and reinstallation of existing upper skin access panels and fairing midsections on the trailing edge of the main flap) in accordance with Part 3 of the Work Instructions of Boeing Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001; or Boeing Alert Service Bulletin 767–57A0079, dated June 20, 2002; as applicable. Accomplishment of the terminating action terminates the repetitive inspection requirements of paragraph (b) of this AD.

Credit for Prior Accomplishment Per Earlier Service Information

(g) Accomplishment before the effective date of this AD of an inspection, associated follow-on and corrective actions, and terminating action in accordance with Boeing Alert Service Bulletin 767–57A0076, dated October 26, 2000, is acceptable for compliance with the corresponding requirements of this AD for applicable airplanes.

Part Installation

(h) As of the effective date of this AD, no person may install on any airplane a hinge fitting assembly that has any part number listed in Table 1 of this AD, unless the applicable requirements of this AD have been accomplished for that fitting. Table 1 follows:

TABLE 1.—HINGE FITTING ASSEMBLY PART NUMBERS

113T2271–13	113T2271–14
113T2271–23	113T2271–24
113T2271–29	113T2271–30
113T2271–33	113T2271–34
113T2271–401	113T2271–402

Alternative Methods of Compliance

(i) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(j) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(k) Unless otherwise specified in this AD, the actions shall be done in accordance with Boeing Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001; and Boeing Alert Service Bulletin 767–57A0079, dated June 20, 2002; as applicable. 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 Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(l) This amendment becomes effective on July 29, 2003.

Issued in Renton, Washington, on June 16, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15594 Filed 6–23–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305 and 1306

[Docket No. DEA–208F]

RIN 1117–AA58

Allowing Central Fill Pharmacies and Retail Pharmacies To Fill Prescriptions for Controlled Substances on Behalf of Retail Pharmacies

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is finalizing a Notice of Proposed Rulemaking (NPRM) defining central fill pharmacy activities and permitting central fill pharmacies to prepare controlled substances prescriptions on behalf of retail pharmacies with which the central fill pharmacies have a contractual agreement to provide such services or with which the pharmacies share a common owner. When one retail pharmacy receives a prescription and a second pharmacy prepares and subsequently delivers the controlled substance medication to the first retail pharmacy for dispensing to the patient, the second pharmacy is engaging in a ''central fill activity''. Records must be maintained by both the central fill pharmacy and the retail pharmacy that completely and accurately reflect the disposition of all controlled substance prescriptions dispensed. With respect to security, central fill pharmacies would be required to comply with the same security requirements applicable to retail pharmacies including the general requirement to maintain effective controls and procedures to guard against theft and diversion of controlled substances. DEA is creating an allowance for retail pharmacies that also perform central fill activities to do so without separate DEA registration, separate inventories, or separate records. This rulemaking is sought by the regulated industry and will allow for more efficient delivery of controlled substance prescriptions to patients.

EFFECTIVE DATE: July 24, 2003.

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:

Background

On September 6, 2001, DEA published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (66 FR 46567) proposing to allow central fill pharmacies to fill prescriptions for controlled substances on behalf of retail pharmacies. The NPRM was published in response to significant changes taking place in the pharmacy industry. Increased demands are being placed on traditional pharmacy systems by the rapid growth in the number of prescriptions written and dispensed.

At present, there is no provision in DEA's regulations for central fill pharmacy operations. Retail pharmacies, including those which utilize the mail service and the Internet, are registered by DEA to dispense prescriptions for controlled substances directly to the patient. ''Dispensing'' is defined in the Controlled Substances Act as delivering a controlled substance ''to an ultimate user'' (21 U.S.C. 802(10)). DEA regulations do not currently provide for central fill pharmacy operations which fill prescriptions for delivery to a traditional retail pharmacy. Current DEA regulations do not permit a prescription for controlled substances to be brought to one pharmacy, filled at a second pharmacy, and then returned to the first pharmacy for dispensing to the patient. Allowing central fill pharmacies to fill prescriptions on behalf of retail pharmacies for subsequent dispensing to the ultimate user is a legitimate extension of current practice.

Therefore, the regulations are being amended to allow for central fill pharmacies to fill prescriptions on behalf of retail pharmacies and to allow retail pharmacies to perform central fill activities without separate DEA registration and separate inventories.

Benefits of This Rulemaking

Regulations finalized in this rulemaking have been developed in conjunction with the regulated industry. Industry indicates that central fill pharmacy activities focus on removing the most time intensive, and, therefore, most costly administrative tasks, from a retail setting and centralizing them in an automated non-retail setting. Currently, many states permit central fill activities for noncontrolled substances, so long as they are otherwise permitted. This final rule is not requiring states to promulgate new regulations to permit central fill activities for controlled substances. The regulated industry has noted that it has realized cost savings from these activities, as the filling of prescriptions is a very labor intensive activity. Further, industry believes that permitting central fill pharmacy activities provides the following benefits:

- Reduces the potential for dispensing errors, resulting in improved patient safety and effective drug utilization.
- Improves pharmacist accessibility, pharmacists will have more time to spend on patient care.
- Patients encounter less ''wait'' time at pharmacy.

Requirements Proposed in the NPRM

The NPRM proposed to allow central fill pharmacies to become registered as pharmacies under 21 CFR 1301.13(e)(1)(iii) so long as and to the extent that their activities are authorized by the state in which they are located. Central fill pharmacies would prepare prescriptions for controlled substances in Schedules II–V for dispensing to a patient by a registered retail pharmacy pursuant to a prescription issued by an authorized practitioner and communicated to the central fill pharmacy by the retail pharmacy. Central fill pharmacies would be permitted to prepare both initial and refill prescriptions, subject to all applicable state and federal regulations. The central fill pharmacy would be allowed to fill prescriptions on behalf of retail pharmacies with which it has a contractual agreement to provide such services or with which it shares a common owner. The NPRM proposed requiring central fill pharmacies to keep current copies of the DEA Certificates of Registration for each retail pharmacy for which it is authorized to fill prescriptions. Similarly, it was proposed that retail pharmacies would be required to keep a list of those central fill pharmacies, along with current copies of their DEA Certificates of Registration, permitted to prepare prescriptions on their behalf.

The NPRM did not allow for a retail pharmacy and a central fill pharmacy to be operated under the same DEA registration, therefore requiring separate inventories and separate records.

The NPRM proposed to permit retail pharmacies to transmit a written prescription via facsimile or communicate prescription information electronically to a central fill pharmacy. The prescription information would be required to be maintained by the retail pharmacy and the central fill pharmacy in a readily retrievable manner and comply with all applicable federal and state recordkeeping requirements.

The NPRM also recognized that pharmacists at central fill pharmacies would be preparing prescriptions for controlled substances and, therefore, must bear a corresponding responsibility, along with the pharmacist at the retail pharmacy, for the proper dispensing of the prescription.

Comments Received in Response to the NPRM

Six comments were received in response to the NPRM: four from trade associations representing the affected industries, one from a DEA registrant and one from a pharmacy software provider. While the comments expressed general support for the changes, concerns were raised regarding specific facets of the proposed rule. Where possible, DEA has adopted changes suggested by the commenters to make the rule more flexible and less burdensome for DEA registrants.

1. Retail Pharmacies Performing Central Fill Functions Without Separate Registration

Three commenters discussed DEA's provisions in the proposed rule that would require separate registration for each facility that performs central fill activities. Commenters stated that registered retail pharmacies should be allowed to perform central fill activities without separate registration. Commenters indicated that retail pharmacies currently perform all activities associated with dispensing controlled substances directly to the patient. Commenters argued that it is not necessary for a retail pharmacy to maintain a separate registration, separate inventory and separate recordkeeping when the same retail pharmacy engages in central fill activities on behalf of another retail pharmacy. By allowing retail pharmacies to perform central fill activities without separate registration, commenters argued, a single stock/inventory of controlled substances can be maintained.

DEA agrees that retail pharmacies may also act in the capacity of a central fill pharmacy as long as complete and accurate records are maintained to indicate which registrant prepared the prescription and which registrant dispensed the prescription. The records must include the name, address, and DEA number of the pharmacies involved. Shipping and receiving records regarding the ''centrally filled'' prescription must be maintained by each pharmacy involved in the transaction.

The original prescription record must be maintained at the pharmacy which dispenses the medication to the patient (end user). If records are maintained electronically, they must be readily retrievable and identifiable as to which records pertain to the retail pharmacy activities and which pertain to the central fill pharmacy activities.

When one retail pharmacy receives a prescription and a second pharmacy prepares and subsequently delivers the controlled substance medication to the first retail pharmacy for dispensing to the patient, the second pharmacy is engaging in a ''central fill activity''. Pharmacies engaging in central fill activities must have a contractual agreement with the retail pharmacy to provide such services, or share a common owner.

2. Transferring Prescriptions for Controlled Substances

One commenter suggested that not allowing a central fill pharmacy to deliver prescription medication directly to the patient would require that the prescription record be transferred. The commenter further stated that this potentially would disrupt patients' continuity of care and could prohibit patients from obtaining proper pharmaceutical care from the pharmacist of their choice. DEA acknowledges that if one retail pharmacy receives and dispenses an initial prescription and a second retail pharmacy prepares and subsequently dispenses/delivers any remaining refills of the controlled substance medication to the patient, this is a ''transfer'' of the prescription. The second retail pharmacy's records must indicate that the prescription record was obtained by transfer. It is not the intent of this rulemaking to change current regulations regarding the ''transfer'' of controlled substance prescriptions records. However, controlled substance prescriptions that are prepared by a

central fill pharmacy are not considered ''transferred'' prescriptions.

3. Requirement To Maintain Copies of Each Pharmacy's DEA Registration Certificate

Three commenters stated that pharmacies participating in central fill activities should not be required to maintain copies of each pharmacy's DEA registration certificate. Commenters indicated that such a requirement would be burdensome, requiring them to maintain large quantities of paper. Commenters suggested that DEA permit registrants to verify the registration of the affiliated retail pharmacies, noting that such a requirement would be similar to what is required of suppliers when registrants are purchasing controlled substances.

Upon further review, DEA agrees that requiring retail pharmacies and central fill pharmacies to maintain copies of the DEA registration certificates for their partner pharmacies is unnecessary. However, DEA is requiring that the participating registrants verify that they are doing business with DEA registrants prior to sending and receiving controlled substances prescriptions. Therefore, DEA is amending this final rule to require that central fill pharmacies verify the registration of each affiliated retail pharmacy. Further, retail pharmacies contracting with other pharmacies performing central fill activities must verify the registration of each affiliated registrant. Such a requirement is less burdensome than the one initially proposed by DEA, but will still permit DEA, and registered pharmacies, to ensure that the persons they are conducting business with are, indeed, DEA registrants permitted to handle controlled substances.

4. Miscellaneous Comments

One commenter requested that DEA allow controlled substance prescriptions that are prepared and packaged at a central fill pharmacy to be delivered through DEA registered distribution facilities. The filled prescriptions, placed in a sealed container, would be delivered from the central fill pharmacy to a DEA registered distribution facility. At the distribution facility the sealed containers would be sorted for subsequent delivery to the retail pharmacy. The commenter further stated that registered distribution facilities have much better security than common or contract carrier locations and the employees at the registered distribution facilities have experience in handling controlled substances. There are no provisions in the current regulations to allow for patient specific controlled substances prescriptions to be delivered from one registered pharmacy location, through a registered distribution facility, to another registered pharmacy location for dispensing to the patient. Therefore, no change is being made from the language of the proposed rule.

One commenter suggested that DEA allow for hospitals to engage in central fill activities. While DEA does not disagree that hospitals may benefit from ''central fill activities,'' the pharmacy activities of a hospital are significantly different than those of a retail pharmacy. Hospitals generally maintain stocks of non-patient specific controlled substances in a variety of locations throughout the hospital. The controlled substances are often dispensed and administered on an urgent and frequently changing basis. Controlled substances that are prepared by a central fill pharmacy, as defined in this rulemaking, are issued pursuant to a patient specific prescription and generally requested and subsequently delivered within 24 hours. When non-patient specific controlled substances are transferred from one DEA registrant to another DEA registrant, this constitutes distribution and not dispensing. With this rulemaking, DEA is allowing only retail pharmacies to utilize the services of a central fill pharmacy.

One commenter suggested that DEA's proposed requirement that both the retail pharmacist and central fill pharmacist have a corresponding liability regarding the manner of issuance of a prescription is considered a dual verification and, therefore, unnecessary. DEA is not suggesting that each centrally filled controlled substance prescription be independently verified by a retail pharmacist and a central fill pharmacist. Rather, the intent is to confirm that if either the retail pharmacist or the central fill pharmacist believes that the prescription is not issued in a manner that is in compliance with federal regulations, then the prescription should not be dispensed.

One commenter suggested that DEA indicate what course of action should be taken if a patient does not pick up a controlled substance prescription that has been ''centrally filled.'' The retail pharmacy's records should indicate that the prescription was ''filled'' at the central fill pharmacy and subsequently delivered to the retail pharmacy. Therefore, the retail pharmacy in possession of the controlled substance prescription is responsible for the proper disposition of the controlled substance if the patient fails to pick up the prescription, as would be the case with any prescription dispensed by the pharmacy.

One commenter suggested that DEA clarify section 1306.05(a), which was not proposed to be changed in the NPRM and states that written prescriptions must be written with ink or indelible pencil or by typewriter and shall be manually signed by the practitioner. While this amendment is not within the scope of this regulation, DEA wishes to clarify and reiterate that a prescription that is generated by a computer software application and subsequently printed is acceptable so long as it is manually signed by the practitioner and contains all required elements of a prescription.

One commenter suggested that DEA require pharmacies engaged in central fill activities to establish a mechanism to ensure that printed literature developed by the pharmaceutical manufacturer accompanies every prescription. While DEA does not have any objection to central fill pharmacies or retail pharmacies providing printed drug information to patients, requiring pharmacies to provide such information is not within the purview of the DEA's regulatory authority regarding controlled substance prescriptions.

Further Clarifications

In this final rule DEA has changed the titles of Sections 1306.15 and 1306.27 due to the perceived confusion with using the word ''transfer'' to describe the action of a retail pharmacy providing prescription information to a central fill pharmacy.

Conclusion

This final rule permits central fill pharmacies to become registered as pharmacies under 21 CFR 1301.13(e)(1)(iii) so long as and to the extent that their activities are authorized by the state in which they are located. At present, the business activities under 21 CFR 1301.13(e)(1)(iii) include practitioners, hospitals/clinics, retail pharmacies, and teaching institutions. DEA is creating a new business activity to be known as ''central fill pharmacy.'' This allows the central fill pharmacy to prepare prescriptions for controlled substances in Schedules II–V for dispensing to a patient by a registered traditional retail pharmacy pursuant to a prescription issued by an authorized practitioner and communicated to the central fill pharmacy by the retail pharmacy.

DEA has determined that central fill pharmacy activities are better characterized as ''dispensing'' activities as opposed to ''distributing'' activities.

Therefore, central fill pharmacies will not be limited by the restrictions on ''distributions'' from one practitioner to another set forth in 21 CFR 1307.11, in particular the 5% limitation which limits the amount of controlled substances that can be distributed by one practitioner to another. Similarly, no official order forms (DEA Form 222) will be required for transfer of Schedule II controlled substances from a central fill pharmacy to a retail pharmacy since DEA has deemed this activity to be a form of dispensing, not a distribution. Title 21, CFR 1305.03 is amended to clarify that the order form requirement does not apply to such transfers.

Central fill pharmacies are permitted to prepare both initial and refill prescriptions, subject to all applicable state and federal regulations. Only a licensed pharmacist may fill such prescriptions (21 CFR 1306.06). By definition, the filled prescriptions must be transported to the retail pharmacy from which the prescription information was received for delivery to the patient. Both the pharmacist employed by the central fill pharmacy and the pharmacist who dispenses the prescription to the patient have a corresponding responsibility to ensure that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and otherwise in the manner specified by DEA regulations (21 CFR 1306.04(a), 1306.05(a)).

DEA is creating an allowance for a central fill pharmacy to prepare prescriptions on behalf of retail pharmacies with which it has a contractual agreement to provide such services or with which it shares a common owner. The central fill pharmacy is required to keep a list of retail pharmacies for which it has agreed to provide such services. The central fill pharmacy is also required to verify the DEA registration of any retail pharmacy they are doing business with prior to sending or receiving controlled substance prescriptions. Similarly, retail pharmacies are required to keep a list of those central fill pharmacies permitted to prepare prescriptions on their behalf and verify that they are DEA registrants. This information must be made available for inspection upon request by DEA.

A central fill pharmacy will not be permitted to prepare prescriptions provided directly by a patient or individual practitioner or to mail or otherwise deliver a filled prescription directly to a patient or individual practitioner.

DEA regulations do not prohibit central fill pharmacies in one state which have a contractual relationship or common ownership with a retail pharmacy located in another state from filling prescriptions transmitted by the retail pharmacy to the central fill pharmacy. However, each state involved in the transaction must permit this cross-state activity.

If authorized by the state in which they are located, a retail pharmacy may engage in central fill pharmacy activities as a coincidental activity associated with their retail pharmacy DEA registration. Therefore, a retail pharmacy may operate as both a retail pharmacy and a central fill pharmacy at the same location without maintaining separate registration, inventories, or records.

Retail pharmacies are permitted to transmit prescription information to a central fill pharmacy in two ways. First, a facsimile of a prescription for a controlled substance in Schedule II, III, IV or V may be provided by the retail pharmacy to the central fill pharmacy. The retail pharmacy must maintain the original hard copy of the prescription and the central fill pharmacy must maintain the facsimile of the prescription. Alternatively, DEA is allowing for the prescription information to be communicated electronically by the retail pharmacy to the central fill pharmacy. Since there appears to be little risk that an outside party will divert such prescription information, DEA is not requiring specific security standards with respect to electronic transmission in this particular situation. When setting up the transmission system, the participating pharmacies must be mindful of all federal and state requirements regarding patient confidentiality, network security, and use of shared databases. Both pharmacies must maintain the prescription information in a readily retrievable manner and comply with all applicable federal and state recordkeeping requirements.

With respect to security, central fill pharmacies are required to comply with the same security requirements applicable to other pharmacies (21 CFR 1301.71, 1301.75, 1301.76). While not specifically required by DEA regulations, central fill pharmacies may choose to implement additional security measures based on the volume of controlled substances handled, number of employees in the facility, or other unique factors. Such additional security measures may be needed in order to comply with the general requirement to maintain effective controls and procedures to guard against theft and diversion of controlled substances (21 CFR 1301.71). As indicated above, since pharmacists at central fill pharmacies are preparing prescriptions for controlled substances, they shall bear a corresponding responsibility, along with the pharmacist at the retail pharmacy, for the proper dispensing of the prescription (21 CFR 1306.04(a)). Additionally, central fill pharmacies must be vigilant in their choice of carriers to transport filled prescriptions to retail pharmacies and be aware of their responsibilities for reporting in-transit losses (21 CFR 1301.74(e)).

Application for Registration for Central Fill Pharmacies

As have been previously noted in this rulemaking, persons wishing to conduct central fill pharmacy activities must register with DEA to do so. To apply for registration, persons must complete a DEA Form 224, Application for Registration. As DEA has not yet issued updated forms specifically referencing the central file pharmacy business activity, persons wishing to register as central fill pharmacies must choose the retail pharmacy business activity on the form and then must attach a written statement signed by the person signing the registration application acknowledging that the pharmacy wishes to register as a central fill pharmacy.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. In fact, it is anticipated that this rule, by affording additional flexibility to pharmacies in the dispensing of prescriptions, will help lower total health care costs.

As has been discussed elsewhere in this rulemaking, permitting controlled substance prescriptions to be processed through the use of central fill pharmacies will provide benefits to the regulated industry. The filling of prescriptions is a labor intensive process. There are significant cost reductions associated with the cost of filling a prescription through the use of central fill pharmacies. The regulated industry has indicated that labor costs are significantly reduced. For example, industry has indicated that, depending on the number of prescriptions

dispensed per day, the cost savings can be between $1.00 and $5.00 per prescription dispensed.

Executive Order 12866

The Deputy Assistant Administrator, Office of Diversion Control, further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant regulatory action. Therefore, this action has not been reviewed by the Office of Management and Budget. As previously noted, this rule will provide a number of benefits to the regulated industry as efficiencies are gained in the processing of controlled substance prescriptions.

Executive Order 12988

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 1306

Drug traffic control, prescription drugs.

■ For the reasons set out above, title 21, Code of Federal Regulations, parts 1300, 1301, 1304, 1305, and 1306 are amended 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)(43) to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

(43) The term *central fill pharmacy* means a pharmacy which is permitted by the state in which it is located to prepare controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed ''authorized'' to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

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.

■ 2. Section 1301.13 is amended by revising 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.

* * * * *

(e) * * *

(1) * * *

(iii) Dispensing or Instructing (Includes Practitioner, Hospital/Clinic, Retail Pharmacy, Central Fill Pharmacy, Teaching Institution).	Schedules II–V	New—224 ..... Renewal—224a	210 210	3	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II–V in a proportion not exceeding 20% of the complete solution, compound or mixture. A retail pharmacy may perform central fill pharmacy activities.

* * * * *

■ 3. Section 1301.76 is amended by adding new paragraph (d) to read as follows:

§ 1301.76 Other security measures for practitioners.

* * * * *

(d) Central fill pharmacies must comply with § 1301.74(e) when selecting private, common or contract carriers to transport filled prescriptions to a retail pharmacy for delivery to the ultimate user. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106. Retail pharmacies must comply with § 1301.74(e) when selecting private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy. When retail pharmacies contract with private,

common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106.

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 1304.05 is added to read as follows:

§ 1304.05 Records of authorized central fill pharmacies and retail pharmacies.

(a) Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central fill pharmacies, including name, address and DEA number, that are authorized to fill prescriptions on its behalf. The retail pharmacy must also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf. These records must be made available upon request for inspection by DEA.

(b) Every central fill pharmacy must keep a record of all retail pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy must also verify the registration for all retail pharmacies for which it is authorized to fill prescriptions. These records must be made available upon request for inspection by DEA.

PART 1305—[AMENDED]

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

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

■ 2. Section 1305.03 is revised to read as follows:

§ 1305.03 Distributions requiring order forms.

An order form (DEA Form 222) is required for each distribution of a Schedule I or II controlled substance except to persons exempted from registration under part 1301 of this chapter; which are exported from the United States in conformity with the Act; for delivery to a registered analytical laboratory, or its agent approved by DEA; or for delivery from a central fill pharmacy, as defined in § 1300.01(b)(43), to a retail pharmacy.

PART 1306—[AMENDED]

■ 1. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

■ 2. Section 1306.05 is amended by revising paragraph (a) to read as follows:

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (*e.g.*, J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by these regulations.

* * * * *

■ 3. Section 1306.06 is revised to read as follows:

§ 1306.06 Persons entitled to fill prescriptions.

A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.

■ 4. Section 1306.11 is amended by adding a new paragraph (d)(5)to read as follows:

§ 1306.11 Requirement of prescription.

* * * * *

(d) * * *

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

* * * * *

■ 5. Section 1306.14 is amended by redesignating existing paragraphs (b) and (c) as paragraphs (c) and (d), and by adding a new paragraph (b) to read as follows:

§ 1306.14 Labeling of substances and filling of prescriptions.

* * * * *

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (*i.e.* the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

* * * * *

■ 6. Section 1306.15 is added to read as follows:

§ 1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(1) Write the word ''CENTRAL FILL'' on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(2) Ensure that all information required to be on a prescription pursuant to Section 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(3) Maintain the original prescription for a period of two years from the date the prescription was filled;

(4) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration

number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist filling the prescription, and the date of filling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (*i.e.* private, common or contract carrier).

■ 7. Section 1306.24 is amended by redesignating the existing paragraphs (b) and (c) as paragraphs (c) and (d), and by adding a new paragraph (b) to read as follows:

§ 1306.24 Labeling of substances and filling of prescriptions.

* * * * *

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (*i.e.* the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

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■ 8. Section 1306.26 is amended by adding a new paragraph (g) to read as follows:

§ 1306.26 Dispensing without prescription.

* * * * *

(g) Central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this section.

■ 9. Section 1306.27 is added to read as follows:

§ 1306.27 Provision of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule III, IV or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(1) Write the word ''CENTRAL FILL'' on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(2) Ensure that all information required to be on a prescription pursuant to § 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(3) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

(4) Maintain the original prescription for a period of two years from the date the prescription was last refilled;

(5) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (*i.e.* private, common or contract carrier).

Dated: June 17, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309 and 1310

[Docket No. DEA–198F2]

RIN 1117–AA57

Control of Red Phosphorus, White Phosphorus and Hypophosphorous Acid (and Its Salts) as List I Chemicals; Exclusions and Waivers

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: On October 17, 2001, DEA published a Final Rulemaking (66 FR 52670) in which DEA added red phosphorus, white phosphorus (also known as yellow phosphorus) and hypophosphorous acid (and its salts) as List I chemicals. This action was taken because of the use and importance of these chemicals in the illicit manufacture of methamphetamine (a Schedule II controlled substance).

As List I chemicals, handlers of these materials became subject to Controlled Substances Act (CSA) chemical regulatory controls including registration, recordkeeping, reporting, and import/export requirements. DEA had determined that these controls are necessary to prevent the diversion of these chemicals to clandestine drug laboratories.

In order to provide flexibility for legitimate businesses, the October 17, 2001 rule established, on an interim basis, specific exclusions and waivers for chemical handlers engaged in certain activities. DEA has completed its review of comments pertaining to these interim provisions. This rulemaking finalizes these exclusions and waivers related to the handling of the listed chemicals red phosphorus, white phosphorus, and hypophosphorous acid (and its salts).

EFFECTIVE DATE: This final rule is effective June 24, 2003.

FOR FURTHER INFORMATION CONTACT: Frank L. Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537 at (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

On September 25, 2000, DEA published a Notice of Proposed Rulemaking proposing that red phosphorus, white phosphorus, and hypophosphorous acid (and its salts) be made List I chemicals (65 FR 57577). On October 17, 2001, DEA published a Final Rulemaking (66 FR 52670) in which DEA added red phosphorus, white phosphorus (also known as yellow phosphorus) and hypophosphorous acid (and its salts) as List I chemicals. This action was taken because of the use and importance of these chemicals in the illicit manufacture of methamphetamine (a Schedule II controlled substance).

As List I chemicals, handlers of these materials became subject to CSA chemical regulatory controls including registration, recordkeeping, reporting, and import/export requirements. DEA had determined that these controls are necessary to prevent the diversion of these chemicals to clandestine drug laboratories.