Distribution of Controlled Substances and Dangerous Drugs to Registrants

Distributing Pharmacy

A pharmacy distributing controlled substances or dangerous drugs to another pharmacy (or doctor) must adhere to the following procedures.

Schedule II Controlled Substances

Either the Controlled Substance Ordering System (CSOS) or the DEA Order Form (DEA Form 222) must be used for distributing Schedule II controlled substances. The receiving registrant issues copy 1 (brown) and 2 (green) of the DEA order form to the distributing pharmacy. The distributing pharmacy must record the quantity of controlled substances distributed and the actual date of distribution on copy 1 (brown) and 2 (green). The distributing pharmacy must maintain copy 1 (brown) in their records and mail copy 2 (green) to the divisionaloffice of the Drug Enforcement Administration by the end of the month during which the distribution occurred. For mailing addresses, see *State and Federal Agencies* in this section.

Schedule III-V Controlled Substances

Records for distribution must be maintained for Schedule III, IV or V controlled substances. These records (*e.g.*, invoices) must indicate the following information:*

(1) the actual date of distribution;
(2) name, strength, and quantity of the controlled substance distributed;
(3) name, address and DEA registration number of the distributing pharmacy; and
(4) name, address and DEA registration number of the pharmacy or practitioner to whom the controlled substances are distributed.

**Note: The distributing pharmacy must provide a copy of the record of distribution (invoice) to the receiving registrant.*

Dangerous Drugs

Records of distribution must be maintained for dangerous drugs. These records (*e.g.*, invoices) must indicate the following information:*

(1) the actual date of distribution;
(2) name, strength, and quantity of the dangerous drug distributed;
(3) name and address of the distributing pharmacy; and
(4) name and address of the pharmacy or practitioner to whom the dangerous drugs are distributed.

**Note: The distributing pharmacy must provide a copy of the record of distribution (invoice) to the receiving pharmacy or doctor.*

Maintenance of Records

All records must be maintained by the distributing pharmacy for a period of two years. Records of controlled substances listed in Schedule II must be maintained separately from all other records of the pharmacy. Records of controlled substances listed in Schedules III-V must be maintained separately from all other records of the pharmacy. If controlled substances, dangerous drugs, and/or non-prescription items are listed on the same record, the controlled substances must be asterisked, redlined, or in some other manner readily identifiable apart from all other items appearing on the record.

5% Rule — Controlled Substances

The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5% of all controlled substances distributed and dispensed by the pharmacy during each calendar year in which the pharmacy is registered. If at any time it does exceed 5%, the pharmacy is required to obtain an additional registration as a distributor.

If at any time it does exceed 5%, the pharmacy is required to obtain an additional registration as a distributor from the DEA and Texas Department of State Health Services.

Excessive Purchases

When acting as a distributor (whether registered with DEA or not), the pharmacy must report any excessive purchases by a physician to the divisional office of the Drug Enforcement Administration.

Receiving Registrant

The registrant receiving the controlled substances must adhere to the following procedures.

Schedule II Controlled Substances

The receiving pharmacy must maintain copy 3 (blue) of all DEA order forms (DEA 222), including all copies of each unaccepted or defective order form and any attached statements or other documents. These forms must show the quantity of drugs received, the date the drug was received and the initials of the person responsible for the receipt of the Schedule II drugs.

Schedule III-V Controlled Substances

A copy of the distributing pharmacy's invoice for Schedule III, IV or V drugs must be maintained for two years. The receiving pharmacist, doctor, or other responsible individual must clearly initial and record the actual date of receipt of the drugs on the invoice.

Dangerous Drugs

A copy of the distributing pharmacy's invoice for dangerous drugs must be maintained for two years. The receiving pharmacist, doctor, or other responsible individual must clearly initial and record the actual date of receipt of the drugs on the invoice.

Maintenance of Records

All records must be maintained by the receiving pharmacy for a period of two years. Records of controlled substances listed in Schedule II must be maintained separately from all other records of the pharmacy. Records of controlled substances listed in Schedules III-V must be maintained separately from all other records of the pharmacy. If controlled substances, dangerous drugs, and/or nonprescription items are listed on the same record, the controlled substances must be asterisked, redlined, or in some other manner readily identifiable apart from all other items appearing on the record.

Although not required by law, the Board recommends that the distributing pharmacy have proof of delivery of controlled substances, *i.e*., the signature of an authorized agent of the registrant receiving the controlled substances. If the pharmacy is distributing drugs to a doctor, the Board also recommends that the pharmacy have a signed order from the doctor, which indicates the doctor (not his/her agent) is requisitioning the controlled substances.

Since improperly documented distribution of controlled substances could indicate a source of diversion of the substances, the failure of a pharmacist to legally document the distribution of controlled substances may result in disciplinary action by the Board. In summary, the above procedures must be followed whenever a pharmacy distributes controlled substances to another registrant. A pharmacy cannot *loan* or *borrow* controlled substances.