Drug Enforcement Administration Diversion Control Division Guidance Document

Title: Drug Enforcement Administration (DEA) Registered Pharmacies Dispensing Electronic Prescriptions During a Cyberattack.

Summary: A recent cyberattack caused a major healthcare organization to temporarily shut down its electronic prescribing system. Accordingly, the DEA-registered pharmacies affected by this cyberattack, or potential future disruptions to electronic prescribing systems, are reminded of alternative means to receive prescriptions, including via facsimile transmission.

Activity: DEA-Registered Pharmacies Dispensing Prescriptions During a Cyberattack.

To Whom It Applies: The DEA-registered pharmacies that are unable to receive and dispense electronic prescriptions for controlled substances (EPCS) during a cyberattack.

Dear DEA-Registered Pharmacies:

The Drug Enforcement Administration (DEA) is providing the following guidance regarding the dispensing of electronic prescriptions for controlled substances by pharmacies affected by the cyberattack on a healthcare organization or similar cyberattacks that may occur in the future.

Background

DEA received information regarding a cyberattack experienced by a healthcare organization, which is one of the largest processors of prescription medications in the United States. To minimize the impact of the cyberattack, the healthcare organization took its systems offline on February 21, 2024. As a result, practitioners and pharmacies that route prescriptions through the healthcare organization's network were unable to verify insurance coverage, copays, and drug pricing, essentially leading to widespread disruption of electronic prescribing of controlled and noncontrolled medications. On March 1, 2024, the healthcare organization launched a new iteration of its electronic prescribing service. DEA has been informed that the system is operational and prescriptions (controlled and noncontrolled) are being transmitted electronically with minimal issues.

We note that DEA does not require electronic prescribing of controlled substances. Prescribing practitioners are still able to write and manually sign prescriptions for schedule II, III, IV, and V controlled substances and pharmacies are still able to dispense controlled substances based on those paper prescriptions. Oral prescriptions remain valid for schedule III, IV, and V controlled substances. EPCS are only permissible if the electronic prescription and the pharmacy application meet DEA's requirements. In addition, EPCS may be subject to state laws and regulations. If state requirements are more stringent than DEA's regulations, the state requirements would supersede any less stringent DEA provision. EO-DEA022R1, DEA-DC-9 R1.

As set forth in <u>21 CFR 1306.11(a)</u>, a pharmacist may dispense directly a controlled substance in schedule II only pursuant to a paper prescription signed by the practitioner, except as provided in <u>21</u> <u>CFR 1306.11(d)</u>. A paper prescription for a schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in <u>21 CFR 1306.11(e)</u>, (f) and (g). The original prescription shall be maintained in accordance with 21 CFR 1304.04(h) of this chapter.

As set forth in <u>21 CFR 1306.21(a)</u>, a pharmacist may dispense directly a controlled substance listed in schedule III, IV, or V only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets the requirements of <u>21 CFR parts 1306</u> and <u>1311</u>, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in <u>21 CFR 1306.05</u>, except for the signature of the practitioner. We hope this information is helpful. For information regarding DEA's Diversion Control Division, please visit <u>www.DEAdiversion.usdoj.gov/index.html</u>. Please contact the Diversion Control Division, Policy Section at (571) 362-3260 or <u>DPY@dea.gov</u> if you seek assistance regarding this or any other matter.

The guidance contained in this document does not have the force and effect of law and is 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.

EO-DEA306, DEA-DC-84, June 12, 2024