

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

www.dea.gov

Elinore McCance-Katz, M.D., Ph.D. Assistant Secretary for Mental Health and Substance Use Substance Abuse and Mental Health Services Administration U.S. Department of Health and Human Services MAR 1 6 2020

Dear Dr. McCance-Katz:

This is in response to your email dated March 15, 2020, to the Drug Enforcement Administration (DEA) requesting an exception to 21 CFR 1301.74(h), pursuant to 21 CFR 1307.03. 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, but in no case shall the Administrator be required to grant an exception to any person which is otherwise required by law or DEA regulation. This authority has been delegated to the Assistant Administrator of the Diversion Control Division. DEA appreciates the opportunity to address your request.

As you are aware, under 21 CFR 1301.74(h), narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either: (1) the licensed practitioner; (2) a registered nurse under the direction of the licensed practitioner; (3) a licensed practical nurse under the direction of the licensed practitioner; or (4) a pharmacist under the direction of the licensed practitioner.

On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a public health emergency. Pursuant to this public health emergency, you have asked for DEA registered narcotic treatment programs (NTPs) to have an exception to 21 CFR 1301.74(h) in order to provide consistent dosing to patients enrolled at these NTPs. In the event a patient is quarantined due to the coronavirus, you have asked for alternative delivery methods using the NTP's established chain of custody protocol for take-home medications. You have asked that the NTP make a "doorstep" delivery of take-home medication in an approved lock-box. You further propose that the delivery of the medications may be conducted by an authorized NTP staff member, law enforcement officer, or national guard personnel – rather than limiting the persons who may so deliver to those specified in 21 CFR 1301.74(h).

DEA has reviewed your request for an exception to 21 CFR 1301.74(h). DEA has also taken into account the safeguards against diversion incorporated into your guidance for Opioid Treatment Programs, currently published on your website. Based on these considerations, DEA **grants** the exception to 21 CFR 1301.74(h) that you requested, but only to the extent that such activities will take place during the HHS-declared public health emergency.

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I trust this letter adequately addresses your inquiry. For information regarding DEA's Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Policy Section at (571) 362-3260.

Sincerely,

William T. McDermott Assistant Administrator Diversion Control Division