Mike DeWine, Governor Jim Tressel, Lt. Governor Steven W. Schierholt, Executive Director

Responsible Person Requirements for Licensure

Updated 6/3/2025

Pursuant to rules <u>4729:5-2-01</u> and <u>4729:6-2-01</u> 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 <u>page 3</u> of this document.

The requirements for distributors of dangerous drugs* begin on page 18 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 June 3, 2025, 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 <u>4729:5-19</u>)		

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

			(OAC <u>4729:5-19</u>)
UR	Urgent Care + Convenience Care Clinic	DO, MD, APRN, PA, RPH	Clinic and Prescriber Office (OAC <u>4729:5-19</u>)

	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 <u>4729:5-19</u>)	

	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 <u>4729:5-21</u>)	

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>)	

TERMINAL - 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	Animal Shelter (OAC <u>4729:5-15)</u>

			* Drug List Required	
BB	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		Institutional (OAC 4729:5-9)
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*, Management*, RPH, DVM, DDS/DMD	* Chemist or Management must 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.	<u>Laboratory</u> (OAC <u>4729:5-16</u>)

	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 <u>4729:5-13</u>)	
НН	Home Health Care - providing services to the patient's homes or vaccinations off-site	DO, MD, RPH		Limited Facility (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	Management		<u>Limited Facility</u>
	directly to the patient's home, RPh does			(OAC <u>4729:5-23</u>)
	not perform final verification			
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	If injecting into humans,	<u>Limited Facility</u>
		PROGRAM (RN), RPH, APRN,	must be – DDS/DMD, DO,	(OAC <u>4729:5-23</u>)
		PA, OD, DVM	MD, DDS/DMD, OD, RPH,	
			PA or APRN.	

	TERMINAL - MEDICAL GAS - LIMITED					
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide / OAC Code Section		
CX	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.	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	Non-Resident (OAC <u>4729:5-8</u>)
			Pharmacies	
MO	Mail Order Pharmacy	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.	
NU	Nuclear 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>)
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 4729:5-5)
СР	Clinic Pharmacy	RPH		Outpatient Pharmacy (OAC 4729:5-5)
DM	Durable Medical Equipment	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
DR	Drug Repository	RPH		Outpatient Pharmacy (OAC 4729:5-5)
FL	Fluid Therapy	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
НОС	Hospital Outpatient Community Access	RPH		Outpatient Pharmacy (OAC <u>4729:5-5</u>)
HOL	Hospital Outpatient Limited Access	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.	<u>Institutional</u> (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 <u>4729:5-5</u>)
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	Outpatient Pharmacy
			compounding	(OAC <u>4729:5-5</u>)

TERMINAL - PHARMACY - LIMITED* *Category 2 only **Subcategory Definition Approved Credentials for Special Requirements** Applicable Inspection Guide / Subcategory **OAC Code Section Responsible Person** CR **Consulting Pharmacy** RPH **Outpatient Pharmacy** (OAC 4729:5-5) or **Institutional** (OAC 4729:5-9) CRP **Contract Remote Order Entry** RPH **Outpatient Pharmacy** or Institutional - Specifically Remote Order Entry Requirements Medication Therapy Management **Medication Therapy Management RPH** MTM (OAC <u>4729:5-12</u>) Ы **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 / OAC Code Section
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
МТМ	Medication Therapy Management	RPH	Must hold pharmacist license in state where pharmacy is located.	Medication Therapy Management (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 / 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		Institutional (OAC <u>4729:5-9</u>)	
HS	Hospital	Ohio RPH		Institutional (OAC <u>4729:5-9</u>)	
МН	Mental Health Institution	Ohio RPH		Institutional (OAC <u>4729:5-9</u>)	
NH	Nursing Home	Ohio RPH		Institutional (OAC <u>4729:5-9</u>)	

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 / OAC Code Section
MF	Manufacturer	Management		Manufacturer (OAC <u>4729:6-8</u>)
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 (OAC <u>4729:6-10</u>)
RE	Repackager	Management	Must provide FDA registration	<u>Repackager</u> (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 (OAC 4729:6-11)

WHOLESALER					
Subcategory	Subcategory Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide / OAC Code Section	
ВС	Bulk Pharmaceutical Chemical Seller	Management		Wholesale Distributor (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		<u>Wholesale Distributor</u> (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		<u>Wholesale Distributor</u> (OAC <u>4729:6-5</u>)	

PU	Public Health Preparedness*	Management		Wholesale Distributor
	NOTE: A board of health, as defined in			(OAC <u>4729:6-5</u>)
	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.			
SD	Samples Distributor	Management		Wholesale Distributor
				(OAC <u>4729:6-5</u>)
VW	Virtual Wholesaler - NO DRUGS ONSITE	Management	If out of state, must have	<u>Virtual Wholesalers</u>
			licensure from home state	(OAC <u>4729:6-6</u>)
			or VAWD Accreditation.	
WD	Waste Disposal/Reverse Distributor	Management	Must provide DEA & EPA	Wholesale Distributor
			registration	(OAC <u>4729:6-5</u>)