



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

www.dea.gov

DEA Registered Hospitals/Clinics
DEA Registered Manufacturers
DEA Registered Distributors

Dear DEA Registrant:

Following the nationwide public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, as a result of the Coronavirus Disease 2019 (COVID-19) pandemic, the Drug Enforcement Administration (DEA) has learned that some DEA-registered hospital/clinics need to utilize additional satellite hospital/clinic locations to accommodate the large influx of patients presenting for treatment. These satellite locations generally need to use controlled substances in the course of providing treatment to their patients. Given the urgency of the situation, and because it is not feasible for these satellite hospitals/clinics to immediately obtain a DEA registration, the DEA-registered hospitals/clinics that utilize the satellite locations have asked DEA whether they may allow the satellite locations to handle controlled substances using the hospital/clinic's existing registration.

To facilitate appropriate patient care and assist the nation in responding effectively to these unprecedented scenarios that have arisen during the COVID-19 pandemic, DEA is issuing this letter to provide DEA-registered hospital/clinics with the flexibility to utilize alternate satellite hospital/clinic locations under their current registrations. In addition, to allow these satellite hospitals/clinics to receive shipments of controlled substances more expeditiously, DEA is further providing flexibility to allow distributors to ship controlled substances directly to these satellite hospitals/clinics, even though they are nonregistered locations. These two allowances are in effect from April 10, 2020, until the public health emergency declared by the Secretary ends, unless DEA specifies an earlier date.

Allowance 1: Handling of Controlled Substances by Satellite Hospitals/Clinics at Nonregistered Locations

With regard to the utilization of alternate satellite hospital/clinic locations, we first note the following background information. Under the Controlled Substances Act (CSA) and DEA regulations, every person who dispenses controlled substances (with limited exceptions) must be registered with DEA at each principal place of business or professional practice where the person dispenses controlled substances. 21 U.S.C. 822(a)(2), (e)(1); 21 CFR 1301.12(a). When it comes to hospitals/clinics, this has always meant that each hospital/clinic must hold a DEA registration at each location it operates. DEA has long allowed hospitals/clinics with multiple buildings to handle controlled substances under a single registration, provided all such activity occurs on a single, contiguous campus. Under normal circumstances, DEA would not consider allowing deviations

from this historical approach of limiting activities under a single registration to a contiguous campus. However, due to the extraordinary circumstances arising out of the COVID-19 pandemic, DEA is providing flexibility as described in this letter. Specifically, DEA will allow a DEA-registered hospital/clinic, under its existing DEA registration, to handle controlled substances at a satellite hospital/clinic location (one or more) if all of the following conditions are met:

- The satellite/hospital clinic was set up to provide temporary services connected to the public health emergency resulting from the COVID-19 pandemic.
- The satellite/hospital clinic is authorized by the State in which it operates to handle controlled substances and is doing so in a manner permitted by the State.
- The DEA-registered hospital/clinic is responsible for maintaining all records required by the DEA regulations with respect to all controlled substances received, stored, administered, dispensed, distributed, and otherwise disposed of by the satellite hospital/clinic. Such records shall be maintained at the registered location.
- The DEA-registered hospital/clinic is responsible for ensuring that the satellite hospital/clinic maintains physical security of the controlled substances it handles in compliance with the DEA regulations, and that the satellite hospital/clinic otherwise maintains effective controls against diversion.
- The DEA-registered hospital/clinic notifies the local DEA field office in writing (by email or other electronic submission) that it is utilizing a satellite hospital/clinic that will handle controlled substances. Such notification to DEA must occur before the satellite hospital/clinic begins handling controlled substances. Satellite hospital/clinic who are already handling controlled substances must notify the DEA field office within 72 hours. The local field office may be found at www.DEAdiversion.usdoj.gov. The DEA-registered hospital/clinic must also maintain, with its records relating to controlled substances, a current list of all satellite hospitals/clinics that it utilizes which handle controlled substances.
- Except as provided in the next bullet, the satellite hospital/clinic that will handle controlled substances must be a corporate affiliate of, or owned by the entity that holds the DEA registration of the hospital/clinic at the registered location.
- If the satellite hospital/clinic that will handle controlled substances either is *not* a corporate affiliate of, or owned by, the entity that holds the DEA registration of hospital/clinic at the registered location, the DEA-registered hospital/clinic that utilizes such satellite hospital/clinic must enter into a written agreement that creates an agency relationship with the satellite hospital/clinic. The written agreement must specify that the satellite hospital/clinic is subject to “the direction of” the DEA-registered hospital/clinic (21 U.S.C. 802(3)) with respect to the handling of controlled substances, including all security, recordkeeping, reporting, and dispensing requirements imposed by the CSA and DEA regulations. The written agreement must further specify that the DEA-registered hospital/clinic is responsible for ensuring compliance with the CSA and DEA regulations by the satellite hospital/clinic. A copy of the executed written agreement must be provided to the local DEA field division office no later than seven (7) days. The DEA-registered

hospital/clinic must maintain a copy of the executed agency agreement with its records relating to controlled substances.

As indicated, the provisions outlined in this letter do not apply to independent satellite hospital/clinic locations that are not affiliated, whether by ownership or an agency relationship, with a current DEA-registered hospital/clinic. Any entity which does not meet either of these criteria but which needs to handle controlled substances to treat patients must email DEA at Natural.Disaster@usdoj.gov with a request for an emergency DEA hospital/clinic registration for that location. A local field office representative will respond to the request and expedite the registration process.

Allowance 2: Delivery of Controlled Substances Directly to Satellite Hospitals/Clinics at Nonregistered Locations

The DEA regulations provide that controlled substances must be shipped only to the purchaser and the location printed by DEA on the Form 222 or associated with the digital certificate used to sign the order (with limited exceptions inapplicable here). 21 CFR 1305.13(c) & 1305.22(f). It is also part of distributor's general obligation to maintain effective controls against diversion to deliver controlled substances only to the address that appears on the purchaser's certificate of registration. However, as indicated above, in view of the extraordinary circumstances related to the COVID-19 epidemic, DEA is providing flexibility to allow distributors to ship controlled substances directly to these satellite hospitals/clinics. Specifically, DEA will consider the requirements of the CSA and DEA regulations relating to distributions of controlled substances satisfied if all of the following conditions are met:

- The DEA-registered distributor delivers the controlled substances to the premises of the satellite hospital/clinic, and such satellite hospital/clinic satisfies the requirements described above under Allowance 1.
- The delivery is received by an employee or agent of the satellite hospital/clinic.
- If, due to social distancing considerations, the delivery is not made inside the building or structure in which the satellite hospital/clinic operates, the receiving employee or agent of the satellite hospital/clinic comes outside, identifies himself/herself, and picks up the shipment.
- The delivery driver records this delivery in his/her log, and observes the receiving individual take the shipment inside the satellite hospital/clinic (if the delivery is not made inside the premises).
- The distributor must ensure that this is a person-to-person delivery of the controlled substances order. In other words, the controlled substances may not be left at a location for pickup at another time by the satellite hospital/clinic. The employee or agent of the satellite hospital/clinic must appear in person at the time of delivery to physically receive the controlled substances order.

Again, the two allowances set forth in this letter are in effect from April 10, 2020, until the

public health emergency declared by the Secretary ends, unless DEA specifies an earlier date.

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

DEA084 – April 10, 2020