

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

www.dea.gov

Mr. Patrick Kelly Executive Vice President, Government Affairs Healthcare Distribution Alliance 901 N. Glebe Road, Suite 1000 Arlington, Virginia 22203

Dear Mr. Kelly:

The Drug Enforcement Administration (DEA) received your email sent March 19, 2020, expressing your members' concerns regarding a purchaser's inability to mail a hard copy version of a DEA Form 222 to the supplier for fulfillment. In light of the public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of Coronavirus Disease 2019 (COVID-19) and the determination by the World Health Organization on March 11, 2020 that the global COVID-19 outbreak constitutes a pandemic, DEA will grant an exception to those provisions of 21 CFR 1305.13 that normally require the purchaser to submit the original to the supplier, as specified below.

As you know, the Controlled Substances Act provides that the distribution of a schedule I or II controlled substance must be pursuant to an order form that complies with the DEA regulations. *See* 21 U.S.C. 828. The DEA regulations provide that either a DEA Form 222 or its electronic equivalent is required for each distribution of a schedule I or II controlled substance. 21 CFR 1305.03. A purchaser of a schedule I or II controlled substance that utilizes a paper copy must make a copy of the original DEA Form 222 for its records and then submit the original to the supplier. 21 CFR 1305.13(a).

The DEA Administrator is permitted by 21 CFR 1307.03 to grant an exception to the application of any provision in 21 CFR, Chapter II. This authority has been re-delegated to the Assistant Administrator of the Diversion Control Division. In light of the public health emergency, DEA recognizes that it may not be feasible for a purchaser to mail a hard copy of the DEA Form 222 to a supplier. In order to ensure an adequate supply of controlled substances and for the duration of this public health emergency, DEA will **grant** an exception to those provisions of 21 CFR 1305.13 that normally require the purchaser to submit the original to the supplier. Under this exception being granted today, all DEA registrants who order controlled substances are permitted to fax or scan/email a DEA Form 222 to their respective suppliers. Likewise, when a supplier receives a faxed or scanned/emailed DEA Form 222 pursuant to this exception, the supplier shall treat the faxed or scanned/emailed form as the original for purposes of 21 CFR 1305.13. This exception is granted from March 20, 2020 through the duration of this public health emergency as declared by the Secretary of HHS.

During the officially declared public health crisis, forms transmitted via email or facsimile will be treated as the original under this granted exception. When the COVID-19 public health crisis declared by the Secretary of Health and Human Services ends, purchasers and suppliers will again be required to utilize hard copies as specified under 21 CFR 1305.13. In addition, upon the expiration of the state of emergency, purchasers will be required to send suppliers hard copies of executed DEA Form 222 that were transmitted to the supplier via email or fax during the public health emergency. Suppliers will be required to attach hard copies of DEA Form 222 to the faxed or scanned/emailed copies used to execute orders during the COVID-19 public health crisis.

We hope this information is helpful. For information regarding DEA's Diversion Control Division please visit www.DEAdiversion.usdoj.gov. Please contact the Diversion Control Division, Policy Section at (571) 362-3260 if you seek additional assistance regarding this or any other matter.

Sincerely,

William T. McDermott Assistant Administrator, Diversion Control Division .

DEA066 – March 25, 2020