

The supplier and purchaser, both of whom are required to "annotate" the file with information on the substances shipped and received, would have to create a separate record with the needed information and electronically link the record of the required information to the original order. The supplier's linked file would have to contain packages shipped and date shipped and any other item on the order that the supplier completes. The purchaser's linked file would have to contain the number of packages received and the date received. The software must archive both the original and the linked record. The original and linked records constitute the complete order form, the equivalent of a Form 222 that has been annotated. The same process would apply to partially filled orders, endorsed orders, or canceled orders; the records of these actions must be linked to the original order and maintained as a record of the transaction. Both the purchaser and the supplier must keep the original digitally signed order and the linked files for a period of two years.

Can An Order Be Endorsed to Another Supplier?

DEA allows suppliers to endorse a DEA Form 222 to another supplier if the first supplier cannot fill the order. This requires the initial supplier to record on the back of each copy of the DEA Form 222 the name and address of the second supplier, and the signature of a person authorized by that initial supplier to obtain and execute order forms. Paper orders must be endorsed in their entirety; a supplier cannot fill part of the order and endorse the rest to a second supplier because the paper 222 must accompany the order.

Electronically, both complete and partial endorsement would be possible. To endorse the whole order to a second supplier, the initial supplier would make a copy of the incoming order, link the copy to a record of the name and address of the secondary supplier, then digitally sign the copy of the order and the linked file using his or her DEA issued digital certificate. The initial supplier may then transmit the original order and linked endorsement record to the secondary supplier. As an alternative, the initial supplier could fill part of the order, create a linked record indicating what had been filled, then endorse the remainder of the order to a second supplier, adding a second linked record with the second supplier's name and address, and digitally signing the order and linked records. The secondary supplier would have to validate both the purchaser's and the initial supplier's

digital certificates before filling the order.

Because the customer can easily generate a new electronic order, the supplier may simply choose to notify the purchaser that the order cannot be filled or filled in its entirety, allowing the purchaser to directly place the order electronically with another supplier. The supplier would then create a linked record voiding all or part of the order.

Can a Centralized Processing Facility Be Used?

DEA has determined that with electronic orders, it is possible for a distributor to process an order centrally and have separate registered locations belonging to the same distributor fill parts of the order. DEA is, therefore, proposing to allow purchasers to transmit orders to a specific supplier. The supplier may initially process the orders (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. This proposed approach to decentralized filling of orders applies only to registered locations that belong to the same company. This approach would allow distributors to maximize the efficiency of their distribution system without compromising the system of control of Schedule I and II substances.

What Information Is a Supplier Required To Report To DEA?

Under the current regulations, suppliers must send DEA copies of filled DEA Forms 222 on a monthly basis. With electronic orders, DEA is proposing that suppliers submit copies of the electronic orders and linked records to DEA every other business day based on when the order is filled; these orders may include information on substances other than Schedule I and II substances. In lieu of submitting copies of orders, suppliers may submit a daily report that contains the following information on Schedule I and II controlled substances from each electronic order:

- (1) The supplier's name.
- (2) The supplier's complete address.
- (3) The supplier's DEA registration number.
- (4) The purchaser's name.
- (5) The purchaser's complete address.
- (6) The purchaser's DEA registration number.

(7) The schedules the purchaser is authorized to receive.

(8) The purchaser's business activity.

(9) The unique tracking number the purchaser assigned to the order.

(10) The date the order was signed.

(11) The name of the controlled substance product.

(12) The National Drug Code (NDC) number of the controlled substance.

(13) The quantity in a single package or container.

(14) The number of packages or containers of each item ordered.

(15) The number of packages or containers shipped.

(16) The date shipped.

Because any orders or reports sent to DEA must be readable by DEA offices, DEA intends to specify, before the rule is final, the formats in which the information may be submitted. DEA requests comments on which software platforms and systems registrants would be likely to use to submit either the electronic orders or reports.

Why Does the Reporting Period Change for Electronic Orders?

In the paper system, DEA serially numbers all order forms. DEA requires that copy 2 of these order forms be submitted to the Administration on a monthly basis. DEA's requirements under the paper system are such that all order forms issued to any registrant must be accounted for. All forms issued by DEA are traceable to the specific registrant to whom they were issued. In addition, currently mandated supplier reports to DEA contain the order form number involved in all transactions completed. This ensures that Schedule I and II controlled substances will not be distributed without DEA's knowledge. Due to the significant volume of paper involved in the current process, DEA requires copy 2 of the Form 222 to be forwarded to DEA once monthly to limit the paper handling. This monthly reporting has little effect on DEA's ability to monitor and track all orders by serial number.

The electronic system does not involve the use of serially numbered, DEA-issued forms. Consequently, DEA's ability to track and account for orders must rely on timely reports by the suppliers. DEA determined that the 30-day reporting period is too long for electronic orders. Because all order reporting would be handled electronically, the daily transmission of reports should represent a minimal burden on suppliers.