

Alaska Native Medical Center

Electronic Prescribing for Controlled Substances (EPCS) Procedure #500-Draft
Reference Policy: Provision of Care, Treatment and Services Policy # 500D

**THIS IS A DRAFT DOCUMENT BEING DISTRIBUTED TO USE AS A STARTING POINT
FOR POLICY DEVELOPMENT**

1. Purpose:

To establish the processes to enable Alaska Native Medical Center (ANMC) providers to electronically prescribe (ePrescribe) controlled substances, in accordance with applicable law, regulations, and standards, including those established by the Drug Enforcement Agency (DEA) regulations (21 CFR 1311, Subpart C).

2. Scope:

All organizational components of the ANMC accredited campus, defined as its patients, guests, staff, residents, non-physician interns, students, volunteers, and contractors prescribing controlled substances

3. Definitions:

- 3.1. Authentication means the process or action of proving or showing something to be true, genuine or valid.
- 3.2. Authentication Modalities may include hard token, soft token, biometrics, or other modality accepted by ANMC.
- 3.3. Identity Proofing means definitively confirming the practitioner is who they claim to be.
- 3.4. Logical Access Control (LAC) means verifying the authenticated user has the authority to perform the requested operation.

4. Procedure:

- 4.1. EPCS Application: ANMC will ensure its EPCS application meets all regulatory requirements, including the requirement that a qualified third-party auditor or certification organization has determined the application meets DEA requirements.
 - 4.1.1. Documentation of the third-party determination will be maintained by Informatics and a copy will be provided to the director of any pharmacy using the EPCS system.

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- 4.1.2. If notice is received the EPCS application no longer in compliance, its use for controlled substance prescriptions will cease until notice the application is again compliant.
- 4.2. Prescribers Requirements: To ePrescribe controlled substances, a prescriber must:
 - 4.2.1. Be configured with a unique identifier;
 - 4.2.2. Have a National Provider Identifier (NPI);
 - 4.2.3. Have a *Surescripts* Provider Identifier (SPI);
 - 4.2.4. Have a DEA Number and be in good standing with the DEA; and
 - 4.2.5. Be appropriately privileged and credentialed.
- 4.3. Identity Proofing. Before being assigned an EPCS authentication credential, each ANMC practitioner will have his or her identity proofed and his or her ability to prescribe controlled substances validated by the Medical Staff Office (MSO).
 - 4.3.1. Designated Individuals. ANMC must designate, in writing, which individuals, by name or by job title, within the MSO, may perform identity proofing. ANMC must maintain a record of the designation.
 - 4.3.2. Process. The designated individual must proof the practitioner's identity by:
 - 4.3.2.1. Physically matching the practitioner to official photographic identification issued by the Federal or State government (e.g., driver's license or passport);
 - 4.3.2.2. Verify the practitioner is authorized to practice in Alaska by checking a state medical license or other state certification/accreditation/licensure for health care providers, and authorized in Alaska to prescribe controlled substances; and
 - 4.3.2.3. Verify the practitioner is authorized by the DEA to prescribe controlled substances (either under his/her own DEA registration number or the institutional practitioner's DEA registration number);

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- 4.3.2.4. If the identity proofing process is successfully passed, the MSO will add the practitioner to the list of providers authorized for EPCS. The list must be approved by two designated individuals in the MSO and submitted to the Logical Access Control Team.
- 4.3.3. Documentation. ANMC will retain a record of the identity-proofing process, including:
 - 4.3.3.1. The identity of the person(s) who performed the identity proofing with signatures attesting to the validity of the process;
 - 4.3.3.2. The date the identity proofing was conducted;
 - 4.3.3.3. The form of photographic identification used to verify the identity of the prescriber, including the type of identification, the issuing authority, any unique identification numbers (e.g., passport number), of the ID document.
 - 4.3.3.4. The type of state licensure or other state certification verified, any unique identification numbers for this licensure, and the means used to verify the licensure is current (e.g., confirmatory documents, conversations, emails).
 - 4.3.3.5. The practitioner's DEA registration number (if prescribing under that number), or the institutional practitioner's DEA registration number along with attestation by the institutional practitioner it authorizes use of its DEA registration (if prescribing under that number).
- 4.4. Issuing Authentication Credentials: Credentials are the two-factor authentication tokens required to access the EPCS signing function.
 - 4.4.1. Enrollment Supervisors. Credentials are issued by the Enrollment Supervisors, based on the list of approved practitioners provided by the MSO; the list must be approved by two individuals.
 - 4.4.2. Process. For each approved practitioner, an Enrollment Supervisor generates credentials associated with the practitioner's user account and delivers them to the practitioner through a process in which the Enrollment Supervisor:

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- 4.4.2.1. Meets with the practitioner (in person or remotely over video) and re-confirms the practitioner's identity by verifying photographic identification issued by the federal or state government matching the person presenting the identification.
- 4.4.2.2. Assists with downloading the appropriate software on the practitioner's device.
- 4.4.2.3. Authorizes and assigns the practitioner a two-factor authentication credential.
- 4.4.3. Documentation. A record of the issuance of the credential must be kept. The record of the federal or state government issued ID number used by the Enrollment Supervisor for identity proofing and the issuance of two-factor authentication credentials is maintained in the authentication token management tool.
- 4.5. Logical Access Control (LAC):
 - 4.5.1. Designated Individuals. ANMC must designate in writing at least two individuals by name or job title on the LAC Team to enter logical access control data and must maintain a record of this designation.
 - 4.5.2. Enabling LAC. Each approved practitioner's user account must be configured to allow ePrescribing by setting the appropriate "access control" privileges. To prevent a single person from granting a practitioner the ability to ePrescribe controlled substances:
 - 4.5.2.1. One LAC team member *nominates* the practitioner.
 - 4.5.2.2. A second LAC team member *approves* the practitioner.
 - 4.5.3. Revoking LAC: A practitioner's ability to ePrescribe controlled substances must be revoked immediately (on the date the occurrence is discovered) by the LAC Team, if:
 - 4.5.3.1. The practitioner's two-factor authentication token is lost, stolen, or compromised;
 - 4.5.3.2. The practitioner's DEA registration expires, unless the registration has been renewed;

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- 4.5.3.3. The practitioner's DEA registration is terminated, revoked, or suspended; or
 - 4.5.3.4. The practitioner leaves ANMC or otherwise loses access rights.
 - 4.5.3.5. Revocation or suspension is also appropriate in response to a report by a practitioner made under the following "Practitioner Responsibilities" section.
- 4.6. Practitioner Responsibilities:
- 4.6.1. General Responsibilities. Failure to comply with the requirements for electronic prescribing of controlled substances may lead to revocation or suspension of the practitioner's DEA registration, or to responsibility for electronic prescriptions written using their credentials. These requirements are in addition to those established in other ANMC policies and procedures, including those established by ANMC Pharmacy and Therapeutics procedures regarding controlled substances, and including the following:
 - 4.6.2. Practitioners have an obligation to keep their tokens, passwords, and other credentials safe and private and may not share that information with any other person or allow any other person to use the authentication.
 - 4.6.3. Practitioners must request and periodically review an Ad Hoc *Prescriber EPCS Activity Report* detailing the practitioner's EPCS activity for the most recent time period.
 - 4.6.4. Additionally, if a practitioner is notified an electronic prescription was not successfully delivered, they must issue a replacement prescription. The practitioner must ensure any paper or oral prescription (where permitted) issued as a replacement of the original electronic prescription indicates the prescription was originally transmitted electronically to a particular pharmacy and the transmission failed.
 - 4.6.5. Notification Requirements. Practitioners must also immediately and not longer than one business day, notify ANMC IT Help Desk via e-mail or phone (ext. 2626), upon discovery that:

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- 4.6.5.1. A token is lost, stolen, or compromised, including where a device (such as a cellular phone) housing a token application is replaced; or
- 4.6.5.2. A prescription is placed under his or her name was not signed by the practitioner or was not consistent with a signed prescription. In addition to internal notification requirements, the DEA must be notified of these events within one business day of discovery.
- 4.6.6. IT Help Desk Responsibility. During business hours, the IT Help Desk will notify the LAC Team of these practitioner reports. If the report is made after hours, the IT Help Desk will notify the on-call Informatics Team member, who will notify the LAC Team. Upon notification, the LAC Team terminates the provider's ability to ePrescribe until the underlying concern is resolved.
- 4.7. Audit Reports:
 - 4.7.1. Monthly Prescriber Report. A monthly *Prescriber EPCS Activity Report* is generated monthly and transmitted to the practitioner's message center for the practitioner to review, in order to allow determination as to whether any identified auditable event represents a security incident potentially compromising the integrity of the prescription records.
 - 4.7.2. Daily Audit Report. The EPCS application generates daily audit reports, although the review of the reports may vary.
- 4.8. Incident Reports: ANMC must review any incident reports generated by the EPCS audit tool.
 - 4.8.1. Report Content. At a minimum, the EPCS application must generate an incident report that includes:
 - 4.8.1.1. Attempted unauthorized access to the electronic prescription application, or successful unauthorized access where the determination of such is feasible.
 - 4.8.1.2. Attempted unauthorized modification or destruction of any information or records required by this part, or successful unauthorized modification or destruction of any

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information or records required by this part where the determination of such is feasible.

- 4.8.1.3. Interference with application operations of the prescription application.
- 4.8.1.4. Any setting of or change to logical access controls related to the issuance of controlled substance prescriptions.
- 4.8.1.5. Attempted or successful interference with audit trail functions.
- 4.8.2. Review of Incident Reports. Incident reports will be monitored by the Ethics and Compliance Services (ECS). ECS will notify the Pharmacy Director and the CORE Team of any incidents to facilitate review.
 - 4.8.2.1. Any incidents representing successful attacks on the application or other incidents in which someone gains unauthorized access must be reported to the electronic prescription application provider and the DEA within one business day. Any identified auditable event representing a security incident compromising or could have compromised the integrity of the prescription records must be reported to the electronic prescription application provider and the DEA within one business day.
 - 4.8.2.2. The Ethics and Compliance Services Department, in coordination with the Pharmacy Director, reports incidents to the DEA.
 - 4.8.2.3. The CORE Team reports incidents to the application provider via *Cerner Support*.
- 4.9. Pharmacy Responsibilities: Responsibilities for pharmacies using the EPCS application are addressed in the ANMC Pharmacy and Therapeutics procedures regarding controlled substances.