

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

Department: Health Services-Pharmacy

Policy Number: HHS-HS-PHM 1842

Policy Title: 340B Noncompliance Material Breach

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: Mille Lacs Band of Ojibwe (MLBO) Indians doing business as Ne-Ia-Shing (NIS) Clinic will contact Health Resources and Services Administration (HRSA) as soon as reasonably possible if there is any material breach or any instance of noncompliance with any of the 340B Program requirements.

PURPOSE: To define MLBO's material breach of 340B compliance and self-disclosure process.

DEFINITIONS:

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.

Example of thresholds include:

- a. X% of total 340B purchases or impact to any one manufacturer.
- b. \$X (fixed amount), based on total 340B spend, or impact to any one manufacturer.
- c. X% of total 340B inventory (units)
- d. X% of audit sample X% or prescription volume/prescription sample.

PROCEDURE:

- MLOB's established threshold of what constitutes a material breach of 340B Program compliance is 10% of total 340B purchases.
- MLBO assesses materiality based on 10% of McKesson Account 780269 purchases = \$53,411.
- MLBO reports identified material breach immediately to HRSA and applicable manufactures.
- MLBO maintains records of material breach violations, including manufacturer resolution correspondence, as defined by organizational policy.
- The HRSA/OPA template will be used for self-reporting 340B noncompliance to HRSA/OPA and to manufactures.

Internal and/or External References	
Compliance - Posting Date	4/22/2020 HH
Replaces – Policy Number	
Next Review - Due Date	4/22/2021