



GRETCHEN WHITMER, GOVERNOR | ELIZABETH HERTEL, DIRECTOR

MDHHS STI 340B PROGRAM WEBINAR

May 13th and 14th, 2024

WELCOME TO THE MDHHS 340B STI
PROGRAM - RECERTIFICATION AND
UPDATES WEBINAR.

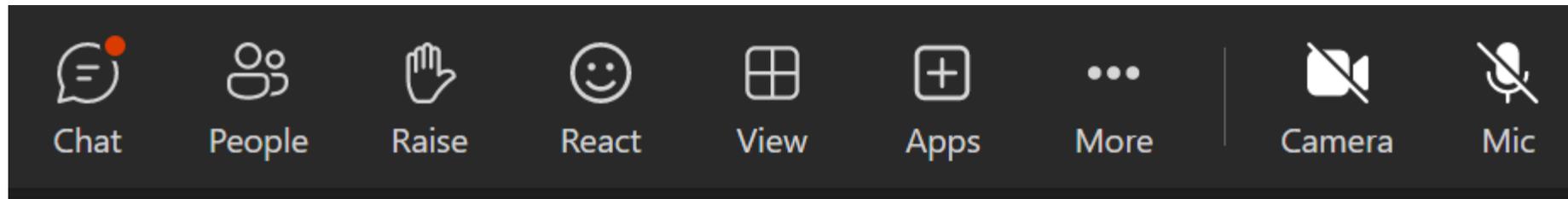
PLEASE ENSURE THAT YOUR MICROPHONE
IS ON MUTE.

THANK YOU FOR PARTICIPATING IN OUR
WEBINAR.

WELCOME!



- Please keep yourself on mute and cameras off is preferred
 - Please utilize the chat box for questions



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

MDHHS 340B STI PROGRAM WEBINAR – AGENDA

- 2024 Recertification
- SGRX Flex Application Update
- 2024 Program Audit Process
- 340B STI Program Updates: Policy & Procedures Update, Template and New HRSA Registration Process
- 340B STI Program Medications
- Question and Answer Session

RECERTIFICATION FOR 2024

TOM DUNN

MDHHS AUTHORIZING OFFICIAL

DUNNT2@MICHIGAN.GOV

AUTHORIZING OFFICIAL



- One Authorizing Official (AO) for MDHHS centralized model for in-kind distribution of 340B STI medications state-wide.
- Covered entity must designate its own AO if operating their own STD 340B Program.
- Primary Contact (PC) role at *each* STD covered entity.

RECERTIFICATION



- Required by statute
- Ensures program integrity, compliance, transparency and accountability.
- Ensures accuracy of covered entity information in the 340B OPAIS.
- All fields can be edited during recertification for accuracy and compliance.

RECERTIFICATION TIMEFRAME



- Title X Family Planning and CDC (STD, TB) Grantee recertification period is from May 6 – June 3, 2024.
- Recertification must be completed by June 3, 2024.
 - We are asking for your agency to make any updates directly in the OPAIS database by **Friday, May 17th** to allow time for Authorizing Official to make necessary attestation.
- 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.

RECERTIFICATION



STI entities should reflect the following information in their recertification submission and keep as a part of auditable records:

- Grant Number should be: ***NH25PS005170***
- Notice of Funding Opportunity (NOFO) Number should be: ***PS19-1901***
- Time period section 318 funding or in-kind support was received should be: ***1/1/2019 start date***
(use actual start date if after 1/1/2019)

Time period section 318 funding or in-kind support was received

From 01/01/2019 

Valid until no longer receiving

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 CE and verify that contract pharmacy information associated with the CE is accurate.

340B RECERTIFICATION STEPS (CONT.)



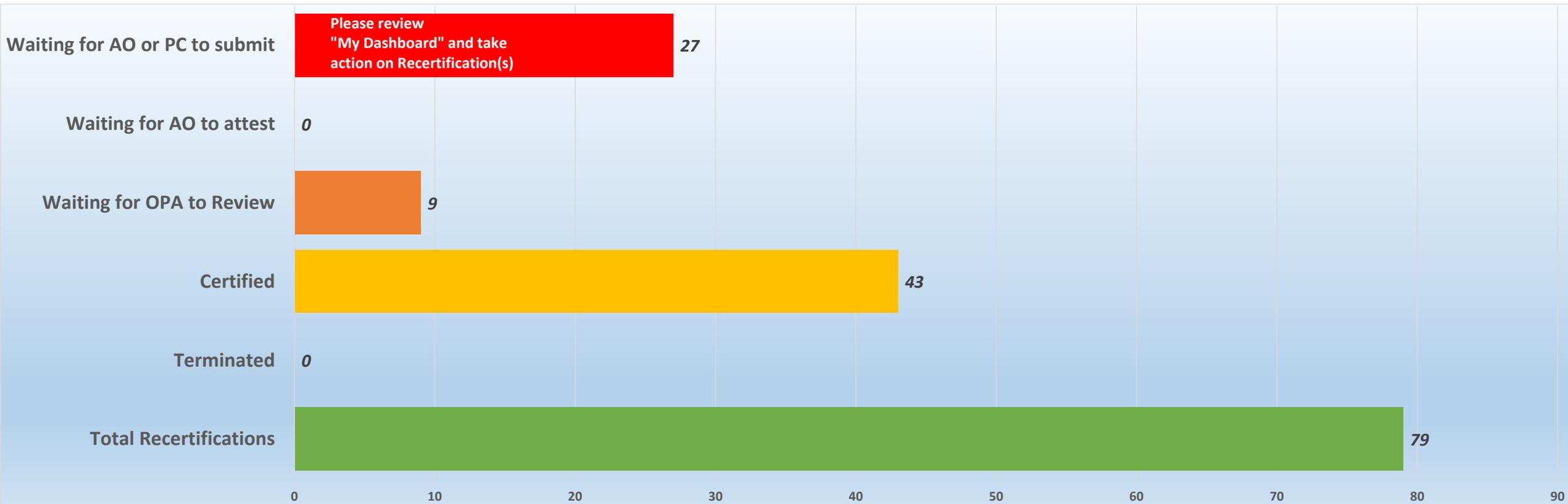
4. After completing all program updates, the AO will “Certify” the information is true, accurate, and the covered entity will be in compliance with all program requirements. The AO must attest and hit “submit” for certification to be completed.

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 CE.

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

340B RECERTIFICATION STATUS



RECERTIFICATION LESSONS LEARNED

HELPFUL TIPS



- Purpose of recertification is to verify and update covered entity information listed in OPAIS and attest to compliance.
- It is highly recommended that covered entities print the recertification user guide for assistance (available in the *help* menu when logged in).
- Once recertification begins, only change requests for AOs shall be processed.

RECERTIFICATION LESSONS LEARNED

HELPFUL TIPS



- Have your 340B ID available when requesting technical assistance.
- Contract 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 by the established deadline will result in removal from the 340B Program.

RECERTIFICATION LESSONS LEARNED

HELPFUL TIPS



- 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 and submits.

RECERTIFICATION LESSONS LEARNED

HELPFUL HINTS



- Once recertification has started only change requests for AOs shall be processed.
- If a site requires termination, it should be prepared to answer the following:
 - 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 340B ID.

2024 STD RECERTIFICATION CHECKLIST:



- Pull up “My Entities” Spreadsheet or find your covered entity on the OPAIS database
- Verify Primary Contact information is updated and correct
- Verify all addresses, making sure that shipping addresses reflect where medications are being dispensed for each STD 340 ID
- Verify that the following information has been entered:
 - Grant Number should be: **NH25PS005170**
 - NOFO Number should be: **PS19-1901 (or text that include ”19-1901”)**
 - Period covered should be: Start date is **1/1/2019** (use actual start date if after 1/1/2019)
Check box labeled “Valid until no longer receiving
- Complete Recertification for your Covered Entity
- AO will certify the recertification

HRSA'S 340B RESOURCES



Office of Pharmacy Affairs (OPA)

Phone: 301-594-4353

Web: <http://www.hrsa.gov/opa>

Prime Vendor Program (PVP)

Phone: 1-888-340-2787

Web: <http://www.340bpvp.com>

(PVP is the primary resource for technical assistance with the 340B Program recertification.)



ORDERING AND MANAGING INVENTORY

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SGRX340BFLEX



SGRX 340BFLEX launched 10/1/2021

Application integrates:

- Medication Ordering
- Medication Dispensing
- Inventory Tracking (receiving, dispensing)
- Quarterly Track Logs
- Reporting

Quick Facts

- Over 220 Active Users
- Over 1,800 Orders Processed

USER MANAGEMENT



Main Contact Access

- Click on User Access
- Review all Users in LHD
- Edit or add New Users

#	First Name	Last Name	Email	Phone #	Active User	Main Contact	Rcv Email
Edit New	Dave	Parks	dparks@test.com	810-521-2100	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

First Name:*	<input type="text" value="Dave"/>
Last Name:*	<input type="text" value="Parks"/>
Email:*	<input type="text" value="dparks@test.com"/>
Phone #:	<input type="text" value="810-521-2100"/>
Password:*	<input type="text" value="test"/>
Active User:	<input checked="" type="checkbox"/>
Main Contact:	<input type="checkbox"/>
Rcv Email:	<input type="checkbox"/>

Update Cancel

Edit Access allows **Main Contact** to:

- Update any information about the employee,
- Add employee as a Main Contact,
- Add employee to receive emails from the system.

Main Contact can also mark user as Active User or remove check mark to block sign in ability.

USER MANAGEMENT



Main Contact Access

- Create New Users – Click New by the name of one of the existing users

First Name:*

Last Name:*

Email:*

Phone #:

Password:*

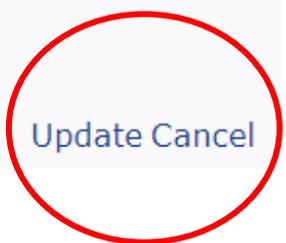
Active User:

Main Contact:

Rcv Email:

Enter the required information:

- Name, Email, Phone Number (Optional), Initial Password
- Check the box for Active User
- Check the box **IF** the new user should also be a Main Contact (with ability to add users)
- Check the box **IF** the user should receive the system generated emails related to order processing
- Click **Update** upon completion



MULTIPLE LOCATIONS



Management of Multiple Locations

- If you manage inventory at multiple locations, you are now able to select the location at the top of the page (vs. each tab).



AGENCY	DISTRICT #2 HEALTH DEPARTMENT STD48661 630 PROGRESS ST, WEST BRANCH, MI 48661			
	STD No	AGENCY	Address	Address
Transfer I	STD48647	DISTRICT #2 HEALTH DEPARTMENT	393 S MT TOM ROAD,	MIO, MI 48647
	STD48764	DISTRICT #2 HEALTH DEPARTMENT	420 W LAKE ST,	TAWAS CITY, MI 48764
	STD48661	DISTRICT #2 HEALTH DEPARTMENT	630 PROGRESS ST,	WEST BRANCH, MI 48661

This is designed to ensure you are able to manage the required ordering and inventory management for each site that you have responsibility.

Please notify SGRX if you are responsible for managing multiple sites.

ORDERS



Order Submission Process

- Order can be initiated and saved until ready for submission
- Once “Submit Order” is clicked, order goes through approval process for review and processing

Note: Order enough Medication for up to 2 months supply

Date Requested	5/14/2023
Contact Person	Bill Smith
Telephone	810-457-2010
Email Address	bsmith@gmail.com
Notes	

Save

Note: Bicillin 2 syringes = 1 Dose

#	Medication	Doses Req
Edit	Azithromycin (Zithromax) / Dose: 1gm (pkg)	0
Edit	Bicillin LA / Dose: 2.4 mu (1 Syringe)	0
Edit	Bicillin LA / Dose: 2.4 mu (2 Syringes)	0
Edit	Cefixime / Dose 800mg pkg (EPT Use Only)	0
Edit	Ceftriaxone (Rocephin) / Dose: 500mg vial for injection	0
Edit	Doxycycline / Dose: 100mg #14 btl	0
Edit	Lidocaine (Xylocaine) / 10X 2ml	0
Edit	Lidocaine (Xylocaine) / 25X 2ml	0
Edit	Lidocaine (Xylocaine) / 25X 5ml	0
Edit	Metronidazole / Dose: 500mg #14 btl	0
Edit	Metronidazole / Dose: 500mg #4 btl	0

DISPENSE MEDICATION



Dispense Medication Process

- Please note all options for Dispense Type:
 - Damaged
 - Dispense – EPT
 - Dispense – Patient
 - Expired
 - Physical Inventory Adjustment
 - Recall
 - Transfer Out to Another Agency
- You are able to make certain adjustments to your inventory based on these options



Dispense Medication

Legend: [Coral] Medications expiring within 30 days. [Yellow] Medications expiring 31 to 60 days
Note: Bicillin: 2 syringes = 1 Dose

ScriptGuide Rx STD00001 15400 E Jefferson Ave Grosse Point Park MI 48320

Available Inventory to Dispense		
#	Medication	Lot Exp Date
	Azithromycin (Zithromax) / Dose: 1gm (pkg)	01/01/2022
	Doses Dispensed:* <input type="text"/>	
	Date Dispensed:* <input type="text"/>	
	Dispense Type:* <input type="text"/>	
	Patient/Client #:	
	Note:	
Edit	Azithromycin (Zithromax) / Dose: 1gm (pkg)	02/28/2022
Edit	Azithromycin (Zithromax) / Dose: 1gm (pkg)	02/28/2022
Edit	Azithromycin (Zithromax) / Dose: 1gm (pkg)	06/24/2022
Edit	Azithromycin (Zithromax) / Dose: 1gm (pkg)	06/24/2022
Edit	Bicillin LA / Dose: 2.4 mu (2 Syringes)	10/31/2022
Edit	Bicillin LA / Dose: 2.4 mu (2 Syringes)	11/01/2022
Edit	Bicillin LA / Dose: 2.4 mu (2 Syringes)	11/30/2022
Edit	Bicillin LA / Dose: 2.4 mu (2 Syringes)	01/31/2023
Edit	Bicillin LA / Dose: 2.4 mu (2 Syringes)	01/31/2023
Edit	Doxycycline / Dose: 100mg #14 btl	09/30/2022
Edit	Doxycycline / Dose: 100mg #14 btl	11/30/2022
Edit	Metronidazole / Dose: 500mg #14 btl	01/31/2022

MEDICATION – VISUAL INDICATORS



Legend: [Red] Medication Expired [Coral] Medications expiring within 30 days [Yellow] Medications expiring 31 to 60 days

MED: 340B		
View	Azithromycin (Zithromax) / Dose: 1gm (pkg)	1
View	Bicillin LA / Dose: 2.4 mu (2 Syringes)	14
View	Cefixime / Dose 800mg pkg (EPT Use Only)	2
View	Ceftriaxone (Rocephin) / Dose: 500mg vial for injection	12
View	Doxycycline / Dose: 100mg #14 btl	9
View	Doxycycline PEP / Dose: 200mg (pkg)	3
View	Lidocaine (Xylocaine) / 25X 5ml	7
View	Metronidazole / Dose: 500mg #14 btl	2
View	Metronidazole / Dose: 500mg #4 btl	4

Colors updated to more clearly identify status of medications that require attention:

- Yellow – Expiring within 31-60 days
- Coral – Expiring within 30 days
- RED TEXT – Medication is EXPIRED!

Visible when reviewing inventory as well as selecting medications to dispense!

MEDICATION – VISUAL INDICATORS



Medication	Lot Exp Date	Lot Number	NDC	Doses
Cefixime / Dose 800mg pkg (EPT Use Only)	4/24/2024	B2572506-102023	70518-2749-05	2

Medication	Lot Exp Date	Lot Number	NDC	Doses
Lidocaine (Xylocaine) / 25X 2ml	5/24/2024	6029594	63323-201-02	2
Lidocaine (Xylocaine) / 25X 2ml	10/31/2026	6129357	63323-492-27	1

Medication	Lot Exp Date	Lot Number	NDC	Doses
Cefixime / Dose 800mg pkg (EPT Use Only)	6/14/2024	B2672329-121423	70518-2749-05	2

Colors updated to more clearly identify status of medications that require attention:

- **Yellow** – Expiring within 31-60 days
- **Coral** – Expiring within 30 days
- **RED TEXT** – Medication is EXPIRED!

MEDICATION – INVENTORY



Expired Medication should be removed from inventory using the Dispense Medication Process

Available Inventory to Dispense						
#	Medication	MED	Lot Exp Date	Lot Number	NDC	Doses on Hand
	Azithromycin (Zithromax) / Dose: 1gm (pkg)	340B	05/25/2024	347901	65409-5422-02	8

Doses Dispensed:*	<input type="text"/>
Date Dispensed:*	<input type="text"/>
Dispense Type:*	<input type="text"/>
Patient/Client #:	<input type="text"/>
Note:	<input type="text"/>
Update Cancel	

- Dispense - EPT
- Dispense - Patient
- Expired**
- Physical Inventory Adjustment
- Recall
- Transfer Out to Another Agency

Edit	Azithromycin (Zithromax) / Dose: 1gm (pkg)	340B	05/20/2025	4780	00054-0571-08	5
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MDHHS-BHSP 340B PROGRAM AUDIT PROCESS

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MDHHS-BHSP 340B PROGRAM AUDIT PROCESS



- **2023 Audits- August 2024**

- **Purpose of the Audits**

To ensure compliance with all 340B federal regulations

- **Site Selection Process**

MDHHS randomly selects site locations

2 on-site visits

20 off-site record reviews



MDHHS-BHSP 340B PROGRAM AUDIT PROCESS



Three Phases of the Audit Process

Pre-Audit Phase



Audit Phase



Post Audit Phase

- MDHHS Email Announcing Intent to Audit (30 Days)
- Request Pre-audit Documents
- Pre-Audit Orientation

- Onsite or Virtual Chart Review

- Initial Audit Reports to MDHHS
- Share Final Report & Corrective Action Plans (if necessary).
- Evaluation Surveys



MDHHS-BHSP 340B PROGRAM AUDIT PROCESS



Topics

- Covered Entity Eligibility
- 340B Program Enrollment, Recertification, and Change Request
 - 340B Staff Roles & Responsibilities
 - Personnel Credentials
- Patient Eligibility/Definition
- Expedited Partner Therapy (EPT)
- Prevention of Duplicate Discounts
- 340B Program Roles and Responsibilities
- 340B Program Education & Competency
- Inventory Management
- 340B Non-compliance/Material Breach



How can you prepare for audits?

MDHHS & SGRX strongly encourages your team to compare your current program operations to the requirements outlined in the STI 340B Policy and Procedure Manual.

MDHHS-BHSP 340B PROGRAM AUDIT PROCESS



Evaluation Survey's

Thank you for your feedback on 2022 audits

We value your feedback as we work to improve the audit process

Selected sites for 2023 audit will have the opportunity to complete a survey

Thank you!



POLICY & PROCEDURES UPDATE, TEMPLATE AND NEW HRSA REGISTRATION PROCESS

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340B ANALYST

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UPDATED POLICIES AND PROCEDURES – 2024 CHANGES



In April 2024, MDHHS-BHSP updated our 340B STI Program Policies & Procedures. The two main changes to be aware of:

- For wasted 340B medication, If a covered entity identifies extra, almost expiring or unnecessary 340B medications, they must contact BHSP to return the medication. Any wasted or destroyed medication must be communicated to SGRX & MDHHS-BHSP Staff and accurately reflected in the Flex Application.
- For audit frequency...for patient record audits, selected sites each year will be exempt from selection the following year, and for on-site audits low morbidity partners will not be selected more than once in 5 years and high morbidity partners will not be selected more than once in 3 years.

340B STI PROGRAM P&P'S TEMPLATE



MDHHS-BHSP created a template for grant-supported covered entities to create their own 340B STI Program Policies & Procedures which was sent in January 2024 with the close of our 2022 audit cycle communication.

340B STI PROGRAM POLICY AND PROCEDURE MANUAL

340B STD ID(s):

[Redacted]

[Redacted]

NEW HRSA REGISTRATION PROCESS



If you are seeking a new HRSA registration or making a change to your existing 340B Program, MDHHS-BHSP created a reference sheet with first steps for creating or changing existing 340B Registrations.



FIRST STEPS FOR CREATING OR CHANGING EXISTING 340B REGISTRATIONS

FOR ENTITIES CURRENTLY ENROLLED IN THE 340B DRUG PRICING PROGRAM

STEP	IF YES	IF NO
1. Will the entity generate 340B revenue under their ID(s)?	Proceed to STEP 2	STOP. No further steps are necessary.
2. Contact the state grantee (MDHHS-BHSP) and let them know that you will be operating your own 340B program.	Proceed to STEP 3	
3. Submit Change Request(s) in the HRSA OPAIS database to update the Authorizing Official and Primary Contact information to so that 340B OPAIS email notifications are received.		

FOR ENTITIES SEEKING NEW REGISTRATION FOR THE 340B DRUG PRICING PROGRAM

STEP
1. Contact the state grantee (MDHHS-BHSP) and let them know you are applying to the 340B Drug Pricing Program, and they will receive an email notification from HRSA.
2. To verify eligibility, HRSA will send an email to the appropriate Project Director (PD) or Program Manager (PM) to confirm the entity receives eligible grant funding (direct or in-kind).
3. The PD or PM has five business days to confirm the entity receives eligible grant funding. If they don't respond to the email by the deadline or responds that entity is not eligible, HRSA will reject the registration(s).

Questions related to grant eligibility or registration steps for the 340B Drug Pricing Program can be addressed to MDHHS Bureau of HIV and STI Programs at MDHHS-HIVSTIOPERATIONS@MICHIGAN.GOV.

340B STI PROGRAM MEDICATIONS

JENINE CLEMENTS

REGION 2 CLIENT, PARTNER AND COMMUNITY OUTREACH

UNIT MANAGER

CLEMENTSJ@MICHIGAN.GOV

340B MEDICATIONS STOCKED



All medications are packaged for use in accordance with the CDC's [2021 Sexually Transmitted Infections Treatment Guidelines](#)

- Azithromycin – 1 g
- Bicillin L-A – 1.2 MU syringe (dose = 2 syringes; box contains 5 doses), 2.4 MU syringe (dose = 1 syringe, box contains 10 doses)
- Cefixime – 800 mg for expedited partner therapy (EPT)
- Ceftriaxone – 500 mg vial
- Doxycycline – #14 capacity
- Doxycycline PEP – 200 mg (UD) and 60 Count (bottle)
- Metronidazole – #4 and #14 capacity

BICILLIN SHORTAGE



Due to bicillin shortage:

- Bicillin LA 2.4 MU size was added to inventory
- Internally current bicillin recommendations are being reviewed for possible relaxation
- Your compliance with restrictions during the shortage is appreciated
- Currently there is a good amount available
- Email Jenine Clements and copy Dan Lowery with any questions or concerns

CONDITIONS



Conditions that our 340B Medications Treat:

- Bacterial Vaginosis
- Chlamydia
- Gonorrhea
- Lymphogranuloma venereum
- Mycoplasma genitalium
- Syphilis
- Trichomoniasis

QUESTION & ANSWER SESSION



RESOURCES



Forget?? Or Questions??
SGRX email address is located within
the ordering application.

Order Application link is:

[SGRX340BFLEX Application](#)

- 340bMI@sgrxhealth.com
- mdhhshivstiooperations@michigan.gov

A screenshot of a web browser showing the login page for the SGRX340BFlex application. The browser's address bar shows "sgrx340bflex.com/Login". The page has a light orange background. At the top right is the "SGRX340BFlex" logo, which consists of a blue circular icon with a white leaf-like shape and the text "SGRX340BFlex" in blue. Below the logo are two input fields: "Email Address" with the placeholder text "Enter email address" and "Password" with the placeholder text "Enter password". Below these fields is a "Login" button. At the bottom of the form area, there is a note: "Login and Password are case sensitive".



THANK YOU!