

### 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