Central-Fill Pharmacies and Processes

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Over the past years, traditional pharmacy settings have seen an increased demand for services as a result of increased prescription volume. For this reason, many pharmacies and other health-care settings choose to utilize the services of central fill pharmacies. In response to inquiry regarding central-fill processes and central pharmacies in the state of North Dakota, the North Dakota Board of Pharmacy is issuing the following guidance document.

Currently there are no ND laws, rules, or regulations that specifically govern central-fill pharmacies or central-fill processes. However, these processes have been allowed within the state of ND. Pharmacies that fulfill central-fill pharmacy duties are held to the same legal requirements and professional standards as any other licensed pharmacy and are expected to be fully compliant with any rule pertaining to the practice of pharmacy. Thanks to a final rule issued by the DEA (effective June 24, 2003) regarding the filling of controlled substances by central-fill pharmacies on behalf of retail pharmacies, many of these questions have been addressed. This rule resulted in the amendment of various parts of the Title 21 Code of Federal Regulations (CFR) which in turn led to a better explanation of how central-fill pharmacies operate.

The DEA's definition of central-fill pharmacy (21 CFR 1300.01(b)(44)) explains that they are allowed to prepare both initial and refill prescriptions on behalf of a retail pharmacy (providing that the retail and central-fill pharmacies are under contractual agreement or share a common owner) as long as the filled and labeled prescription is subsequently delivered to the originating retail pharmacy. For example, a central-fill pharmacy cannot deliver a prescription to Pharmacy B, when it originated at Pharmacy A. In addition, as long as both state's laws permit, this central-fill/retail pharmacy operation is allowed to cross state lines.

Transmitting, Filling, and Dispensing Prescriptions

The terminology used by both this guidance and the DEA, is that the communication of prescription information between the retail pharmacy and the central fill pharmacy, is termed transmission of prescriptions and is NOT considered a prescription "transfer". Therefore, the retail pharmacy is the one directly responsible to the patient, as contrasted with a transferred prescription, where the new pharmacy is now responsible.

Retail pharmacies may transmit prescriptions in any way allowed (facsimile, electronic submission, etc.). In addition to non-controlled prescriptions, a central-fill pharmacy is also allowed to prepare Schedule II-V controlled substances as long as both pharmacies are registered with the DEA. With this goes the responsibility of verifying the other pharmacy's DEA registration number prior to filling prescriptions for them.

To ensure compliance with DEA requirements (21 CFR 1306.15 and 1306.27), when transmitting controlled prescriptions, the retail pharmacy transmitting the prescription must:

- Write “CENTRAL FILL” on the face of the original prescription and record the name, address, and the name of the retail pharmacy pharmacist transmitting the prescription, the date of transmittal and if for a controlled substance, the DEA registration number of the central fill pharmacy to which the prescription has been transmitted;
- Ensure that all information required to be on the prescription pursuant to NDAC 61-04-06-02 or 03 (Federal 1306.05), is transmitted to the central fill pharmacy(either on the face of the prescription or in the electronic transmission);
- Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining, if a non-controlled or schedule III-V prescription
- Maintain the original prescription for a period of five years from the date the prescription was last filled;
- 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.

The central-fill pharmacy receiving the prescription must:

- Keep a copy of the prescription(if sent via facsimile) or and electronic record of all the information transmitted by the retail pharmacy, including the name, address, and if controlled, the DEA number of the retail pharmacy transmitting the prescription;
- Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist responsible for filling the prescription, and dates of filling or refilling of the prescription.
- 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).

Both pharmacies are equally responsible for ensuring that the prescription is valid, being used for a legitimate medical purpose, and that the practitioner is acting in the usual course of professional practice (21 CFR 1306.04(a) and 1306.05(a)). This does not mean that both retail and central-fill pharmacies are required to verify the same prescription; instead, the purpose of the regulation is to allow either pharmacy to discontinue preparation of the prescription if they feel the prescription is not valid. Also, both pharmacies are required to maintain records of transmitted prescriptions for at least 5 years, according to NDAC 61-04-05.1. When prescriptions are transmitted, the retail pharmacy must keep the original hard copy and the central-fill location is required to keep the copy. Prescriptions shared by electronic transmission must bear the respective federal and state regulations, which can be seen in NDAC 61-02-06 and 61-04-05-03; there are no additional security requirements specifically pertaining to central-fill pharmacies. Both businesses must also maintain a list of pharmacies it contracts with (their names, addresses, and DEA registration numbers). For example, a central-fill pharmacy must keep a list of retail pharmacies it dispenses to and verify their DEA numbers; and vice versa, a retail pharmacy must keep a list of central-fill pharmacies it transmits prescriptions to, and verify their DEA numbers.

Labeling of prescriptions will occur within the central-fill pharmacy and contain all components required according to NDAC 61-04-06. More specific to this unique situation, it will contain the name and address of the retail pharmacy on the label, as well as a “unique identifier” for the central-fill

pharmacy (e.g. the central-fill pharmacy's DEA number). Although the retail pharmacy is ultimately responsible for consulting and dispensing the prescription, it is important that the patient is aware that their prescription was filled at a place other than the retail pharmacy.

Although, a Scheduled III-IV prescription may only be transferred once between pharmacies, according to NDAC 61-04-05.1-04; however, because the DEA ruled that the transmission is not a transfer, the prescription can be filled by a central-fill pharmacy as many times as there are refills on the prescription. In an emergency, a central-fill pharmacy is not allowed to prepare a Scheduled II controlled substance prescription upon an oral order from another retail pharmacy or an individual practitioner (21 CFR 1306.11(d)(5)). This is in contrast to the rest of 1306.11(d) where pharmacies may normally fill Scheduled II controlled substance prescriptions in the case of emergency upon an oral order from a practitioner.

To clarify the definition of central-fill pharmacies, the DEA ruled that central-fill pharmacies have responsibilities more similar to "dispensers". This distinction allows central-fill pharmacies to be excluded from limitations that affect distributors. Most importantly, they are not subject to the 5% limitation on the distribution of scheduled substances between practitioners (1307.11), they are exempted from filing a DEA Form 222 when delivering Scheduled II controlled substances to the retail pharmacy (1305.03(d)), and they do not need to file for a separate DEA Registration Number if they will be operating (and handling Scheduled controlled substances) at the same location as a retail pharmacy. This allows both businesses to use the same drug inventory and maintain collective records; however, complete and accurate records must be maintained to indicate which pharmacy business actually prepares the prescriptions and which pharmacy dispenses the prescriptions.

In conclusion, central-fill pharmacies are allowed to receive non-controlled and controlled substance prescriptions from retail pharmacies (in the manner described in the preceding paragraphs) as long as they subsequently dispense the prepared prescription to the same originating retail pharmacy. A purely central fill pharmacy is not allowed to take prescriptions directly from a patient or practitioner or dispense prescriptions directly to a patient or practitioner. Allowing the practice of taking prescriptions from and dispensing prescriptions to patients/practitioners would better classify a pharmacy under the description of "retail pharmacy", not "central-fill pharmacy", although the retail pharmacy can fulfill both roles.

Reporting loses of controlled substances in shipment

When the central fill pharmacy contracts 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 within one business day of discovery of such loss to the Board of Pharmacy and to the DEA by use of a DEA Form 106. When the retail pharmacy contracts with private, common or contract carriers to transport filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses within one business day of discovery of such loss to the Board of Pharmacy and to the DEA by use of a DEA Form 106.

For any further questions or comments, please contact:
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