New STD 340B Inventory Reporting Process

February 13/15, 2018

Tom Dunn, Operations Monitoring Unit Manager
Justin Hill, Fiscal Analyst

Michigan Department of Health and Human Services
Population Health Administration
Bureau of Health and Wellness
Who is in the room?
Objectives

• Describe the Michigan STD 340B Program

• Summarize covered entity (CE) oversight of STD 340B program

• Discuss evolution with recordkeeping, documentation, and increasing audit readiness

• Describe processes for tracking STD 340B medications
Describe the Michigan STD 340B Program
HOW OUR POINT OF PURCHASE DISCOUNT SYSTEM WORKS

PHARMACEUTICAL MANUFACTURER

STD DRUGS

DRUG WHOLESALER/DISTRIBUTER (AMERISOURCEBERGEN et al.)

STD DRUGS

340B Discount Price

MDHHS (STD SECTION)

STD DRUGS

In-Kind

LOCAL HEALTH DEPARTMENTS

STD DRUGS

PATIENTS
# STD 340B Implementation Plan

<table>
<thead>
<tr>
<th>Task Name</th>
<th>Duration</th>
<th>Start</th>
<th>Finish</th>
</tr>
</thead>
<tbody>
<tr>
<td>STD 340B Implementation Plan</td>
<td>455 days</td>
<td>Mon 1/2/17</td>
<td>Mon 10/1/18</td>
</tr>
<tr>
<td>Project Definition and Development</td>
<td>283 days</td>
<td>Mon 1/2/17</td>
<td>Wed 1/31/18</td>
</tr>
<tr>
<td>Secure access to 340B discount pricing on STD drugs</td>
<td>0 days</td>
<td>Mon 1/2/17</td>
<td>Mon 1/2/17</td>
</tr>
<tr>
<td>Define scope of STD 340B coverage and identity gaps</td>
<td>177 days</td>
<td>Mon 1/2/17</td>
<td>Tue 9/5/17</td>
</tr>
<tr>
<td>Review current STD inventory flow</td>
<td>36 days</td>
<td>Wed 9/6/17</td>
<td>Wed 10/25/17</td>
</tr>
<tr>
<td>Assess inventory reporting needs</td>
<td>49 days</td>
<td>Thu 10/26/17</td>
<td>Tue 1/2/18</td>
</tr>
<tr>
<td>Developed MS Access db module to track STD 340B inventory</td>
<td>106 days</td>
<td>Wed 9/6/17</td>
<td>Wed 1/31/18</td>
</tr>
<tr>
<td>Implement new STD 340B inventory Tracking Module</td>
<td>164 days</td>
<td>Tue 2/13/18</td>
<td>Mon 10/1/18</td>
</tr>
<tr>
<td>Webinar -- New 340B Inventory Reporting Process</td>
<td>0 days</td>
<td>Tue 2/13/18</td>
<td>Tue 2/13/18</td>
</tr>
<tr>
<td>Webinar -- New 340B Inventory Reporting Process</td>
<td>0 days</td>
<td>Thu 2/15/18</td>
<td>Thu 2/15/18</td>
</tr>
<tr>
<td>Report current inventory quantities of STD 340B Drugs</td>
<td>0 days</td>
<td>Mon 4/2/18</td>
<td>Mon 4/2/18</td>
</tr>
<tr>
<td>Submit STD 340B Inventory Report for April 2018</td>
<td>0 days</td>
<td>Tue 5/1/18</td>
<td>Tue 5/1/18</td>
</tr>
<tr>
<td>Submit STD 340B Inventory Report for May 2018</td>
<td>0 days</td>
<td>Fri 6/1/18</td>
<td>Fri 6/1/18</td>
</tr>
<tr>
<td>Submit STD 340B Inventory Report for June 2018</td>
<td>0 days</td>
<td>Mon 7/2/18</td>
<td>Mon 7/2/18</td>
</tr>
<tr>
<td>Begin STD 340B Inventory 3rd Qtr Reporting (July-Sept, 2018)</td>
<td>0 days</td>
<td>Mon 10/1/18</td>
<td>Mon 10/1/18</td>
</tr>
</tbody>
</table>

**Diagram:**

- Management, STD Section
  - Analyst, Warehouse Manager, Management
  - Management, LHD
  - Analyst, Management

**Timeline:**

- 1/2

**MDHHS Division of HIV & STD Programs**

February 13/15, 2018
Reporting Logistics

• Reports must use Excel template developed by MDHHS

• Email to: MDHHS-HIVSTDoperations@michigan.gov & TrimD@michigan.gov beginning 1st work day of the month following the end reporting period.
Covered Entity Oversight of STD 340B Program
STD 340B Program Oversight

• Ensure that CEs prevent diversion of 340B purchased drugs to ineligible patients;

• Ensure that arrangements with CEs do not result in duplicate discounts; and

• Conduct oversight of CEs to detect and remedy any instances of diversion, duplicate discounts, or other violations.
340B Oversight – Patient Definition

The CE has established a relationship with the individual, such that the CE:

• Maintains records of the individual’s health care; and

• The individual receives health care services from a health care professional who is either employed by the CE or provides health care under contractual or other arrangements (e.g., referral or consultation) such that the care provided remains with the covered entity; and

• The individual receives a health care service or range of services from the CE which is consistent with the service or range of services for which grant funding for Federally-qualified health center look-alike status has been provided to the entity.
340B Oversight – Diversion

Applies to all covered entities:

• A drug is provided to an individual who is not a patient of that entity;

• A drug is dispensed in an area of a larger facility that is not eligible (e.g., an inpatient service, a non-covered clinic); and

• Required to follow patient definition guidelines – 61 Fed. Reg. 55156 (October 24, 1996)
When does a duplicate discount occur?

When the same drug is:

- Purchased with an up-front 340B discount
- Credited with a back-end transaction Medicaid rebate

and
STD 340B Drug Detail Tracking

• Access to accurate, updated details on purchases and utilization is vital to 340B compliance and savings maximization;

• Tracking and reporting enables CEs to conduct regular self-audits; and

• Provide appropriate information auditors require to determine 340B compliance, including expedited partner therapy (EPT) to consistently link meds given to a partner back to an index patient.
STD 340B Program
Recordkeeping Evolution
Michigan STD 340B Program

• Began purchasing STD drugs at 340B discounted pricing in late 2016
• Was using paper based system to manage 340B inventory
• Developed inventory tracking system for 340B compliance
Poll Question #1

How frequently will the reporting be submitted?
Please select one:

- Real time reporting
- Daily
- Weekly
- Monthly for the first three months then quarterly
Describe Processes for Tracking STD 340B Medications
340B Excel Tool
Tab Overview

Instruction and FAQs Tab describes the tool and how to use it

Each of the six medications has its own tab

Summary Tab gives a snapshot of what is on hand for each medication
## Instructions and FAQs Tab

This tab contains instructions, expectations, and FAQs regarding this tool.

### Required Fields
- **Medication IN Invoice Number**: X
- **Medication OUT Type**: X
- **Date Dispensed/Secured OR Received**: X
- **Quantity Dispensed/Secured OR Received**: X
- **Lot #:** X
- **Expiration Date**: X
- **Status**: X
- **Reason for Issue**: X
- **Dispensary Name**: X
- **Dispensary Address**: X
- **Dispensary Phone**: X
- **Dispensation Type**
  - **Dispensed to Patient**
  - **Dispensed via EPT**
  - **Dispensed to Another SHIB Entity**
  - **Dispensed to Other Provider**

### Definitions:
- **SAMPLE**: The sample is used to identify the type of event.
- **Medication:** The medication is provided to the patient.

### Other Notes:
1. Template must be kept up to date in order to stay in compliance with the federal 5401 program.
2. Every transaction must be logged.
3. Begin each reporting period with a blank template, transferring the **Total On Hand** from the previous report to the beginning balance for the new report.

### Sample Lines:

<table>
<thead>
<tr>
<th><strong>Medication IN Invoice Number</strong></th>
<th><strong>Medication OUT Type</strong></th>
<th><strong>Dispensary Name</strong></th>
<th><strong>Dispensary Address</strong></th>
<th><strong>Dispensary Phone</strong></th>
<th><strong>Dispensation Type</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1234</td>
<td>ABCD</td>
<td>01/01/17</td>
<td>123 Main St</td>
<td>555-1234</td>
<td>Dispensed to Patient</td>
</tr>
<tr>
<td>01/01/17</td>
<td>ABCD</td>
<td>01/01/17</td>
<td>123 Main St</td>
<td>555-1234</td>
<td>Dispensed via EPT</td>
</tr>
<tr>
<td>01/01/17</td>
<td>ABCD</td>
<td>01/01/17</td>
<td>123 Main St</td>
<td>555-1234</td>
<td>Dispensed to Another SHIB Entity</td>
</tr>
<tr>
<td>01/01/17</td>
<td>ABCD</td>
<td>01/01/17</td>
<td>123 Main St</td>
<td>555-1234</td>
<td>Dispensed to Other Provider</td>
</tr>
</tbody>
</table>

### Notes:
- **Reconciliation**: Must be conducted quarterly.
- **Discrepancies** must be reported to MDHHS STD Section immediately. **RECONCILIATION** should be used in the **Dispensation Type** column.

### Negative **Total On Hand**:
If you have received a warning that an entry will result in a negative **Total On Hand**, please immediately perform a physical inventory on the drug and log it as a **Reconciliation** on the spreadsheet. Any discrepancies found must be reported to MDHHS STD Section immediately.
Summary Tab

Enter your entity name here. This will be copied automatically to the medication tabs.

<table>
<thead>
<tr>
<th>[ENTITY NAME]</th>
<th>Total on Hand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azithromycin 500mg 2 tablets</td>
<td>5</td>
</tr>
<tr>
<td>Bicillin L-A 2.4mu 1 syringe</td>
<td>0</td>
</tr>
<tr>
<td>Ceftriaxone 250mg 1 vial</td>
<td>0</td>
</tr>
<tr>
<td>Doxycycline 100mg 14 tablets</td>
<td>0</td>
</tr>
<tr>
<td>Metronidazole 500mg 4 tablets</td>
<td>0</td>
</tr>
<tr>
<td>Metronidazole 500mg 14 tablets</td>
<td>0</td>
</tr>
</tbody>
</table>

Lists each medication

Pulls the Total on Hand from each of the individual medication tabs
Log each time a medication is received, dispensed, or disposed of.

Total on Hand adjusts automatically based on information in previous fields.

NDC, Lot#, and Expiration Date allow for tracking specific medications.
**Medication Tabs – Initial On Hand**

### STD Administration Tracking Log

**[ENTITY NAME]**

**Medication Name:** Azithromycin 500mg 2 tablets

<table>
<thead>
<tr>
<th>Medication IN: Invoice Number</th>
<th>Medication OUT: Type</th>
<th>Medication OUT: Patient ID/Chart #</th>
<th>Date Dispensed/Administered OR Received</th>
<th>Quantity Dispensed/Administered OR Received</th>
<th>Total On Hand</th>
<th>NDC #</th>
<th>Lot #</th>
<th>Expiration Date</th>
<th>Nurse or Designee</th>
<th>Provider Name</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning Balance</td>
<td></td>
<td></td>
<td>10/01/17</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Beginning Balance:**

The date and beginning balance entered will automatically show up on the first line.

Perform a hard count of the total number on hand. Enter the number in this field.

Enter the date the hard count was completed.
## Medication Tabs – Drug Intake

**STD Administration Tracking Log**

<table>
<thead>
<tr>
<th>[ENTITY NAME]</th>
<th>Azithromycin 500mg 2 tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication IN:</td>
<td>Medication OUT:</td>
</tr>
<tr>
<td>Invoice Number</td>
<td>Type</td>
</tr>
<tr>
<td>Beginning Balance</td>
<td>1234</td>
</tr>
</tbody>
</table>

**Instructions:**

- **Enter the Invoice/Packing Slip #, the date received, and the number of units received.**
- **The Total On Hand will update when you enter data in the fields to the left.**
- **Enter the NDC, Lot #, and Expiration date.**
- *All of this information will be included on the packing slip.*
Medication Tabs – Drug Intake, cont.

PACKING LIST # 100TES

Ship To:  
testfn testIn  
testco  
1234 test ave  
lansing mi 48917

Order Date 2/2/2018  
Invoice Date 2/2/2018  
Shipped Date 2/2/2018  
Order # 12

For assistance, please contact:  
Patsy Villegas: VillegasP@michigan.gov  
Operations: MDHHS-HIVSTDoperations@michigan.gov

<table>
<thead>
<tr>
<th>Lot Number</th>
<th>Product Description</th>
<th>NDC</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZ-500-2</td>
<td>Azithromycin 500mg 2 tablets</td>
<td>00069-3070-30</td>
<td>1</td>
</tr>
</tbody>
</table>
Medication Tabs – Drug Dispensation

Enter the Type, Patient ID/Chart #, the date dispensed, and the number of units dispensed.

*DO NOT use personally identifiable information in the Patient ID field (*HIPAA*)

Enter the NDC, Lot #, and Expiration date, Nurse/Designee, and Provider
- Nurse/Designee – Person responsible for handing the drugs to the client
- Provider – Prescribing physician

The Total On Hand will update when you enter data in the fields to the left.

<table>
<thead>
<tr>
<th>Medication IN: Invoice Number</th>
<th>Medication OUT: Type</th>
<th>Medication OUT: Patient ID/Chart #</th>
<th>Date Dispensed/Administered OR Received</th>
<th>Quantity Dispensed/Administered OR Received</th>
<th>Total On Hand</th>
<th>NDC #</th>
<th>Lot #</th>
<th>Expiration Date</th>
<th>Nurse or Designee</th>
<th>Provider Name</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning Balance</td>
<td></td>
<td></td>
<td>10/01/17</td>
<td>10</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1234</td>
<td></td>
<td></td>
<td>10/05/17</td>
<td>10</td>
<td>20</td>
<td>XXXX-XXXX-XX-XX</td>
<td>XXXX</td>
<td>01/01/19</td>
<td>T. DOE</td>
<td>F. SMITH</td>
<td></td>
</tr>
<tr>
<td>DISPENSED TO PATIENT</td>
<td>ABCDE</td>
<td></td>
<td>10/06/17</td>
<td>1</td>
<td>10</td>
<td>XXXX-XXXX-XX-XX</td>
<td>XXXX</td>
<td>01/01/19</td>
<td>T. DOE</td>
<td>F. SMITH</td>
<td></td>
</tr>
<tr>
<td>DISPENSED VIA EPT</td>
<td>ABCDE</td>
<td></td>
<td>10/06/17</td>
<td>1</td>
<td>18</td>
<td>XXXX-XXXX-XX-XX</td>
<td>XXXX</td>
<td>01/01/19</td>
<td>T. DOE</td>
<td>F. SMITH</td>
<td></td>
</tr>
</tbody>
</table>
**Medication Tabs – Reconciliation**

Choose RECONCILIATION from dropdown, enter the date of the reconciliation, and the number 0 under quantity.

The Total On Hand should not change when you enter data in the fields to the left.

Enter notes regarding any discrepancies found.

*MDHHS-DHSP must be alerted when discrepancies are identified.*

---

### STD Administration Tracking Log

<table>
<thead>
<tr>
<th>Medication IN:</th>
<th>Medication OUT:</th>
<th>Date Dispensed/Administered</th>
<th>Quantity Dispensed/Administered</th>
<th>Total On Hand</th>
<th>NDC #</th>
<th>Lot #</th>
<th>Expiration Date</th>
<th>Nurse or Designee</th>
<th>Provider Name</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invoice Number</td>
<td>Type</td>
<td>Patient ID/Chart #</td>
<td>OR Received</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beginning balance</td>
<td></td>
<td>10/01/17</td>
<td>10</td>
<td>10</td>
<td>XXXXX-XXXX-XX</td>
<td>XXXXX</td>
<td>01/01/19</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1234</td>
<td>DISPENSED TO PATIENT</td>
<td>10/06/17</td>
<td>10</td>
<td>20</td>
<td>XXXXX-XXXX-XX</td>
<td>XXXXX</td>
<td>01/01/19</td>
<td>T. DOE</td>
<td>F. SMITH</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DISPENSED VIA PPT</td>
<td>10/06/17</td>
<td>1</td>
<td>19</td>
<td>XXXXX-XXXX-XX</td>
<td>XXXXX</td>
<td>01/01/19</td>
<td>T. DOE</td>
<td>F. SMITH</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RECONCILIATION</td>
<td>10/01/17</td>
<td>0</td>
<td>18</td>
<td>XXXXX-XXXX-XX</td>
<td>XXXXX</td>
<td>01/01/19</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Choose the adjustment type from the drop down, enter the date of adjustment, and the number of units removed from inventory.

The Total On Hand will update when you enter data in the fields to the left.

Enter the NDC, Lot #, and Expiration date, and note regarding adjustment.
Medication Tabs – Warnings

These fields will highlight if information is entered in the first two fields.
An error will show if you enter a negative number here.

If you enter a number that will reduce the Total On Hand below zero, it will show an error.
Poll Question #2

Where do you submit your reports?

Please select all that apply:

- FIFO@michigan.gov
- MDHSS-HIVSTDoperations@michigan.gov
- TrimD@michigan.gov
- LIFO@michigan.gov
- Drugsforfree@michigan.gov
340B Excel Application
Poll Question #3

MDHHS is now implementing a virtual inventory order and replenishment system.

Please select one:

- True
- False
Discussion and Questions
TOM DUNN, MANAGER, OPERATIONS MONITORING UNIT
PHONE: (517) 373-3725
EMAIL: DunnT2@michigan.gov

JUSTIN HILL, FISCAL ANALYST, OPERATIONS MONITORING UNIT
PHONE: (517) 373-3427
EMAIL: HillJ29@michigan.gov

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LANSING, MICHIGAN 48913