

Wisconsin Department of Safety and Professional Services

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PHARMACY EXAMINING BOARD

BUSINESS MODELS AND THE REQUIREMENTS FOR LICENSURE

(PHARMACY, PRESCRIPTION DRUG OR DEVICE DISTRIBUTOR AND DRUG MANUFACTURER)

Drug Manufacturers:

1. Drug or device manufacturing facilities which are located within the state of Wisconsin are required to obtain a manufacturer's license from the board.
2. A corporate headquarters for a drug manufacturer, located in this state, does not need to be licensed as a manufacturer if the headquarters is not a facility where manufacturing occurs.
3. A drug manufacturer may retain title to prescription drugs distributed to pharmacies until the medications are actually sold to a consumer pursuant to a prescription order. The pharmacy laws in this state do not prohibit the business arrangement proposed.
4. No distributor's license would be required for an out-of-state manufacturing facility that engages in the wholesale distribution of prescription drugs in this state from that manufacturing facility.

Prescription Drug and/or Device Distributors:

1. A distributor's license authorizes a facility to sell prescription drugs or devices to pharmacists, pharmacies, researchers, hospitals, authorized agents of the federal government and other distributors. A distributor's license does not authorize a facility to dispense prescription drugs directly to patients pursuant to a prescriber's prescription order. Dispensing directly to patients under a prescription order requires a pharmacy license.
2. Out-of-state or in-state wholesale distributors of prescription drugs are required to obtain a distributor's license in Wisconsin for each facility from which the prescription drugs are distributed.
3. A prescription device distributor does not need to be registered with the Food and Drug Administration, if it is not a manufacturer or initial importer and distributes a device from the original location of the manufacturer to the person who is making the final delivery or sale of the device to the ultimate consumer and/or user. A Wisconsin prescription device distributor license is still needed.

Out-of-State Pharmacies:

Effective April 13, 2006

1. This state requires a Wisconsin pharmacy license be obtained by pharmacies licensed in another state which dispense prescription medications, including schedule II controlled substances, by mail or other delivery to patients in this state.