340B STI PROGRAM POLICY AND PROCEDURE MANUAL

State of Michigan Department of Health and Human Services
Bureau of HIV and STI Programs (BHSP)

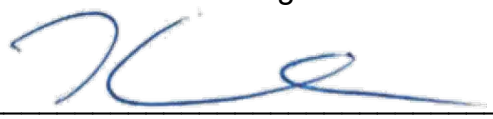
Policy and procedure Manual adapted from the Apexus 340B Prime Vendor Program

Policy and Procedure Manual
Michigan Department of Health and Human Services –
Bureau of HIV and STI Programs 340B Medication program

Statement of Approval

This Policy and Procedure manual for the State of Michigan Department of Health and Human Services (MDHHS) Bureau of HIV and STI programs (BHSP) 340B STI Program is effective as of 05-11-2020. The last revision took place on 05/02/2025.

Per MDHHS-BHSP policy, this Policy and Procedure manual has been approved by the following individuals on the following date:



MDHHS-BHSP Executive Approval — Date: 5/7/2025

Authorizing Official Approval — Date: 05/02/2025

Third Party Administrator Approval — Date: 05/06/2025

Michigan Department of Health and Human Services
Bureau of HIV and STI Programs

340B Standard Operating Procedure Table of Contents

I. Purpose 3
II. Background 3
III. 340B Policy Statements 4
IV. Definitions 4
V. References 4
VI. Policy Review, Update, and Approval: 4
VII. Covered Entity Eligibility 5
VIII. 340B Program Enrollment, Recertification, and Change Requests 6
IX. Patient Eligibility/Definition 8
X. Expedited Partner Therapy (EPT) 10
XI. Prevention of Duplicate Discounts 12
XII. 340B Program Roles and Responsibilities 13
XIII. 340B Program Education and Competency 16
XIV. Inventory Management 17
XV. 340B Noncompliance/Material Breach 20
XVI. 340B Program Compliance Monitoring/Reporting 21
XVII. Appendices 23

I. Purpose

This document contains the written policies and procedures that the Michigan Department of Health and Human Services (MDHHS) Bureau of HIV and STI Programs (BHSP) uses to oversee the 340B STI Program operations, provide oversight of covered entities participating this program. MDHHS-BHSP covered entities include local health departments and contracted non-government providers that are supported directly or in-kind via the CDC STI cooperative agreement and section 318 of the Public Health Service Act (PHSA) regarding the prevention and control of sexually transmitted infections. Covered entities are required to provide or refer for core STI clinical services; at minimum, this includes testing and treatment for syphilis, gonorrhea, and chlamydia.

MDHHS-BHSP partners with a Third Party Administrator (TPA) to carry out oversight and compliance monitoring tasks for MDHHS-BHSP grant-supported covered entities. MDHHS-BHSP also partners with a wholesale company and warehouse to ensure that dispensing protocols are in place to significantly lessen the likelihood of expiring medication clients not being able to access needed medication.

MDHHS-BHSP participates in the 340B program to stretch already scarce federal resources as far as possible, which allows for more patients to be served and more comprehensive services. With the savings gleaned from lower medication costs, MDHHS-BHSP and grant-supported covered entities work to ensure that low-income, uninsured, and underinsured patients can afford their medication and to support programming that increases access for the general patient population throughout the State of Michigan.

II. Background

Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the US Secretary of Health and Human Services.

a) This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient medication.

The 340B Program is administered by the federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (HHS). To participate in the 340B Program, eligible organizations/covered entities must register and be enrolled with the 340B program and comply with all 340B program requirements. Once enrolled, covered entities are assigned a 340B identification number that vendors verify before allowing an organization to obtain 340B discounted drugs.

Upon registration on 340B Office of Pharmacy Affairs Information System (OPAIS), MDHHS-BHSP and grant-supported covered entities:

a) Agree to abide by specific statutory requirements and prohibitions.
b) May access 340B medication.

III. 340B Policy Statements

A. The MDHHS-BHSP and grant-supported covered entities comply with all requirements and restrictions of Section 340B of the PHSA and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring medication purchased under the 340B Program to anyone other than a patient of the entity. (REFERENCE: Public Law 102-585, Section 602, 340B Guidelines, 340B Policy Releases).

B. The MDHHS-BHSP and grant-supported covered entities have systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.

C. The MDHHS-BHSP and grant-supported covered entities maintain auditable records demonstrating compliance with the 340B Program.
    a. These reports are reviewed by MDHHS-BHSP and its Third Party Administrator quarterly and upon request as part of its 340B oversight and compliance program.

IV. Definitions

Definitions of terms may be found in [Appendix: 340B Glossary of Terms].

V. References

Each section includes other references to Policies and Procedures, 340B Glossary of Terms, HRSA website, etc.

VI. Policy Review, Update, and Approval:

These written policies and procedures will be amended and approved by MDHHS-BHSP staff and the 340B Oversight Committee whenever there is a clarification, or change, in the rules, regulations, or guidelines to the 340B Program requirements. Otherwise, the policy will be reviewed and approved annually.

VII. Covered Entity Eligibility

Policy: MDHHS-BHSP and grant-supported covered entities must meet the requirements of 42 USC §256b(a)(4)(C) to be eligible for enrollment in, and the purchase of medication through, the 340B Program.

Purpose: To ensure MDHHS-BHSP and grant-supported covered entities eligibility to participate in the 340B Program

Definitions: Covered outpatient drug: Defined in Section 1927(k) of the Social Security Act (https://www.ssa.gov/OP_Home/ssact/title19/1927.htm).

Procedure:

1. The basis for 340B eligibility for the MDHHS-BHSP is determined by the receipt of federal dollars awarded under eligible grant designations as determined through section 318 of the PHSA. An entity receiving in-kind contributions through section 318 may also qualify for the 340B Drug Pricing Program. Qualifying in-kind contributions must be paid for by section 318 grant funds to qualify a site as 340B eligible. All eligible grant-supported covered entities must have a contract with the MDHHS-BHSP and/or receive qualified in-kind support.

2. The MDHHS-BHSP has identified locations where it dispenses or prescribes 340B medication (e.g., within the four walls of the covered entity).
    a. Grant-supported covered entities should maintain auditable records, policies, and procedures related to the definition of covered outpatient drug that is consistent with the 340B statute and Social Security Act. All entities must agree to participate in compliance monitoring activities of their 340B Program. Refer to MDHHS-BHSP Policy and Procedure "340B Program Compliance Monitoring/Reporting."
    a. Currently, the MDHHS-BHSP and grant-supported covered entities are not using contract pharmacies for 340B STI programming purposes.
    b. Grant-supported covered entities must agree to both federal and state legislation that govern the 340B program.

3. The MDHHS-BHSP ensures that the 340B OPAIS is complete, accurate, and correct or in the process of recertification for all 340B eligible locations. Refer to MDHHS-BHSP Policy and Procedure "340B Program Enrollment, Recertification, and Change Request."

4. The MDHHS-BHSP informs HRSA immediately of any changes to its Medicaid information by updating the 340B OPAIS Medicaid Exclusion File.
    a. MDHHS-BHSP prohibits grant-supported covered entities that participate in the centralized distribution model from billing private insurances or Medicaid for 340B medication provided in-kind from MDHHS-BHSP.

5. The MDHHS-BHSP annually recertifies all grant-supported covered entity's information on 340B OPAIS. Refer to MDHHS-BHSP Policy and Procedure "340B Program Enrollment, Recertification, and Change Request."

VIII. 340B Program Enrollment, Recertification, and Change Requests

Policy: Eligible entities must maintain the accuracy of 340B OPAIS and be actively registered to participate in the 340B Program.

Purpose: To ensure that the MDHHS-BHSP and grant-supported covered entities are registered appropriately on 340B OPAIS and maintain accurate records

References: 340B Drug Pricing Program: Grantee Registration Instructions
https://www.hrsa.gov/opa/registration/index.html

340B Program Registration Dates:

- January 1–January 15 for an effective start date of April 1
- April 1–April 15 for an effective start date of July 1
- July 1–July 15 for an effective start date of October 1
- October 1–October 15 for an effective start date of January 1

Procedures:

MDHHS-BHSP Centralized Distribution Model

MDHHS-BHSP uses a centralized approach for purchasing and distributing medications for its 340B STI Program known as a Centralized Distribution Model which was approved by HRSA in July 2020. Under this model, MDHHS-BHSP purchases STI medications under a single 340B account and distributes to covered entities throughout the State of Michigan. In this model there is one authorizing official from MDHHS-BHSP who acts as the main contact and, along with covered entities, bears responsibility for 340B compliance. Each site that dispenses medications must have its own STD 340B ID, have a primary contact from their covered entity listed on the OPAIS site, and during initial enrollment sign an attestation form agreeing to participate in program. (See Appendix (5) for Attestation Form). MDHHS-BHSP prohibits 340B STI covered entities that participate in the Centralized Distribution Model from billing private insurances or Medicaid for 340B medication provided in-kind from MDHHS-BHSP. 340B STI covered entities that wish to purchase their own medications and generate program income through billing must assign its own authorization official, bear responsibility for 340B compliance and independently operate their 340B STI program.
If a grant-supported covered entity opts out of participating in this MDHHS-BHSP Centralized Distribution Model, it must notify the MDHHS-BHSP authorizing official.

Initial Enrollment

1. MDHHS-BHSP and grant-supported covered entities are eligible to participate in the 340B Program [Refer to MDHHS-BHSP Policy and Procedure "Covered Entity Eligibility"].
2. MDHHS-BHSP identifies upcoming registration dates and deadlines.
3. MDHHS-BHSP is identified as the authorizing official. MDHHS-BHSP grant-supported covered entities serve as the clinic primary contact.
4. MDHHS-BHSP has the required documents/contracts available.
    a. The documents/contracts include a federal grant number.

5. MDHHS-BHSP Authorizing Official completes registration on the 340B OPAIS website (https://340bopais.hrsa.gov/).
6. Attestation Form must be signed and returned to MDHHS-BHSP during initial enrollment.

Recertification Procedure

1. MDHHS-BHSP identifies upcoming registration dates and deadlines.
2. MDHHS-BHSP is identified as the authorizing official. MDHHS-BHSP grant-supported covered entities serve as the clinic primary contact.
3. MDHHS-BHSP emails grant-supported covered entities to review their information in OPAIS.
    a. MDHHS-BHSP grant-supported covered entities must review address, primary contact information, Medicaid billing status, and their current grant number in the HRSA OPAIS database.
4. MDHHS-BHSP grant-supported covered entities review, update, and submit any changes to MDHHS-BHSP staff.
5. MDHHS-BHSP Authorizing Official annually completes the recertification process for all grant-supported covered entities on 340B OPAIS.
    a. MDHHS-BHSP submits specific recertification questions to 340b.recertification@hrsa.gov.

Procedure for Changes to MDHHS-BHSP Information in 340B OPAIS

1. MDHHS-BHSP grant-supported covered entities will immediately notify HRSA of any changes to their grant status, changes to their information on 340B OPAIS, or other such changes. Refer to MDHHS-BHSP Policy and Procedure "Covered Entity Eligibility."
2. MDHHS-BHSP, in turn, notifies HRSA immediately of any changes to grant-supported covered entity's grant status or other such changes.
    a. MDHHS-BHSP and grant-supported covered entity will stop the purchase of 340B medication as soon as the grant-supported covered entity loses 340B Program eligibility through a grant status change or termination from the 340B program.
3. The authorizing official for the MDHHS-BHSP will complete the online change request as soon as a change in eligibility is identified.
    a. MDHHS-BHSP will expect changes to be reflected within two weeks of submission of the changes/requests.
4. Submit documentation of changes to MDHHS-BHSP within 48 hours of completion
    a. Grant-supported covered entity and MDHHS-BHSP will discuss changes and impact on relationships.
5. MDHHS-BHSP will provide final determination on status in the program as a result of changes, when applicable.

IX. Patient Eligibility/Definition

Policy: Per the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 340B medication are to be provided only to individuals eligible to receive 340B medication from covered entities.

Purpose: To ensure that 340B medication are dispensed/administered/prescribed only to eligible patients

Definitions:

Administer: Give medication to an individual, typically in a clinic, based on a health care provider's order.

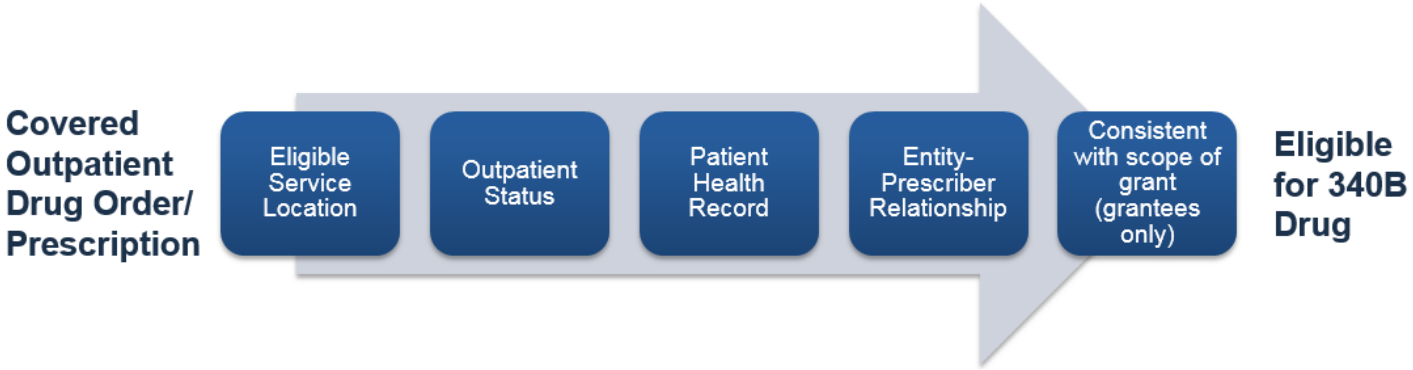
Dispense: Provide medication, typically in clinic, based on a health care provider's order to be administered to a patient. If a medical provider (RN, NP, PA, etc.) has signed off on the medication, but is not the physician or medical director, it is allowable under a current standing order.

Outpatient status: A patient who receives screening, testing, and/or treatment of an STI without being admitted into a hospital. All participating patients of MDHHS-BSHP 340B STI Program must have outpatient status.

Prescribe: Provide a prescription for medication to an individual to be filled at an outpatient pharmacy.

Procedure:

Note: Covered entities need to ensure that the following 340B eligibility determination filters are implemented:



1.MDHHS-BHSP validates site/service eligibility. Refer to MDHHS-BHSP Policy and Procedure "Covered Entity Eligibility."

2. MDHHS-BHSP grant-supported covered entities verify records of an individual's health care in their own electronic medical records (EMRs).
    a. MDHHS-BHSP and/or its Third Party Administrator conduct compliance monitoring on an annual basis.

   b. Refer to MDHHS-BHSP Policy and Procedure "340B Program Compliance Monitoring/Reporting."
3. MDHHS-BHSP determines provider eligibility.
   a. Provider is either employed by the grant-supported covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that the responsibility for the care provided remains with the covered entity.
   b. MDHHS-BHSP maintains an eligible provider list gathered from the HRSA OPAIS database.
      i. MDHHS-BHSP partners with its Third Party Administrator to maintain eligible provider list.
4. MDHHS-BHSP and grant-supported covered entities determine that the individual receives a health care service from the covered entity consistent with the service for which grant funding has been provided to the entity.
   a. Refer to MDHHS-BHSP Policy and Procedure "340B Program Compliance Monitoring/Reporting."
5. MDHHS-BHSP prohibits grant-supported covered entities from billing private insurances or Medicaid for 340B medication provided in-kind from MDHHS-BHSP.
   a. Refer to MDHHS-BHSP Policy and Procedure "340B Program Compliance Monitoring/Reporting."
6. In the event of an issue or challenge, information from the grant-supported covered entity should be reported to MDHHS-BHSP and/or its Third Party Administrator.

X. Expedited Partner Therapy (EPT)

Policy: 340B medication may be used for the purposes of Expedited Partner Therapy (EPT) to ensure that partner(s) of eligible patients are treated and to prevent secondary infection.

Purpose: To ensure that MDHHS-BHSP grant-supported covered entities can dispense /prescribe 340B medication to partner(s) of eligible patients when carrying out EPT

According to the CDC, EPT is a useful option to facilitate partner management, particularly for treatment of male partners of women with chlamydial infection or gonorrhea. Public act 525 of 2014 authorized the use of EPT for certain sexually transmitted infections in the State of Michigan.

Definitions:

Dispense: Provide medication, typically in clinic, based on a health care provider's order to be administered to a patient. If a medical provider (RN, NO, PA, etc.) has signed off on the medication but is not the physician or medical director, it is allowable under a current standing order.

EPT: A legal statue in Michigan that enables clinicians to provide patients with medication or a prescription to deliver to their sex partner(s).

Partner: The sexual partners of an eligible patient who may be untreated.

Prescribe: Provide a prescription for medication to an individual to be filled at an outpatient pharmacy.

Procedure:

1. MDHHS-BHSP grant-supported covered entities determine that the eligible patient meets the patient eligibility/definition.
    a. Refer to MDHHS-BHSP Policy and Procedure "Patient Eligibility/Definition."
2. MDHHS-BHSP grant-supported covered entities determine that in order to effectively treat the eligible patient, EPT must be administered to the partner(s) of the eligible patient.
    a. According to the MDHHS EPT Guidance for Healthcare Providers, EPT should not be used for the following:
        i. In cases of suspected child abuse or sexual assault
        ii. In situations where a patient's safety is in question
        iii. For partners with known allergies to antibiotics
        iv. For patients who are co-infected with STIs other than chlamydia or gonorrhea
        v. For treating gonorrhea among men who have sex with men
3. MDHHS-BHSP grant-supported covered entities dispense/administer/prescribe 340B medication to partner(s) of eligible patient.
4. Instances of medication dispensed for the purposes of EPT must be documented in the TPA application.

a. Instances of medication dispensed for the purposes of EPT must be logged in TPA Application.
    i. The *Patient ID/Chart #* should be filled out with the patient's name and not the partner's name.
b. Refer to MDHHS-BHSP Policy and Procedure "340B Program Compliance Monitoring/Reporting."

XI. Prevention of Duplicate Discounts

Policy: 42 USC §256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts. MDHHS-BHSP prohibits grant-supported covered entities from billing private insurances or Medicaid for 340B medication provided in-kind from MDHHS-BHSP.

Purpose: To ensure that MDHHS-BHSP and grant-supported covered entities are preventing duplicate discounts and clarify how MDHHS-BHSP-provided medication provided in-kind to a grant-supported covered entity may be used

References: Medicaid Provider Manual (http://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf)

Procedure: MDHHS-BHSP grant-supported covered entities may not bill private insurance or Medicaid for 340B STI medication provided in-kind from MDHHS-BHSP.

If a MDHHS-BHSP grant-supported covered entity elects to purchase 340B medication outside of the 340B STI medication provided in-kind from MDHHS-BHSP, they may choose to dispense 340B medication to Medicaid patients (carve-in) OR purchase medication for Medicaid patients through other mechanisms (carve-out). The covered entity should develop their own policies and procedures for how this is done.

XII. 340B Program Roles and Responsibilities

Policy: Covered entities participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements.

Purpose: To identify MDHHS-BHSP key stakeholders and determines their roles and responsibilities in maintaining 340B Program integrity and compliance.

Procedure:

1. MDHHS-BHSP key stakeholders involved with MDHHS-BHSP 340B Program include its Third Party Administrator and grant-supported covered entities.
2. MDHHS-BHSP key stakeholders' roles and responsibilities with MDHHS-BHSP 340B Program are ensuring that grant-supported covered entities meet compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.
3. MDHHS-BHSP has established a 340B Oversight Committee that is responsible for the oversight of the 340B Program, or other similar oversight process, including that the committee:
    a. Meets on a regular basis.
    b. Reviews 340B rules/regulations/guidelines to ensure consistent policies/procedures/oversight throughout the entity.
    c. Identifies activities necessary to conduct comprehensive reviews of 340B compliance.
    d. Ensure that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.
    e. Integrate departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.
    f. Oversees the review process of compliance activities, as well as taking corrective actions based on findings.
    g. 340B Oversight Committee assesses if the results are indicative of a material breach (Refer to MDHHS-BHSP Policy and Procedure "340B Non-Compliance/Material Breach").
    h. Reviews and approves work group recommendations (process changes, self-monitoring outcomes and resolutions).

The following MDHHS-BHSP staff are potential key players in the 340B Program, including governance and compliance, and should be standing members of the 340B Oversight Committee. MDHHS-BHSP will identify who serves as the entity's authorizing official and primary contact for the 340B Program. These individuals should be the sponsors of the 340B Oversight Committee.

MDHHS-BHSP Authorizing Official:

1. Responsible as the authorizing official in charge for the compliance and administration of the program
2. Responsible for attesting to the compliance of the program through recertification
3. Responsible as the authorizing official in charge for the compliance and administration of the program in many cases
4. Accountable agent for 340B compliance

MDHHS-BHSP Grant-supported Covered Entities primary contact:

1. Responsible for attesting and updating information for the compliance of the program through recertification
2. Accountable agent for 340B compliance
3. Often responsible as the primary contact for the 340B Program
4. Day-to-day manager of the 340B Program

MDHHS 340B Analyst:

1. Develop proper 340B quality assurance training for employees as appropriate
2. Provide proactive education to staff on policies and procedures related to inventory management and 340B procedures
3. Be involved in all 340B audits
4. Develop reports that can be used to educate staff and assist management in tracking the overall financial impact to the organization
5. Build other reports, as appropriate, to monitor and improve 340B Program compliance and performance

MDHHS-BHSP Grant-supported Covered Entities:

1. Monitor any changes in clinic eligibility/information
2. Responsible for maintaining documentation of policies and procedures
3. Manages purchasing, receiving, and inventory control processes
4. Performs annual inventory and monthly cycle counts
5. Responsible for communication of all changes to Medicaid or other reimbursement for pharmacy services/products that affect 340B status
6. Provides and ensures access to historical data to make them available to auditors when audited
7. Responsible for segregation, removal, and/or return of 340B medication, including reverse distributor transactions

Third Party Administrator:

1. Day-to-day manager of the 340B Program
2. Responsible for maintenance and testing of tracking software
3. Maintains system databases to reflect changes in the drug formulary or product specifications

4. Manages purchasing, receiving, and inventory control processes
5. Continually monitors product minimum/maximum levels to effectively balance product availability and cost-efficient inventory control
6. Ensures appropriate safeguards and system integrity
7. Ensures compliance with 340B Program requirements for qualified patients, medication, providers, vendors, payers, and locations
8. Reviews and refines 340B cost savings report, detailing purchasing, and replacement practices as well as dispensing patterns
9. Monitors ordering processes, integrating most current pricing from wholesaler
10. Develop report detailing purchasing, and replacement practices as well as dispensing patterns
11. Ensures compliance with 340B Program requirements for qualified patients, medication, providers, vendors, payers, and locations
12. Ensures appropriate safeguards and system integrity
13. Maintains system databases to reflect changes in the drug formulary or product specifications
14. Aware of products covered by 340B

MDHHS-BHSP Warehouse:

1. Manages purchasing, receiving, and inventory control processes
2. Continually monitors product minimum/maximum levels to effectively balance product availability and cost-efficient inventory control
3. Performs annual inventory and monthly cycle counts
4. Analyzes invoices, shipping, and inventory processes
5. Responsible for segregation, removal, and/or return of 340B medication, including reverse distributor transactions

MDHHS-BHSP 340B Program Oversight Committee:

1. Maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes
2. Responsible for documentation of policies and procedures
3. Develop, review, and refine 340B Program cost savings report
4. Designs and maintains an internal audit plan of the compliance of the 340B Program
5. Designs the annual plan to cover all changes in the 340B Program from the preceding year
6. Responsible for ordering all medication from the specific accounts as specified by the process employed
7. Monitors ordering processes, integrating most current pricing from wholesaler

XIII. 340B Program Education and Competency

Policy: Program integrity and compliance are the responsibility of all 340B key stakeholders. Ongoing education and training are needed to ensure that these 340B key stakeholders have the knowledge to guarantee compliant 340B operations.

HRSA's Program Integrity guiding principles are to maximize oversight reach and manage compliance risks. Efforts to follow these principles include audits of covered entities and manufacturers to enforce requirements for these stakeholders. Other efforts include annual recertification to give covered entities an opportunity to review their 340B Drug Pricing Program (340B Program) responsibilities and re-attest to being currently in full compliance. HRSA performs program integrity checks regarding eligibility requirements and documentation necessary to demonstrate compliance.

Purpose: To establish 340B education and competency requirements for MDHHS-BHSP 340B key stakeholders based on their roles and responsibilities in the 340B Program

Procedure:

1. MDHHS-BHSP determines the knowledge and educational requirements for each 340B Program role (Refer to [MDHHS BHSP Policy and Procedure "340B Program Roles and Responsibilities"]).
2. 340B key stakeholders are encouraged to complete initial basic training upon appointment to role.
    a. Watch 'Introduction to the 340B Drug Pricing Program'
    b. Complete OnDemand modules on the Apexus website
    c. Attend 340B University (available online or in person)
    d. Read any associated 340B policies that the 340B program maintains
    e. Attend 340B related training opportunities or meetings provided within the BHSP
3. MDHHS-BHSP provides educational updates and training, as needed (e.g., 340B policy changes, updates in HRSA guidance, MDHHS Policy updates, etc.).
4. Training and education records are maintained per organizational policy and available for review.
5. MDHHS-BHSP will conduct annual verification of 340B program competency via an annually distributed acknowledgement of and adherence to policies and procedure form. All MDHHS-BHSP grant-supported covered entities must complete and return this form on an annual basis.

XIV. Inventory Management

Policy: MDHHS-BHSP grant-supported covered entities must be able to track and account for all 340B medication to prevent diversion.

Purpose: To ensure the proper procurement and inventory management of 340B medication

Background:
340B inventory is procured and managed by MDHHS-BHSP and Third Party Administrator in the following settings:

- MDHHS-BHSP Grant-supported covered entity clinic site
- MDHHS warehouse

Inventory methods for each of the above areas shall be described within this inventory management policy and procedure.

If the grant-supported covered entity has 340B medication provided in-kind from MDHHS-BHSP and medication purchased by the grant-supported covered entity outside of 340B, then they must maintain physically separated 340B and non-340B inventory.

Clinicians dispense 340B medication only to patients meeting all the criteria in [Refer to MDHHS-BHSP Policy and Procedure "Patient Eligibility/Definition."

Procedure:

1. MDHHS-BHSP places the order for 340B medication with a wholesaler company, which then transmits the order to a registered 340B manufacturer.
    a. Covered entities are required to submit their 340B Medication Inventory reports to the Third Party Administrator on a quarterly basis. The Third Party Administrator shares these reports with MDHHS-BHSP.
    b. For a visual of the 340B Program Supply Chain Process, please see Appendix [4].
2. 340B Manufacturer ships the medication to the warehouse. The Third Party Administrator confirms medication orders and 340B covered entity actual medication needs.
    a. The warehouse distributes medication to MDHHS-BHSP covered entities.
3. MDHHS-BHSP covered entities maintain physical inventory (both 340B and non-340B medication) in their certified locations.
    a. MDHHS-BHSP covered entities identify all 340B and non-340B accounts used for purchasing medication in each practice setting.
    b. MDHHS-BHSP covered entities separate 340B inventory from non-340B inventory.
    c. MDHHS-BHSP covered entities perform monthly inventory reviews and shelf inspections of periodic automatic replenishment (PAR) levels to determine purchase order.
    d. MDHHS-BHSP covered entities place 340B and non-340B drug orders at minimum once every two months. This ordering frequency may change based on inventory review.

e. For 340B orders, a designated staff member at the covered entity submits the medication order form in the TPA application.
f. Third Party Administrator contact edits purchase order based on current inventory, warehouse inventory, and usage.
g. The MDHHS-BHSP covered entity medication order is approved by the Third Party Administrator with MDHHS-BHSP oversight.
h. Once approved, the medication order is sent to MDHHS warehouse to fulfill.
i. MDHHS-BHSP covered entities receive shipment.
    i. Medications are typically shipped within the week after ordering via the TPA application and approval via Third Party Administrator.
j. MDHHS-BHSP covered entities verify quantity received with quantity ordered.
    i. Identify any inaccuracies.
    ii. Resolve inaccuracies via email to MDHHS-BHSP and Third Party Administrator contact.
    iii. Document resolution of inaccuracies in the TPA application.
k. MDHHS-BHSP covered entities maintain records of 340B-related transactions for an indefinite period in a readily retrievable and auditable format.
    i. MDHHS-BHSP covered entities submit reports on a quarterly basis by the 10th of the month through the TPA application. These reports are reviewed by Third Party Administrator quarterly as part of its 340B oversight and compliance program.
        1. Refer to MDHHS-BHSP Policy and Procedure "340B Program Compliance Monitoring/Reporting."
l. MDHHS-BHSP covered entities sharing bicillin with an external provider to treat a patient must do so with an MOU (memorandum of understanding). The covered entity will coordinate with DIS who will upload completed form in MDSS/MIDASH. MOUs involve sharing bicillin with an external provider to dispense on covered entity's behalf (shared client – syphilis infection/exposure, but they are not in clinic). External provider should be indicated when tracking the medication as well as the investigation ID of the client.

Wasted 340B Medication

1. MDHHS-BHSP grant-supported covered entities are encouraged to not waste any 340B ordered medication.
    a. If a covered entity identifies extra, almost expiring, or unnecessary 340B medication in their clinic, they must contact BHSP to return the medication.
    b. All covered entities must report any 340B medication transfers to other entities via the TPA application.
2. Any wasted or destroyed medication not administered to the patient, MDHHS-BHSP grant-supported covered entities clinician staff communicates the wastage to the Third Party Administrator & MDHHS-BHSP staff and accurately reflects this outcome in the TPA application.
3. MDHHS-BHSP may need to replace medication through an appropriate purchasing account.

XV. 340B Noncompliance/Material Breach/Recalls

Policy: Covered entities are responsible for contacting MDHHS-BHSP and HRSA within 24 hours of any material breach by the covered entity or any instance of noncompliance with any of the 340B Program requirements.

Purpose: To define MDHHS-BHSP material breach of 340B compliance and self-disclosure process.

Definitions:

Material breach is a significant case(s) of missing or diverted medication, ineligible recipients, or duplicate discounts.

Materiality: A convention within auditing/accounting pertaining to the importance/significance of an amount, transaction, and/or discrepancy.

Threshold: The point that must be exceeded, as defined by the covered entity, resulting in a material breach.

Reference:
340B PVP Education Tool: Defining Material Breach Documentation Tool
https://docs.340bpvp.com/documents/public/resourcecenter/establishing-material-breach-threshold.docx

340B PVP Education Tool: Self-Disclosure to HRSA and Manufacturer Template
https://docs.340bpvp.com/documents/public/resourcecenter/self-disclosure-to-hrsa-and-manufacturer-template.docx

Procedure:

1. MDHHS-BHSP established thresholds for what constitutes a material breach of 340B Program compliance is 10% of the total 340B inventory or 10% of an audit sample.
    a. MDHHS-BHSP ensures that identification of any threshold variations occurs among all its 340B settings.

2. Violations identified through internal self-audits, independent external audits, or otherwise that meet or exceed the noted threshold will be immediately reported to HRSA and applicable manufacturers.

3. In the event of a product recall, a notice will be sent to the entities regarding the affected product.
    a. Entities are required to review their inventory for the recalled product and to remove it from inventory immediately, no longer than 5 days.
    b. The entity will contact the MDHHS warehouse to facilitate the return of the recalled product.
    c. The entity will track the recalled medication in the TPA application as appropriate.
    d. MDHHS warehouse will gather all affected product and then ship back to the wholesale distributor or repackaging company as indicated.

XVI. 340B Program Compliance Monitoring/Reporting

Policy: Covered entities are required to maintain auditable records demonstrating compliance with the 340B Program requirements.

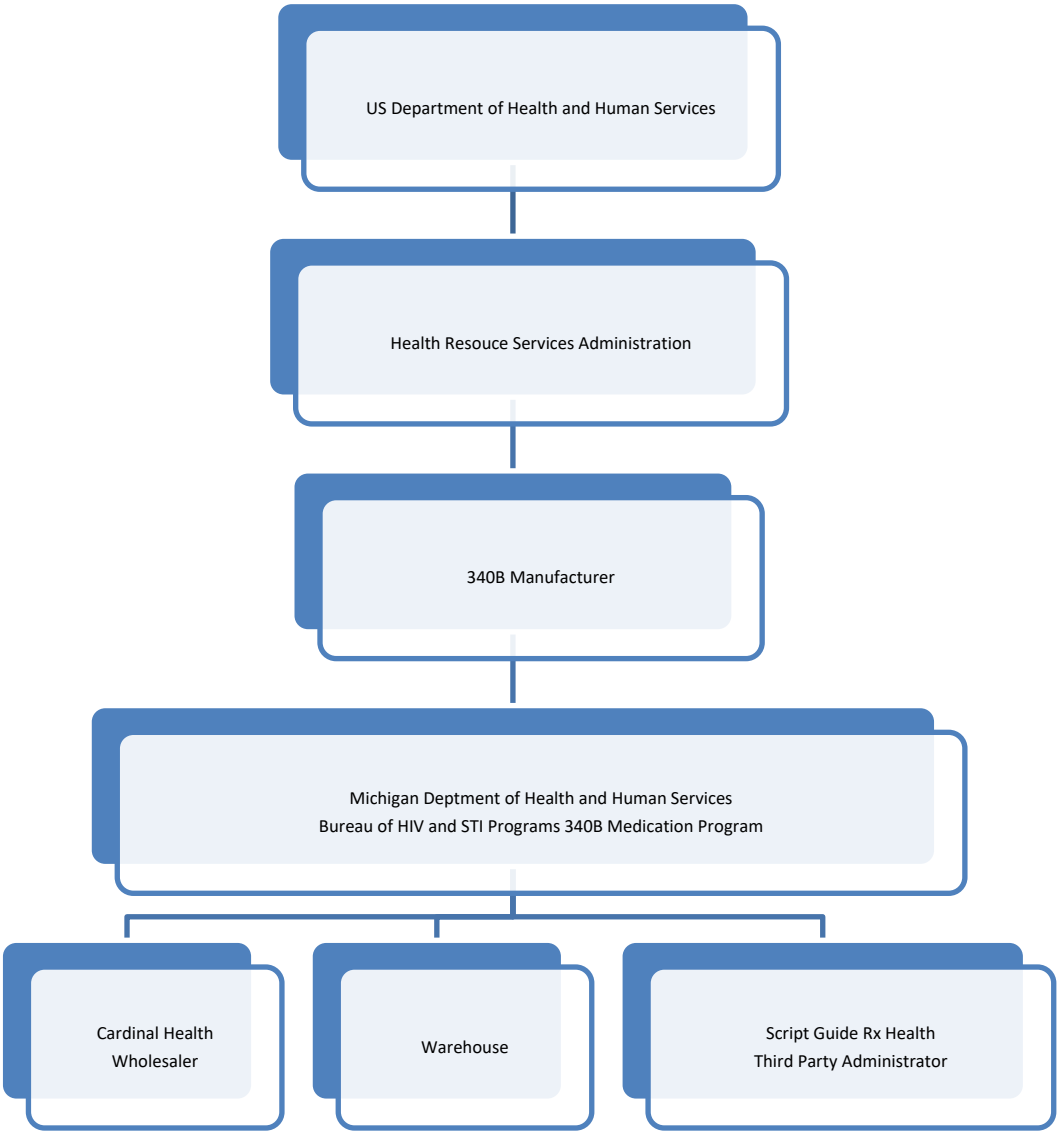
Purpose: To provide an internal monitoring program to ensure comprehensive compliance with the 340B Program

Procedure:

1. MDHHS-BHSP develops an annual internal audit plan approved by the internal compliance officer or as determined by organizational policy.
2. MDHHS-BHSP reviews 340B OPAIS to ensure the accuracy of the information for all site locations.
3. Third Party Administrator reconciles purchasing records and dispensing records quarterly to ensure that covered outpatient medication purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B medication and that any variances are not the result of diversion.
    a. Third Party Administrator is responsible for sending documentation of reconciliation purchasing records and dispensing records to MDHHS-BHSP to ensure that covered outpatient medication receive 340B medication and that any variances are not the result of diversion.
4. MDHHS-BHSP and grant-supported covered entities reconcile dispensing records to patients' health care records to ensure that all medication dispensed were provided to patients eligible to receive 340B medication. MDHHS-BHSP will randomly select (20) STD 340B ID's and select one record from each site to perform a record review audit. MDHHS-BHSP and its Third Party Administrator will perform the record review audit annually. Selected sites each year will be exempt from selection the following year.
5. MDHHS-BHSP and its TPA will select two contract partner entity sites for an on-site audit annually. This may be conducted jointly with other MDHHS programs. For on-site audits low morbidity partners will not be selected more that once in 5 years and high morbidity partners will not be selected more than once in 3 years.
    a. Selection of sites for audit may be random or may be tied to risk concerns related to past issues in proving continuing compliance with 340B medication program requirements.
    b. Sites will be notified of audit 30 days prior to audit visit.
    c. MDHHS-BHSP reserves the right to conduct more frequent site visits to covered entity locations within one grant year.
    d. Part of the on-site audit will include auditing a minimum of 2.5% of total chart records for high morbidity areas and 5% of total chart records for low morbidity areas.
6. MDHHS-BHSP 340B Oversight Committee reviews the internal audit results and shares the findings with the contracted entity. A final summary of the compliance audit will be provided to each entity. Corrective action plans will be providing within the summary, wherever applicable.
    a. Assess whether audit results are indicative of a material breach. Refer to MDHHS-BHSP Policy and Procedure "340B Non-Compliance/Material Breach."
7. MDHHS-BHSP maintains records of 340B-related transactions for a period of an indefinite period in a readily retrievable and auditable format.

XVII. Appendices

Appendix [1]: 340B Program Organizational Structure



Appendix [2]: MDHHS 340B STI Program BHSP 340B Resources

MDHHS STI 340B PROGRAM
BUREAU OF HIV AND STI PROGRAMS
340B RESOURCES

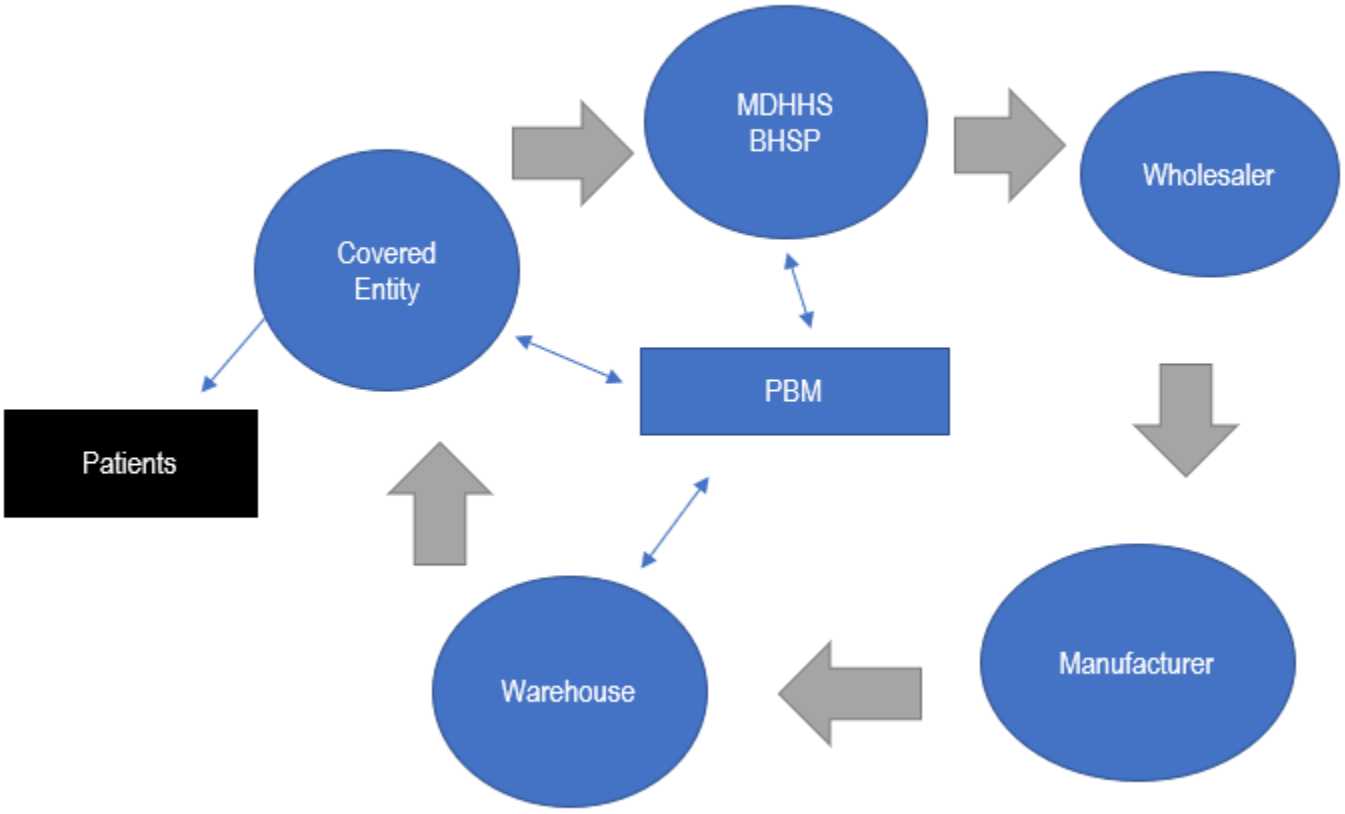
Resource and Description	Link
Introduction to the 340B Drug Pricing Program Basic Foundations: Provides a foundational overview of the 340B program and serves as a primer for the rest of the modules in the curriculum. Part of the 340B University On Demand series.	https://education.apexus.com *note: an account is required for access to the course
340B Stakeholder Perspectives Describes the major stakeholders and their roles in the 340B program. Part of the 340B University On Demand series.	https://education.apexus.com *note: an account is required for access to the course
Eligibility Overview Basic Foundations: Outlines the types of 340B-eligible organizations and eligibility and compliance requirements for covered entities. Part of the 340B University On Demand series.	https://education.apexus.com *note: an account is required for access to the course
340B Drug Pricing Program This website through HRSA provides an overview of the 340B program and any program updates. It also provides an opportunity to sign up for 340B E-Mail Updates.	https://www.hrsa.gov/opa/index.html
Apexus – 340B Prime Vendor Program Apexus is the HRSA-designated Prime Vendor for the 340B Drug Pricing Program. This website provides frequently asked questions and program overviews.	https://www.340bhealth.org/members/340b-program/overview/

Appendix [3]: MDHHS 340B STI Program Key Contacts

MDHHS-BHSP
340B STI Program Key Contacts

Name	Role	Email Address
Tom Dunn	Operations Section Manager	DUNNT@MICHIGAN.GOV
Kris Tuinier	Director, Division of HIV/STI Programs, Client, and Partner Services	TUINIERK@MICHIGAN.GOV
Dan Lowery	HIV/STI Client, Partner and Community Outreach Section Manager	LOWERYD@MICHIGAN.GOV
Shawna Brown	Financial Reporting and Analysis Unit Manager	BROWNS74@MICHIGAN.GOV
Andrew Hoffman	340B Analyst	HOFFMANA6@MICHIGAN.GOV
Jenine Clements	Region 2 Unit Manager - Client, Partner and Community Outreach Section	CLEMENTSJ@MICHIGAN.GOV
Carla Powell	Director, 340B Program Administration Services	CPOWELL@SGRXHEALTH.COM

Appendix [4]: MDHHS 340B STI Program Supply Chain Process for Providing Medication to Covered Entities and Patients



Appendix [5]: MDHHS 340B STI Program Attestation Form

Preliminary Agreement to Participate in Michigan Department of Health and Human Services (MDHHS) Bureau of HIV and STI Programs (BHSP) 340B STI Medication Distribution

Date: _____
Covered Entity: _____
Type of support from MDHHS-BHSP: In-kind / Direct

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

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

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

- Maintaining policies and procedures which promote receipt, storage, and dispensing of 340B medications within HRSA OPA regulations.
- Keeping auditable health records which will be available as necessary for program monitoring.
- Consistently maintaining documentation of chain of possession of medications, medication supply, and dispensing of medications; provide documentation to MDHHS-BHSP as needed for program participation.
- Reporting any waste or loss of MDHHS-BHSP 340B STI medications or any discovered non-compliance with HRSA OPA regulations to MDHHS-BHSP as soon as possible.
- Not billing Medicaid or other payers for medications distributed by MDHHS-BHSP 340B STI program.
- Permitting remote documentation monitoring or on-site audit and monitoring visits by MDHHS-BHSP staff or associated third party administer to ensure compliance with HRSA OPA regulations.
- Suspension from the MDHHS-BHSP 340B STI medication program if the above conditions cannot be met until issues can be documented as resolved.
- Notifying MDHHS-BHSP 340B STI 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.

_____ understands that this is a preliminary agreement to participate in the distribution model. 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 MI BHSP.

Primary Contact Signature: _____

Name: _____

Position title: _____