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

www.dea.gov

Lee Ann C. Stember
President
National Council for Prescription Drug Programs, Inc.
9240 E. Raintree Drive
Scottsdale, Arizona 85260

MAR 1 4 2017

Dear Ms. Stember:

This is in response to your letter dated February 8, 2016, and subsequent communications you have had with the Drug Enforcement Administration (DEA) regarding electronic prescriptions for controlled substances (EPCS). Please accept DEA's apology for the delay in responding to your inquiry. You mentioned that the National Council for Prescription Drug Programs (NCPDP) is an American National Standards Institute-Accredited Standards Development. Furthermore, NCPDP's website states that "software vendors … take the standards documents and create software for the exchange of data using these standards." You stated that the NCPDP recently learned that the DEA has expressed reservations about the use of the NCPDP's Refill Prescription Request Transaction (formerly known as RxRenewalRequest) for EPCS, and that it is NCPDP's belief that the DEA's reservations are related to the "notion of pre-population of faxed prescription refill requests that are sent from pharmacies to prescribing practitioners." Therefore, NCPDP requested that the DEA confirm that NCPDP's Refill Prescription Request Transaction does not constitute pre-population.

Initially, please be advised that the DEA cannot provide you with a private legal opinion. Consistent with the laws governing federal agencies and basic principles of fairness, any statements by the DEA interpreting the law as applied to specific factual scenarios must be disseminated in a public manner. Accordingly, our response to your inquiry must be limited to reiterating general legal principles that are germane to your inquiry.

One of the most important principles underlying the Controlled Substances Act (CSA) and its implementing regulations is that **to be valid every prescription for a controlled substance must be based on a determination by an individual practitioner that the dispensing of the controlled substance is for a legitimate medical purpose in the usual course of professional practice.** *United States v. Moore,* 423 U.S. 122 (1975) and Title 21, Code of Federal Regulations, Section 1306.04(a) (21 C.F.R. § 1306.04(a)). The prescribing practitioner may authorize his or her agent to prepare a controlled substance prescription based upon his or her instructions as to the required elements of a valid prescription. 21 C.F.R. §§ 1306.05(a) and 1306.05(f). A pharmacy cannot provide in whole, or in part, pre-populated information on a document and have that document then become the prescription. A partially or fully pre-populated prescription for a controlled substance send to a prescribing practitioner, who has yet to make a medical determination for the patient in question, is in violation of the CSA. Therefore, any communication with a prescribing practitioner regarding prescriptions for controlled substances must comply with these requirements. Title 21 C.F.R. § 1311.102(k) states "The practitioner has the same responsibilities when issuing

prescriptions for controlled substances via electronic means as when issuing a paper or oral prescription."

The DEA published the EPCS Interim Final Rule (IFR) in the Federal Register on March 31, 2010. 75 FR 16235. The IFR revised DEA's regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically, and permit pharmacies to receive, dispense, and archive these electronic prescriptions. Title 21 C.F.R., Part 1311 (21 C.F.R. Part 1311) outlines the standards and requirements for the systems used to electronically handle prescriptions for controlled substances and the practitioners (e.g., prescribers and pharmacies) who utilize these systems. Any company that develops such an application for controlled substances must ensure that the **application** is in compliance with these requirements, to include an independent third party audit to certify that the application performs the required functions, and all other applicable requirements of 21 C.F.R. Part 1306.

For information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. Located on that website you will find electronic copies of the Federal Regulations referenced above. If you have any additional questions on this issue, please contact the Diversion Control Division's Liaison and Policy Section at (202) 307-7297.

Sincerely,

James Arnold

James Arnold, Chief
Liaison and Policy Section
Diversion Control Division