

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

Department: Health Services-Pharmacy

Policy Number: HHS-HS-PHM 1849

Policy Title: 340B Program Enrollment, Recertification, and Change Requests

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 is registered on, and maintains the accuracy of, the Health Resource & Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System (OPAIS) to participate in the 340B Program.

PURPOSE: To ensure MLBO registration on, and accuracy of, the HRSA 340B OPAIS.

PROCEDURE: 340B Drug Pricing Program: On-line registration instructions at <http://opanet.hrsa.gov/OPA/CERregister.aspx?isnew=true>

Registration dates: January 1-January 15 for an effective start date of April 1
 April 1-April 15 for an effective date of July 1
 July 1-July 15 for an effective date of October 1
 October 1-October 15 for an effective date of January 1

1. MLBO HHS Commissioner is the authorizing official.
2. MLBO Pharmacy Manager is the primary contact.
3. MLBO has available the required document conferring the 340B eligibility.
4. The authorizing official completes registration on the HRSA 340B OPAIS <https://opanet.hrsa.gov/340B/default>.

Recertification Procedure

The authorizing official completes the annual recertification by following the directions in the recertification email sent from HRSA to the authorizing official prior to the stated deadline. Specific recertification questions should be submitted to 340b.recertification@hrsa.gov

Enrollment Procedure: New Outpatient Facilities

MLBO determines that a new service site of facility is eligible to participate in the 340B Program. The criteria used to include that service site must be identified in the grant, have outpatient drug use, and have patients who meet the 340B patient definition.


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Enrollment Procedure: New Contract Pharmacy

1. MLBO has a signed contract pharmacy services agreement, containing the 12 essential compliance elements in the Contract Pharmacy Guidance, in place between the entity and contract pharmacy prior to registration on the HRSA 340B OPAIS <http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>
 - a. MLBO’s legal counsel has reviewed the contract and verified that all federal, state and local requirements have been met.
2. MLBO has contract pharmacy oversight and monitoring policy and procedure developed, approved and implemented.
3. MLBO’s authorizing official or designee completes the online registration during one of four registration windows.
 - a. Within 15 days from the date of the online registration, the authorizing official certifies online that the contract pharmacy registration request was completed.
4. MLBO begins using the contract pharmacy services arrangement only on or after the effective date shown on the HRSA 340B OPAIS

Changes to MLBO Information in HRSA 340B OPAIS Procedure

1. MLBO notifies HRSA immediately of any changes to MLBO’s eligibility to participate in the 340B Drug Program (such as termination of grant or change in designation).
 - a. MLBO will stop the purchase of 340B drugs as soon as the change in 340B eligibility is identified; refer to MLBO 340B Eligibility Policy.
 - b. MLBO’s authorizing official will complete the online change request as soon as a change in eligibility is identified.
 - i. MLBO will expect changes to be reflected within 2 weeks of submission of the changes/requests.
2. MLBO will notify HRSA immediately of any changes to MLBO’s information on its HRSA 340B OPAIS. Refer to MLBO 340B Eligibility Policy
3. MBLO’s authorizing official will complete the online change request as soon as a change in eligibility is identified.
 - a. MLBO will expect changes to be reflected within about 2 weeks of submission of the changes/requests.

Internal and/or External References	HHS-HS-PHM 1840 Covered Entity Eligibility
Compliance - Posting Date	4/22/2020 
Replaces – Policy Number	
Next Review - Due Date	4/22/2021