

- (2) The name of the supplier.
- (3) The complete address of the supplier.
- (4) The supplier's DEA registration number (may be completed by either the purchaser or the supplier).
- (5) The date the order is signed.
- (6) The name (including strength where appropriate) of the controlled substance product.
- (7) The National Drug Code (NDC) number (may be completed by either the purchaser or the supplier).
- (8) The quantity in a single package or container.
- (9) The number of packages or containers of each item ordered.

(c) An electronic order may include controlled substances that are not in Schedules I and II and non-controlled substances.

§ 1305.22 Procedure for filling electronic orders.

(a) A purchaser must submit the order to a specific supplier. The supplier may initially process the order (e.g., entry of the order into the computer system, billing functions, inventory identification, etc.) centrally at any location, regardless of its registration with DEA. Following centralized processing, the order is distributed to one or more registered locations maintained by the supplier for filling. The registrant must maintain control of the processing of the order at all times.

(b) A supplier may fill the order for a Schedule I or II controlled substance, if possible and if the supplier desires to do so and is authorized to do so under § 1305.04.

(c) A supplier must do the following before filling the order:

(1) Verify the integrity of the signature and the order by having software that complies with part 1311 of this chapter validate the order.

(2) Verify that the digital certificate has not expired.

(3) Check the validity of the certificate holder's certificate by checking the Certificate Revocation List. The supplier may cache the Certificate Revocation List until it expires.

(4) Verify the certificate holder's eligibility to order the controlled substances by checking the certificate extension data.

(d) The supplier must retain an electronic record of every order, and, linked to each order, a record of the number of commercial or bulk containers furnished on each item and the date on which the supplier shipped the containers to the purchaser. The linked record must also include any data on the original order that the supplier completes. Software used to

handle digitally signed orders must comply with part 1311 of this chapter.

(e) If an order cannot be filled in its entirety, a supplier may fill it in part and supply the balance by additional shipments within 60 days following the date of the order. No order is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (h) of this section.

(f) A supplier must ship the controlled substances to the registered location of the purchaser, except as specified in paragraph (h) of this section.

(g) When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.

(h) Registered procurement officers of the Defense Supply Center of the Defense Logistics Agency may order controlled substances for delivery to armed services establishments within the United States. These orders may be shipped to locations other than the registered location, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

§ 1305.23 Endorsing electronic orders.

(a) If a supplier cannot fill all or a part of an electronic order within 60 days of the date of the order, the supplier may endorse the order to a supplier owned by another registrant for filling. Only the supplier to whom the order was first made may endorse the order to another supplier. To endorse the order the first supplier must do the following:

(1) Make an electronic copy of the original order.

(2) Create a linked record to the copy with the name, address, and DEA registration number of the second supplier.

(3) Digitally sign the linked record and copy using a DEA-issued digital certificate that meets the requirements in part 1311 of this chapter.

(b) The first supplier may endorse a partial order or an order in its entirety. The first supplier must transmit both the original order and the signed copy and linked record of the order to the second supplier indicating, where necessary, the partial filling of the original order. The second supplier must fill the order, if possible and if he/she desires to do so, in accordance with the requirements of this part concerning electronic orders.

(c) Distributions made on endorsed orders must be reported by the second supplier in the same manner as all other

distributions except that where the name of the supplier is requested in the report, the second supplier must record the name, address, and registration number of the first supplier.

§ 1305.24 Central processing of orders.

(a) A supplier that has one or more registered locations and maintains a central processing computer system in which orders are stored may have one or more of the supplier's registered locations fill an electronic order if the supplier does the following:

(1) Assigns each item on the order to a specific registered location for filling.

(2) Has each location filling part of the order create a record linked to the central file noting both which items the location filled and the location identity.

(3) Ensures that no item is filled by more than one location.

(4) Maintains the original order with all linked records on the central computer system.

(b) A company that has central processing of orders must assign responsibility for filling parts of orders only to registered locations that the company owns and operates.

§ 1305.25 Unaccepted and defective electronic orders.

(a) No electronic order may be filled if:

(1) The required data fields have not been completed.

(2) The order is not signed using a digital certificate issued by DEA.

(3) The digital certificate being used was expired or had been revoked prior to signature.

(4) The purchaser's public key will not decrypt the digital signature.

(5) The validation of the order shows that the order is invalid for any reason.

(b) If an order cannot be filled for any reason under this section, the supplier must notify the purchaser and provide a statement as to the reason (e.g., improperly prepared or altered). A supplier may, for any reason, refuse to accept any order, and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(c) When a purchaser receives a rejected electronic order from the supplier, the purchaser must electronically link the statement of reasons for rejection to the original. The original and the statement must be retained in accordance with § 1305.26 of this part.

(d) Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.