657—17.1 (155A) Definitions.

"Authorized collection program" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at http://deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant's Iowa controlled substances Act registration shall not be required.

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the Iowa board of pharmacy.

"DEA" means the United States Department of Justice, Drug Enforcement Administration.

"Distribute" means the delivery of a prescription drug or device.

"Drug sample" means a drug that is distributed without monetary consideration to a pharmacist or practitioner. "Drug sample" does not include drugs intended for patients who would otherwise not receive needed drugs due to their inability to pay.

"Manufacturer" means a person or business engaged in the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes packaging or repackaging of the substances or labeling or relabeling of the substances' containers.

"Prescription drug" means any of the following:

1. A substance for which federal or state law requires a prescription before it may be legally dispensed to the public.
2. A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with one of the following statements:
   - Caution: Federal law prohibits dispensing without a prescription.
   - Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
   - Rx only.
3. A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

"Proprietary medicine" or *"over-the-counter (OTC) medicine"* means a nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with applicable state or federal law.

"Reverse distribution" means the receipt of prescription drugs including controlled substances, whether received from Iowa locations or shipped to Iowa locations, for the purposes of destroying the drugs or returning the drugs to their original manufacturers or distributors.

"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

1. The sale, purchase, or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons. For purposes of this chapter, "emergency medical reasons" includes transfers of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;
2. The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;
3. The lawful distribution of drug samples by manufacturers' representatives or wholesale salespersons;
4. The sale, purchase or trade of blood and blood components intended for transfusion; or
5. Intracompany sales.

"Wholesale distributor" or *"wholesaler"* means a person or business operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs, medicinal chemicals, medicines, or poisons are sold, manufactured, dispensed, stocked, exposed, or offered for sale at wholesale in this state. "Wholesaler" includes, but is not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; reverse distributors; and pharmacies that conduct wholesale distributions exceeding 5 percent of gross annual sales of prescription drugs. "Wholesaler" does not include those wholesalers who sell only OTC medicines or manufacturers' representatives lawfully distributing drug samples to authorized practitioners.

"Wholesale salesperson" or *"manufacturer's representative"* means an individual who takes purchase orders on behalf of a wholesaler for prescription drugs, medicinal chemicals, medicines, or poisons. "Manufacturer's representative" also means a person designated by a pharmaceutical manufacturer to lawfully distribute drug samples to authorized practitioners.

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