State of Florida
Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics

Application for Permit as a Medical Oxygen Retail Establishment
Form No.: DBPR-DDC-223

APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

APPLICATION	APPLICATION REQUIREMENTS
Application for Permit as a Medical Oxygen Retail Establishment	☐ Submit fee of $750.00, which includes $600.00 biennial application fee and $150.00 initial application/on-site inspection fee. ☐ Make cashier's check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation. ☐ If you answer "Yes" to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation. ☐ If you take possession of medical Oxygen at your establishment, provide a photocopy of the establishment's current fire inspection report. ☐ Sign and date the Affidavit section of the application.
	Submit the completed application with enclosures to: Department of Business and Professional Regulation 2601 Blair Stone Road Tallahassee, FL 32399

PLEASE NOTE:
Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact's mailing address and may take longer to resolve.

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If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at **850.717.1800.** ***For additional information see the instructions at the beginning of this application.***

Section I – Application Type

CHECK ONE OF THE APPLICATION TYPES
☐ New Application [3332/1020]
☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3332/1020] Current Permit Number: _____

Section II – Applicant Information

APPLICANT INFORMATION
TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER
This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).
Applicant's TIN/FEIN:
FULL LEGAL NAME
The "full legal name" is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation's full legal name would normally be the name that is found in the corporation's articles of incorporation.
Applicant's Full Legal Name:
FICTITIOUS, TRADE, OR BUSINESS NAME
If the applicant intends to operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a "dba", "D/B/A", or "doing business as" name – this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.
☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above. ☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name: _____ The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number: _____.

APPLICANT'S MAILING ADDRESS		
Street Address or P.O. Box:		
City:	State:	Zip Code (+4 optional):

PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED (only if different from mailing address) Check ☐ if not applicable		
Street Address:		
City:	State:	Zip Code (+4 optional):
County (if located in Florida):	Country:	
E-Mail Address:	Phone Number:	Fax Number:

APPLICATION CONTACT			
The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.			
Last/Surname:	First:	Middle:	Suffix:
Address:			
City:	State:	Zip Code (+4 optional):	
Telephone Number:	Fax Number:		
E-Mail Address:			

EMERGENCY CONTACT			
The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.			
Last/Surname:	First:	Middle:	Suffix:
Position/Title:			
Address:			
City:	State:	Zip Code (+4 optional):	
Phone Number:	E-Mail Address:		

OPERATING HOURS	
List the establishment's daily hours of operation in terms of Eastern Time. REMEMBER to circle "a.m." or "p.m." for each time indicated below.	
Mon ____:____ a.m./p.m. to ____:____ a.m./p.m. Tue ____:____ a.m./p.m. to ____:____ a.m./p.m. Wed ____:____ a.m./p.m. to ____:____ a.m./p.m. Thu ____:____ a.m./p.m. to ____:____ a.m./p.m.	Fri ____:____ a.m./p.m. to ____:____ a.m./p.m. Sat ____:____ a.m./p.m. to ____:____ a.m./p.m. Sun ____:____ a.m./p.m. to ____:____ a.m./p.m.

Section III – **Ownership Information**

TYPE OF OWNERSHIP		
☐ Publicly Held Corporation	☐ Closely Held Corporation	☐ Limited Liability Company
☐ Charitable Organization—501(c)(3)	☐ Sole Proprietorship	☐ Government
☐ Partnership – General	☐ Professional Corporation or Association	☐ Professional Limited Liability Company
☐ Partnership – Other, Including Limited Liability Partnership and Limited Partnership	☐ Other:_____	

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization. ☐ N/A (Partnership – General or Sole Proprietorship)
State or Country:

List name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations' webpage, that the applicant's registered agent is registered with the Florida Department of State, Division of Corporations. ☐ N/A (Partnership – General or Sole Proprietorship)		
Name:		
Address:		
City:	State:	Zip Code (+4 optional):

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

1.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
2.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:

	Street Address:	City:	State:	Zip Code:
3.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
4.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
5.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
6.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
7.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
8.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity.				
1.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
2.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:

3.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
4.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
5.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
6.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
7.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
8.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:

List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box ☐ and write N/A on the lines below.	

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary). Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant's name and address. (If no, please check this box ☐ and write "N/A" in the lines below).	☐ Yes ☐ No

Parent Company Name	% of Ownership

Section IV – Background Questions

BACKGROUND QUESTIONS			
1.	☐ Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** any "affiliated party" (defined below) been found guilty of (regardless of adjudication), or pled nolo contendere to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?
2.	☐ Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** any affiliated party (defined below) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?
3.	☐Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** any affiliated party (defined below) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?
4.	☐Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** any affiliated party (defined below) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?
5.	☐Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** any affiliated party (defined below) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?
6.	☐ Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** any affiliated party (defined below) ever held a permit issued under Chapter 499, F.S., in a different name than the applicant's name? (If yes, provide the names in which each permit was issued and at what address).

The term "affiliated party" means: (a) a director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (b) a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; (c) a person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or (d) the five largest natural shareholders that own at least 5 percent of the permittee or applicant..

If you answered "YES" to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

Section V – Explanation(s) for "Yes" response(s) to background question(s) in Section IV

EXPLANATION

Section V (cont'd)

Section VI – **Other Permits or Licenses**

PERMITS OR LICENSES			
1.	Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If no, please check this box ☐ and write "N/A" in the lines below).		☐ Yes ☐ No
1a.	Permit/License Name	Permit/License Type	Permit/License Number

Section VII – **Medical Oxygen Retail Establishment Activity**

DISTRIBUTION ACTIVITIES			
The Medical Oxygen Retail Establishment permit only authorizes distribution of oxygen to patients with a prescription.			
1.	Will all required records be stored and maintained at applicant's physical address? (If no, provide the address of the establishments where all required records will be stored and maintained under question #1a.)		☐ Yes ☐ No
1a.	Physical address where required records will be stored: Street Address:		
	City:	State:	Zip Code (+4 optional):
2.	Will the required records be computerized, automated or stored electronically? If yes, will you have a back-up procedure to be able to provide required records?		☐ Yes ☐ No ☐ Yes ☐ No

3.	Will you possess medical oxygen at your establishment? (If yes, attach a copy of your most recent fire inspection.) Fire inspection attached? ☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No
4.	Does the applicant intend to fill Medical Oxygen Containers? (Answer NO if you intend to have another permit holder fill the tanks.)	☐ Yes ☐ No
5.	If you intend to fill Medical Oxygen Containers, please provide your FDA establishment number? (You must provide the FDA establishment number or a copy of the application you submitted to the FDA.)	Est. No: _____
6.	If you intend to fill Medical Oxygen Containers, do you have labels of your product ready for inspection?	☐ Yes ☐ No ☐ N/A
7.	Do you intend to sell medical oxygen you have refilled to a person other than a patient? (If yes, you must also be permitted by the division as a Medical Gas Manufacturer.)	☐ Yes ☐ No
8.	What type of Medical Oxygen do you intend to handle (including back-up method for concentrators)? ☐ Gas (vaporized) Oxygen ☐ Liquid Oxygen ☐ Neither	
9.	Is there a quarantine area at the applicant's establishment? (If no, please provide a written explanation). Explanation included? ☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No
10.	Is the applicant's establishment equipped with an alarm system to detect entry after hours and a security system protecting against theft and diversion? (If yes, provide a written description of the alarm and security systems, that include: the type of system and how the system is monitored). Description included? ☐ Yes ☐ No ☐ N/A (If no, provide a written explanation of why the establishment is not equipped with an alarm or security system). Explanation included? ☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No
11.	Does the applicant have written policies and procedures to include: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural disasters and other emergencies; segregation and destruction of outdated products; temperature and humidity monitoring? (If no, provide written explanation for lack of specific policy or procedure identified above). Explanation attached? ☐ Yes ☐ No ☐ N/A If yes, provide a copy of each policy and procedure. Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy or procedure for receipt, security, storage, inventory could be labeled or identified as "Policy and/or Procedure for receipt, security, storage, inventory" or in another manner similar to this example. Policies attached? ☐ Yes ☐ No ☐ N/A Policies labeled? ☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No

12.	Who will be supplying the medical oxygen to your patients? (Your supplier must hold a Medical Gas Manufacturer or Medical Gas Wholesale Distributor permit to sell to you, and a Medical Oxygen Retail Establishment permit to deliver to your patients).	

Name	Address	Permit No.

13.	If the applicant is not taking possession of medical oxygen, does the applicant have written policies and procedures to include: maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; and natural disasters and other emergencies? (If no, provide written explanation for lack of specific policy or procedure identified above). Explanation attached? ☐ Yes ☐ No ☐ N/A If yes, provide a copy of each policy and procedure. Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy or procedure for prescription drug recalls could be labeled or identified as "Policy and/or Procedure for prescription drug recalls" or in another manner similar to this example. Policies attached? ☐ Yes ☐ No ☐ N/A Policies labeled? ☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No
14.	Does the applicant intend to sell or provide Medical Oxygen Containers purchased from another establishment to a person (including another branch) other than a patient? (If yes, you will be required to obtain a Medical Gas Wholesale Distributor permit.)	☐ Yes ☐ No
15.	If the applicant uses delivery vehicles, are the vehicles secured with alarm systems?	☐ Yes ☐ No
16.	Do you understand you must maintain either the original or a copy of the prescription, or order, for each patient?	☐ Yes ☐ No
17.	Do you understand that the prescription, or order, is only valid for one year from when it was originally filed?	☐ Yes ☐ No
18.	Provide the date the establishment will be ready and available for inspection. <u>This is the earliest date the application may be deemed complete.</u>	___/___/20___

Section VIII – Affidavit

AFFIDAVIT	
Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law. Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law. I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A. I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA'S OR D/B/A'S. I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.	
Signature of Applicant, Owner or Chief Executive:	Date:
Print Name:	Title:

Mail completed application to:

Department of Business and Professional Regulation
2601 Blair Stone Road
Tallahassee, FL 32399