

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 fill 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