



Missouri Department of Health and Senior Services

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Obtaining Controlled Substances for Infusion

Physicians Obtaining Compounded Medications from Compounding Pharmacies

The mission of the Missouri Bureau of Narcotics and Dangerous Drugs is to protect the public's health and safety by preventing the diversion and misuse of controlled substances, without prohibiting their appropriate and effective use. The bureau supports the legitimate and appropriate treatment of pain. The bureau recognizes that the administration of specially compounded controlled substance orders within physicians' offices provides for efficient and convenient treatment. The instructions provided below are for physicians in their offices and clinics and not for licensed facilities such as hospitals, surgery centers or long-term care facilities.

Physicians who store controlled substances in their offices for administration must obtain those controlled substances from another registrant via the required transfer forms and not by solely issuing prescriptions to be dispensed by retail pharmacies. In obtaining compounded controlled substance medications for office or clinic administration, physicians and pharmacies are to meet the following requirements:

OPTION ONE—The patient picks up their own prescription from the pharmacy:

1. The physician writes a controlled substance prescription for the compounded medication;
2. The compounding pharmacy may prepare the prescription and dispense it to the patient as a properly labeled patient-specific prescription. The pharmacy must be in compliance with Missouri Board of Pharmacy compounding regulations;
3. The compounding pharmacy is registered as a retail pharmacy so the medications must be dispensed to a patient and not sent to the physician;
4. The patient picks up their medication and takes it to their physician's office for administration;
5. The physician documents the prescription and administration in the patient's chart and then destroys any unwanted remainder;
6. This option does not require the pharmacy to be registered as a distributor and it does not require a transfer record of controlled substances between the pharmacy and the registered physician;
7. The prescription was issued to the patient, was picked up by the patient and the doctor did not store or stock the controlled substances in their office.

OPTION TWO—Pharmacies send the compounded medications to the physician's office:

1. The physician writes a controlled substance prescription for the compounded medication;
2. The compounding pharmacy may prepare the prescription as a properly labeled patient-specific prescription. The pharmacy must be in compliance with Missouri Board of Pharmacy compounding regulations;
3. The pharmacy will not dispense the prescription to the patient but may send it directly to the prescribing physician for office administration;
4. The compounding pharmacy must be registered with BNDD and DEA as a distributor since controlled substances will be sent to other registered practitioners and not just dispensed to patients as a retail pharmacy;
5. If the medications are sent through the U.S. Postal Service, or private delivery service or common carrier, the medications should be packaged in non-descript packaging so that the contents are not disclosed. The packages should be signed for;
6. Physicians should write the prescriptions with all of the required information for a controlled substances prescription and be sure to include all of the information needed for the pharmacy to compound the medications;
7. The compounding pharmacy/distributor will be transferring the compounded controlled substances so the pharmacy will document controlled substances transferred out and the physician must maintain controlled substance receipt records for controlled substances entering their possession;
8. Upon receipt of controlled substances a registrant must document the date, drug name, strength, dosage form and quantity received. The record must also document the names, addresses and DEA numbers of the supplier and the

receiver. A transfer form may be used that is available on the BNDD website at www.dhss.mo.gov/BNDD under the forms section. This form could be used for controlled substance compounds with drugs in Schedule III, IV, and V. Schedule II medications require a DEA Form 222 Official Order Form.

DEA Order Forms for Schedule II Medications:

1. The physician writes a Schedule II prescription with all of the information required;
2. The compounding pharmacy will be preparing the medication and transferring possession to the Physician;
3. The physician must submit a DEA Form 222 Official Order Form to the compounding pharmacy along with the prescription. DEA Order Forms may be obtained online at the DEA website www.deadiversion.usdoj.gov;

Prescriptions and Transfer Records for Controlled Substance Schedules III, IV, and V:

1. The physician writes a Schedule III—V prescription with all of the information required;
2. The compounding pharmacy will be preparing the medication and transferring possession to the Physician;
3. A transfer record must be maintained at the pharmacy and the physician's office. The record must document the drug name, strength, dosage form, and quantity. A transfer form is available at the BNDD website www.dhss.mo.gov/BNDD. The pharmacy must document the quantity transferred out and the date transferred out. The physician's records must document the quantity received and the date of receipt.

Record Keeping Requirements for Physicians:

1. All controlled substance prescriptions must be documented in the patient's chart;
2. All controlled substance administrations must be documented in the patient's chart;
3. DEA Order Forms must be filed separately from all other records and be maintained in chronological order.
4. Physicians must maintain records of all controlled substances received in the practice. DEA Order Forms will document the Schedule II medications. For medications in Schedules III, IV, and V, there must be a receipt record that documents the drug name, strength, dosage form, quantity received, the date received and the names, addresses and DEA numbers of both the supplier and the receiver. These receipt records should be filed separately from other records in the practice;
5. Administration Log: Physicians must maintain a log that is separate from patients' charts that documents the administration of controlled substances. The record must document the date, patient name, patient address, drug name, strength, form, quantity, and name or initials of person administering. There is an administration/dispensing form on the BNDD website at www.dhss.mo.gov/BNDD. This form may also be used to document the wastage of compounded medications;
6. If the practice is a multi-physician practice or clinic, each physician must maintain their own controlled substance records separately from the controlled substance records of the other practitioners. Each physician will have forms and documents with their own name and DEA number documented on them.

Record Keeping Requirements for Pharmacies:

1. The pharmacy must have separate registrations as a compounding pharmacy and a distributor;
2. The pharmacy will have two separate DEA numbers;
3. The prescriptions should be filed in the appropriate pharmacy file as normal;
4. The two types of DEA Order Forms should be separated; one file for the retail business and a separate file for the distribution registration.

Physicians' Destruction/Wastage of Compounded Medications:

1. The compounded medications prescribed to a patient may be destroyed on site;
2. This must be documented on the administration log so that quantities balance;
3. The destruction must document the date, drug name, strength, form, quantity wasted, reason for the waste and the destruction must be performed by two people and both people must sign the log;
4. All controlled substances must be wasted beyond reclamation.

Security Requirements for Physicians:

Physicians are required to provide effective controls and procedures to guard against theft and diversion of controlled substances. Physicians are responsible for the record keeping, security and accountability for all controlled substances in their possession and compliance with state and federal controlled substance laws.

- A. All controlled substances received should be checked in to verify what was received;
- B. Controlled substances must be secured in a locked safe or cabinet;

- C. For Scheduled II - All DEA Order Forms must be filed separately from other records and be filed in chronological order;
- D. For Schedule III—V medications received, there must be complete receipt records with the same information documented as described above;
- E. Every activity with controlled substances must be documented so that a continuous paper trail exists. There must be records for receipt, administration and wastage. Complete records must be maintained so that an audit can be performed to verify the accountability and proper balances for all controlled substances.;
- F. Physicians should have a policy for staff that includes the supervision and regular review of records and procedures to insure compliance.

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