

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.