

Overview of the 340B Tuberculosis Drug Pricing Program for Health Departments

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Common Terms and Phrases

HRSA: Health Resources and Services Administration. Federal agency that operates the 340B program

OPAIS: Office of Pharmacy Affairs Information System. Online system where users can view and update their profile and look up 340B drug prices

Covered Entity: An agency that is certified and approved to participate in the 340B program. This includes public health departments, hospitals and community health centers.

340B ID: A unique identification number assigned to each Covered Entity. 340B ID numbers are specific to both the agency and the program. For example, a health department that is certified for both TB and STD services will have a unique 340B ID number for both TB and STD prescription drugs. 340B TB ID numbers are formatted as TBXXXXXX or TBXXXXX.

Covered Drug: A drug that is covered by or included in the 340B program.

Authorizing Official: The person identified to the 340B program and HRSA who gives final approval and is considered legally responsible for a Covered Entity. Peter is the Authorizing Official for almost all HDs. This makes many of the administrative tasks simpler to complete and reduces hassle for HD users.

Primary Contact: The person identified to the 340B Program and HRSA as “go to” for each Covered Entity. Generally, this is the Communicable Disease or Personal Health supervisor, Health Officer or Medical Director. The Primary Contact can be changed to another person, either by the current Primary Contact (assigning their role to another person) or by Peter. The Primary Contact can’t be the same person as the Authorizing Official.

NPI number: National Provider Identifier. A unique identification number for health care providers covered under the Health Insurance Portability and Accountability Act (HIPAA). HRSA and the 340B program use a physician’s NPI number to help make sure that if Covered Entities bill Medicaid for drugs purchased at 340B prices, the appropriate purchase price is documented for Medicaid reimbursement. HDs only need to provide an NPI number to the 340B program if they will bill Medicaid for drugs purchased at 340B prices. Generally, this should be your Medical Director’s NPI number.

Billing & Shipping Addresses: The OPAIS allows Covered Entities to declare different addresses for billing or shipping than the primary address. You could specify these in your 340B profile in OPAIS so pharmacies or distributors will know and verify that shipments of TB drugs should go to your clinic address.

Frequently Asked Questions

What is the 340B drug pricing program?

Named for Section 340(B) of the Federal Public Health Service Act, this Federal program empowers the Health Resources and Services Administration to negotiate and set purchase prices for drugs directly with the manufacturers of those drugs. These 340B prices are less than wholesale and are only available to agencies that participate in the 340B program.

- i. 340B Info page: <https://www.hrsa.gov/opa/index.html>. This site contains general information about the 340B program and requirements of agencies to participate in 340B.
- ii. 340B Office of Pharmacy Affairs Information System page: <https://340bregistration.hrsa.gov/login>. This site contains 340B Program user profiles, allows users to update or recertify their profiles and look up pricing information.

Why is my health department eligible now?

Effective 10/1/2019, the MDHHS TB Program provided funding from our CDC TB grant to all health departments (HDs). Receiving this funding makes your HD eligible to participate in 340B for TB drugs.

The website listed above also contains details about eligibility and program requirements to participate in 340B.

Who from my health department can access the 340B website?

The person identified as your HD's Primary Contact. If you aren't sure who that is for your HD, contact Peter at davidsonp@michigan.gov or 517-284-4922.

Are health departments allowed to bill Medicaid for TB drugs purchased through the 340B TB program?

Yes. Your HD will need to provide your unique NPI number, which can be found in your OPAIS profile.

How do I find my health department's 340B ID number?

Log in to your HD's OPAIS profile and it will be listed on the main page of your profile, near the Agency Name. Your 340B ID will be formatted as TBXXXXXX or TBXXXX. See the "Navigating the 340B OPAIS Website" section for more information.

Do I have to do anything different now that my health department is certified in 340B?

No. Peter will handle most of the administrative issues like updating certification or recertifying your HD.

How do I get 340B pricing when I order TB drugs?

Tell whomever you order drugs from (pharmacy, distributor, etc.) that your HD is a 340B Covered Entity and give them your 340B ID number. Confirm with them that they are quoting you the 340B price and that they use that price when you place the order.

How can I look up the current 340B prices for TB drugs?

HRSA updates their pricing info quarterly, on the first business day of January (covers January – March), April (covers April – June), July (July – September), October (October – December). See the "Checking 340B Drug Prices" section in "Navigating the 340B OPAIS Website" for more detailed information.

Does my health department need to use specific funds to purchase TB drugs?

Your HD can't use the TB money provided by MDHHS to purchase TB drugs. This is a restriction by CDC that does not allow CDC grant funds to be used by any recipient for purchasing drugs. Other than this, there are no other requirements or restrictions of how your HD pays for drugs purchased at 340B price.

Do I need to report drug purchases from the 340B program to HRSA or MDHHS?

No, there is no reporting requirement to participate in this program.

Who at MDHHS can help me with 340B TB questions?

Peter Davidson, 517-284-4922, davidsonp@michigan.gov

Navigating the 340B OPAIS Website

Login to Your 340B Profile

1. Open <https://340bregistration.hrsa.gov/login> in your browser window. The OPAIS website will only work in Chrome or Internet Explorer version 9, 11, or later.
2. In the “Email address” field, enter your HD’s Primary Contact email. In the “Password” field, enter your Primary Contact’s password for the OPAIS site. Click “Sign in”.
3. OPAIS uses two-factor authentication. The OPAIS system will send an email with a unique 6-digit code to the Primary Contact’s email account.

Watch for that email and enter the code in the field under “Enter Authentication Code.” Click “Submit code.”

4. Mark the checkbox indicating that you agree to the Rules of Behavior, then click “Agree”.

5. Your home screen contains a list of options or activities available to you. Click the “My Entities” button to view the list of 340B programs to which you have access.

- You will see a list of all 340B IDs for which you are listed as the Primary Contact or Authorizing Official. In the example below, we see two Family Planning (begin with “FP”) and one TB (begin with “TB”) 340B IDs. Click your TB 340B ID to open your HD’s profile.

My Entries Export

340B ID	MPN/Grant Number	Name	SubName	Address Line 1	Address Line 2	City	State	Type	340B Status
FP-████	██████████	██████████ County Health Department	██████████	██████████	██████████	██████████	MI	FP	Active
FP-████	██████████	██████████ COUNTY HEALTH DEPARTMENT	██████████	██████████	██████████	██████████	MI	FP	Active
TB-████	██████████	██████████ COUNTY HEALTH DEPARTMENT	██████████	██████████	██████████	██████████	MI	TB	Pending

- Your profile shows all the key details of your 340B certification and status. For example, your 340B ID is displayed near the top under your Agency name. Medicaid Billing and NPI details are available by clicking the “Medicaid Billing” tab under the Authorizing Official and Primary Contact box.

Name ██████████ COUNTY HEALTH DEPARTMENT

Subdivision Name ██████████

Type Tuberculosis

340B ID TB496844

Grant Number ██████████

Employer Identification Number (EIN) ██████████

Nature of Support Direct Funding (dollars received from CDC or an intermediate organization)
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.

Authorizing Official Michigan Department of Health & Human Services
 PETER DAVIDSON, TB PROGRAM MANAGER
 (517) 284-4922
 davidsonp@michigan.gov

Primary Contact ██████████

Current Program Status Pending

Registration Date 10/8/2019

Participating Start Date

Participating Approval Date

Last Recertification Date

Street Address ██████████

Billing Address Same as Street Address

Comments **Medicaid Billing** CE Attachments Shipping Addresses Contract Pharmacies History

Comment ↑

No records to display.

- To log out from the OPAIS system, click your username at the top right of the profile window, and then the drop-down for “Logout”.

HRSA Office of Pharmacy Affairs
 Health Resources & Services Administration 340B OPAIS

Home davidsonp@michigan.gov Help

Only Favorites Edit Favorites

Edit Profile
 Logout ←

Editing Your 340B Profile

1. Log in to your profile as described above. To change or edit any information in your profile, click “Change Request” at the top right of your profile window.

The screenshot shows a web interface for a 340B profile. At the top, there is a header bar with the text "COUNTY HEALTH DEPARTMENT (Active)" and a red arrow pointing to a "Change Request" button. Below the header, the profile information is organized into several panels:

- Name:** COUNTY HEALTH DEPARTMENT
- Subdivision Name:** Tuberculosis
- Type:** Tuberculosis
- 340B ID:** [Redacted]
- Grant Number:** [Redacted]
- Employer Identification Number (EIN):** [Redacted]
- Nature of Support:** Direct Funding (dollars received from CDC or an intermediate organization). 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.
- Authorizing Official:** Michigan Department of Health & Human Services, PETER DAVIDSON, TB PROGRAM MANAGER, (517) 284-4922, davidsonp@michigan.gov
- Primary Contact:** [Redacted]
- Current Program Status:** Active
- Registration Date:** 1/1/2003
- Participating Start Date:** 1/1/2003
- Participating Approval Date:** 11/21/2004
- Last Recertification Date:** 5/17/2019
- Street Address:** [Redacted]
- Billing Address:** Same as Street Address

At the bottom of the profile, there are tabs for "Comments", "Medicaid Billing", "CE Attachments", "Shipping Addresses", "Contract Pharmacies", and "History". Below these tabs is a comment section with a text input field, dropdown menus for "Comment Type", "Last Updated By", and "Last Updated On", and a "No records to display" message.

2. Notice that each section of information is now displayed as its own panel, with a link at the top right of each panel to Edit the contents. For example, to edit your HD’s address info, you’d click “Edit Addresses”.

The screenshot shows the "Covered Entity Details" panel. It contains the following information:

- 340B ID:** [Redacted]
- Entity Name:** COUNTY HEALTH DEPARTMENT
- Entity Sub-Division Name:** Tuberculosis
- Entity Type:** Tuberculosis
- Employer Identification Number (EIN):** [Redacted]
- Grant Number:** [Redacted]
- 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.
- Street Address:** [Redacted]
- Buttons:** A red arrow points to an "Edit Addresses" link.
- Other Options:**
 - Billing Address same as Street Address
 - Shipping Address same as Street Address

- After making any changes, scroll to the bottom of the screen and click “Continue”. You will then get a screen showing all information in your profile. When you are finished making edits, scroll to the bottom of the screen, check the confirmation box and click “Submit.”

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

Cancel Submit

Checking 340B Drug Prices

- Log in to your profile as described above. In the home screen, click the “Pricing” icon. The OPAIS will require you to login again.



- The Drug Pricing home screen will show you all Covered Drugs by default. Use the “Product Name” field to search for specific drugs by name. For example, to search for Isoniazid, type it in the “Product Name” field and filter by “Contains”.

National Drug Code	Product Name	Manufacturer Name
	isoniazid	
00002120001	AMYVID VIAL	
00002140701	QUINIDINE GLUC 80 MG/ML VIAL	
00002143301	TRULICITY 0.75 MG/0.5 ML PEN	
00002143380	TRULICITY 0.75 MG/0.5 ML PEN	

Filter dropdown menu:

- NoFilter
- Contains
- DoesNotContain
- StartsWith
- EndsWith
- EqualTo
- NotEqualTo

- This search will show you all covered formulations of Isoniazid in the 300 mg tablet by all Manufacturers. Prices are shown in the “Ceiling Price” column.

National Drug Code	Product Name	Manufacturer Name	Market Date	Ceiling Price	Flag
	isoniazid 300 mg tablet				
00143126101	ISONIAZID 300 MG TABLET	HIKMA PHARMACEUTICAL USA, INC.	12/09/1996		
00143126110	ISONIAZID 300 MG TABLET	HIKMA PHARMACEUTICAL USA, INC.	12/09/1996		
00143126130	ISONIAZID 300 MG TABLET	HIKMA PHARMACEUTICAL USA, INC.	12/09/1996		
00185435001	ISONIAZID 300 MG TABLET	EON LABS, INC.	09/30/1990		
00185435010	ISONIAZID 300 MG TABLET	EON LABS, INC.	09/30/1990		
00185435030	ISONIAZID 300 MG TABLET	EON LABS, INC.	09/30/1990		
00527110901	ISONIAZID 300 MG TABLET	LANNETT COMPANY, INC.	02/28/2002	\$0.06	
00527110910	ISONIAZID 300 MG TABLET	LANNETT COMPANY, INC.	02/28/2002	\$0.06	
00527110930	ISONIAZID 300 MG TABLET	LANNETT COMPANY, INC.	02/28/2002	\$0.06	
00555007101	ISONIAZID 300 MG TABLET	BARR LABORATORIES INC.	09/30/1990	\$0.06	
00555007102	ISONIAZID 300 MG TABLET	BARR LABORATORIES INC.	09/30/1990	\$0.06	
00555007105	ISONIAZID 300 MG TABLET	BARR LABORATORIES INC.	09/30/1990	\$0.06	
51079008301	ISONIAZID 300 MG TABLET	MYLAN INSTITUTIONAL, INC.	09/30/1990	\$0.10	
51079008320	ISONIAZID 300 MG TABLET	MYLAN INSTITUTIONAL, INC.	09/30/1990	\$0.10	
51079008324	ISONIAZID 300 MG TABLET	MYLAN INSTITUTIONAL, INC.	09/30/1990		
51079008340	ISONIAZID 300 MG TABLET	MYLAN INSTITUTIONAL, INC.	09/30/1990		
60687015801	ISONIAZID 300 MG TABLET	AMERICAN HEALTH PACKAGING	04/06/2016	\$0.84	
60687015811	ISONIAZID 300 MG TABLET	AMERICAN HEALTH PACKAGING	04/06/2016	\$0.84	

Note that prices are show per unit. For tablets, this means the price shown is per single tablet.

- Click the “National Drug Code” for a given item to view its packaging details and package price information. Many listings will include a Package Size (e.g. bottle of 100 tablets) and a Package Adjusted Price (e.g. price per bottle).

Manufacturer Contact Information

Manufacturer Name: LANNETT COMPANY, INC.
Contact Name: Freddy Rosado
City, State Zip Code: PHILADELPHIA, PA 19154

Product Information

NDC: 00527110901
Market Date: 02/28/2002
Brand Name: ISONIAZID 300 MG TABLET
Termination Date:
Reactivation Date:
Drug Category: Non-Innovator Multiple Source
FDB Unit Type: Each (tablets, kits, etc.)
Drug Type: Prescription (RX)
CMS Unit Type: Tablet

Ceiling Price Chart

Effective Date	Ceiling Price
2019-2	\$0.09
2019-3	\$0.06
2019-4	\$0.06

Ceiling Price History

National Drug Code	Effective Year	Effective Quarter	Package Size	Case Package Size	Ceiling Price	Raw Ceiling Price	Package Adjusted Price	Flag
00527110901	2019	4	100.000	1	\$0.06	\$0.057343	\$5.73	
00527110901	2019	3	100.000	1	\$0.06	\$0.057343	\$5.73	
00527110901	2019	2	100.000	1	\$0.09		\$8.56	