Drug Enforcement Administration Diversion Control Division Guidance Document Public Health Emergency – COVID-19

Title: Administering Certain CS in the parking lot of a healthcare provider's DEA-registered location during the COVID-19 public health emergency

**Question:** The Food and Drug Administration (FDA) made an allowance for certain Risk Evaluation and Mitigation Strategies (REMS)-certified healthcare providers (HCPs) to provide medically supervised treatment in the patient's home during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. As an alternative to this, would DEA allow HCPs to administer REMS-designated controlled substances to patients in the parking lot at the HCPs' DEA-registered locations?

Answer: The Controlled Substances Act (CSA) and its implementing regulations require a separate registration for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed, as set forth in 21 U.S.C. 822(e) and 21 C.F.R. 1301.12(a). The term "dispense," as defined in 21 U.S.C. 802(10), means to "deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance...." Neither the CSA nor DEA regulations specifically address whether healthcare providers may dispense controlled substances to patients in the parking lots of their DEAregistered locations. Nevertheless, in consideration of safety concerns for the aforementioned healthcare providers and their patients, DEA is exercising its authorities to provide flexibilities in the dispensing of controlled substances so as to permit the dispensing of controlled substances in provider parking lots under certain conditions. For the duration of the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of COVID-19 (unless this allowance is first modified or withdrawn by DEA), DEA will consider it permissible under the CSA for healthcare providers to provide medically supervised treatment using controlled substances, including REMS-designated controlled substances, in the parking lots of their DEA-registered healthcare facilities, so long as a provider's parking lot is located immediately adjacent to the provider's DEA-registered facility. This activity, however, must be carried out in compliance with all other applicable federal, state, and tribal laws and regulations.

Guidance documents, like this document, are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement. Consistent with Executive Order 13891 and the Office of Management and Budget implementing memoranda, the Department will not cite, use, or rely on any guidance document that is not accessible through the Department's guidance portal, or similar guidance portals for other Executive Branch departments and agencies, except to establish historical facts. To the extent any guidance document sets out voluntary standards (e.g., recommended practices), compliance with those standards is voluntary, and noncompliance will not result in enforcement action. Guidance documents may be rescinded or modified in the Department's complete discretion, consistent with applicable laws.

EO-DEA213, DEA-DC-043, July 28, 2020