



# State of Wisconsin

LEGISLATIVE REFERENCE BUREAU

## Appendix A

### LRB BILL HISTORY RESEARCH APPENDIX

 The drafting file for

2013 LRB-4539/1 (For: DSPS)


has been transferred to the drafting file for

**2015 LRB-0472** (For: DSPS)



**RESEARCH APPENDIX -**  
**PLEASE KEEP WITH THE DRAFTING FILE**

Date Transfer Requested: 10/21/2014 (Per: MPG)

 The attached draft was incorporated into the new draft listed above. For research purposes the attached materials were added, as a appendix, to the new drafting file. If introduced this section will be scanned and added, as a separate appendix, to the electronic drafting file folder.

**2013 DRAFTING REQUEST**

**Bill**

Received: **8/12/2014** Received By: **mgallagh**  
Wanted: **As time permits** Same as LRB:  
For: **Safety and Professional Services 267-9794** By/Representing: **Jeff Grothman**  
May Contact: Drafter: **mgallagh**  
Subject: **Occupational Reg. - prof lic** Addl. Drafters:  
Extra Copies: **MED**

Submit via email: **YES**  
Requester's email: **jeffrey.grothman@wisconsin.gov**  
Carbon copy (CC) to: **michael.gallagher@legis.wisconsin.gov**

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**Pre Topic:**

No specific pre topic given

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**Topic:**

Licensure of medical oxygen suppliers

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**Instructions:**

See attached

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**Drafting History:**

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/P1	mgallagh 8/12/2014	kfollett 8/21/2014	rschluet 8/21/2014	_____	lparisi 8/21/2014		

FE Sent For:

<END>

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/P1	mgallagh	1P/15f 8/21	 8/21/14	==			

FE Sent For:

<END>



### 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.

→ ∴ no medicare coverage

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.

April 28, 2014 (DSPS)(Pharmacy Examining Board)

So, the "filling" or "refilling" must occur on a site other than the ultimate user's residence? Otherwise, need a pharmacist license?

Wisconsin Department of Safety and Professional Services  
Division of Legal Services & Compliance  
1400 East Washington Avenue  
PO Box 8368  
Madison WI 53708-8368



Phone: 608-266-2112  
Web: <http://dsps.wi.gov>  
Email: [dsps@wisconsin.gov](mailto:dsps@wisconsin.gov)

**Scott Walker, Governor**  
**Dave Ross, Secretary**

Secretary Kathleen Sebelius  
Department of Health and Human Services  
200 Independence Avenue  
Washington D.C., Maryland 20201

May 1, 2014

Dear Secretary Sebelius:

The Wisconsin Department of Safety and Professional Services (DPS) serves as the credentialing and oversight body for many of Wisconsin's licensed healthcare professionals and business entities. The Department has recently been made aware through a Centers for Medicare & Medicaid Services (CMS) audit that a number of Wisconsin's medical oxygen suppliers, distributors, and manufacturers are out of compliance with state law, and are therefore ineligible to receive Medicare reimbursement for services rendered to Wisconsin citizens.

According to a letter from Palmetto GBA:

The SACU [Supplier Audit and Compliance Unit] is charged with the responsibility of protecting the integrity of the Medicare Trust Fund by ensuring that all suppliers of Part-B-covered items are in full compliance with these standards. The standards can be found in the *Code of Federal Regulations* (42 CFR §424.57). More specifically, we would like to draw your attention to the following standard(s):

**42 CFR §424.57(c)(1):** Operates its business and furnishes Medicare-covered items in compliance with the following applicable laws:

- (i) Federal regulatory requirements that specify requirements for the provision of DMEPOS [Durable Medical Equipment, Prosthetics, Orthotics and Supplies] and ensure accessibility for the disabled.
- (ii) State licensure and regulatory requirements. If a State requires licensure to furnish certain items or services, a DMEPOS supplier—
  - (A) Must be licensed to provide the item or service; and
  - (B) May contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law.

As the Wisconsin governmental body charged with ensuring statutory compliance and consumer protection as it relates to the dispensing of prescription medications, DPS is committed to providing medical oxygen to patients in a manner that is compliant with both State and Federal regulatory requirements.

Pursuit of a statutory solution will occur in the next legislative session. However, because the legislature has adjourned, a statutory remedy is not possible until January 2015 at the earliest. Until that time, the Department requests a one year extension to allow oxygen suppliers, distributors, and manufacturers to come into compliance with the law.

Thank you for your consideration.

Sincerely,

Dave Ross  
Secretary  
Wisconsin Department of Safety and Professional Services

Handwritten notes: "So, until Jan 1, 2015 May?"

DEPARTMENT OF HEALTH & HUMAN SERVICES  
CENTERS for MEDICARE & MEDICAID SERVICES  
7500 Security Boulevard,  
Mail Stop AR-18-50  
Baltimore, Maryland 21244-1850



Center for Program Integrity  
Provider Enrollment Operations Group

May 15, 2014

Wisconsin Department of Safety and Professional Services  
Division of Legal Services and Compliance  
Attn: Secretary Dave Ross  
1400 East Washington Avenue  
PO Box 8368  
Madison WI 53708-8368

Dear Secretary Ross:

Thank you for the opportunity to respond to your letter dated May 1, 2014. As a result of an audit conducted by Palmetto GBA's Supplier Audit and Compliance Unit (SACU), a number of Wisconsin's medical oxygen suppliers, distributors and manufacturers were determined to be out of compliance with the current State law. You have requested that a one year extension be granted to allow the oxygen suppliers, distributors and manufacturers to come into compliance with the law. This is based upon your advice that you will pursue a statutory change to the law in the next legislative session. At your request, the Centers for Medicare & Medicaid Services (CMS) will not proceed with taking administrative action against those suppliers determined to be non-compliant until May 1, 2015. We will continue to monitor any changes made in the law based on your pursuit of a statutory solution. All suppliers who have been revoked as a result of the audit by our enrollment contractor have been notified and advised of our intent to suspend the enforcement efforts.

Sincerely,

A handwritten signature in black ink, appearing to read "Zabeen Chong", written in a cursive style. The signature is positioned above the printed name and title.

Zabeen Chong  
Director  
Provider Enrollment Operations Group

**Gallagher, Michael**

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**From:** Grothman, Jeffrey - DSPS <Jeffrey.Grothman@wisconsin.gov>  
**Sent:** Wednesday, July 23, 2014 12:09 PM  
**To:** Gallagher, Michael  
**Subject:** Medical Oxygen Suppliers, Distributors, and Manufacturers in WI

<http://dsps.wisconsin.gov/Home/Latest-News>



**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.

The Department of Safety and Professional Services has provided further guidance on this issue. Please visit the [Pharmacy Examining Board's Position Statements](#) for more information.

[Click here](#) to view a copy of the letter that DSPS sent to the Department of Health and Human Services on this topic.

[Click here](#) to view a copy of the response from the Centers for Medicare & Medicaid Services on behalf of the Department of Health and Human Services

8/7/2014

meeting w/ Tom Engels & Jeff  
Brothman - PSFS

— separate credential through PEB that  
will satisfy CMS.

— P-Draft.

— current Wholesale Lic. from grandfather  
in.



Handwritten signature

**PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION**

Gen

1 AN ACT ...; relating to: licensure of home medical oxygen suppliers and granting  
2 rule-making authority.

***Analysis by the Legislative Reference Bureau***

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

***The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:***

3 SECTION 1. 440.08 (2) (a) 38h. of the statutes is created to read:  
4 440.08 (2) (a) 38h. Home medical oxygen supplier: June 1 of each  
5 even-numbered year.

\*\*\*\*NOTE: Do you want to add home medical oxygen suppliers to the list under 440.03 (13) (b)? Note that, as currently drafted, a licensed supplier could be either an entity or an individual because any "person" may apply for a license.

6 SECTION 2. 450.03 (1) (e) of the statutes is amended to read:  
7 450.03 (1) (e) Any person lawfully practicing within the scope of a license,  
8 permit, registration, certificate, or certification granted to provide home medical

✓  
1 oxygen under s. 450.076, to practice professional or practical nursing or  
2 nurse-midwifery under ch. 441, to practice dentistry or dental hygiene under ch.  
3 447, to practice medicine and surgery under ch. 448, to practice optometry under ch.  
4 449 or to practice veterinary medicine under ch. 453, or as otherwise provided by  
5 statute.

6 SECTION 3. 450.076 of the statutes is created to read: ✓

7 **450.076 Home medical oxygen suppliers; licensure.** (1) DEFINITIONS. In  
8 this section: ✓

9 (a) “Home medical oxygen supplier” means a person that provides medical  
10 oxygen for compensation directly to an individual where the individual resides in  
11 this state, for the individual’s own use. ✓

12 (b) “Licensed supplier” means a home medical oxygen supplier licensed under  
13 this section. ✓

14 (c) “Medical oxygen” means oxygen that is a prescription drug. ✓

15 (2) LICENSE REQUIRED. (a) Except as provided in par. (b), no person may operate  
16 as a home medical oxygen supplier, use the title “home medical oxygen supplier” or  
17 any similar title, or hold itself out as a home medical oxygen supplier unless the  
18 person is a licensed supplier. ✓

19 (b) No license under this section is required for any of the following: ✓

20 1. A person that holds a current credential, as defined in s. 440.01 (2) (a), and ✓  
21 is acting within the scope of that credential.

22 2. A hospital, excluding any home medical oxygen supplier that is owned or ✓  
23 operated by a hospital.

24 3. An employee or agent of a licensed supplier acting within the scope of his or  
25 her employment or agency.

\*\*\*NOTE: Please let me know if any of these exemptions are not consistent with your intent or if you want to include additional exemptions.

1           **(3) LICENSURE.** The board shall grant a license to act as a home medical oxygen  
2 supplier to a person that does all of the following:

3           (a) Submits an application for licensure on a form provided by the board.

4           (b) Pays the fee specified in s. 440.05 (1).

5           (c) Satisfies any other requirements established by the board by rule.

\*\*\*NOTE: Let me know if you want to add other specific requirements for the initial application.

6           **(4) RULES.** The department shall adopt rules implementing this section. The  
7 rules shall include rules governing the professional conduct of licensed suppliers and  
8 their employees and agents.

\*\*\*NOTE: Let me know if you want to include any other specific rule-making requirements.

9           **SECTION 4.** 450.08 (2) (b) of the statutes is amended to read:

10           450.08 (2) (b) A pharmacy, manufacturer's or distributor's, or home medical  
11 oxygen supplier's license may be renewed by paying the applicable fee determined  
12 by the department under s. 440.03 (9) (a) on or before the applicable renewal date  
13 specified under s. 440.08 (2) (a).

History: 1985 a. 146; 1991 a. 39; 1997 a. 68; 1997 a. 237 s. 727m; 2007 a. 20; 2013 a. 124.

\*\*\*NOTE: As drafted, licensed suppliers would be subject to the applicable discipline and penalty provisions under ss. 450.10 and 450.17 and 450.18. Please let me know if you want to include any discipline or penalty provisions specific to home medical oxygen suppliers.

14           **SECTION 5. Nonstatutory provisions.**

15           (1) **EMERGENCY RULES.** The pharmacy examining board may promulgate  
16 emergency rules under section 227.24 of the statutes implementing section 450.076  
17 of the statutes, as created by this act. Notwithstanding section 227.24 (1) (c) and (2)  
18 of the statutes, emergency rules promulgated under this subsection remain in effect  
19 until June 30, 2017, or the date on which permanent rules take effect, whichever is

1 sooner. Notwithstanding section 227.24 (1) (a) and (3) of the statutes, the board is  
 2 not required to provide evidence that promulgating a rule under this subsection as  
 3 an emergency rule is necessary for the preservation of the public peace, health,  
 4 safety, or welfare and is not required to provide a finding of emergency for a rule  
 5 promulgated under this subsection.

6 (2) TRANSITIONAL PROVISION; CURRENT HOME MEDICAL OXYGEN SUPPLIERS.  
 7 Notwithstanding section 450.076 (3) of the statutes, as created by this act, the  
 8 pharmacy examining board shall grant a home medical oxygen supplier's license  
 9 under section 450.076 of the statutes, as created by this act, to any person who, before  
 10 May 1, 2015, submits an application for licensure that includes evidence satisfactory  
 11 to the board that the person has been engaged as a home medical oxygen supplier,  
 12 as defined in section 450.076 (1) (a) of the statutes, as created by this act, for all of  
 13 the 3-year period immediately preceding the effective date of this subsection.

\*\*\*NOTE: This grandfathering provision coincides with the May 1, 2015, compliance deadline provided by the Federal Department of Health and Human Services. If that deadline is extended before this proposal becomes law, you may want to amend the grandfathering provision accordingly. Also, note that the provision waives the initial licensure fee. Please let me know if that is not consistent with your intent. Finally, please let me know if you want the prior practice period to be shorter or longer than three years.



State of Wisconsin  
2013 - 2014 LEGISLATURE



LRB-4539/P1  
MPG:kjf:rs

**PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION**

1     **AN ACT to amend** 450.03 (1) (e) and 450.08 (2) (b); and **to create** 440.08 (2) (a)  
2             38h. and 450.076 of the statutes; **relating to:** licensure of home medical oxygen  
3             suppliers and granting rule-making authority.

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13 this section.

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15 (2) LICENSE REQUIRED. (a) Except as provided in par. (b), no person may operate  
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\*\*\*\*NOTE: As drafted, licensed suppliers would be subject to the applicable discipline and penalty provisions under ss. 450.10 and 450.17 and 450.18. Please let me know if you want to include any discipline or penalty provisions specific to home medical oxygen suppliers.

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10 May 1, 2015, submits an application for licensure that includes evidence satisfactory  
11 to the board that the person has been engaged as a home medical oxygen supplier,  
12 as defined in section 450.076 (1) (a) of the statutes, as created by this act, for all of  
13 the 3-year period immediately preceding the effective date of this subsection.

\*\*\*\*NOTE: This grandfathering provision coincides with the May 1, 2015, compliance deadline provided by the federal Department of Health and Human Services. If that deadline is extended before this proposal becomes law, you may want to amend the grandfathering provision accordingly. Also, note that the provision waives the initial licensure fee. Please let me know if that is not consistent with your intent. Finally, please let me know if you want the prior practice period to be shorter or longer than three years.