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.

77 S. High Street, 17th Floor Columbus, OH 43215 U.S.A. Phone: 614 | 466 4143 Fax: 614 | 752 4836



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 | | <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 <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 | | Institutional (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 | | 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 | | 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. | | | |