9, 1999. This incorporation by reference was approved by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1-L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on August 23, 2000.

Issued in Renton, Washington, on July 11, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–18040 Filed 7–18–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, and 1307

[DEA–143F]

RIN 1117–AA36

Establishment of Freight Forwarding Facilities for DEA Distributing Registrants

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This rule defines the term freight forwarding facility and establishes storage, security, and recordkeeping requirements for controlled substances that transit such facilities. It also provides a waiver to a freight forwarding facility from the requirement for registration with the Drug Enforcement Administration. This rule will afford a registrant who is authorized to engage in the general distribution of controlled substances a more efficient and competitive means to distribute controlled substances and should minimize in-transit losses.

EFFECTIVE DATE: August 18, 2000.

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

SUPPLEMENTARY INFORMATION:

Why Is DEA Taking This Action and Whom Does It Affect?

On December 18, 1996, DEA published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (61 FR 66637) entitled Establishment of Freight Forwarding Facilities for DEA Distributor Registrants. The NPRM was published in response to requests by registrants within the controlled substances distribution industry that registrant-operated freight forwarding facilities be exempted from the registration requirement. (Currently there is no provision in the regulations that would allow the storage and distribution of controlled substances from such a location without a DEA registration.) Following discussion with registrants and trade association representatives within the affected industries, DEA determined that such a waiver could be provided to registrants within the controlled substances distribution industry, pursuant to 21 U.S.C. 822(d), subject to certain requirements with respect to the activity conducted, security, and recordkeeping.

What Requirements Were Proposed in the NPRM?

The NPRM proposed to define freight forwarding facility as a separate facility operated by a DEA distributor registrant through which sealed, packaged controlled substances, in unmarked (*i.e.,* without indication of the contents) containers, are stored for less than 24 hours while being routed to the ultimate DEA registrant consignee. The proposed definition specifically excluded a facility through which controlled substance returns are processed. Freight forwarding facilities would be granted a waiver from the registration requirement, provided that the registrant operating the facility gave required notice to DEA of the intent to operate such a facility and DEA issued no objection.

With respect to security, the NPRM proposed that during temporary storage at the facility, all Schedule II–V controlled substances must be under constant observation by designated responsible individuals in a segregated area, or, if not under constant observation, stored in a caged and alarmed area that meets the requirements set forth in Title 21, Code of Federal Regulations (CFR), Section 1301.72(b). Proposed recordkeeping consisted of the requirement that the registrant maintain records documenting the transfer of the controlled substances from the long-distance conveyance to the local conveyance, reflecting the date, time of transfer, the number of cartons, crates, drums, or other packages in which commercial containers of controlled substances were shipped and authorized signatures for each transfer.

What Comments Were Received in Response to the NPRM?

Six comments were received in response to the NPRM: three from DEA pharmacy registrants, two from trade associations representing the affected industries, and one from a state regulatory agency. While the comments expressed general support for the changes, concerns were raised regarding each specific facet of the proposed rule. With regard to several of the matters, DEA adopted changes suggested by the commenters to make the rule more flexible and the waiver from registration for a freight forwarding facility more broadly available.

1. Use of the Freight Forwarding Facility by More Than One Registrant

Four commenters objected to the proposed requirement that a freight forwarding facility be for the exclusive use of the named DEA distributor registrant, precluding its use by another DEA registrant. The commenters suggested that the new regulations allow multiple registrants to utilize a single freight forwarding facility. Two of the four commenters addressed the issue in terms of multiple registrants of the same company, while the other two addressed the use of a single freight forwarding facility by multiple unrelated registrants. Another commenter questioned whether it would be possible for a non-DEA registrant to lease space at a freight forwarding facility to more than one DEA registered distributor.

The proposal to exempt a freight forwarding facility from the DEA registration requirement was based upon the facility being an extension of a specific distributing registrant, thus simplifying the issue of responsibility for any diversion or lack of compliance with the regulations at the facility. However, taking such a simplified approach does limit use of the facility to only that one distributing registrant.

DEA acknowledges the comments that limiting the definition to such as extent, while simplifying the issue of responsibility under the law and regulations, could result in complex, inefficient, and duplicative efforts for a company that operates multiple distributing registrations. The company would be required to maintain and operate a separate freight forwarding facility for each registered distributing location. Therefore, the proposal is

being amended to allow a corporate entity that maintains multiple distributing registrations the ability to operate a single freight forwarding facility for shipments in transit from any of its registered distributing locations. Such a provision remains consistent with the existing framework of DEA's requirements because the controlled substances remain in the custody and control of the corporate entity who maintains both the freight forwarding facility and the various registrations with DEA. That corporate entity is responsible for ensuring that the laws and regulations are adhered to and for the safekeeping of the controlled substances transiting the facility. The ultimate responsibility for compliance would, of course, rest with the DEA registered location making the shipment, should there be any violations or thefts or losses of controlled substances from the shipment.

The exemption of a freight forwarding facility is based on the premise that Company A ships controlled substances to its customers utilizing an in-transit location owned or leased by Company A. In this instance the controlled substances remain the legal responsibility of Company A until they are actually received by the customers. If, on the other hand, Company A were to ship controlled substances to its customers utilizing a freight forwarding facility which is owned by Company B, the custody and control of the shipment, as well as the legal responsibility, shifts from Company A to Company B at the freight forwarding facility. DEA is waiving the registration requirement only with respect to freight forwarding facilities operated by the distributing registrant; a transfer of custody, control, and legal responsibility of controlled substances between two different companies remains subject to the registration requirements set forth in 21 U.S.C. 822 and may only occur between registered locations of the two companies. Additionally, all applicable records, reports, and security required for controlled drug transactions would continue to apply to such transactions.

With respect to the question of whether a non-registrant could lease space at a freight forwarding facility to more than one DEA registrant, it should be noted that the definition of a freight forwarding facility refers to a facility operated by the company that maintains one or more distributing registrations with DEA. It is expected that the facility will be under the full direction and control of that company and will be staffed by employees of that company. Therefore, the sharing of the same freight forwarding facility by more than one company would not be possible. However, this does not preclude different companies from operating separate freight forwarding facilities within a single building, provided that each is maintained as a physically separate facility from the others.

One commenter suggested that registrants other than distributors may wish to operate a freight forwarding facility. DEA recognizes that, in addition to distributors, there are other registrants (*i.e.* manufacturers and importers) who are authorized to distribute controlled substances under their registration. Therefore, DEA is amending the proposal to include controlled substances distributors, manufacturers, and importers.

2. Storage and Security of Controlled Substances

Four commenters expressed concerns with the proposed requirement that controlled substance storage at a freight forwarding facility be limited to less than 24 hours. Questions were raised about dealing with emergency circumstances (bad weather, natural disaster, and other unforeseen circumstances) that may require the temporary storage of controlled substances at the freight forwarding facility for more than the allowable 24 hour time limit. One commenter suggested that a plan for unforeseen emergencies be submitted at the time of application.

One of the factors in DEA's decision to establish the waiver of the registration requirement for freight forwarding facilities was that in the normal course of freight forwarding activities, shipments of controlled substances will transit a facility with minimal delay. As one commenter noted, ''* * * Product arrives at the facility via the long distance conveyance and is transferred to the appropriate short distance conveyance, typically within a matter of 2 hours or less * * *'' However, recognizing that there are a variety of factors, such as bad weather, mechanical breakdowns, scheduling errors, etc., that may interfere with the timely transit of shipments through the facility, DEA included in the definition of a freight forwarding facility the provision that controlled substances may be stored for less than 24 hours. DEA expects that any registrant operating a freight forwarding facility will ensure that any controlled substances transiting the facility will remain there for less than 24 hours.

DEA does recognize that there may be emergency circumstances that may temporarily prevent full compliance with the regulations.

In such a case, the registrant operating the facility must take the necessary steps to safeguard the controlled substances and effect a return to normal operations as quickly as possible. Additionally, the registrant must notify the local DEA office of the circumstances and what actions are being taken to address the situation. DEA will not penalize a registrant for non-compliance with the requirements in such emergency circumstances, provided the registrant has taken appropriate steps to safeguard the controlled substances and to return to normal operations as soon as possible.

With respect to what constitutes emergency circumstances, DEA wishes to note that the commenters included in their description of emergency circumstances such events as late delivery before a holiday weekend and inclement weather. These are not, in and of themselves, emergency circumstances that would warrant allowing the storage of controlled substances at a freight forwarding location in excess of the 24 hour time limit. Certainly unpredictable circumstances that are entirely beyond a registrant's control (fire, earthquake, flash flood, tornado, etc.) would be emergency events that may require storage for 24 hours or more. However, where an event can be predicted or anticipated (winter storm, hurricane, mechanical breakdowns, labor disturbances, etc.), DEA expects that a registrant will have in place contingency plans (rescheduling or re-routing shipments, emergency backup transportation or labor arrangements, etc.) to try to insure that controlled substances are not stored at the facility for 24 hours or more.

DEA is not going to attempt to define in these regulations what would constitute an emergency. Any attempt to do so would inevitably fall short of its intended purpose. There are simply too many variables that could influence whether an event would, or would not, qualify as an emergency. Each event will have to be looked at individually, not only in terms of what has occurred, but also in terms of what efforts the registrant had taken prior to the event to anticipate and prevent any disruption of operations and what efforts are taken following the event to safeguard the controlled substances and return to normal operations. Registrants should approach this issue from the perspective of taking all possible steps to anticipate unusual events and ensure that these events do not prevent compliance with the regulations.

Two commenters objected to the proposed security requirement that controlled substances be stored in accordance with 21 CFR 1301.72(b) whenever they are not under continuous observation by designated individuals.

DEA believes that in the normal course of freight forwarding activities, shipments of controlled substances will transit a facility with minimal delay and there would be no need for the distributing registrant to implement specific physical security measures to guard against losses since the loading/unloading areas would be continuously attended and under the general observation of employees. However, when circumstances arise requiring temporary storage of controlled substances, the distributing registrant must either maintain continuous observation of the controlled substances or implement physical security measures that meet the requirements of 21 CFR 1301.72(b) in order to guard against losses.

As an alternative to continuous observation of controlled substances, two commenters suggested a ''lock down'' of the facility.

DEA believes that a distributing registrant who has the ability to ''lock down'' a freight forwarding facility equipped with the appropriate alarm system or kept under constant visual surveillance by security patrols would, in effect, secure the controlled substances in a manner equivalent to the security requirements stated in 21 CFR 1301.72(b)(3), thus satisfying the requirement in the new 21 CFR 1301.77(a)(2).

Two commenters noted that controlled substance containers are required to be unmarked, this making identification of those containers in a large shipment extremely difficult, if not impossible, and requiring that the entire facility be subject to the security requirements of 21 CFR 1301.72(b) or that all containers in the facility be kept under constant observation. One commenter suggested that discrete marking or coding of the containers of controlled substances should be allowed.

In evaluating these comments, the presumption exists that all containers transiting a freight forwarding facility have a certain amount of controlled substances in them. As noted earlier in this document, DEA believes that specific security measures should not be necessary in the normal course of operations since the loading/unloading areas would be continuously attended and under the general observation of employees. It is only when circumstances require the temporary (less than 24 hours) storage of these containers that they must be maintained in a segregated area of the facility under continuous observation in order to prevent access by unauthorized individuals (*i.e.* maintenance personnel, non-employee service personnel). Whether continuous observation is performed by an authorized employee of the facility or by contracted security personnel is the responsibility of the distributing registrant. If there is not continuous observation of these containers, the distributing registrant would be required to have the appropriate physical security measures in place that are consistent with the requirements of 21 CFR 1301.72(b).

With respect to the issue of discrete marking or coding of containers of controlled substances, the intent of unmarked containers is to prevent the identification of those that contain controlled substances, thus helping to prevent diversion of the controlled substances. As the commenters noted, the identification of such containers in a large shipment would be extremely difficult, if not impossible. The act of segregating, during temporary storage, only the marked or coded containers would defeat this basic security measure by specifically identifying the containers with controlled substances, making them easier targets for diversion. Under the circumstances, DEA will hold with the requirement that the controlled substances be in unmarked containers.

3. Recordkeeping

Four commenters suggested that DEA allow a person the ability to store controlled substance records for freight forwarding facilities at a central location.

A distributing registrant who operates a freight forwarding facility must maintain complete records of controlled substance activity including a clearly defined audit trail for all controlled substances transferred through the facility. Records of controlled substances must contain the dates, times of transfer, authorized signatures and the number of cartons, crates, drums or other packages in which commercial containers of controlled substances are shipped. This will enable the distributing registrant to trace the flow of controlled substances from the long distance conveyance through the freight forwarding facility to the local conveyance or from the long distance conveyance directly to the local conveyance.

Records are required to be maintained at the freight forwarding facility, however, a distributing registrant may request central recordkeeping authority with the initial facility exemption request. Approval of this request will be granted as part of the approval of the waiver by DEA. Subsequent requests for maintaining records at a central location would be handled in accordance with 21 CFR 1304.04.

4. Returns

One commenter suggested that controlled substance returns should be allowed to transit a freight forwarding facility.

The NPRM prohibited the use of a freight forwarding facility for handling the transit of controlled substance returns due to concerns that the custody and control of the controlled substance returns would be transferred from the registered customer at a non-registered location. DEA is amending its proposal to allow controlled substance returns within a single corporate structure to be routed through the corporate owned or operated freight forwarding facility only when the distributing registrant provides the same transfer, storage, security, and recordkeeping controls as outlined in this regulation for controlled substance distributions through a freight forwarding facility. In other words, a distributing registrant may pick up a pre-authorized customer return in the same manner it makes deliveries. DEA is amending Section 1307.12 of the regulations to acknowledge the fact that a person may return controlled substances to a supplier either directly or through a freight forwarding facility provided that the return is pre-arranged and the returning registrant delivers the controlled substance(s) directly to an agent on employee of the receiving registrant. DEA is also making a technical correction in this section to the U.S. Code citation which should read ''21 U.S.C. 822(c)'' rather than ''21 U.S.C. 823(c)''.

In order to accept transfer of controlled substance returns, a distributing registrant must have received advance notification from the customer of its intent to return controlled substances. Controlled substance returns can only be transferred from a customer to an authorized representative of a distributing registrant in sealed, packaged, unmarked containers. The transfer of controlled substance returns from the customer to the authorized representative must be properly documented by both parties to the transaction so that there is an ability to track the flow of the returns from the customer back through the freight forwarding facility to the distributing registrant. Controlled substance returns cannot be shipped by a customer

directly to a freight forwarding facility nor can controlled substance returns be distributed from the freight forwarding facility to any other registrant except the original seller since the freight forwarding facility is a non-registered entity. Further, returns must transit the freight forwarding facility in less than 24 hours.

The distributing registrant is to submit, along with the required notification requesting exemption from registration for a freight forwarding facility, specific procedures for the processing of controlled substance returns.

5. Miscellaneous Comments

Three commenters suggested that a denial of an application(s) should be communicated to the applicant.

DEA has addressed this issue by indicating in the final regulations that written approval or disapproval will be provided to the distributing registrant within thirty days after confirmed receipt of the notice of intent to operate a freight forwarding facility. If a request to operate a facility is disapproved, the reasons for disapproving the request will be provided in writing to the requesting registrant.

Two commenters suggested that facilities operating under current agreements with the DEA should be grandfathered.

With the publication of this final rule, a person who is operating or desiring to operate a freight forwarding facility is required to notify DEA of both the location(s) of the facility and the registrant(s) who will utilize the facility and fully abide by the regulations set forth in this publication. Those freight forwarding facilities currently operating pursuant to Memoranda of Understanding (MOU) with the DEA must initiate the approval process within thirty days of the effective date of this final rule. Failure to initiate the approval process within the specified time period will void the existing MOU.

One commenter questioned whether DEA would coordinate with the appropriate State authorities regarding freight forwarding facilities. The waiver of the registration requirement by DEA does not imply similar exemption at the state level. The appropriate state agency should be contacted by the requesting registrant prior to obtaining authorization from the DEA to determine whether state licensure is required. Notice regarding whether state licensure is, or is not, required should be provided to DEA as part of the request to operate a freight forwarding facility. DEA will coordinate with the appropriate state authorities to ensure that freight forwarding operations within their states are in full compliance with state requirements.

What Do These Final Regulations Allow?

Under these final regulations, a distributing registrant (*i.e.,* a distributor, manufacturer, and/or importer) may establish a freight forwarding facility through which the distributing registrant may transfer controlled substances in the course of delivery to customers. If the distributing registrant maintains multiple registrations as a distributor, manufacturer, and/or importer, all of those registered locations may transfer controlled substances through the facility. The distributing registrant and the freight forwarding facility must be part of the same corporate entity; a distributing registrant from a different corporate entity may not transfer controlled substances through the facility.

The registration requirement for a freight forwarding facility will be waived provided that the distributing registrant submits proper notice to DEA of their intent to operate the facility.

Controlled substances that are being transferred through a freight forwarding facility may be stored in the facility for less than 24 hours. During storage, containers with controlled substances must be kept under continuous observation by designated individuals or maintained in a secured area that meets the present requirements for storage of Schedule III through V controlled substances. 'Locking down' a facility that also has a monitored alarm system or is subject to continuous monitoring by security personnel is consistent with the security requirements under 21 CFR 1301.72(b)(3) and 1301.77(a)(2).

If controlled substances are stored in the facility for 24 hours or more, then the facility does not meet the definition of freight forwarding facility and does not qualify for waiver of the registration requirement.

Records are required to be maintained by the distributing registrant at the freight forwarding facility regarding the transfer of controlled substances through the facility. The records must reflect the date; time of transfer; number of cartons, crates, drums, or other packages in which controlled substances are shipped; and authorized signatures for each transfer. The records may be maintained centrally, provided that the registrant operating the facility has been approved to maintain central records. In addition, each shipment should contain the usual documentation of controlled substances in the shipment, *i.e.,* invoices, packing slips, etc.

Customer returns may be transferred through a freight forwarding facility, provided that the returns are pre-authorized, the official transfer from the customer to the distributor takes place upon pick-up at the customer's registered location, and the returns are treated in the same manner as distributions to customers through the facility.

These final regulations represent the best possible provisions that could be established while remaining consistent with the requirements of the CSA. Certain other provisions were considered in the establishment of these regulations, such as inter-company freight forwarding; however, the difficulties associated with the assignment of responsibility under the law and regulations that such activities would present, prevents their adoption.

OMB Information Collection Requirements

This final rule contains a new information collection requirement, Notice of Intent to Operate a Freight Forwarding Facility, that has been reviewed and approved by OMB and assigned the OMB approval number 1117–0035.

Plain English

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this regulation, call or write Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7297.

Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control has reviewed this rule in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and certifies that it will not have a significant economic impact on a substantial number of small entities. This final rule provides an alternative system that may allow certain person(s) authorized to distribute controlled substances a more efficient means of delivering controlled substances. In fact, the regulated industry has represented that this procedure will benefit the industry by allowing it to lower costs associated with shipping controlled substances.

Executive Order 12866

This final rule has been drafted and reviewed in accordance with Executive Order 12866, § 1(b), Principles of Regulation. The Deputy Assistant Administrator, Office of Diversion Control, has determined that this rule is not a significant regulatory action under Executive Order 12866, § 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget. This regulation provides an exemption for freight forwarding facilities operated by a person from certain requirements of the CSA, thus allowing them a more efficient and cost effective means of doing business.

Executive Order 13132

This action has been analyzed in accordance with the principles and criteria in Executive Order 13132 and it has been determined that the final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Unfunded Mandates Reform Act

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

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.

It should be noted that due to earlier amendments to the regulations, certain section designations in the NPRM have changed. The appropriate adjustments have been made in the final rule to reflect the new section designations.

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 1307

Drug traffic control.

For reasons set out above, DEA is amending 21 CFR Parts 1300, 1301, 1304 and 1307 to read as follows:

PART 1300—[AMENDED]

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 adding a new paragraph (b) (42) to read as follows:

§ 1300.01 Definitions.

* * * * *

(b) * * *

(42) The term *freight forwarding facility* means a separate facility operated by a distributing registrant through which sealed, packaged controlled substances in unmarked shipping containers (i.e., the containers do not indicate that the contents include controlled substances) are, in the course of delivery to, or return from, customers, transferred in less than 24 hours. A distributing registrant who operates a freight forwarding facility may use the facility to transfer controlled substances from any location the distributing registrant operates that is registered with the Administration to manufacture, distribute, or import controlled substances, or, with respect to returns, registered to dispense controlled substances, provided that the notice required by § 1301.12(b)(4) of Part 1301 of this chapter has been submitted and approved. For purposes of this definition, a distributing registrant is a person who is registered with the Administration as a manufacturer, distributor, and/or importer.

PART 1301—[AMENDED]

1. The authority citation for Part 1301 continues to read as follows:

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

2. Section 1301.12 is amended by adding a new paragraph (b)(4) to read as follows:

§ 1301.12 Separate registrations for separate locations.

* * * * *

(b) * * *

(4) A freight forwarding facility, as defined in § 1300.01 of this part, provided that the distributing registrant operating the facility has submitted written notice of intent to operate the facility by registered mail, return receipt requested (or other suitable means of documented delivery) and such notice has been approved. The notice shall be submitted to the Special Agent in Charge of the Administration's offices in both the area in which the facility is located and each area in which the distributing registrant maintains a registered location that will transfer controlled substances through the facility. The notice shall detail the registered locations that will utilize the facility, the location of the facility, the hours of operation, the individual(s) responsible for the controlled substances, the security and recordkeeping procedures that will be employed, and whether controlled substances returns will be processed through the facility. The notice must also detail what state licensing requirements apply to the facility and the registrant's actions to comply with any such requirements. The Special Agent in Charge of the DEA Office in the area where the freight forwarding facility will be operated will provide written notice of approval or disapproval to the person with thirty days after confirmed receipt of the notice. Registrants that are currently operating freight forwarding facilities under a memorandum of understanding with the Administration must provide notice as required by this section no later than September 18, 2000 and receive written approval from the Special Agent in Charge of the DEA Office in the area in which the freight forwarding facility is operated in order to continue operation of the facility.

3. Part 1301 is amended by adding a new § 1301.77 to read as follows:

§ 1301.77 Security controls for freight forwarding facilities.

(a) All Schedule II–V controlled substances that will be temporarily stored at the freight forwarding facility must be either:

(1) stored in a segregated area under constant observation by designated responsible individual(s); or

(2) stored in a secured area that meets the requirements of Section 1301.72(b) of this Part. For purposes of this requirement, a facility that may be locked down (*i.e.,* secured against physical entry in a manner consistent

with requirements of Section 1301.72(b)(3)(ii) of this part) and has a monitored alarm system or is subject to continuous monitoring by security personnel will be deemed to meet the requirements of Section 1301.72(b)(3) of this Part.

(b) Access to controlled substances must be kept to an absolute minimum number of specifically authorized individuals. Non-authorized individuals may not be present in or pass through controlled substances storage areas without adequate observation provided by an individual authorized in writing by the registrant.

(c) Controlled substance being transferred through a freight forwarding facility must packed in sealed, unmarked shipping containers.

PART 1304—[AMENDED]

1. 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.

2. Section 1304.03 is proposed to be amended by adding a new paragraph (g) to read as follows:

§ 1304.03 Persons required to keep records and file reports.

* * * * *

(g) A distributing registrant who utilizes a freight forwarding facility shall maintain records to reflect transfer of controlled substances through the facility. These records must contain the date, time of transfer, number of cartons, crates, drums or other packages in which commercial containers of controlled substances are shipped and authorized signatures for each transfer. A distributing registrant may, as part of the initial request to operate a freight forwarding facility, request permission to store records at a central location. Approval of the request to maintain central records would be implicit in the approval of the request to operate the facility. Otherwise, a request to maintain records at a central location must be submitted in accordance with § 1304.04 of this part. These records must be maintained for a period of two years.

PART 1307—[AMENDED]

1. The authority citation for Part 1307 continues to read as follows:

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

2. Section 1307.12 is revised to read as follows:

§ 1307.12 Distribution to supplier.

(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 obtained it or to the manufacturer of the substance, 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.

(b) Distributions referred to in paragraph (a) may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

Dated: July 13, 2000.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 00–18147 Filed 7–18–00; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 31

[TD 8891]

RIN 1545–AW59

Increase In Cash-Out Limit Under Sections 411(a)(7), 411(a)(11), and 417(e)(1) for Qualified Retirement Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the increase from $3,500 to $5,000 of the limit on distributions from qualified retirement plans that can be made without participant or spousal consent. This increase is contained in the Taxpayer Relief Act of 1997. In addition, these regulations eliminate the ''lookback rule'' pursuant to which certain qualified plan benefits are deemed to exceed this limit on involuntary distributions. The final regulations affect sponsors and administrators of qualified retirement plans, and participants in those plans.

DATES: *Effective Date:* These regulations are effective October 17, 2000.

Applicability Date: These regulations generally apply to distributions made on or after October 17, 2000.

FOR FURTHER INFORMATION CONTACT: Robert Walsh, (202) 622–6090 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 21, 1998, a notice of proposed rulemaking (REG–113694–98) was published in the **Federal Register** (63 FR 70356) regarding the ''cash-out limit'' under sections 411(a)(7), 411(a)(11), and 417(e)(1) of the Internal Revenue Code. That same day, temporary and final regulations (TD 8794) were published in the **Federal Register** (63 FR 70335) which amended the Income Tax Regulations and the Employment Tax Regulations (26 CFR parts 1 and 31) relating to the increase in the cash-out limit enacted by section 1071 of the Taxpayer Relief Act of 1997, Public Law 105–34, 111 Stat. 788 (1997) (TRA '97). The text of the temporary regulations served as a portion of the text of the proposed regulations. Very few comments were submitted on the proposed regulations; no hearing was requested or held. After consideration of the comments, these final regulations adopt the provisions of the proposed regulations.

Explanation of Provisions

The temporary regulations made several changes to the cash-out rules under sections 411(a)(7), 411(a)(11), and 417(e)(1). In accordance with section 1071 of TRA '97, the temporary regulations increased the cash-out limit from $3,500 to $5,000. Thus, a qualified plan can generally distribute vested accrued benefits valued at $5,000 or less without participant or spousal consent. The temporary regulations also provided that, for purposes of section 411(a)(7)(B)(i), an involuntary distribution of an employee's vested accrued benefit valued at $5,000 or less could be treated as made due to termination of the employee's participation if the distribution could have been made at termination of