number and state become read-only but you can edit or delete them by clicking the appropriate button.

Medicaid Exclusion Tutorial

Medicaid Number(s): Add

Medicaid Number	State	
2837484981	MD	Edit Delete

NPI Number(s): Add

NPI Number	
	Insert Cancel

Continue Cancel

- 19) Click **Add** to record a NPI number in the same manner.
- 20) Click the **Insert** button to add the NPI number.
- 21) Click the **Continue** button.

The registration page will expand to include contact information for the Authorizing Official and Primary Contact.

Contact Information

This section is for the name and contact information for the Authorizing Official who can legally bind the entity hospital into a contract with the federal government and for a primary contact if that person is different from the Authorizing Official. It is preferable to have different individuals listed as the Authorizing Official and Primary Contact.

- 22) **Authorizing Official:** Enter the name and contact information of the Authorizing Official.

Contact Information

Authorizing Official Continue Undo

*Name:

*Title:

*Phone: (xxx-xxx-xxxx) Ext:

Fax: (xxx-xxx-xxxx)

*Email:

Make Primary Contact Information same as Authorizing Official

Primary Contact Continue Undo

*Name:

*Title:

*Phone: (xxx-xxx-xxxx) Ext:

Fax: (xxx-xxx-xxxx)

*Email:

The primary contact should be someone employed by the Covered Entity

Continue Cancel

- 23) **Make Primary Contact Information the same as Authorizing Official:** Enter the name and contact information for the Primary Contact. If the Authorizing Official and the Primary Contact are the same, select the checkbox to fill The **Primary Contact** fields with the Authorizing Official's information.

- 24) **Primary Contact:** If the primary contact is different from the Authorizing Official, enter contact data for that individual.

- 25) Click the button.

A message will display requesting you to review the registration form for accuracy and completeness before continuing.

Review Information Above

Please review all the information listed above and click "Continue" to proceed to the next step.

Continue Cancel

- 26) Click the button.

Authorize and Submit

You will now affirm that you are the Authorizing Official and can submit your registration.

- 27) Check the box indicating that the individual identified in the **Signed by Official** section has reviewed the registration documentation and is authorized to sign.

Authorizing Signature

The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. The undersigned further acknowledges the 340B covered entity's responsibility to abide by the following:

As an Authorized Official, I certify on behalf of the covered entity that:

- (1) all information listed on the 340B Program database for the covered entity is complete, accurate, and correct;
- (2) the covered entity meets 340B Program eligibility requirements;
- (3) the covered entity will comply with all requirements of Section 340B of the Public Health Service Act and any accompanying regulations including, but not limited to, the prohibition against duplicate discounts and diversion (section 340B(a)(5)(A) and (B) of the Public Health Service Act;
- (4) the covered entity maintains auditable records pertaining to compliance with the requirements described in paragraph (3) above, pursuant to section 340B(a)(5)(C) of the Public Health Service Act;
- (5) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines;
- (6) the covered entity acknowledges its responsibility to contact OPA as soon as possible if there is any change in 340B eligibility and/or breach by the covered entity of any of the foregoing; and
- (7) the covered entity acknowledges that if there is a breach of the requirements described in paragraph (3) that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to removal from the list of eligible 340B entities.

In addition, I have read all applicable registration instructions and I am aware that my registration will not be reviewed if the required supporting documents are not submitted today.

Please provide any additional information that may be helpful in reviewing this registration for 340B eligibility:

Required By checking this box, I confirm that I have read the above statements and fully understand my obligations.

Signed By Official

*** Name:**

*** Title:**

*** Phone:** Ext:

Fax:

*** Email:**

Contract Pharmacies

Contract Pharmacies Information* - You must answer the following questions for Contract Pharmacies.

*** Would you like to register one or more Contract Pharmacies at this time?** Yes No

Adding Contract Pharmacies (New Registrations)

- 28) If are submitting a new entity registration (i.e., not a reinstatement), you will be asked if you want to add one or more contract pharmacies at this time, select the **Yes** option and proceed as follows.

If you do not want to add any contract pharmacies, select the **No** option (skip to step 33).

- 29) Click the button.

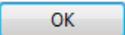
The following message window is displayed to inform you that contract pharmacy agreements must be registered online and to certify that fully executed agreements are in effect; that the agreements must conform to 340B guidelines an applicable federal, state, and local requirements; and that the start date for the contract pharmacy agreement is set when OPA approves it and may not precede the participating start date for the covered entity.

Covered entities that plan to utilize contract pharmacy arrangements to dispense drugs purchased under the 340B Drug Pricing Program must register the arrangements online and must certify electronically that fully executed agreement(s) are in effect with the contract pharmacy or pharmacies.

All agreements must satisfy the elements outlined in the guidelines that govern the operation and compliance of contract pharmacies for 340B covered entities. Prior to registration, covered entities are strongly encouraged to have their legal counsel review all contracts and associated documents to ensure compliance with applicable Federal, State and local requirements. OPA will not review contracts.

START DATE – The Contract Pharmacy start date is set at the time OPA approves the contract pharmacy arrangement or at a later date if requested. The contract pharmacy arrangement should not begin prior to the start date shown on the OPA database. OPA will NOT post a retroactive start date. The contract pharmacy start date may not precede the participating start date of the covered entity. For example, an organization added as a covered entity for the quarter beginning April 1 may not have a contract pharmacy start date prior to that same date.

OK Cancel

30) Click the  button to continue.

If you elected to add contract pharmacies, the **Contract Pharmacy** message prompts you to confirm that the contract between the covered entity and the pharmacy has been fully executed by both parties.

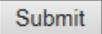
Contract Pharmacy

Has the written contract between the covered entity and the pharmacy been fully executed by both parties?

Yes No

(Do NOT register a contract pharmacy arrangement if the contract terms are still under negotiation.)

Cancel Submit

31) Select the **Yes** option and click the  button.

The **Covered Entity Authorizing Official Verification** page prompts you to confirm that the Authorizing Official information is correct.

Covered Entity Authorizing Official Verification

	340B ID	Entity Type	Entity Name	Sub Name	Address	City	State	Start Date	Term Date	Edit Date
<input checked="" type="radio"/>	Pending	FP	Downtown Family Planning		123 Main Street	Denver	CO			

Is the authorizing official information correct for the selected covered entity? Yes No

The Authorizing Official for the covered entity will receive a separate email with instructions on how to certify the contract pharmacy arrangement(s) you are about to register.

CE Authorizing Official

Name: Dave Tester
Title: Tester
Phone: 888-555-1212 **Ext:**

Continue Cancel

32) Select the **Yes** option and click the  button.

The Contract Pharmacy Search Criteria page is displayed to allow you to search for contract pharmacies to add. (Refer to [Registering a Contract Pharmacy](#) for more information on adding contract pharmacies.)

	340B ID	Entity Type	Entity Name	Sub Name	Address	City	State	Start Date	Term Date	Edit Date
<input checked="" type="radio"/>	Pending	FP	Downtown Family Planning		123 Main Street	Denver	CO			

Search Criteria

Pharmacy selection– The 340B database relies on information received from the U.S. Drug Enforcement Administration (DEA); you may search for pharmacies by DEA number, name, city, state or zip code.

DEA Number:

I do not know the Pharmacy DEA number (**search** by name, city, state, and/or zip).

If the pharmacy will never have a DEA certificate because the pharmacy does not dispense controlled substances, contact **OPA** for assistance.

- 33) If you did not elect to add any contract pharmacies, the last page notifies you that your registration request has been submitted to OPA.

Register TB Online

**YOUR ELECTRONIC REGISTRATION REQUEST HAS BEEN SUBMITTED TO
THE OFFICE OF PHARMACY AFFAIRS!**

Your registration will be reviewed to determine eligibility for the 340B program. You will be contacted if any additional information is required.

If you have any questions, please contact the 340B Prime Vendor at 888-340-2787 or ApexusAnswers@340Bpvp.com.

Once an online registration is submitted, it will be reviewed by OPA. If approved, the Authorizing Official and primacy contact will receive a registration confirmation email notifying them of the effective date for participation in the 340B Program, a unique 340B ID for the covered entity, and links to the covered entity’s detailed record, OPA contact information, and other relevant information.

(Back to [Getting Started Guide for Public Users.](#))

[\[Back to the top\]](#)

Other Covered Entities Guides

[Searching, Viewing, and Exporting Covered Entity Data](#)

[Submitting a Change or Termination Request](#)

[Daily Covered Entities Report](#)

[Recertifying/Decertifying a Covered Entity](#)