U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

NOV 3 0 2015

CAPT Susan V. Karol, MD, FACS
Chief Medical Officer
Department of Health and Human Services
Public Health Service
Indian Health Service
Rockville, Maryland 20852

Dear Dr. Karol:

This is in response to your letter dated April 27, 2015, to the Drug Enforcement Administration (DEA). On behalf of Indian Health Service (IHS), and pursuant to Title 21, Code of Federal Regulations, Section 1307.03 (21 C.F.R. § 1307.03) you requested an exception to the conditions of 21 C.F.R. Part 1311, Subpart C. Specifically, you requested an exception to 21 C.F.R. §§ 1311.115, 1311.120(b)(9), (b)(13), (b)(23), (b)(25), 1311.150, 1311.215(b), and 1311.300 because IHS anticipates completion of software development, testing, certification, and release to bring IHS's Resource and Patient Management System Electronic Health Record (RPMS/EHR) into conformity with the Interim Final Rule (IFR) titled, *Electronic Prescriptions for Controlled Substances* by December 2018. This IRF became effective June 1, 2010.

Pursuant to 21 C.F.R. § 1307.03, the Administrator of the DEA may grant an exception to the application of the regulations contained in chapter II of Title 21 of the Code of Federal Regulations; however, the Administrator may not grant any exceptions to the requirements of the Controlled Substances Act. This authority is delegated to the Deputy Assistant Administrator, Office of Diversion Control.

Upon review of IHS's request for an exception seeking to utilize an electronic prescription application that does not meet the requirements outlined in 21 C.F.R., Part 1311, Subpart C, the DEA must deny your request. All requirements of 21 C.F.R. Part 1311, Subpart C must be followed by IHS.

IHS's RPMS/EHR application must meet the below listed requirements:

(1) application **must** require the practitioner to authenticate to the application using an authentication protocol that uses, at minimum, two-factors as defined in 21 C.F.R. § 1311.115;

(2) application **must** present for the practitioner's review and approval, specific data for each controlled substance prescription as listed in 21 C.F.R. § 1311.120(b)(9);

(3) application **must** allow the practitioner to indicate, individually, that each controlled substance prescription is ready to be signed as explained in 21 C.F.R. § 1311.120(b)(13);

(4) application **must** maintain an audit trail of specific data as listed in 21 C.F.R. § 1311.120(b)(23);

(5) application **must** conduct internal audits and generate reports on any of the events specified in 1311.150 in a format that is readily retrievable as explained in 21 C.F.R. § 1311.120(b)(25);

(6) application **must** establish and implement a list of auditable events as listed in 21 C.F.R. § 1311.150;

(7) application **must** analyze the audit trail at least once every calendar day and generate an incident report that identifies each auditable event as explained in 21 C.F.R. § 1311.215(b); and

(8) application **must** have a third-party audit of the application that determines that the application meets the requirements as listed in 21 C.F.R. § 1311.300.

For information regarding the DEA Office of Diversion Control visit www.DEAdiversion.usdoj.gov. If you have additional questions on this issue, please contact the DEA Office of Diversion Control Liaison and Policy Section at (202) 307-7297.

Sincerely,
/Louis J. Milione/
Louis J. Milione
Deputy Assistant Administrator
Office of Diversion Control

Indian Health Service
Rockville MD 20852

April 27, 2015

Ruth A. Carter
Chief, Liaison & Policy Section
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Ms. Carter:

Per recent conversations between our offices, the Indian Health Service (IHS) requests that the Drug Enforcement Administration recognize a deviation from Title 21 CFR Part 1311 "Requirements for Electronic Orders and Prescriptions" to facilitate the use of IHS's Resource and Patient Management System Electronic Health Record (RPMS/EHR) system for electronically ordering and prescribing Schedule II-V drugs through December 2018. IHS anticipates completion of software development, testing, certification, and release to bring the RPMS/EHR into conformity with the rule by December 2018.

IHS is required under 25 U.S.C. § 1662 to maintain an automated management information system. Section 1662 directs IHS to make this information system available to Tribal Health Programs. The IHS RPMS/EHR, established consistent with this directive, is utilized for documentation of patient care and health information, including ordering and processing of prescriptions, in all IHS facilities and the majority of Tribal and Urban facilities across the Indian Health system. RPMS/EHR is a complete electronic medical record and pharmacists using the system have access to patient progress notes, diagnosis, laboratory values, and other information generally not available to pharmacists in a traditional pharmacy practice. RPMS/EHR[1] partially complies with 21 CFR 1311, but IHS requests a deviation from the following sections so that software development, testing, certification, and release can be completed without negative impact to patient care or patient safety:

§ 1311.115 Additional requirements for two-factor authentication

The current IHS system requires a series of sequential single-factor authentication steps, including unique network access (username and password or two-factor Personal Identity Verification PIV card), separate RPMS/EHR username and password, and a separate electronic signature code to electronically sign prescriptions. IHS will complete software and hardware

[1] This deviation is requested only for the IHS RPMS/EHR system and is not intended to imply waiver and/or authorization for any other electronic medical record software that may be in use within the Indian Health system.

changes to incorporate two-factor authentication for electronic digital signature of controlled substance prescription orders but cannot fully implement a two-factor authentication process until it can transition tribal users of RPMS/EHR.

RPMS/EHR single-factor authentication is encrypted, transmitted to the server over secured network connection, unencrypted, and then hashed for comparison with access credentials stored on the server. In addition to encrypted single-factor authentication for RPMS/EHR access, several security keys, DEA registration number, National Provider Identifier (NPI) and Surescripts Provider Identifier (SPI) are required for access to e-prescribe medications including controlled substances. Electronic verification of SPI is used to ensure providers are enrolled before e-prescribing is enabled. Until IHS can fully implement a two factor authentication system, IHS believes these procedures are sufficiently secure and do not raise a heightened risk of diversion.

§ 1311.120(b)(13) Individually indicate each prescription is ready for signature

RPMS/EHR currently allows providers to indicate that all prescriptions are ready for signature. IHS will complete software changes to require provider to individually indicate that each controlled substance prescription is ready for signature.

§ 1311.120(b)(23), § 1311.120(b)(25), § 1311.150, § 1311.215(b) Auditable events

RPMS/EHR currently maintains comprehensive audit trails of actions related to signing and transmitting prescriptions, access control permissions related to ordering and dispensing controlled substance prescriptions, and controlled substance prescription records. IHS will make software changes to comply with the required auditable events, analyze audit trail, and generate reports as required by these sections.

§ 1311.120(b)(9)The electronic prescription application must present for the practitioner's review and approval all required data for each controlled substance prescription.

IHS will make software changes to display required information at the point of electronic signature of prescriptions and in cases of more than one prescription, also at the point when the practitioner individually indicates that each controlled substance prescription is ready to be signed, pursuant to § 1311.120(b)(13).

§ 1311.300 Application provider requirements – Third-party audits or certifications

Upon completion of software development and testing, IHS will attain third-party certification.

Recordkeeping

IHS currently maintains records of controlled substance prescriptions in compliance with Title 21 CFR 1304 "Records and Reports of Registrants." Additionally, RPMS/EHR stores electronic records of electronic medication orders and prescriptions including order creation and electronic signature timestamps, pharmacy processing timestamp, dispensing timestamps, and

all system users involved in the process. Additional security processes and practices are included in the section below.

Additional security/safeguards

RPMS/EHR, IHS networks and information technology systems and procedures must meet NIST 800-53 physical security controls and Department of Health and Human Services (HHS) policy which serve as further security and safeguards preventing unauthorized access to IHS networks and the RPMS/EHR system. RPMS/EHR employs additional security controls regarding access due to federal security authorization requirements. The IHS EHR is capable of storing and tracking audit logs and the ability to mark sensitive patient records for additional scrutiny and control. IHS is reviewing audit log technologies to provide automated alerting and review capabilities to all medical equipment deployed on the network. This automated alerting can potentially be used to better manage controlled substances using an automated reporting function.

Comprehensive review of medication orders and prescriptions, including the patient's full medical record, to ensure appropriateness of care is a standard of pharmacy practice in the Indian Health system. This comprehensive review process also serves as an additional safeguard to prevent diversion and unauthorized or inappropriate electronic prescribing of controlled substances.

Electronic prescribing of controlled substances (EPCS) is a critical function to the IHS providing patient care. Failing to recognize this deviation would result in a negative impact on patient care that far outweighs any risk the deviation will facilitate diversion. IHS anticipates obtaining third-party certification for EPCS by December 2018. Thank you for considering this request to use the IHS RPMS/EHR system for electronic prescribing of controlled substances.

Sincerely,

/Susan V. Karol MD/

CAPT Susan V. Karol, MD, FACS
Chief Medical Officer