Mike DeWine, Governor Jon Husted, Lt. Governor Steven W. Schierholt, Executive Director

RESPONSIBLE PERSON REQUIREMENTS FOR LICENSURE

Updated 4/9/2024

Pursuant to rules 4729:5-2-01 and 4729:6-2-01 of the Ohio Administrative Code, the Ohio 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 page 2 of this document.

The requirements for distributors of dangerous drugs* begin on page 17 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 DEAregistration.
- 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.

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Effective, April 9, 2024, the Board hereby adopts the following responsible person requirements:

	TERMINAL - CLINIC				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide / OAC Code Section	
AS	Ambulatory Surgery	DO, MD, RPH, DDS/DMD		Institutional (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 <u>4729:5-19</u>)	
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		Institutional (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 / OAC Code Section	
IV	IV Therapy	DO, MD, APRN, PA, RPH		Clinic and Prescriber Office (OAC <u>4729:5-19</u>)	
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 / OAC Code Section	
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 - PAIN MANAGEMENT CLINIC				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide / OAC Code Section	
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 <u>4729:5-11</u>)	

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

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

	ד	FERMINAL - FACILITY - NON-	LIMITED	
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide / OAC Code Section
AS	Animal Shelter - Humane Society or Dog Pound	DVM	* Drug List Required	Animal Shelter (OAC <u>4729:5-15</u>)
ASCC	Animal Shelter with Chemical Capture	DVM	Complies with ORC 4729.534 * Drug List Required	Animal Shelter (OAC <u>4729:5-15)</u>
ВВ	Blood Bank	DO, MD		Non-Limited Facility (OAC <u>4729:5-22</u>)
СС	Custodial Care, Pediatric Respite, Group Home	DO, MD, APRN, PA, RN	RN - only if medication is delivered patient specific	Non-Limited Facility (OAC <u>4729:5-22</u>)
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 <u>4729:5-22</u>)
LA	Laboratory/Research	DO, MD, PHD, Chemist*, Management*, RPH, DVM, DDS/DMD	* Chemist or Management must provide a proof of a degree in one of the following: chemistry, biochemistry, forensic	<u>Laboratory</u> (OAC <u>4729:5-16</u>)

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 / OAC Code Section	
AS	Animal Shelter – Humane Society or Dog Pound	CET, DVM, DOG WARDEN, Executive Director	* Drug List Required	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 * Drug List Required	Animal Shelter (OAC 4729:5-15)	
DG	Dog Trainer	Management + LENA	Law Enforcement Affiliation or contract required. * Drug List 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		<u>Limited Facility</u> (OAC <u>4729:5-23</u>)
PD	Peritoneal Dialysis Center - ships directly to the patient's home, RPh does not perform final verification	Management		<u>Limited Facility</u> (OAC <u>4729:5-23</u>)
PT	Physical Therapy	DO, MD, RPH		<u>Limited Facility</u> (OAC <u>4729:5-23</u>)
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 <u>4729:5-23</u>)

	TERMINAL - MEDICAL GAS - LIMITED					
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide / OAC Code Section		
СХ	Contingency Stock	RN, LNHA, Management, RRT		Medical Gases (OAC <u>4729:5-17</u>)		
GM	Manufacturer Process Use + Food Processor	Management		Medical Gases (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 (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 / OAC Code Section
CF	Central Fill Pharmacy	RPH	Must hold pharmacist license in state where pharmacy is located and Ohio RPH license if shipping compounded medications.	<u>Non-Resident</u> (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	Non-Resident (OAC <u>4729:5-8</u>)
MO	Mail Order Pharmacy	RPH	Must hold pharmacist license in state where pharmacy is located and Ohio RPH license if shipping compounded medications.	<u>Non-Resident</u> (OAC <u>4729:5-8</u>)
NU	Nuclear Pharmacy	RPH	Must hold pharmacist license in state where pharmacy is located and	<u>Non-Resident</u> (OAC <u>4729:5-8</u>)

			Ohio RPH license if shipping compounded medications.	
PI	Prescription Intermediary	RPH	Must hold pharmacist license in state where pharmacy is located and Ohio RPH license if shipping compounded medications.	<u>Non-Resident</u> (OAC <u>4729:5-8</u>)
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 / OAC Code Section
CF	Central Fill Pharmacy	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
СН	Charitable Pharmacy	RPH	Must provide tax exempt paperwork.	Outpatient Pharmacy (OAC <u>4729:5-5</u>)
СР	Clinic Pharmacy	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
DM	Durable Medical Equipment	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
DR	Drug Repository	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
FL	Fluid Therapy	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
HS	Hospital	RPH		Institutional (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 <u>4729:5-5</u>)
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 <u>4729:5-5</u>)
KI	Kiosk	RPH		Institutional (OAC <u>4729:5-9</u>)
MD	Multi-Disciplinary	RPH	May include compounding	Outpatient Pharmacy (OAC 4729:5-5)
МО	Mail Order Pharmacy	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
NU	Nuclear Pharmacy	RPH		Nuclear (<u>OAC 4729:5-6</u>)
ONC	Oncology Pharmacy	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
PI	Prescription Intermediary	RPH		Outpatient Pharmacy (OAC 4729:5-5)
SP	Specialty Pharmacy - High \$ Drugs	RPH	May include compounding	Outpatient Pharmacy (OAC <u>4729:5-5</u>)

TERMINAL - PHARMACY - LIMITED* *Category 2 only **Subcategory Definition Special Requirements Applicable Inspection Guide /** Subcategory **Approved Credentials for OAC Code Section Responsible Person** CR **Consulting Pharmacy** RPH **Outpatient Pharmacy** (OAC 4729:5-5) or Institutional (OAC 4729:5-9) CRP **Outpatient Pharmacy** Contract Remote Order Entry RPH or Institutional - Specifically Remote Order Entry Requirements Medication Therapy Management MTM **Medication Therapy Management RPH** (OAC 4729:5-12) Ы **Prescription Intermediary** RPH **Outpatient Pharmacy** (OAC 4729:5-5)

*Category 2 only Subcategory **Subcategory Definition Approved Credentials for Special Requirements Applicable Inspection Guide / Responsible Person OAC Code Section** CR **Consulting Pharmacy** RPH Must hold pharmacist Non-Resident license in state where (OAC 4729:5-8) pharmacy is located. **CRP Contract Remote Order Entry RPH** Must hold pharmacist **Outpatient Pharmacy** license in state where or <u>Institutional</u> pharmacy is located. - Specifically Remote Order Entry

RPH

RPH

Must hold pharmacist

license in state where

pharmacy is located.

Must hold pharmacist

license in state where

pharmacy is located.

MTM

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Medication Therapy Management

Prescription Intermediary

TERMINAL - NON-RESIDENT PHARMACY - LIMITED*

Requirements

Medication Therapy Management

(OAC 4729:5-12)

Non-Resident

(OAC 4729:5-8)

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

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

WHOLESALER				
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide / OAC Code Section
ВС	Bulk Pharmaceutical Chemical Seller	Management		<u>Wholesale Distributor</u> (OAC <u>4729:6-5</u>)
BG	Buying Group - A group of wholesalers/stores that leverage for better pricing	Management		Wholesale Distributor (OAC <u>4729:6-5</u>)
BR	Broker	Management	If out of state, must have licensure from home state.	Wholesale Distributor (OAC <u>4729:6-7</u>)
СМ	Compressed Medical Gases	Management		Wholesale Distributor (OAC <u>4729:6-5</u>)
CN	Clinic Wholesaler: Blood Banks, Health Departments	Management		Wholesale Distributor (OAC <u>4729:6-5</u>)
FS	Full Service	Management		Wholesale Distributor (OAC <u>4729:6-5</u>)
IE	Import/Export - importing drugs from in/out of the country	Management		Wholesale Distributor (OAC <u>4729:6-5</u>)
	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	Management		<u>Wholesale Distributor</u> (OAC <u>4729:6-5</u>)

WD	Waste Disposal/Reverse Distributor	Management	Must provide DEA & EPA registration	Wholesale Distributor (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.	<u>Virtual Wholesalers</u> (OAC <u>4729:6-6</u>)
SD	Samples Distributor	Management		Wholesale Distributor (OAC <u>4729:6-5</u>)
	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.			