

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

Department: Health Services-Pharmacy

Policy Number: HHS-HS-PHM 1860

Policy Title: Electronic Prescribing of Controlled Substances


Attachments:

Revision History: new policy

Revised by/Date: Jesse Godding, 7/2021

Approved by: 
Jan Manary, Executive Director of Health Services

Date: 8.30.2021

Approved by: 
Nicole Anderson, Commissioner of HHS

Date: 8.31-2021

POLICY STATEMENT: All Mille Lacs Band Health and Human Services (HHS) providers with prescribing privileges to order controlled substances will electronically sign and transmit controlled substance prescriptions (EPCS) using two-factor authentication (USB token and digital signature) in accordance with DEA regulations.

PURPOSE: The purpose of this policy is to implement the Drug Enforcement Administration (DEA) final regulations contained in Title 21 CFR Subpart 1311 surrounding electronic transmission and receipt of controlled substance prescriptions. The use of modern technology for controlled substance prescriptions will assist the health system with meeting Minnesota requirements for controlled substance prescription transmission as well as create a closed system of controls on internal controlled substances prescriptions.

PROCEDURE:

I. Identity Proofing and Credentialing Providers

1. The Credentialing Office will be responsible for credentialing providers, and will conduct the vetting, identity proofing, and credentialing of a provider to conduct EPCS.
2. Any provider who is credentialed with Mille Lacs Band HHS will be considered to have met the credentialing requirements for EPCS.
3. The Quality and Compliance Director or designee will review and authorize the creation and activation of the provider's EPCS profile in the Electronic Health Record (EHR) and forward the authorization to the Provider Profile Administrator (PPA) and Pharmacy Manager.
4. The Medical Director/Lead Physician will serve as backup for the Quality and Compliance Director for EPCS authorization.

II. Creating Provider EPCS Profile

1. The EPCS Provider Profile Administrator (PPA) will verify the information provided by the Credentialing Office for accuracy. If correct, the PPA will create an EPCS profile for the provider and enter the information into the EHR. The role of PPA will be fulfilled by the HIM Coordinator or designee.
2. The EPCS Provider Access Admin (PAA) will verify the provider EPCS information entered into the EHR by the PPA. The role of PAA will be fulfilled by the Pharmacy Manager or designee.

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3. The Director of Informatics will act as a backup for both PPA and PAA roles should a backup be necessary.

III. Controlled Substance Medication Ordering

1. All providers approved for EPCS will need to obtain a USB token and certificate by redeeming a voucher from an authorized secure access solution (such as IdenTrust) to electronically sign and transmit controlled substance prescriptions.
2. The Pharmacy Manager, or designee, will be responsible for vouchers, certificate renewals and for tracking token digital signing certificates.
3. Upon notification by the Quality and Compliance Director or designee, the Pharmacy Manager will send approved providers a voucher which will be used to obtain a certificate and token from the secure access vendor.
4. In the event that a token is lost or stolen, or a provider with EPCS authorization leaves the organization the Pharmacy Manager and secure access vendor must be notified within 24 hours and the token and associated certificate will be revoked.
5. All providers with privileges to write controlled substances and HHS issued hardware will electronically sign and transmit controlled substance prescriptions using two-factor authentication (USB token and digital signature).
6. Instances where a prescriber creates a situation where the UDS token is temporarily unavailable will be addressed by the providing using paper prescriptions until the situation is resolved.
7. All providers who have been approved for EPCS will be allowed to prescribe Schedules II-V electronically

IV. Audit and Incident Response Report

1. Audit and Incident Response Reports RPMS mailman messages will be reviewed daily by pharmacy staff. Any identified anomalies will be reported, investigated, and addressed. A log of report findings and resolutions will be stored electronically within the pharmacy department.
2. The Pharmacy Manager is responsible for Incident Response if anomalies are discovered.

V. Record Retention

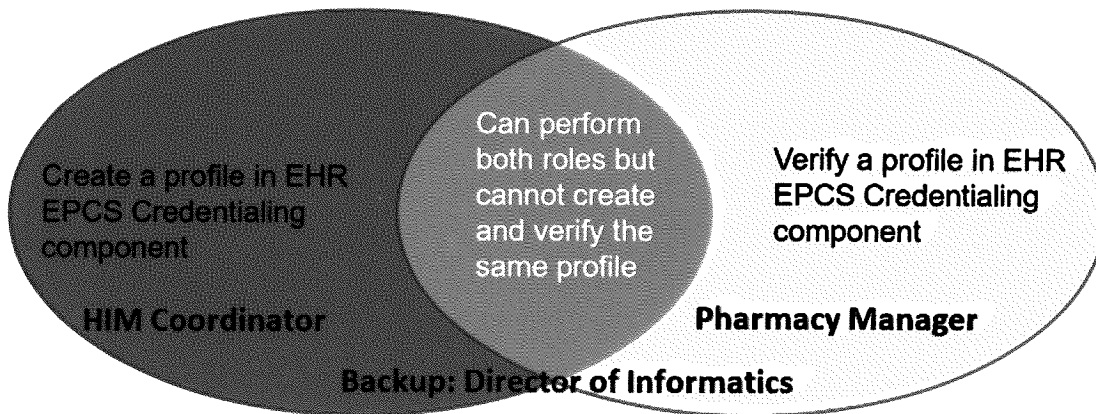
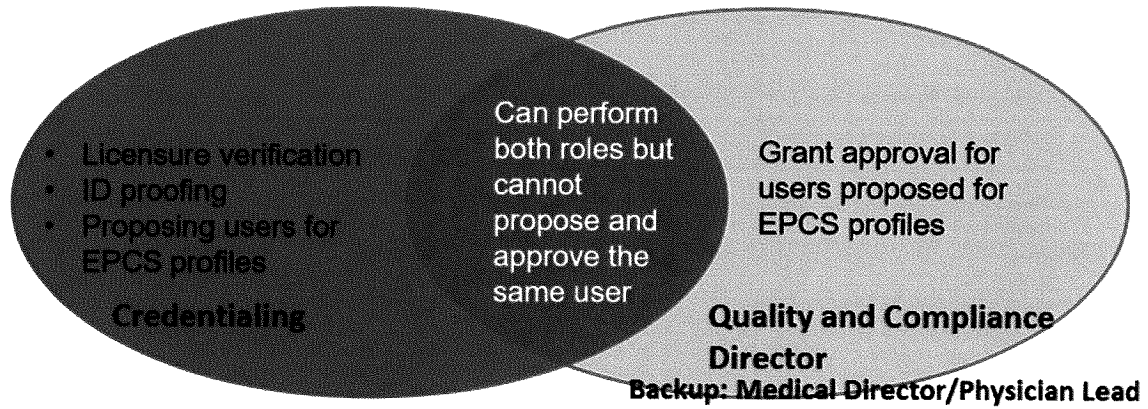
1. Digitally signed medication orders and EPCS audit logs are to be retained according to DEA and the National Archives and Records Administration (NARA) requirements.
2. Records must be kept of individuals who are authorized to perform the various roles involved in EPCS.

VI. Contingency Planning

1. The primary contingency option for EPCS failure is to fall back to issuing paper prescriptions until root causes can be identified and resolved.

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VII. Roles



Internal and/or External References	Title 21 CFR Subpart 1311
Compliance - Posting Date	8/31/2021
Replaces – Policy Number	
Next Review - Due Date	