

which ensure that all controlled substances are accounted for from their creation until their consumption or destruction.

When a controlled substance has become outdated or otherwise unusable, the registered person who possesses the substance must dispose of it. However, over the past decade, environmental concerns and regulatory changes have caused drug manufacturers and government agencies (including DEA and State authorities) to become increasingly reluctant to be involved in the disposal process. Thus, many disposal options are no longer available.

Nonetheless, disposal of controlled substances can occur in several ways:

1. The distributor or dispenser can return the controlled substances to the pharmaceutical manufacturers who, as a service to their customers, accept returns of outdated/damaged controlled substances. Distributors, dispensers, and manufacturers are all registered with DEA.

2. The distributor, dispenser, or manufacturer can itself dispose of the controlled substances under the procedures outlined in 21 CFR 1307.21. Under 21 CFR 1307.21, any person may request permission to dispose of controlled substances without the benefit of a DEA or State witness. In many cases, blanket permission for disposal of controlled substances is granted to registrants who have an ongoing need to dispose of unwanted controlled substances. The disposal must be authorized by DEA in writing, and DEA may require that a set schedule be established. Other registrants are granted disposal authority on a case-by-case basis. DEA normally requires that the registrant provide two designated responsible individuals to accompany the drugs to the disposal site and witness the destruction. This achieves DEA's goal of assuring the controlled substances are rendered nonrecoverable. Disposal under the authority of 21 CFR 1307.21 maintains the closed distribution system because the controlled substances remain under the legal control of a registered person at all times.

3. The distributor, dispenser, or manufacturer can distribute the controlled substances to a reverse distributor to take control of the controlled substances for the purpose of returning them to the manufacturer or, if necessary, disposing of them.

For many years, DEA opposed granting DEA registrations to firms solely or primarily engaged in the disposal (whether the transportation portion, actual disposal, or both) of controlled substances because they were

not considered an essential link in the closed distribution system that the Controlled Substances Act established to control the flow of drugs from the manufacturer to the ultimate user. In recent years, however, increasingly stringent requirements imposed by the U.S. Environmental Protection Agency (EPA) resulted in fewer and fewer approved disposal facilities. As a result, a new type of business has developed that collects controlled substances from registrants and either returns them to the manufacturer or arranges for their disposal. The businesses performing this middleman service refer to themselves as "reverse distributors" or "returns processors."

This interim final rule deals only with the distribution of controlled substances to reverse distributors. The first two categories—direct returns of controlled substances by distributors or dispensers to manufacturers, and disposals by the distributor, manufacturer or dispenser—are already covered by the existing rules. Only the third category, *i.e.*, persons who distribute controlled substances to reverse distributors, is not expressly covered by the current regulations, although DEA has regulated reverse distributors for many years, first, as distributors generally, and second, as reverse distributors specifically under the terms of Memoranda of Understanding (MOUs), through which they are granted DEA registrations. This rule will eliminate the need for MOUs. However, since this amendment essentially codifies current DEA policies and practices, it does not impose any significant additional burden on reverse distributors.

On August 23, 1995, DEA issued a Notice of Proposed Rulemaking (NPRM) (60 FR 43732) that proposed regulatory standards governing disposers of controlled substances. DEA proposed to accomplish this by amending its regulations to define the term "Disposer" to account for this middleman function in the regulations and establish a new category of manufacturer registration under which persons performing this function would be registered. DEA also proposed amending the regulations to exempt disposers from the quota requirements; to identify the records and reports required of disposers; and to establish order form procedures for disposers. Finally, DEA proposed amendments to a number of gender-specific sections to make them gender neutral.

DEA originally based its decision to define the persons performing the reverse distribution function as disposers on the definition of "manufacturer." In 21 CFR

1300.01(b)(27), DEA defines manufacture in part as "the producing, preparation, propagation, compounding, or processing of a drug or other substance . . . ." The section further defines a manufacturer as "a person who manufactures a drug or other substance . . . ." In the proposed rule, DEA stated that by its nature, a disposer processes a drug or other substance. Therefore, DEA proposed to place disposers within the definition of manufacturer, under a new disposer subcategory. Commenters to the proposed rule objected to being categorized as disposers and manufacturers for the reasons explained below under "Comments." Therefore, in this interim final rule, DEA is establishing a definition for "reverse distributor" and is establishing a new category of registration as reverse distributors.

DEA is using an interim final rule because it will give interested persons an additional opportunity for comment even though the substance of this interim final rule is consistent with the purpose of the August 1995 NPRM, the comments submitted in response to that NPRM, and with current DEA and industry practice.

Currently DEA registers persons performing reverse distributor functions as distributors. Since reverse distributors are not specifically identified in the current regulations, DEA enters into a Memorandum of Understanding (MOU) with the person performing the reverse distribution function. The Memorandum of Understanding (MOU) specifies conditions which the reverse distributor must follow in addition to the regulations that apply to distributors. These registrations must be renewed annually and operations under them are limited to products in schedules listed on the registration. DEA has not experienced any difficulties in treating reverse distributors as distributors for purposes of registration and other requirements. Any reverse distributor that was registered under the terms of a MOU will be reregistered as a reverse distributor under the terms of this interim final rule in the next renewal cycle and will be specifically identified in DEA's records as a reverse distributor. Persons currently conducting reverse distribution operations must notify DEA by no later than the time of renewal of their registration so that they may be properly identified as reverse distributors in DEA's records.

The requirements for a reverse distributor in this interim final rule are similar to those currently imposed on