

RESPONSIBLE PERSON REQUIREMENTS FOR LICENSURE

Updated 4/4/2023

Pursuant to rules <u>4729:5-2-01</u> and <u>4729:6-2-01</u> of the Ohio Administrative Code, the Board of Pharmacy is required to adopt a resolution providing the credential types or qualifications required for the responsible person of each classification of terminal distributor of dangerous drugs and drug distributor license. Unless otherwise noted, only individuals that hold the credentials specified by an Ohio licensing authority (board or commission) may be the responsible person for that classification type.

Additionally, the resolution also provides additional guidance to licensees regarding compliance with the Board's rule chapters. For each licensee, there is a link (if applicable) to an inspection guide that applies to the specific license type.

The requirements for terminal distributors of dangerous drugs begin on <u>page 2</u> of this document.

The requirements for distributors of dangerous drugs* begin on page 14 of this document.

*NOTES:

- A distributor of dangerous drugs includes the following license types: manufacturer
 of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of
 dangerous drugs and wholesale distributor of dangerous drugs (includes broker and
 virtual wholesaler).
- "APRN" refers to the following license types: Certified Registered Nurse Anesthetist, Certified Nurse Practitioner, Certified Nurse-Midwife, and Clinical Nurse Specialist who have prescriptive authority via chapter 4729. of the Revised Code.
- "PA" refers to a physician assistant subject to authorization of physician-delegated prescriptive authority. For category III license, must demonstrate proof of mid-level DEA-registration.
- An executive director for the purposes of a limited terminal distributor of dangerous drugs license for animal shelter, humane society, or dog pound means any person that meets both of the following requirements:
 - 1. Maintains control over day-to-day operations of a location; and
 - 2. Is responsible for staffing decisions (including volunteers) such as hiring, termination, promotion, or allocation of staff resources or structure.



Effective, April 4, 2023, the Board hereby adopts the following responsible person requirements:

	TERMINAL - CLINIC				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
AS	Ambulatory Surgery	DO, MD, RPH, DDS/DMD		<u>Institutional</u> (OAC <u>4729:5-9</u>)	
CI	Correctional Institution - clinic or med room that is located within a correctional facility or jail.	DO, MD, RPH, APRN, PA		Institutional (OAC <u>4729:5-9</u>)	
CL	Clinic - Health Dept., Free Clinic, Specialty Clinic	DO, MD, RPH, APRN, PA, DDS/DMD, DPM	*If possessing RU-486 (mifepristone) must be MD or DO	Clinic and Prescriber Office (OAC 4729:5-19)	
СТ	Chemical Treatment	DO, MD, RPH, APRN, PA		Clinic and Prescriber Office (OAC 4729:5-19) or Institutional (OAC 4729:5-9)	
ED	Free Standing Emergency Department	DO, MD, RPH		Institutional (OAC <u>4729:5-9</u>)	
IV	IV Therapy	DO, MD, APRN, PA, RPH		Clinic and Prescriber Office (OAC 4729:5-19)	

MC	Mobile Clinic - Drugs stored on a truck, aircraft, bus, etc.; includes non-emergent helicopters and aircraft.	DO, MD, RPH, DVM, APRN, PA, DDS/DMD		Limited Facility (OAC 4729:5-23) or Non-Limited Facility (OAC 4729:5-22)
MH	Mental Health	DO, MD, RPH, APRN, PA		Clinic and Prescriber Office (OAC 4729:5-19) or Institutional (OAC 4729:5-9)
ONC	Oncology Clinic	DO, MD, RPH		Clinic and Prescriber Office (OAC 4729:5-19)
PC	Prescriber Practice	DO, MD, APRN, PA, DDS/DMD, OD, RPH, DPM	OD must provide therapeutic number *If possessing RU-486 (mifepristone) must be MD or DO	Clinic and Prescriber Office (OAC 4729:5-19)
POC	Point of Care - Pyxis located in another Hospital	RPH		<u>Institutional</u> (OAC <u>4729:5-9</u>)
RT	Clinical Trials	DO, MD, RPH, DVM, OD, DDS/DMD, DPM	OD must provide therapeutic number	Clinic and Prescriber Office (OAC 4729:5-19)
SC	Sports Training Facility	DO, MD, RPH, APRN, PA		Clinic and Prescriber Office (OAC 4729:5-19)
UR	Urgent Care + Convenience Care Clinic	DO, MD, APRN, PA, RPH		Clinic and Prescriber Office (OAC 4729:5-19)

	TERMINAL - CLINIC - SOLE PRACTITIONER/DENTIST				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
IV	IV Therapy	DO, MD, APRN, PA, RPH		Clinic and Prescriber Office (OAC 4729:5-19)	
PC	Prescriber Practice	DO, MD, APRN, PA, DDS/DMD, OD, RPH, DPM	OD must provide therapeutic number *If possessing RU-486 (mifepristone) must be MD or DO	Clinic and Prescriber Office (OAC 4729:5-19)	

	TERMINAL - OPIOID TREATMENT PROGRAM				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
ОТР	Opioid Treatment Program - personally furnish buprenorphine and/or administer methadone.	DO, MD	*Category III only. Obtain SAMHSA or CARF accreditation after licensure.	Opioid Treatment Program (OAC 4729:5-21)	

	TERMINAL - OFFICE-BASED OPIOID TREATMENT				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
OBOT	Office-Based Opioid Treatment Clinic	DO, MD, APRN, PA – must have <u>DATA 2000 Wavier</u>	*Category III only. Required background check on Owners, RP and employees.	Office-Based Opioid Treatment Clinic (OAC 4729:5-18)	

	TERMINAL - PAIN MANAGEMENT CLINIC				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
GPMC	Grandfathered Pain Management Clinic **Approved by the Medical and Pharmacy Boards in 2011	DO, MD	*Category III only. Required background check on Owners, RP and employees.	Pain Management Clinic (OAC <u>4729:5-11</u>)	
PMC	Pain Management Clinic	DO, MD	*Category III only. Required background check on Owners, RP and employees. **RP must meet requirements in OAC 4729:5-2-01(C)(3)	Pain Management Clinic (OAC 4729:5-11)	

	TERMINAL - EMS - LIMITED				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
EM	EMS Headquarters	DO, MD, RPH		EMS (Coming Soon) (OAC <u>4729:5-14</u>)	
EMSS	EMS Satellite	DO, MD, RPH		EMS (Coming Soon) (OAC <u>4729:5-14</u>)	

	TERMINAL - FACILITY - VETERINARY MEDICINE			
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
VT	Veterinary Practice, Zoo, Veterinary Hospital	DVM		<u>Veterinary Clinic</u> (OAC <u>4729:5-20</u>)

	TERMINAL - FACILITY - NON-LIMITED				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
AS	Animal Shelter - Humane Society or Dog Pound	DVM		Animal Shelter (OAC 4729:5-15)	
ASCC	Animal Shelter with Chemical Capture	DVM	Complies with ORC 4729.534	Animal Shelter (OAC <u>4729:5-15)</u>	
ВВ	Blood Bank	DO, MD		Non-Limited Facility (OAC 4729:5-22)	
CC	Custodial Care, Pediatric Respite, Group Home	DO, MD, APRN, PA, RN	RN - only if medication is delivered patient specific	Non-Limited Facility (OAC 4729:5-22)	
DU	Dialysis Unit	DO, MD, APRN, PA, RPH		Non-Limited Facility (OAC 4729:5-22)	
НС	Hospice	DO, MD, RPH		Non-Limited Facility (OAC 4729:5-22)	
IC	Infusion Center	DO, MD, RPH, APRN, PA		Non-Limited Facility (OAC 4729:5-22)	
IM	Imaging	DO, MD, RPH		Non-Limited Facility (OAC 4729:5-22)	

LA	Laboratory/Research	DO, MD, PHD, Chemist*,	* Chemist or	<u>Laboratory</u>
		Management*, RPH, DVM,	Management must	(OAC <u>4729:5-16</u>)
		DDS/DMD	provide a proof of a	
			degree in one of the	
			following: chemistry,	
			biochemistry, forensic	
			science, biology,	
			microbiology, or related	
			pure applied science or	
			proof of certified training	
			in the field of expertise.	

	TERMINAL - FACILITY - LIMITED				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
AS	Animal Shelter – Humane Society or Dog Pound	CET, DVM, DOG WARDEN, Executive Director		Animal Shelter (OAC <u>4729:5-15</u>)	
ASCC	Animal Shelter with Chemical Capture	CET, DVM, DOG WARDEN, Executive Director	Comply with ORC 4729.534	Animal Shelter (OAC 4729:5-15)	
DG	Dog Trainer	Management + LENA	Law Enforcement Affiliation or contract required.	<u>Limited Facility</u> (OAC <u>4729:5-23</u>)	
FA	First Aid Room/Department	DO, MD, APRN, PA, RN	RN only if medication is delivered patient specific or for the purposes of personal furnishing naloxone.	First Aid Department (OAC 4729:5-13)	
НН	Home Health Care - providing services to the patient's homes or vaccinations off-site	DO, MD, RPH		<u>Limited Facility</u> (OAC <u>4729:5-23</u>)	

ND	Nursing Home Drug Stock	DO, MD, APRN, PA		Limited Facility (OAC 4729:5-23)
PD	Peritoneal Dialysis Center - ships directly to the patient's home, RPh does not perform final verification	Management		Limited Facility (OAC 4729:5-23)
PT	Physical Therapy	DO, MD, RPH		Limited Facility (OAC 4729:5-23)
TE	Teaching Institution	DDS/DMD, DO, MD, HEAD OF PROGRAM (RN), RPH, APRN, PA, OD, DVM	If injecting into humans, must be – DDS/DMD, DO, MD, DDS/DMD, OD, RPH, PA or APRN.	Limited Facility (OAC 4729:5-23)

	TERMINAL - MEDICAL GAS - LIMITED				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
CX	Contingency Stock	RN, LNHA, Management, RRT		Medical Gases (Coming Soon) (OAC <u>4729:5-17</u>)	
GM	Manufacturer Process Use + Food Processor	Management		Medical Gases (Coming Soon) (OAC <u>4729:5-17</u>)	
OX	Retail Seller or Biller of Oxygen	MD, DO, RN, APRN, PA, LNHA, RRT, OD, DDS/DMD, DVM, RPH, Management	*Saline and Sterile Water can be included on drug list.	Medical Gases (Coming Soon) (OAC <u>4729:5-17</u>)	

	TERMINAL - NON-RESIDENT PHARMACY - NON-LIMITED				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
CF	Central Fill Pharmacy	RPH	Must hold pharmacist license in state where pharmacy is located and Ohio RPH license if shipping compounded medications.	Non-Resident (OAC <u>4729:5-8</u>)	
IP	Pharmacy Servicing Institutions	RPH	Must hold pharmacist license in state where pharmacy is located and Ohio RPH license if shipping compounded medications. May included Mental Health Pharmacies & Nursing Home Inpatient Pharmacies		
MO	Mail Order Pharmacy	RPH	Must hold pharmacist license in state where pharmacy is located and Ohio RPH license if shipping compounded medications.	Non-Resident (OAC <u>4729:5-8</u>)	
NU	Nuclear Pharmacy	RPH	Must hold pharmacist license in state where pharmacy is located and Ohio RPH license if shipping compounded medications.	Non-Resident (OAC <u>4729:5-8</u>)	
<u>PI</u>	Prescription Intermediary	RPH	Must hold pharmacist license in state where pharmacy is located and Ohio RPH license if	<u>Non-Resident</u> (OAC <u>4729:5-8</u>)	

			shipping compounded medications.	
SP	Specialty Pharmacy - High \$ Drugs	RPH	Must hold pharmacist license in state where pharmacy is located and Ohio RPH license if shipping compounded medications. May include compounding	<u>Non-Resident</u> (OAC <u>4729:5-8</u>)

	TERMINAL - PHARMACY - NON-LIMITED				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
CF	Central Fill Pharmacy	RPH		Outpatient Pharmacy (OAC 4729:5-5)	
СН	Charitable Pharmacy	RPH	Must provide tax exempt paperwork.	Outpatient Pharmacy (OAC 4729:5-5)	
СР	Clinic Pharmacy	RPH		Outpatient Pharmacy (OAC 4729:5-5)	
DM	Durable Medical Equipment	RPH		Outpatient Pharmacy (OAC 4729:5-5)	
DR	Drug Repository	RPH		Outpatient Pharmacy (OAC 4729:5-5)	
FL	Fluid Therapy	RPH		Outpatient Pharmacy (OAC 4729:5-5)	
HS	Hospital	RPH		<u>Institutional</u> (OAC <u>4729:5-9</u>)	
II	Independent Community Retail (1 Outlet)	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)	

IL	Large Chain Retail (12+ Outlets)	RPH		Outpatient Pharmacy (OAC 4729:5-5)
IP	Pharmacy Servicing Institutions	RPH	May include mental health pharmacies & nursing home inpatient pharmacies.	Institutional (OAC <u>4729:5-9</u>)
IS	Small Chain Retail (2-11 Outlets)	RPH		Outpatient Pharmacy (OAC 4729:5-5)
KI	Kiosk	RPH		Institutional (OAC 4729:5-9)
MD	Multi-Disciplinary	RPH	May include compounding	Outpatient Pharmacy (OAC 4729:5-5)
MO	Mail Order Pharmacy	RPH		Outpatient Pharmacy (OAC 4729:5-5)
NU	Nuclear Pharmacy	RPH		Nuclear (Coming Soon)
ONC	Oncology Pharmacy	RPH		Outpatient Pharmacy (OAC 4729:5-5)
PI	Prescription Intermediary	RPH		Outpatient Pharmacy (OAC 4729:5-5)
SP	Specialty Pharmacy - High \$ Drugs	RPH	May include compounding	Outpatient Pharmacy (OAC 4729:5-5)

TERMINAL - PHARMACY - LIMITED*

*Category 2 only

Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
CR	Consulting Pharmacy	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
				or
				<u>Institutional</u> (OAC <u>4729:5-9</u>)
CRP	Contract Remote Order Entry	RPH		Outpatient Pharmacy or Institutional - Specifically Remote Order Entry Requirements
МТМ	Medication Therapy Management	RPH		Medication Therapy Managemen (Coming Soon) (OAC <u>4729:5-12</u>)
PI	Prescription Intermediary	RPH		Outpatient Pharmacy (OAC 4729:5-5)

TERMINAL - NON-RESIDENT PHARMACY - LIMITED* *Category 2 only				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
CR	Consulting Pharmacy	RPH	Must hold pharmacist license in state where pharmacy is located.	<u>Non-Resident</u> (OAC <u>4729:5-8</u>)

CRP	Contract Remote Order Entry	RPH	Must hold pharmacist license in state where pharmacy is located.	Outpatient Pharmacy or Institutional - Specifically Remote Order Entry Requirements
MTM	Medication Therapy Management	RPH	Must hold pharmacist license in state where pharmacy is located.	Medication Therapy Management (Coming Soon) (OAC <u>4729:5-12</u>)
PI	Prescription Intermediary	RPH	Must hold pharmacist license in state where pharmacy is located.	<u>Non-Resident</u> (OAC <u>4729:5-8</u>)

	TERMINAL - PHARMACY SUPPLIED CONTINGENCY STOCK				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
CI	Correctional Institution	RPH		Institutional (OAC <u>4729:5-9</u>)	
CS	Community Pharmacy	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)	
HC	Hospice Facility	RPH		Institutional (OAC 4729:5-9)	
HS	Hospital	RPH		Institutional (OAC <u>4729:5-9</u>)	
МН	Mental Health Institution	RPH		Institutional (OAC 4729:5-9)	
NH	Nursing Home	RPH		Institutional (OAC <u>4729:5-9</u>)	

DISTRIBU	DISTRIBUTOR OF DANGEROUS DRUGS – MANUFACTURER, OUTSOURCING FACILITY, REPACKAGER, AND THIRD- PARTY LOGISTICS PROVIDER				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
MF	Manufacturer	Management		Manufacturer (Coming Soon) (OAC 4729:6-8)	
OSC	Outsourcing Facility – 503B sterile and/or non-sterile compounding at wholesale, not patient specific	Ohio Licensed RPH	Must provide FDA registration and inspection report	Outsourcing Facility (Coming Soon) (OAC <u>4729:6-10</u>)	
RE	Repackager	Management	Must provide FDA registration	Repackager (Coming Soon) (OAC <u>4729:6-9</u>)	
3PL	Third-Party Logistics - stores and distributes drug but does not have ownership	Management	If out of state, must have licensure from home state or VAWD Accreditation.	Third-Party Logistics Providers (Coming Soon) (OAC <u>4729:6-11</u>)	

	WHOLESALER				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide	
ВС	Bulk Pharmaceutical Chemical Seller	Management		Wholesale Distributor (Coming Soon) (OAC <u>4729:6-5</u>)	
BG	Buying Group - A group of wholesalers/stores that leverage for better pricing	Management		Wholesale Distributor (Coming Soon) (OAC <u>4729:6-5</u>)	

BR	Broker	Management	If out of state, must have licensure from home state.	Wholesale Distributor (Coming Soon) (OAC <u>4729:6-7</u>)
СМ	Compressed Medical Gases	Management		Wholesale Distributor (Coming Soon) (OAC <u>4729:6-5</u>)
CN	Clinic Wholesaler: Blood Banks, Health Departments	Management		Wholesale Distributor (Coming Soon) (OAC <u>4729:6-5</u>)
FS	Full Service	Management		Wholesale Distributor (Coming Soon) (OAC <u>4729:6-5</u>)
IE	Import/Export - importing drugs from in/out of the country	Management		Wholesale Distributor (Coming Soon) (OAC <u>4729:6-5</u>)
PU	Public Health Preparedness* NOTE: A board of health, as defined in section 3701.048 of the Revised Code, that is licensed as a terminal distributor of dangerous drugs (TDDD) for the purpose of distributing dangerous drugs to another TDDD during a declared public health emergency or emergency preparedness incident is not required to obtain licensure as a wholesale distributor.	Management		Wholesale Distributor (Coming Soon) (OAC <u>4729:6-5</u>)

SD	Samples Distributor	Management		Wholesale Distributor (Coming Soon) (OAC <u>4729:6-5</u>)
VW	Virtual Wholesaler - NO DRUGS ONSITE	Management	If out of state, must have licensure from home state or VAWD Accreditation.	Virtual Wholesalers (Coming Soon) (OAC <u>4729:6-6</u>)
WD	Waste Disposal/Reverse Distributor	Management	Must provide DEA & EPA registration	Wholesale Distributor (Coming Soon) (OAC <u>4729:6-5</u>)