

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

Department: Health Services - Pharmacy

Policy Number: HHS-HS-PHM 1812

Policy Title: Adverse Drug Experience Reporting

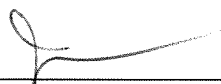
Attachments:

Revision History: 1984, 7/01, 7/12

Revised by/Date: Jesse Godding, PharmD 9/2020

Approved by:

Jesse Godding, PharmD, Pharmacy Manager



Date:

1-12-2021

Approved by:

Nicole Anderson, Commissioner of HHS



Date:

1-13-2021

POLICY STATEMENT: Any adverse drug reactions shall be reported to the Pharmacy Department. The Pharmacy Department will follow procedures in this policy to ensure that further adverse reactions do not occur and file written reports as indicated.

PURPOSE: To establish appropriate protocols for the reporting of adverse drug reactions and drug product defects for the prevention of further events.

PROCEDURE: When adverse drug reactions occur they should be reported to the pharmacy and the prescriber notified. In addition, the reaction shall be noted in the patient's health record.

Forms to communicate adverse reactions to the pharmacy are provided at the nurse's station.

If the reaction is of an uncommon or serious nature, the Pharmacy Department is responsible for completing a Adverse Drug Reaction Report utilizing the MedWatch form and reporting directly to the FDA. A copy of all such reports will be retained in the pharmacy for 3 years. A notation should be made in the patient's health record regarding any Adverse Drug Reaction reports filed.

Internal and/or External References	
Compliance - Posting Date	1/13/21 (HSA)
Replaces – Policy Number	
Next Review - Due Date	