Drug Enforcement Administration Diversion Control Division Diversion Website Q&A – Guidance Document

Title: Prescriptions by e-mail

Summary: This guidance document answers the question: "If electronic prescriptions for controlled substances be sent by e-mail."

Activity: Issuance of Electronic Controlled Substances Prescriptions

To Whom It Applies: DEA Registrants

Question: Can I send electronic controlled substance prescriptions to a pharmacy via e-mail?

Answer: No. "An electronic prescription"—that is, "a prescription that is generated on an electronic application and transmitted as an electronic data file"—must "be created and signed using an application that meets the requirements of part 1311 of this chapter." <u>21 CFR 1300.03</u>, <u>1306.05(e)</u>. These requirements include, among other things, an audit or certification to ensure that the application "records, stores, and transmits" the necessary information "accurately and consistently," the capability to "[1]ink each registrant, by name to at least one DEA registration number," logical access controls "set by individual user name or role" that limit permissions for "signing controlled substance prescriptions," the ability to "accept two-factor authentication," and digital signature functionality that satisfies the relevant Federal Information Processing Standards (FIPS) developed by the National Institute of Standards and Technology. <u>21 CFR</u> <u>1300.03</u>, <u>1311.120(b)</u>. E-mail does not satisfy these requirements.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department policies.

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