

Distributor Questions and Answers on Common Scenarios During the Covid-19 Pandemic
04/10/2020

1. **Question:** Due to Coronavirus Disease 2019 (COVID-19) social distancing measures, pharmacies that are receiving shipments of controlled substances from distributors are refusing to physically sign manifests as Proof of Delivery. What can distributors do to document that the pharmacy received the order upon delivery?

Answer: Neither the Controlled Substances Act (CSA) nor the DEA regulations require a pharmacy to sign for receipt of a shipment of controlled substances. However, the CSA and DEA regulations do require all registrants to maintain records of all controlled substances received, sold, delivered, or otherwise disposed of. 21 USC 827(a)(3); 21 CFR 1304.21(a). It is also a sound practice from a diversion control perspective for registrants to document delivery and receipt of shipments.

2. **Question:** In view of COVID-19, some distributors' customers are establishing what they refer to as "safe zones" to which they want their distributor to deliver their orders of controlled substances. These "safe zones" are not on the premises of a DEA-registered location and are being established to promote social distancing, because at some point customers will not want delivery drivers to enter their clean environment. Is there a way that distributors can legitimately make deliveries of controlled substances to these "safe zones?"

Answer: 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). In light of the nationwide public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, as a result of COVID-19, DEA is exercising its authorities to provide flexibility with regard to the requirements of 21 CFR 1305.13(c) & 1305.22(f). Specifically, for the remainder of the time that the public health emergency declared by the Secretary is in effect (unless DEA specifies an earlier date), DEA will consider the requirements of 21 CFR 1305.13(c) & 1305.22(f) satisfied if all of the following conditions are met:

- The driver who is not admitted into the physical building at the DEA-registered location delivers the controlled substances to the property owned or leased by the registrant that corresponds to the DEA-registered location.
- The delivery is picked up by an agent or employee of the receiving registrant.
- Such agent or employee of the registrant comes outside, identifies himself/herself, and picks up the package.
- The delivery driver records this delivery in their log, and observes the individual take the shipment inside.
- The entity delivering the controlled substances must ensure that this is a person-to-person delivery of the controlled substances order. In other words, the controlled substances

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cannot be left at a location for pickup at another time by the DEA registrant. The agent or employee of the DEA registrant that ordered the controlled substances must appear in person at the time of delivery to physically receive the controlled substances order.

Note: The preceding answer is applicable to the delivery of drugs to DEA-registered pharmacies and hospital/clinics. If the receiving customer is a narcotic treatment program, the requirements of 21 CFR 1301.74(h) must also be satisfied with respect to deliveries of narcotics, in addition to the requirements stated above. This exception is posted at DEA's COVID-19 guidance website at <https://www.deadiversion.usdoj.gov/coronavirus.html>

In addition, it should be noted that, as stated in 21 CFR 1301.74(a), "before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance." Thus, distributors must make a good faith effort to determine that the entity to which they are delivering the controlled substances order is registered with the DEA. Following the bulleted steps above is one way to do so.

3. **Question:** Emergency Alternate sites: How can a distributor set up an alternate location from which to deliver controlled substances to pharmacies and hospitals in the event that a distributor's registered location(s) becomes inoperative due to COVID-19-related circumstances?

Answer: The DEA-registered distributor requesting to establish an alternate site must submit a request to DEA's national disaster email, natural.disaster@usdoj.gov, for an emergency DEA number for each designated alternate location. The email must include the following information for the alternate location: physical address; security measures; and, the name and complete contact information of the person who will be responsible for the controlled substances at this location. Please note that this alternate site is subject to inspection by DEA personnel at any time. The distributor is not authorized to handle controlled substances at the alternate location until DEA issues it a registration for the location. DEA is making every effort to expeditiously review any application for an emergency DEA number and intends to expedite the pre-registration process when warranted.

4. **Question:** Distributors are being inundated with requests to deliver to what distributors are referring to as "pop-up" hospital/triage locations that are located in a variety of locations, including parking lots, hotels, and convention centers – essentially wherever additional space can be found to set up treatment centers. Distributors are concerned that these alternate locations do not comply with the CSA and the DEA regulations regarding the delivery of controlled drugs. How can distributors obtain expedited approval to deliver to an alternate address for their customers in the event that a pharmacy or healthcare facility is shut down for quarantine or cleaning?

Answer: Before addressing this question, we wish to emphasize that DEA is making every effort to expeditiously review any application for an emergency DEA registration number and intends to expedite the pre-registration process when warranted. The DEA registrant requesting to establish

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an alternate site should submit a request to DEA's national disaster email, natural.disaster@usdoj.gov, for an emergency DEA registration number for each designated alternate location. The email must include the following information for the alternate location: physical address; security measures; and, the name and complete contact information of the person who will be responsible for the controlled substances at this location.

Please also see the answer to question 2 regarding what alternate delivery methods will be considered compliant with 21 CFR 1305.13(c) and 1305.22(f) during the COVID-19 public health emergency. In addition, to address the scenario in which, due to COVID-19 related considerations, the purchaser that has recently set up location for which the purchaser's DEA-222 forms do not yet reflect its new location, DEA is issuing an exception to the regulations. This exception is posted at DEA's COVID-19 guidance website at <https://www.deadiversion.usdoj.gov/coronavirus.html>

5. **Question:** The government's current recommendations around social distancing have implications for distributors. For example, some of the regular due diligence functions carried out by the distributor to fulfill "Know Your Customer" expectations may have to be delayed, such as pharmacy site visits. Most wholesalers have imposed travel restrictions on their associates which would preclude these visits until such time the spread of the virus is under control, which could be several months. Many pharmacies are likewise trying to limit unnecessary visits at their locations, especially those that do not directly involve servicing patients with medical needs. How can distributors practice social distancing while remaining in compliance with the CSA and DEA regulations?

Answer: Distributors still remain responsible for maintaining effective controls against diversion by "knowing their customer" and conducting the appropriate due diligence. During the COVID-19 public health emergency declared by the Secretary, due diligence and site inspections via teleconferencing may be acceptable alternatives when the ability to conduct on-site inspections is determined to be impractical by the registrant. Distributors are also still able to obtain and review their customers' utilization reports and other documents as part of their due diligence. This paragraph is not meant to be all encompassing in terms of what distributors should be doing as part of their due diligence, rather, it is provided as examples of some of the evaluations distributors should conduct.

6. **Question:** Distributors are seeing changes in controlled substances ordering behavior by their customers, particularly by DEA-registered pharmacies and hospitals. Some of this behavior is driven by customer fears of disruption to the supply chain. In other instances, prescribing behavior intended to limit social exposure at hospitals, clinics, and pharmacies (such as prescribing in larger quantities to supply the patient for a great period of time), may also lead to changes in pharmacy ordering behavior. What is DEA's guidance for distributors when faced with the issue of changes in customer ordering activity involving controlled substances tied to COVID-19?

Answer: DEA is aware from its engagement with its federal partners and other controlled substances stakeholders that various DEA registrants may be changing their ordering patterns in order to fulfill their customers' and/or patients' needs. Distributors (and other registrants that

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distribute controlled substances) continue to have an obligation to maintain a system to detect suspicious orders of controlled substances and to inform their local DEA field office when suspicious orders are discovered. 21 CFR 1301.74(b). At the same time, recent significant increases in demand for certain controlled substances by pharmacies and hospitals may be attributable to legitimate needs arising out of the COVID-19 pandemic. When in doubt about the legitimacy of an order, distributors should carefully assess the circumstances surrounding the order, including the nature of the practice engaged in by the registrant placing the order, as well as the types, quantities and dosage forms of the controlled substances being ordered. Distributors should inquire with their customers to obtain an explanation for the deviation from their normal ordering patterns and document the changes in ordering behavior and the possible reasons for it in its due diligence file for each customer.

DEA has already drafted guidance on the prescribing of controlled substances in light of COVID-19. Please check DEA's COVID-19 guidance website at <https://www.deadiversion.usdoj.gov/coronavirus.html>

7. **Question:** Some purchasers are having difficulty or are not able to mail DEA-222 forms to their distributors. Can DEA make an allowance during the COVID-19 public health emergency so that purchasers may fax or scan the DEA-222 forms to the supplier registrants in lieu of mailing the hard copy?

Answer: DEA has already drafted guidance on this matter. The guidance document can be found in the [DEA's COVID-19 Guidance Portal](#).

8. **Question:** Whereas it is generally understood that distributors deliver controlled substances to their customers, is there anything in the law that prevents a customer from coming to the distribution center to pick up their order?

Answer: Nothing in the CSA or DEA regulations prohibits a DEA registrant from picking up their controlled substances order from the distributor's location in lieu of having the controlled substances shipped by the distributor. In such circumstances, the registrant picking up the order must then take the controlled substances that it received to its registered location. The controlled substances may not be taken by the registrant to an alternative unregistered site. The purchaser must abide by the applicable security requirements set forth in the DEA regulations, including, but not limited to, those in 21 CFR 1301.71, and otherwise provide effective controls and procedures to guard against theft and diversion of controlled substances.

Please note that a third party courier is not authorized to pick up an order for the purchaser, as they are not the purchaser. The supplier can deliver it themselves to the purchaser, or they can use a common or contract carrier, but safeguarding the delivery of controlled substances remains the distributor's responsibility until it is accepted by the purchaser. Thus, the supplier must notify DEA if

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there is a loss in transit. 21 CFR 1301.74(c). In the case of will-call, the purchaser picks up the drugs. Thus, the supplier has turned the product over to the purchaser.

DEA suggests that the staff from the purchaser that is picking up the drugs from the distribution center take a picture of the boxes/containers they are picking up. The purpose of the picture is to make sure the packages are not tampered with. Additionally, DEA would suggest that once the packages have been delivered to the registered location, that a second employee verifies what is on the DEA-222/invoice.

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