note); E.O. 12829, 3 CFR 1993 Comp., p.570; E.O. 12958, as amended, 3 CFR, 1995 Comp., p.333; E.O. 12968, 3 CFR 1995 Comp., p. 391.

§ 95.1 [Amended]

■ 2. In § 95.1, in the first sentence, remove the words ''security facility approval,'' and add in their place the words ''facility security clearance.''

§ 95.9 [Amended]

■ 3. In § 95.9, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.19 [Amended]

■ 4. In § 95.19, the introductory text of paragraph (a), in the second sentence, remove the words '' Facilities and Security, Office of Administration'' and add in their place the words ''Nuclear Security, Office of Nuclear Security and Incident Response.'' In the third sentence, remove the words ''Facilities and,'' and add in their place the word ''Nuclear,'' and in paragraph (c), remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.20 [Amended]

■ 5. In § 95.20, in the first sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.21 [Amended]

■ 6. In § 95.21, in the first sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.36 [Amended]

■ 7. In § 95.36, in paragraph (a), in the first sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.'' In paragraph (c), in the first sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear,'' and in paragraph (d), in the third and fourth sentences, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

■ 8. In § 95.37, paragraph (c)(1)(iii) is revised to read as follows:

§ 95.37 Classification and preparation of documents.

(c) * * *

(1) * * *

(iii) An example of the marking stamp is as follows:

Derived from _____
(Source/Date)

Reason: _____

Declassify On: _____
(Date/Event/Exemption)

Classifier: _____
(Name/Title/Number)

* * * * *

§ 95.45 [Amended]

■ 9. In § 95.45, in paragraph (a), in the second sentence, remove the words ''Facilities and Security, Office of Administration,'' and add in their place the words ''Nuclear Security, Office of Nuclear Security and Incident Response,'' and in the third sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.53 [Amended]

■ 10. In § 95.53, in the third sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.57 [Amended]

■ 11. In § 95.57, paragraph (c), in the first sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear,'' and in the third sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

Dated at Rockville, Maryland, this 25th day of June 2003.

For the Nuclear Regulatory Commission.

William D. Travers,

Executive Director for Operations.

[FR Doc. 03–17583 Filed 7–10–03; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305, and 1307

[Docket No. DEA–108I]

RIN 1117–AA19

Definition and Registration of Reverse Distributors

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim final rule with request for comment.

SUMMARY: DEA is amending its regulations to define the term ''reverse distributor'' and to establish a new category of registration for persons handling controlled substances. The amendments establish the regulatory standards under which reverse distributors may handle unwanted, unusable, or outdated controlled substances acquired from another DEA registrant. These standards ensure the proper documentation and recordkeeping necessary to prevent diversion of such controlled substances to illegal purposes. Since this amendment mostly codifies DEA's existing practices, it will have no significant impact on existing reverse distributors.

DATES: Effective Date: August 11, 2003.

Comment Date: Written comments must be postmarked on or before September 9, 2003.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA **Federal Register** Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Overview of and Benefits of This Interim Final Rule

As is more fully discussed in this preamble, this interim final rule mostly codifies existing practices that reverse distributors follow under memoranda of understanding (MOUs) with the Drug Enforcement Administration. This approach is consistent with the comments received (also discussed more fully later in this preamble) that stated that reverse distributors would be significantly and adversely impacted if, as was proposed, they were classified as manufacturers. In recognizing this activity as a separate registration category of distributors, DEA believes the entire controlled substances industry will benefit. Existing reverse distributors operating under MOUs will become fully recognized registrants under DEA rules. Thousands of other registrants who need to dispose of unneeded or outdated inventories will be able to turn to a fully registered group of distributors. Furthermore, by essentially codifying existing practices these benefits will be achieved with minimal need for change or for disruption to the affected industry.

Background

The overall goal of the Controlled Substances Act (CSA) and of DEA's regulations in Title 21, Code of Federal Regulations (CFR), parts 1300–1316 is to provide a closed distribution system so that a controlled substance is at all times under the legal control of a person registered, or specifically exempted from registration, by the Drug Enforcement Administration until it reaches the ultimate user or is destroyed. DEA achieves this goal by registering manufacturers, distributors, and dispensers of controlled substances. Thus, any movement of controlled substances between these registered persons is covered by DEA regulations,

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

all registrants at the distributor level. They include, but are not necessarily limited to:

- *Security:* All applicants must install, at the registered premises, physical security controls that meet the existing standards of 21 CFR 1301.71 and 1301.72.
- *Recordkeeping:* In accordance with 21 CFR part 1304, periodic inventories and records of all controlled substances received, destroyed, or returned to the original, registered manufacturers must be maintained for two years. The registrant must adequately describe the receipt and accountability methods and records to be employed to ensure the establishment of effective controls against diversion.
- *Order Forms* must be completed for all Schedule I and II items received and transferred.
- *Reports* are required under the Automation of Reports and Consolidated Orders System (ARCOS), as specified in 21 CFR 1304.33.

In addition to DEA requirements, reverse distribution applicants must obtain the appropriate State and Federal approvals for controlled substances and disposal activities.

After publication of the August 1995 NPRM, DEA completed a rulemaking project in 1997 (62 FR 13938, March 24, 1997) that reorganized and clarified the regulations that would have been affected by that NPRM. The 1997 rulemaking also addressed the gender-specific and other editorial changes that were contained in the 1995 NPRM. Therefore, proposed changes to 21 CFR 1301.26 (now 21 CFR 1301.24), Exemption of law enforcement officers; 21 CFR 1301.32 (now 21 CFR 1301.13), Application forms; contents; signature; and 21 CFR 1304.34 (now 21 CFR 1304.33(a)), Reports generally, are not included in this interim final rule. For the proposed changes that relate to reverse distributors, this interim final rule amends the appropriate CFR sections as changed in 1997. Throughout the preamble, citations to both previous section number and current section number are provided, where relevant.

Public Comments on the NPRM

Eight comments were received regarding the proposed rule. Commenters included reverse distributors and disposers currently operating under Memoranda of Understanding (*i.e.*, facilities such as incinerators that destroy controlled substances) and some of their representative organizations. While some commenters supported the intent of the rule, all commenters were against some or all aspects of the rule. The following discussion summarizes the issues raised by commenters and DEA's response to these issues.

Proposed Definition and Registration Requirements

Most commenters opposed the proposal to classify the activities they engage in as either disposal or manufacturing and stated that doing so would subject them to unnecessary and burdensome regulations.

One commenter stated that since reverse distributors neither process nor package/repackage controlled substances within the meaning of the statutory definition of ''manufacturer,'' it is beyond DEA's statutory authority to regulate these companies as manufacturers. Another commenter stated that the primary goal of disposers is not to render a controlled substance unusable, but, rather, it is to sort, inventory and perform other activities necessary to distribute products back to the original manufacturer and only secondarily, arrange for the actual destruction of controlled substances.

Four commenters stated that the proposed definition of disposer implies that a disposer is manipulating the product and, therefore, that waste is being accepted. This would, in turn, require disposers to comply with the more burdensome guidelines of the Food and Drug Administration (FDA) and EPA.

DEA Response

In response to these comments, DEA has decided to establish a definition for reverse distributor and is establishing a new category of registration as reverse distributors. In this interim final rule, DEA is adding the definition for ''reverse distributors'' to 21 CFR 1300.01(b). Reverse distributors are defined as ''a person who receives controlled substances acquired from another DEA registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or, where necessary, processing such substances or arranging for processing such substances for disposal.'' When reverse distributors return unwanted, unusable, or outdated controlled substances acquired from legitimate medical, scientific, research or other industrial channels to a manufacturer or a manufacturer's agent, they must follow the same DEA requirements as distributors follow. When reverse distributors process controlled substances or arrange for processing controlled substances for disposal, they must follow the same procedures that distributors would follow in complying with 21 CFR 1307.21, ''Procedure for disposing of controlled substances.''

Applicability to Practitioners and Others

One commenter stated that classifying dentists and other small disposers as manufacturers would be burdensome because they would now have to register and pay burdensome registration fees. This could result in dentists removing themselves from regulatory control by refusing to handle controlled substances, which could adversely affect their patients. This commenter recommended that the proposed rule either exempt dentists and other small disposers by quantity, or state that they are not members of the ''disposer'' subcategory.

Another commenter stated that previous contacts with DEA indicated that the rulemaking is intended to regulate disposers that dispose of or offer controlled substances for disposal over which they have legal control. This commenter requested that DEA clarify that it should not be subject to the proposed rule provided that it is acting as an agent of DEA through a contract; or that it disposes of controlled substances for manufacturers provided that the manufacturer's representatives bring the controlled substances to a disposal facility and witness the destruction, thus maintaining legal responsibility for the controlled substances.

DEA Response

In this interim final rule, DEA is not changing the procedures for disposing of controlled substances under 21 CFR 1307.21. Those procedures are designed to ensure that controlled substances are under the control of a DEA registrant until they are destroyed or rendered unusable. If a disposal company never takes legal control of a controlled substance and the actual destruction is witnessed by two representatives of a DEA registrant, the disposal company itself is not required to obtain a DEA registration. On the other hand, if a disposal company receives controlled substances from a DEA registrant and then disposes of them later, the disposal company becomes part of the chain of responsible parties and must therefore be registered by DEA as a reverse distributor.

Under the interim final rule, DEA registrants who need to periodically dispose of controlled substances, such as practitioners, would continue to follow their current procedures for disposal of controlled substances.

Usually this involves obtaining authority and instructions from the local DEA field office as specified in 21 CFR 1307.21. Such registrants also have the option of returning controlled substances to the manufacturer or to a reverse distributor.

Appropriateness of Security and Other Requirements That Apply to Manufacturers

Commenters recommended creating a separate category for reverse distributors, as a subcategory of distributors, who would be subject to the existing registration and other requirements for distributors. Commenters stated that reverse distributors should, therefore, not be subject to the security, inventory, recordkeeping, and reporting requirements of the proposed rule that apply to manufacturers.

DEA's Response

Since DEA has decided to create a completely separate category for reverse distributors, persons who fall under this category will be required to comply with the same security, reporting, and other requirements that apply to distributors rather than the requirements that apply to manufacturers.

Proposed Security Requirements: Monitoring Systems

DEA received one comment on the language in proposed 21 CFR 1301.71(b)(14) which requires the applicant or registrant to document the adequacy of its system for monitoring the receipt, manufacture, distribution, and disposal of controlled substances. The commenter stated that all of the ''waste to energy'' facilities that it operates have demonstrated that the implementation of supervised monitoring of the receipt and disposal process, by the disposer, has proven effective and that it would be physically impossible for them to construct the vaults or other security barriers that the regulations require for storage at manufacturer's locations (under 21 CFR 1301.72). Instead, this commenter recommended that disposers be required to develop a set of Standard Operating Procedures, to be approved by DEA, for the receipt and disposal of controlled substances.

DEA Response

With respect to the issue of physical security, it should be noted that the commenter does not take possession of the controlled substances that are to be destroyed. Instead, the commenter maintains incineration facilities at which DEA registrants carry out witnessed destruction of their controlled substances. As a result, the commenter is not subject to DEA's requirements and does not have to establish or maintain physical security as required under 21 CFR 1301.72 of the regulations.

Proposed Security Requirements: Compliance With Other Laws

One commenter commented on proposed 21 CFR 1301.71(b)(15), which would require DEA to consider the applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste, as they would apply to applicants and registrants. The commenter stated that this requirement would be inappropriate because it would exceed DEA's statutory authority. While DEA inspectors should be concerned with compliance with DEA statutes and regulations during audits, the inspectors should not be empowered to look for violations of other Federal, State, and local laws governing the management of waste. Enforcement of those laws should be left to the other Federal agencies and individual jurisdictions. Therefore, the commenter requested DEA clarification on this issue.

DEA Response

With respect to this comment, the items listed in 21 CFR 1301.71(b)(1) through new (b)(15) are factors that the Administrator may consider in evaluating whether the security controls provided by a DEA registrant are adequate to guard against theft and diversion of controlled substances and appropriate to the registrant's business. Not all of the factors may be relevant for evaluation of a particular registrant's operation. DEA is adding a new factor regarding the applicability of other Federal, State, or local laws, not as an enforcement issue for those specific laws, but only as guidance to the registrant that DEA may consider how the registrant is complying with such laws in making an evaluation of the adequacy of the registrant's security system. DEA has the statutory authority under 21 U.S.C. 823 to consider an applicant's compliance with applicable State and local laws before granting a registration.

Proposed Inventory Requirements

A commenter that provides disposal facilities at which registrants may conduct witnessed destructions recommended that additional language be added to the end of proposed 21 CFR 1304.20 (current 21 CFR 1304.11) to require that the information required under 21 CFR 1304.15(a), (c), and (d) be provided by the manufacturer or its agent when tendering the substances for disposal.

DEA Response

The commenter's suggested change is not necessary because in witnessed destructions the registrant conducting the destruction must accurately document the controlled substances being destroyed on DEA Form 41. Further, a disposal facility of the type operated by the commenter does not take possession of the controlled substances being destroyed and, thus, is not subject to the registration, inventory, and recordkeeping requirements under the law.

Proposed Recordkeeping Requirements

Several commenters made recommendations to change the language of proposed 21 CFR 1304.30(a) (current 21 CFR 1304.22) to make the specific requirements clear.

A commenter also expressed concern about proposed paragraph (b) and stated that the disposer should not be expected to recount and itemize the individual dosage units and containers for each substance being delivered for disposal. This would put their employees at possible risk for exposure to these substances, increase opportunities for diversion, and significantly slow down the disposal operation. Instead, the commenter recommended that sufficient controls be placed on the manufacturer and its representatives prior to disposal so that the disposer can focus on rapid and effective disposal procedures.

DEA Response

The comments primarily address problems that could have arisen if the reverse distribution function was included under manufacturing, as proposed. These concerns are mostly addressed by treating reverse distribution as a separate category of registration. The concerns expressed by disposers are, as previously discussed, not relevant as long as legal control of the controlled substances remains with a person who is registered with DEA.

Recordkeeping requirements for reverse distributors are set forth in new paragraph (e) of 21 CFR 1304.22. These requirements are tailored to the reverse distributor role and address recordkeeping for controlled substances in both bulk and finished form. These requirements are consistent with existing practice.

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

dispose of any controlled substances on hand.

Why Is DEA Publishing This Action as an Interim Final Rule?

As discussed previously, the goal of the NPRM was to give codified status to reverse distributors. While DEA initially proposed doing this by registering reverse distributors in the manufacturer category, comments on the NPRM made it clear that this approach would adversely affect the existing industry (*e.g.* by subjecting reverse distributors to certain EPA and FDA regulations). By registering reverse distributors as distributors, DEA accomplishes its original goal in a manner that is consistent with the intent of the NPRM and with public comments on the NPRM. Also, this approach is beneficial rather than detrimental to the entire controlled substances industry. However, recognizing the time which has elapsed between publication of the NPRM and this action, as well as the growth and evolution of the reverse distributor industry during that time, DEA has determined that, rather than publishing final regulations on this issue, it is in the best interest of industry that DEA publish an interim final rule. Publishing an interim final rule will permit further comment from the affected industry, ensuring that final regulations appropriately address industry evolution and concerns.

Summary

In summary, the registration and other requirements for reverse distributors under this interim final rule are the same as those currently imposed on distributors and the same as currently imposed on reverse distributors under MOUs; Registration requirements under existing 21 CFR 1301.13; Security requirements under existing 21 CFR 1301.71 and 1301.72; Inventory requirements under existing 21 CFR 1304.11; Recordkeeping requirements under existing 21 CFR 1304.22; Reporting requirements under existing 21 CFR 1304.33 (ARCOS reports); Order form requirements under existing 21 CFR 1305.08 (Persons entitled to fill order forms). In some cases these rules have been modified to apply specifically to reverse distributors. In addition, DEA is amending 21 CFR 1307.11 and 1307.12 to clarify that registrants can transfer (''distribute'') controlled substances to a reverse distributor, even if the registrant is not registered as a distributor. As a result of DEA's decision to classify reverse distributors as a new category of registration, instead of as a manufacturer, proposed 21 CFR 1303.12 on quotas is not applicable.

The closed system of distribution established under the CSA for controlled substances relies on certain fundamental principles, including registration, security, and accountability (*i.e.*, inventories, recordkeeping, and reporting), to achieve a system of controls that allows for legitimate commerce while minimizing the potential for diversion. The fact that reverse distributors engage in a unique activity within the controlled substances chain and are faced with certain challenges that other registrants do not normally encounter does not override the fundamental principals of DEA's controls. Reverse distributors must register, provide security, and maintain accurate records for all controlled substances in their possession. However, the regulatory structure does provide some flexibility and, where possible, DEA has made adjustments to address some of the problems the industry has encountered, including use of a separate category of registration and application of the inventory requirements for dispensers and researchers.

Because of the length of time since the NPRM was published and the evolving nature of this industry, DEA is using an interim final rule to give an additional opportunity for comment. DEA will consider comments on the appropriateness and the practical application of these rules to current industry practice and will be flexible where possible in developing final rules.

Application for Registration for Reverse Distributors

As has been previously noted in this rulemaking, persons wishing to conduct reverse distributor activities must register with DEA to do so. To apply for registration, persons must complete a DEA Form 225, Application for Registration. To renew a DEA registration, persons must complete a DEA Form 225a, Application for Registration Renewal. As DEA has not yet issued updated forms specifically referencing the reverse distributor business activity, persons wishing to register as reverse distributors must choose the distributor business activity on the form and then must attach a written statement signed by the person signing the registration or registration renewal application acknowledging that the applicant is conducting or wishes to conduct reverse distributor activities.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this interim final rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866 Section 1(b). DEA has determined that this rule is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget.

Executive Order 12988

The Deputy Assistant Administrator further certifies that this regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-

based companies in domestic and export markets.

List of Subjects

21 CFR Part 1300

Definitions, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1304

Drug traffic control, Reporting requirements.

21 CFR Part 1305

Drug traffic control, Reporting requirements.

21 CFR Part 1307

Drug traffic control.

■ For the reasons set out above, 21 CFR parts 1300, 1301, 1304, 1305, and 1307 are amended as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

■ 2. Section 1300.01 is amended by redesignating paragraphs (b)(41) through (b)(43) as paragraphs (b)(42) through (b)(44), and adding a new paragraph (b)(41) to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

(41) The term *reverse distributor* means a registrant who receives controlled substances acquired from another DEA registrant for the purpose of—

(i) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or

(ii) Where necessary, processing such substances or arranging for processing such substances for disposal.

* * * * *

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 3. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

■ 4. Section 1301.13 is amended by revising paragraph (c), redesignating paragraphs (e)(1)(iii) through (e)(1)(ix) as paragraphs (e)(1)(iv) through (e)(1)(x) and adding a new paragraph (e)(1)(iii) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(c) At the time a manufacturer, distributor, reverse distributor, researcher, analytical lab, importer, exporter or narcotic treatment program is first registered, that business activity shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last date of the month designated for that group. In assigning any of these business activities to a group, the Administration may select a group the expiration date of which is less than one year from the date such business activity was registered. If the business activity is assigned to a group which has an expiration date less than three months from the date of which the business activity is registered, the registration shall not expire until one year from that expiration date; in all other cases, the registration shall expire on the expiration date following the date on which the business activity is registered.

* * * * *

(e) * * *

(1) * * *

(iii) Reverse distributing	Schedules I–V	New—225 Renewal—225a	438 438	1

* * * * * * *

■ 5. Section 1301.71 is amended by revising paragraphs (b)(13) and (b)(14) and adding a new paragraph (b)(15) to read as follows:

§ 1301.71 Security requirements generally.

* * * * *

(b) * * *

(13) The availability of local police protection or of the registrant's or applicant's security personnel;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and

(15) The applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste.

* * * * *

■ 6. Section 1301.72 is amended by revising paragraph (b)(7) to read as follows:

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

* * * * *

(b) * * *

(7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in § 1301.71(b);

* * * * *

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

■ 7. The authority citation for part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

■ 8. Section 1304.11 is amended by revising paragraph (e)(2) and the introductory text of paragraph (e)(3) to read as follows:

§ 1304.11 Inventory requirements.

* * * * *

(e) * * *

(2) *Inventories of distributors.* Except for reverse distributors covered by paragraph (e)(3) of this section, each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of dispensers, researchers, and reverse distributors.* Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher,

or reverse distributor shall do as follows:

* * * * *

■ 9. Section 1304.22 is amended by revising paragraph (b) and adding new paragraph (e) to read as follows:

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, and exporters.

* * * * *

(b) *Records for distributors.* Except as provided in paragraph (e) of this section, each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

* * * * *

(e) *Records for reverse distributors.* Each person registered to distribute controlled substances as a reverse distributor shall maintain records with the following information for each controlled substance:

(1) For each controlled substance in bulk form the following:

(i) The name of the controlled substance.

(ii) The total quantity of the controlled substance to the nearest metric unit weight consistent with unit size.

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the controlled substance was received.

(iv) The quantity returned to the original manufacturer of the controlled substance or the manufacturer's agent, including the date of and quantity of each distribution and the name, address and registration number of the manufacturer or manufacturer's agent to whom the controlled substance was distributed.

(v) The quantity disposed of including the date and manner of disposal and the signatures of two responsible employees of the registrant who witnessed the disposal.

(2) For each controlled substance in finished form the following:

(i) The name of the substance.

(ii) Each finished form (*e.g.*, 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (*e.g.*, 100-tablet bottle or 3-milliliter vial).

(iii) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received.

(iv) The number of commercial containers of each such finished form distributed back to the original manufacturer of the substance or the manufacturer's agent, including the date of and number of containers in each distribution and the name, address, and registration number of the manufacturer or manufacturer's agent to whom the containers were distributed.

(v) The number of units or volume of finished forms and/or commercial containers disposed of including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

■ 10. Section 1304.33 is amended by revising paragraph (c) to read as follows:

§ 1304.33 Reports to ARCOS.

* * * * *

(c) *Persons reporting.* For controlled substances in Schedules I, II or narcotic controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute, including each person who is registered to reverse distribute, shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

* * * * *

PART 1305—ORDER FORMS

■ 11. The authority citation for part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

■ 12. Section 1305.08 is amended by revising paragraph (b) to read as follows:

§ 1305.08 Persons entitled to fill order forms.

* * * * *

(b) A person who has obtained any controlled substance in Schedule I or II by order form may return such substance, or portion thereof, to the person from whom he/she obtained the substance, to the manufacturer of the substance, or to a registered reverse distributor pursuant to the order form of the latter person;

* * * * *

PART 1307—MISCELLANEOUS

■ 13. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

■ 14. Section 1307.11 is revised to read as follows:

§ 1307.11 Distribution by dispenser to another practitioner or reverse distributor.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to—

(1) Another practitioner for the purpose of general dispensing by the practitioner to patients, provided that—

(i) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(ii) The distribution is recorded by the distributing practitioner in accordance with § 1304.22(c) of this chapter and by the receiving practitioner in accordance with § 1304.22(c) of this chapter;

(iii) If the substance is listed in Schedule I or II, an order form is used as required in part 1305 of this chapter; and

(iv) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and § 1301.25 of this chapter during each calendar year in which the practitioner is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(2) A reverse distributor who is registered to receive such controlled substances.

(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to paragraph (a)(1) of this section and § 1301.25 of this chapter will exceed 5 percent of this total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.

■ 15. Section 1307.12 is amended by revising the title and revising paragraph (a) to read as follows:

§ 1307.12 Distribution to supplier or manufacturer.

(a) Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he/she obtained it or to the manufacturer of the substance, or, if designated, to the manufacturer's registered agent for accepting returns, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance in Schedule I or II, an order form shall be used in the manner prescribed in part 1305 of this chapter and be maintained as the written record of the transaction. Any person not required to register pursuant to sections 302(c) or 1007(b)(1) of the Act (21 U.S.C. 822(c) or 957(b)(1)) shall be exempt from maintaining the records required by this section.

* * * * *

Dated: July 3, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 03–17578 Filed 7–10–03; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9075]

RIN 1545–AX52

Compensation Deferred Under Eligible Deferred Compensation Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance on deferred compensation plans of state and local governments and tax-exempt entities. The regulations reflect the changes made to section 457 by the Tax Reform Act of 1986, the Small Business Job Protection Act of 1996, the Taxpayer Relief Act of 1997, the Economic Growth and Tax Relief Reconciliation Act of 2001, the Job Creation and Worker Assistance Act of 2002, and other legislation. The regulations also make various technical changes and clarifications to the existing final regulations on many discrete issues. These regulations provide the public with guidance necessary to comply with the law and will affect plan sponsors, administrators, participants, and beneficiaries.

DATES: *Effective Date:* These final regulations are effective July 11, 2003.

Applicability Date: These regulations apply to taxable years beginning after December 31, 2001. See ''Effective date of the regulations'' for additional information concerning the applicability of these regulations.

FOR FURTHER INFORMATION CONTACT: Cheryl Press, (202) 622–6060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1580. Responses to this collection of information are mandatory.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget.

The estimated burden per respondent varies from .033 hour to 2 hours per trust established depending upon individual respondents' circumstances, with an estimated average of one hour for each trust established, and from 20 hours to 50 hours per application for approval as a custodian with an estimated average of 35 hours for each application submitted to qualify as a custodian.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:T:T:SP Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to this collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

Section 131 of the Revenue Act of 1978 (92 Stat. 2779) added section 457 to the Internal Revenue Code of 1954. On September 27, 1982, final regulations (TD 7836, 1982–2 C.B. 91) under section 457 (the 1982 regulations) were published in the **Federal Register** (47 FR 42335). The 1982 regulations provided guidance for complying with the changes to the applicable tax law made by the Revenue Act of 1978 relating to deferred compensation plans maintained by state and local governments and rural electric cooperatives.

Section 1107 of the Tax Reform Act of 1986 (100 Stat. 2494) extended section 457 to tax-exempt organizations. Section 6064 of the Technical and Miscellaneous Act of 1988 (102 Stat. 3700) codified certain exceptions for certain plans. Notice 88–68, 1988–1 C.B. 556, addressed the treatment of nonelective deferred compensation of nonemployees, and provided an exception under which section 457 does not to apply to certain church plans.

Section 1404 of the Small Business Job Protection Act of 1996 (110 Stat. 1755) added section 457(g) which requires that section 457(b) plans maintained by state and local government employers hold all plan assets and income in trust, or in custodial accounts or annuity contracts (described in section 401(f) of the Internal Revenue Code), for the exclusive benefit of participants and beneficiaries.

Section 1071 of the Taxpayer Relief Act of 1997 (111 Stat. 788) permits certain accrued benefits to be cashed out.

Sections 615, 631, 632, 634, 635, 641, 647, and 649 of the Economic Growth and Tax Relief Reconciliation Act of 2001 (EGTRRA) (115 Stat. 38) included increases in elective deferral limits, repeal of the rules coordinating the section 457 plan limit with contributions to certain other types of plans, catch-up contributions for individuals age 50 or over, extension of qualified domestic relation order rules to section 457 plans, rollovers among various qualified plans, section 403(b) contracts and individual retirement arrangements (IRAs), and transfers to purchase service credits under governmental pension plans.

Section 411(o)(8) and (p)(5) of the Job Creation and Worker Assistance Act of 2002 (116 Stat. 21) clarified certain provisions in EGTRRA concerning section 457 plans, including the use of certain compensation reduction