

**MILLE LACS BAND OF OJIBWE
HEALTH AND HUMAN SERVICES POLICY & PROCEDURE**

Department: Health Services-Pharmacy

Policy Number: HHS-HS-PHM 1848

Policy Title: 340B Program Roles and Responsibilities

Attachments:

Revision History: 9/27/2018

Revised by/Date: Jesse Godding 2/25/2020

Approved by:

Jesse Godding, Pharmacy Manager



Date:

4-21-2020

Approved by:

Nicole Anderson, Commissioner of HHS



Date:

4-22-2020

POLICY STATEMENT: Covered entities participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements, therefore, it is the policy of Mille Lacs Band of Ojibwe (MLBO) Indians doing business as Ne-Ia-Shing (NIS) clinic to define roles and responsibilities as they pertain to the 340B program.

PURPOSE: To identify MLBO's key stakeholders and determine their roles and responsibilities in maintaining 340B Program integrity and compliance

PROCEDURE:

- a) MLBO has established a 340B Committee that is responsible for overseeing the 340B Program. The committee meets on a regular basis at least quarterly.
- 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.
 - a. Ensures MLBO meets compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.
 - b. Integrates departments such as information technology, legal, pharmacy, compliance and patient financial services to develop standard processes for contract/data review to ensure program compliance.
- d) Oversees the review process of compliance activities, as well as taking corrective actions based on findings.
 - i. 340B Committee assesses if the results are indicative of a material breach. (Refer to MLBO's 340B Non-Compliance/Material Breach Policy)
- e) Reviews and approves work group recommendations (process changes, self-monitoring outcomes and resolutions).

The following MLBO staff are potential key players in the 340B Program, including governance and compliance, and should be standing members of the 340B Committee. MLBO will identify who serves as the authorizing official and primary contact for the 340B Committee.

MILLE LACS BAND OF OJIBWE
HEALTH AND HUMAN SERVICES POLICY & PROCEDURE

- 1) Commissioner of Health and Human Services or Designee
 - a) Responsible as the authorizing official in charge for the compliance and administration of the program
 - b) Responsible for attesting to the compliance of the program through recertification
- 2) Finance/Accounting
 - a. Must account for savings and use of funds to provide care for the indigent under the indigent care agreement.
- 3) Pharmacy Manager or Designee
 - a. Accountable agent for 340B compliance
 - b. Agent of the Commissioner of Health and Human Services responsible to administer the 340B Program to fully implement and optimize appropriate savings and ensure that current policy statements and procedures are in place to maintain program compliance
 - c. Must maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to HRSA rules and Medicaid changes
 - d. Must coordinate constant knowledge of any change in clinic eligibility/information
 - e. Responsible as the primary contact for the 340B Program
 - f. Day-to-day manager of the 340B Program
 - g. Responsible for maintenance and testing of tracking software
 - h. Responsible for documentation of policies and procedures
 - i. Maintains system databases to reflect changes in the drug formulary or product specifications
 - j. Manages purchasing, receiving, and inventory control processes
 - k. Continuously monitors product minimum/maximum levels to effectively balance product availability and cost-efficient inventory control
 - l. Ensures appropriate safeguards and system integrity
 - m. Performs annual inventory and monthly cycle counts
 - n. Ensures compliance with 340B Program requirements for qualified patients, drugs, providers, vendors, payers and locations
 - o. Reviews and refines 340B cost savings report, detailing purchasing, and replacement practices as well as dispensing patterns
 - p. Monitors ordering processes, integrating most current pricing from wholesaler, and analyzes invoices, shipping and inventory processes
 - q. Aware of products covered by 340B and Prime Vendor Program pricing
 - r. Works with the medical staff to use effective therapeutic classes that optimize savings with good clinical outcomes see Pharmacy and Therapeutics Committee Policy
 - s. Responsible for establishing two distribution accounts and maintaining those accounts: Non-340B account and 340B account
 - t. Responsible for establishing and maintaining direct 340B accounts
 - u. Responsible for ordering all drugs from the specific accounts as specified by the process employed
 - v. Responsible for segregation, removal and/or return of 340B drugs, including reverse distributor transactions
 - w. Responsible for reconciliation of lend and borrow transactions.

**MILLE LACS BAND OF OJIBWE
HEALTH AND HUMAN SERVICES POLICY & PROCEDURE**

- x. Responsible for communication of all changes to Medicaid reimbursement for pharmacy services/products that affect 340B status
- y. Responsible for modeling all managed care contracts (with/without 340B)
- z. Engages pharmacy in conversations that affect reimbursement
- 4) Compliance Officer
 - a. Designs and maintains an internal audit plan of the compliance of the 340B Program
 - b. Designs the annual plan to cover all changes in the 340B Program from the preceding year.
 - c. Responsible for annual or semiannual physical inventory of pharmacy items
 - d. Responsible for establishment of “inventory average” process approved by the external audit firm
- 5) IT Officer
 - a. Supports the pharmacy software selection of tracking software to manage the 340B Program Supports the interface between EHR and pharmacy software.

Internal and/or External References	HHS-HS-PHM 1842 340B Non-Compliance Material Breach
Compliance - Posting Date	4/22/2020 11/11
Replaces – Policy Number	
Next Review - Due Date	4/22/2021