

855-062-0040

## Record Keeping

(1) A Drug Distribution Agent must establish and maintain records of all transactions regarding the distribution or other disposition of a drug. ~~These records must comply with all federal drug laws and regulations and must include the following information:~~

**(a) If a Drug Distribution Agent distributes product to a wholesaler or pharmacy, the record must contain, but is not limited to the following:**

(a) **(A)** The source of the drug, including the name and physical address of the seller or transferor and any broker or other person involved in the transaction, the address of the location from which the drug was shipped and the address of the location to which the drug was shipped;

(b) **(B)** The name, dose and quantity of the drug distributed;

(c) **(C)** The date of distribution or other disposition of the drug.

**(b) If a Drug Distribution Agent distributes product to another Drug Distribution Agent, the pedigree must be maintained and provided to the recipient of the distribution.**

(2) Records required by this rule must be made available for inspection and copying by any authorized official of the Drug Enforcement Agency, the Food and Drug Administration, the Department of Agriculture, authorized law enforcement agencies, and this Board.

(3) Records required under these rules must be maintained for three years.

(4) Records required under these rules that are less than 13 months old must be kept at the address of record or be immediately retrievable by computer or other electronic means, and must be immediately available for inspection. All other records required by these rules must be made available for inspection within three business days of a request.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155