

### Witness Requirement

A commenter stated that DEA would require two responsible individuals to accompany the drugs to the disposal site and actually witness the destruction. The commenter stated that this would significantly increase the costs of controlled substances destruction for all registrants and that the rule should, therefore, require a regulatory flexibility analysis.

#### DEA Response

The requirement to have two responsible individuals accompany the drugs to the disposal site is also consistent with existing practice. DEA Form 41, Registrants Inventory of Drugs Surrendered, must be completed by a registrant's representative and witnessed by a second representative of the registrant, to document the disposal of controlled substances. This form must be sent to DEA.

### Proposed Reporting Requirements

A commenter stated that ARCOS reporting becomes difficult and costly when a disposer receives a quantity of a controlled substance listed in Schedule I and II and a narcotic controlled substance listed in Schedule III which is contained in a compound, mixture or preparation which is not assigned an NDC number. The commenter stated that this reporting "will become more difficult as more returns are accepted from Pharmacies, Home Infusion Pharmacies, Provider Pharmacies to Long Term Care Facilities, Hospitals, and dispensers."

The commenter recommended adding a new paragraph (e) to current 21 CFR 1304.33 (formerly 21 CFR 1304.39) that would provide for the following exception: "Exceptions. Any controlled substance listed in Schedule I and II and on each narcotic controlled substance listed in Schedule III which material, compounded, mixture or preparation containing a quantity of a substance from a registered dispenser, practitioner, researchers, and analytical registrants, *e.g.*, prescription, IV mixture or non NDC material, may be exempted from filing reports under this section to ARCOS Units of the Administration." The commenter also stated that proposed paragraphs (b) and (c) (with regard to ARCOS reports being filed no later than the 15th day of the month or no later than January 15th) would have a significant economic impact and lead to ARCOS delays. This is because disposers (unlike manufacturers or distributors) deal with open containers that need validation (by count, weight, and/or volume) before the containers

can be placed into inventory; this can be a slow and tedious process. The commenter added that the economic impact and ARCOS delays would increase as the disposer class registration utilization grows.

#### DEA Response

While the commenter addressed the reporting requirements in proposed 21 CFR 1304.39(b) and (c), the commenter's real concern appears to be related to inventory requirements currently in 21 CFR 1304.11. This interim final rule will allow reverse distributors to follow the inventory requirements that currently apply to dispensers and researchers. This would mean that in the circumstances described in 21 CFR 1304.11(e)(3)(ii), it would not be necessary to make an exact count or measure of the contents in all cases, *i.e.*, if the controlled substance is listed in Schedule III, IV, or V, and the container holds fewer than 1,000 tablets or capsules, the reverse distributor could make an estimated count or measure.

Notwithstanding this change, a reverse distributor is required to know what it has on hand from the moment it is received. It is the reverse distributor's responsibility to have the proper documentation and accountability for any controlled substances in his or her possession. The best way for reverse distributors to accomplish this is by doing the following: (1) Require customers to provide a list of the controlled substances to be sent in advance of the shipment; (2) Complete a form or invoice indicating the amount that the customer will be sending, keep a copy of this document, and send 2 copies to the customer; and (3) Require the customer to keep one copy of the document and put the other copy in the package with the shipment. This procedure would maintain a paper trail and provide the data on inventory from the moment the shipment is received by the reverse distributor. Reverse distributors who follow this procedure should not have difficulty preparing the ARCOS reports that are required by current 21 CFR 1304.33 for controlled substances listed in Schedules I and II, and for narcotic controlled substances listed in Schedules III, IV, and V.

With respect to the issue of non-NDC material, such as compounded prescription products or infusion products, DEA's ARCOS Unit has established a listing of generic codes that can be used to identify products that do not have an NDC number assigned. If a product being handled does not have a generic code, please

contact the ARCOS Unit of the Administration for assistance.

Reverse distributors are encouraged to make use of electronic identification and tracking systems, such as bar codes, to aid in meeting the inventory and reporting requirements. Also, reverse distributors may use electronic versions of DEA Form 41 if the electronic version is an exact reproduction of the form. If the electronic version is not identical to the paper version, it is not the official form, and may not be used.

DEA invites manufacturers, reverse distributors, and other distributors to work with the Administration to establish standard operating procedures so there is a standard recordkeeping system for transferring, receiving, and inventorying partial containers. With a standardized system there would be fewer inconsistencies among the records of each registrant when controlled substances are transferred from one to another.

### Proposed Order Form Requirements

A commenter stated that in the preamble, DEA stated that "Order Forms must be completed for all Schedule I and III items received and transferred." The commenter stated that this is incorrect and that the correct statement should be: "Order Forms must be completed for all Schedule I and II items received and transferred."

#### DEA Response

DEA agrees that there was a typographical error in the preamble and is clarifying that order forms (DEA Form 222) required by part 1305 are for Schedule I and II controlled substances received and transferred.

### Reverse Distributor Receipt of Controlled Substances From Non-registrants

Under the interim final rule, reverse distributors may only receive controlled substances from DEA registrants. Non-registrants, such as long term care facilities, do not have direct authority to handle controlled substances. Further, the substances in their possession are no longer part of the closed system of distribution and are no longer subject to DEA's system of corresponding accountability. In cases where long term care facilities must dispose of controlled substances, they should follow the guidelines within their State for disposing of the drugs and maintain appropriate documentation of the disposal. Likewise, a former registrant, such as a pharmacy, whose registration has expired or has been surrendered, would need to coordinate with the local DEA office to develop a procedure to