



MDHHS STD 340B WEBINAR

TUESDAY, MAY 12 – 3:00-4:00PM

WELCOME!



Please enter your first and last name and your organization in the Q & A box on the right-hand side of the screen.

A screenshot of a Q&A form interface. At the top, it shows the user's name "Irda Dothage (You)", the time "11:12 AM", and a "Private" status icon. Below this is a text input field containing "Irda Dothage, MDHHS, Lansing, MI". Underneath the input field is a "Reply" button with a left-pointing arrow. Below the reply button is a section titled "Asking as Irda Dothage". Inside this section is another text input field containing "Ask a question". At the bottom of the form, there is a checkbox labeled "Post as anonymous" and a right-pointing arrow button.

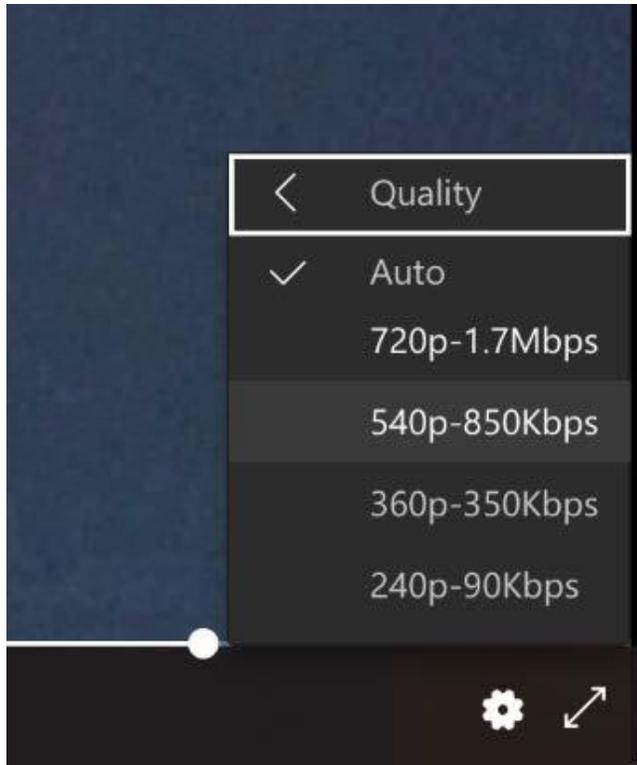
We will be emailing slides, video recording, and all attachments following today's webinar.

AGENDA



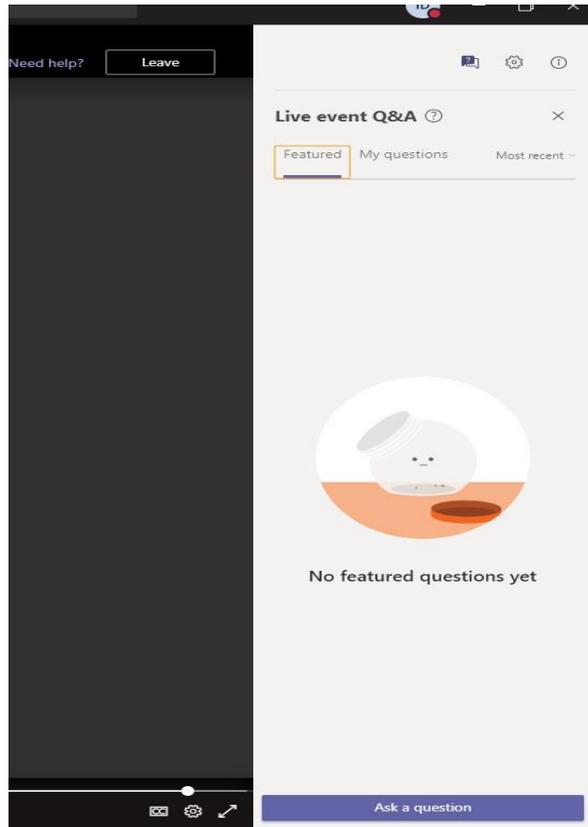
Time:	Topic:	Presenter:
3:00 – 3:04	Welcome Teams: tips for how to use	Marion Pokrzewinski
3:04 – 3:24	Recertification 2020 updates <ul style="list-style-type: none">• Overview of Process• Time frame	Tom Dunn
3:24 – 3:29	Centralized Distribution Model Overview & History	Kris Tuinier
3:29 – 3:34	Centralized Distribution Plan Explanation	Andrew Hoffman
3:34 – 3:44	Attestation Letter & Attestation FAQs Policy and Procedures	Irda Dothage
3:44 – 3:59	Question and Answer Session	All
3:59 – 4:00	Wrap up	Tom Dunn

TIPS ON HOW TO USE TEAMS: SETTINGS

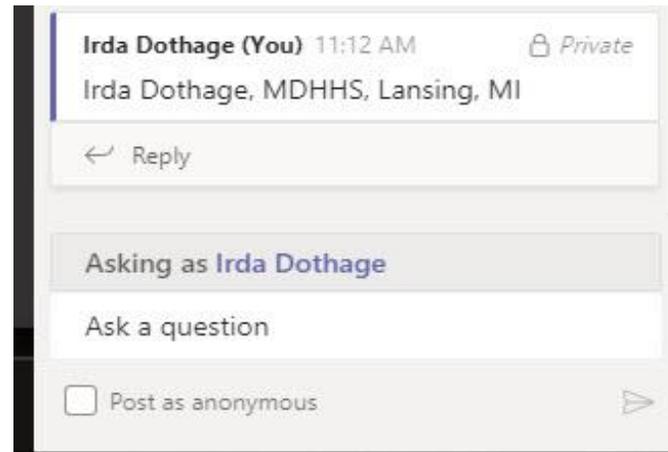


- Please make sure that you are using the supported web browsers like Chrome, Firefox, or Edge for the best experience. Safari is not currently supported.
- If the live event begins in low resolution, you might need to manually reset it to a higher resolution.
- It is suggested to sign in with only one form of audio.
- You will remain on mute throughout the webinar.

PARTICIPATING IN Q & A



- Select Q&A on the right side of the screen.
- Reminder: we ask that you type your first, last name and the name of your organization in the question box.



TEAMS:TROUBLESHOOTING/TIPS



- To turn on live captions and subtitles, select Caption/Subtitles in your video controls.
- You will notice the caption feature at the bottom of your screen like shown below.
- If for some reason you have technical difficulties and you leave the event, you can click on the event link again to rejoin.
- Once the live event is over, you can still watch the recording using the same link.



Caption

RECERTIFICATION



- Required by Statute.
- Ensures program integrity, compliance, transparency and accountability.
- Ensures accuracy of covered entity information in the 340B OPAIS.
- Ensures the accuracy of contract pharmacies listed in 340B OPAIS.



340B REGISTRATION/RECERTIFICATION



Overview:

Registration:

Registration is the process of adding a covered entity, outpatient facility, or contract pharmacy to the 340B program that is not already participating. A new site can only be added to the [HRSA 340B OPAIS](#) during the following quarterly open registration windows:

Register	Start Date
January 1-15	April 1
April 1-15	July 1
July 1-15	October 1
October 1-15	January 1

The steps in the enrollment process are:

1. Entity submits online 340B registration or update to OPA

3. OPA updates 340B OPAIS

2. OPA verifies information in support of 340B program integrity

RECERTIFICATION MUST BE COMPLETED BY 6/10/2020 for Program Group STD. Covered entities that fail to recertify by the completion date will be removed from the 340B program on the first day of the following quarter.



340B RECERTIFICATION KEYS



Keys to successful recertification:

- Verify and update necessary contact information (AO/PC) for **ALL** associated sites in the 340B OPAIS prior to recertification.
- Monitor 340B Program webpage and email messages prior to recertification.
- Do not mistake submission of a 340B OPAIS online change request for performing recertification.
- Review and print out the OPAIS recertification users guide which is available in the “Help” menu.



340B RECERTIFICATION STEPS



1. All entities currently listed in 340B OPAIS will be required to recertify annually (except those sites with a pending termination date).
2. AO/PC will recertify using normal log in credentials. Recertification tasks will appear in the AO and PC “My Tasks” list. OPA will only receive recertification requests that have been attested to by the AO.
3. The AO will be required to recertify the covered entity and verify that contract pharmacy information associated with the covered entity is accurate.



340B RECERTIFICATION STEPS, CONT.



4. After completing all program updates, the AO will “Certify” the information is true, accurate, and the covered entity will be in compliance with all program requirements. The AO must attest and hit “submit” for certification to be completed.

5. HRSA/OPA will review certifications and determine to accept all or reject all proposed changes to the database.

6. HRSA/OPA will recertify or decertify the covered entity.

7. The AO and PC (unless changed during the process) will receive a completion email notification and have the ability to review the covered entity record.



RECERTIFICATION LESSONS LEARNED/HELPFUL TIPS



- The purpose of recertification is to verify and update CE information listed in OPAIS and attest to compliance.
- PO Boxes are only authorized for an entity's billing address.
- It is highly recommended that CEs print the recertification user guide for assistance (available in the “Help” menu when logged in).



RECERTIFICATION LESSONS LEARNED/HELPFUL TIPS CONTINUED



- Have your 340B ID available when requesting technical assistance.
- Pharmacies are not authorized to have their own unique 340B ID.
- An entity will not be able to view changes in 340B OPAIS until HRSA/OPA has signed off on the entity's certification.
- Failure to perform recertification for all sites associated with the AOs user account by the established deadline will result in removal from the 340B Program.



RECERTIFICATION LESSONS LEARNED/HELPFUL TIPS CONTINUED



- Entities that wait until the last days of recertification may experience delays in technical assistance.
- Once a CE certifies all of its sites, the entity loses the ability to adjust its record unless the record is returned by OPA for correction.
- If the PC performs a recertification task, the AO must attest to the task before it is sent to HRSA/OPA.
- HRSA/OPA will only receive recertification tasks once the AO attests to them.



RECERTIFICATION LESSONS LEARNED/HELPFUL TIPS CONTINUED



- Once recertification has started, only change requests for AOs shall be processed.
- Make sure Federal Grant Numbers are updated on all records. Contact your State Program Manager if you are unsure of this number.

Grant number formats:

- ~~STD-IH25PSxxxxxx~~ **NH25PS005170**
- TB-IU52PSxxxxxx
- FP- FHPAxxxxxx
- Grant numbers that do not follow these formats will not be accepted and must be corrected for sites to be certified.



RECERTIFICATION LESSONS LEARNED/HELPFUL TIPS CONTINUED



- Verify your “Nature of Support,” whether “Direct” or “In-Kind.”
- If an entity determines a site requires decertification- it should be prepared to answer the following questions:
 - The date that the reason for termination was effective.
 - A brief description of the facts surrounding the reason for termination and how the effective date was determined; and
 - The last day that 340B drugs were or will be purchased under the 340BID.



HRSA CENTRALIZED DISTRIBUTION PLAN: PART I



- MDHHS Medications
 - Purchased via multi-state contract
 - Supported LHDs and select partner agencies
 - Designated LHDs and other STD providers as 340B covered entities
- Shift in MDHHS-purchasing
 - Significant cost saving
 - Additional process requirements
- Distribution
 - Pre-MDHHS using 340 B
 - Now
 - Savings came with requirements
 - Allowed for program expansion

HRSA CENTRALIZED DISTRIBUTION PLAN: PART 2



MDHHS-DHSP purchases and distributes medications purchased at 340B cost to eligible patients working with eligible contract partner covered entities.

Only entities which agree to the contract requirements will receive medications purchased at the 340B discount and distributed by MDHHS-DHSP

Covered entities agree to support robust monitoring of the distribution and dispensing of these medications to prevent diversion or duplicated discounts.

MDHHS purchases antimicrobial medications for the treatment of syphilis, gonorrhea, chlamydia, bacterial vaginosis and trichomoniasis.

Contract partner covered entities may distribute MDHHS-DHSP 340B Medications azithromycin, cefixime and doxycycline for the treatment of gonorrhea and/or chlamydia for the partner(s) of eligible patients in order to effectively treat eligible patient. (EPT)

MDHHS-DHSP is responsible for compliance for medications purchased using the MDHHS-DHSP 340B ID at each of the sites which are part of this model. As the supplier in this model, the MDHHS-DHSP program, along with a PBM, takes responsibility for monitoring and auditing the program for compliance.



ATTESTATION LETTER



Agreement to Participate in Michigan Department of Health and Human Services (MDHHS) Division of HIV and STD Programs (DHSP) STD 340B Medication Distribution

Date: _____

Covered Entity: _____

Type of support from MDHHS-DHSP: In-kind / Direct

_____ (the covered entity) receives support from the MDHHS-DHSP CDC Sexually Transmitted Disease Prevention and Control for Health Departments (STD PCHD), federal grant number **NH25PS005170** and is therefore eligible to receive STD medications purchased at 340B discount pricing.

As part of the Michigan Sexually Transmitted Disease Clinical Service Safety Net, and an essential partner in providing STD testing and treatment to the population of Michigan, the covered entity agrees that it may receive medications distributed from the MDHHS-DHSP STD 340B Program.

If the centralized distribution model is approved by HRSA, the covered entity will abide by MDHHS-DHSP STD 340B Program requirements to participate in this model. The covered entity understands that this will include the following elements:

- Maintain policies and procedures which ensure receipt, storage, and dispensing of 340B medications within HRSA OPA regulations.
- Keep auditable health records which will be available as necessary for program monitoring.
- Consistently maintain documentation of chain of possession of medications, medication supply, and dispensing of medications; provide documentation to MDHHS-DHSP as needed for program participation.
- Report any waste or loss of MDHHS-DHSP STD 340B medications or any discovered non-compliance with HRSA OPA regulations to MDHHS-DHSP as soon as possible.

- Not bill Medicaid or other payers for medications distributed by MDHHS-DHSP STD 340B program.
- Permit remote documentation monitoring or on-site audit and monitoring visits by MDHHS-DHSP staff or associated pharmacy benefit manager to ensure compliance with HRSA OPA regulations.
- Notify MDHHS-DHSP STD 340B program of any change in organizational policy relating to the distribution, storage, and dispensing of 340B medications or of discontinuation of participation in the program.
- Suspension from the MDHHS-DHSP STD 340B medication program if the above conditions cannot be met until issues can be documented as resolved.

_____ understands that this is an agreement to participate in the centralized distribution model and has reviewed the MDHHS STD 340B Policy and Procedure Manual. Following HRSA approval, additional contractual documentation of agreement to be part of this model will follow, to be approved by both the covered entity and MDHHS-DHSP.

Primary Contact Signature: _____

Name: _____

ATTESTATION LETTER FAQs



What is the purpose of this Attestation Letter?

- HRSA requirement for MDHHS-DHSP Centralized Distribution Model approval
- Agreement to participate in MDHHS-DHSP Centralized Distribution Model
- Signed and submitted by a primary contact from every entity that participates in the model

Is this a contract?

- No, this is not a contract.
- This is an attestation to participate in the MDHHS-DHSP Centralized Distribution Model

ATTESTATION LETTER FAQs CONT.



Does my Local Health Department have to agree to this model to receive medications from MDHHS-DHSP?

- Yes

What will be next steps be after HRSA approves the centralized distribution model?

- MDHHS-DHSP will continue to operate in centralized distribution model.

Will MDHHS-DHSP help my Local Health Department to build and ensure compliance with these elements?

- Yes, we can provide help.
- We want to work with your Local Health Department.

ATTESTATION LETTER ELEMENTS



- Maintain policies and procedures which ensure receipt, storage, and dispensing of 340B medications within HRSA OPA regulations.
- Keep auditable health records which will be available as necessary for program monitoring.
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ATTESTATION LETTER ELEMENTS CONT.



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- Suspension from the MDHHS-DHSP STD 340B medication program if the above conditions cannot be met until issues can be documented as resolved.

SUBMITTING ATTESTATION LETTER



U.S. Department of Health and Human Services > HRSA > OPA

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

[Home](#) [Search](#) [Reports/Files](#)

[dunnt2@michigan.gov](#) [Help](#)

Print

Covered Entity Details

[Edit Main Details](#)

340B ID

STD489109

Entity Name

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

Entity Sub-Division Name

DIVISION OF HIV and STD Programs

Employer Identification Number (EIN)

38-6000134

Entity Type

Sexually Transmitted Diseases

Grant Number

NH25PS005170

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 318 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.

Participant Approval Date

11/26/2004

Last Recertification Date

6/7/2019

SUBMITTING ATTESTATION LETTER CONT.



Addresses Edit Addresses

Type	Name	Address Line 1	Address Line 2	Suite	City	State	Zip
Street Address		MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, FIELD SERVICES AND STD PREVENTION SECTION	109 W. Michigan Avenue	10th Floor	LANSING MI		48913
Billing Address	MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES	BUDGET FINANCE ADMINISTRATION - ACCOUNTING SECTION	PO BOX 30720		LANSING MI		48909
Shipping Address	MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES	927 TERMINAL ROAD	NEW ACCOUNT PACKET/LOA		LANSING MI		48906
Shipping	MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES	525 W. ALLEGAN STREET	MMCAP ID 22010101	1ST	LANSING MI		48933

Contacts Edit Contacts

Authorizing Official
Tom E Dunn
DHSP Operation Manager
Phone: 5173733725
Email: dunnt2@michigan.gov

Primary Contacts
Kristine Tuinier
STD Section Manager
Phone: 3134564426
Email: TuinierK@michigan.gov

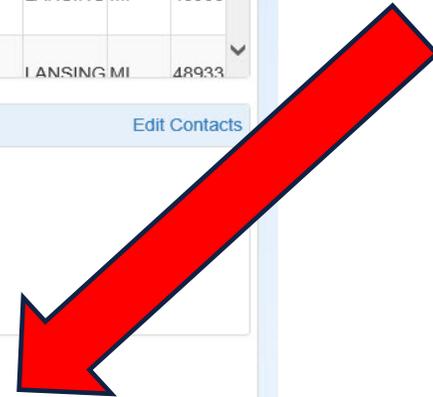
Attachments Info [Medicaid Billing](#) [Comments](#) [History](#)

[Upload Attachments](#) [Select from Existing Attachments](#)

ID	FileName	Document Name	Attachment Type	Uploaded On	Uploaded By	Comment	Modify Attachments

No attachments to display.

- Go to “Upload Attachment”
- Add signed attestation form
- Submit by June 10th



POLICY AND PROCEDURE MANUAL



STD 340B PROGRAM POLICY AND PROCEDURE MANUAL

State of Michigan Department of Health and Human Services
Division of HIV and STD Programs (DHSP)

- Will be emailed in entirety following this webinar
- Will be posted on [Michigan.gov/HIVSTD](https://www.michigan.gov/HIVSTD) website

POLICY AND PROCEDURE MANUAL PURPOSE



- Outlines the policies and procedures that MDHHS-DHSP uses to:
 - Oversee the 340B Program operations
 - Provide oversight of contracted agencies and their 340B programs
 - Maintain a compliant 340B program
- Can be used as a model for your own policies and procedures
- Must be reviewed as a part of the Attestation Letter agreement



QUESTIONS?

PLEASE USE THE Q&A CHAT BOX TO TYPE IN YOUR QUESTIONS.



THANK YOU!

AS A REMINDER, PLEASE MAKE SURE YOU ENTERED YOUR FIRST AND LAST NAME AND YOUR ORGANIZATION IN THE Q & A BOX ON THE RIGHT-HAND SIDE OF THE SCREEN.

WE WILL BE EMAILING SLIDES, VIDEO RECORDING, AND ALL ATTACHMENTS FOLLOWING TODAY'S WEBINAR.