

### **Medical oxygen suppliers, distributors and manufacturers in Wisconsin**

Several questions have been raised concerning the Pharmacy licensure requirements for medical supply companies in Wisconsin, who supply, distribute and/or manufacture medical oxygen. Palmetto GBA, who administers Medicare health insurance for the Centers for Medicare & Medicaid Services (CMS), has advised via their website that such entities must be in compliance with all applicable federal and state licensure and regulatory requirements if such company seeks to receive Medicare reimbursement. Palmetto GBA notes on their website:

A - Effective 03/26/1986 in-state suppliers dispensing oxygen directly to patients must hold a WI pharmacist license and work out of a licensed pharmacy or health care facility (i.e hospital and clinics, nursing facility), unless the oxygen is provided by a licensed practitioner authorized to prescribe and administer drugs in this state. Out-of-state suppliers must hold a Wisconsin out-of-state pharmacy license to provide oxygen to persons in the state of WI.

B - Drug Manufacturing License needed if re-packing/transfilling oxygen tanks, e.g. filling portable tanks from stationary ones.

C - The supplier may dispense prescription items without being licensed as a pharmacy if they are a Remote Dispensing Site and has a licensed supervising pharmacy that oversees the operations and administration of all aspects of the remote dispensing site. Please refer to Wisconsin Administrative Code Chapter Phar 7.095

See <http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~National%20Supplier%20Clearinghouse~Resources~Licensure%20Information~7GLS4M6340?open&navmenu=||>

The above information appears to have raised questions regarding its accuracy. Accordingly, the following information is provided to assist with any questions.

The FDA identifies oxygen as a legend drug. Prescriptions are required for legend drugs. The definition of "dispense" can be found in Wis. Stat. § 450.01(7). Per this definition, dispense is defined as delivering a prescribed drug or device to an ultimate user pursuant to a prescription order. Wisconsin Stat. § 450.01(16) defines the "practice of pharmacy" to include the dispensing of drugs and devices. Wisconsin Stat. § 450.03(1) provides that no person may engage in the practice of pharmacy unless licensed as a pharmacist. Wisconsin Stat. §§ 450.06(1) and 450.062 require licensed pharmacists to dispense at a location that is licensed as a pharmacy or a remote dispensing site. Accordingly, the dispensing of medical oxygen without proper licensure, is a violation of Wis. Stat. ch. 450 and/or Wis. Stat. § 440.21.

Wisconsin Stat. § 450.07 requires a manufacturing license if an entity in Wisconsin is engaging in manufacturing. Manufacturer and Manufacturing are defined in Wis. Stat. § 450.01(12) and (13). The filling and/or refilling of portable medical oxygen containers would qualify as manufacturing under these sections.

Wisconsin Stat. § 450.071 requires licensure for wholesale distributors of prescription drugs (there is an exemption for manufacturers that distribute prescription drugs manufactured by the manufacturer if licensure is not required under federal law). Wisconsin Stat. § 450.01(8) defines “distribute” as “means to deliver, other than by administering or dispensing.” Accordingly, an entity that distributes medical oxygen to another entity such as a long-term care facility, who will then further distribute or dispense, would require licensure per Wis. Stat. § 450.071. A wholesale distributor’s license does not authorize an entity/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 pharmacist and pharmacy license.

Remote dispensing, per Wis. Stat. § 450.62 allows a pharmacist to dispense at a health care facility, as well as other defined locations, if several requirements are met. Medical supply companies are not listed among the allowable remote dispensing sites. For further information concerning remote dispensing, please see Wis. Stat. § 450.62 and Wis. Admin. Code § Phar 7.095.

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