

April 2021 - Resolutions



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NOTE: All resolutions that are starred (*) were initially authorized under the May 5, 2020 COVID-19 resolution.

1) Ohio Department of Health – Off-Site Storage Extension to 12/31/2021

To address storage capacity at your existing warehouse and to promote the safe distribution of COVID-19 vaccines, the State of Ohio Board of Pharmacy temporarily authorizes the Ohio Department of Health to store non-controlled dangerous drugs maintained at its Board of Pharmacy-licensed locations at its storage facility at 6480 Adelaide Ct., Groveport, Ohio 43125 (e.g., Adelaide Facility).

In authorizing the temporary storage of dangerous drugs at this location, the Ohio Department of Health shall ensure that the Adelaide Facility complies with all applicable requirements for wholesale distributors set forth in chapter 4729 of the Revised Code and chapters 4729:6-5 and 4729:6-3 of the Ohio Administrative Code.

This authorization shall remain in effect until December 31, 2021 but may be extended by the Board at the request of the Department.

2) Contingency Stock License Resolution*

To promote improved access to vaccinations during the COVID-19 pandemic, the State of Ohio Board of Pharmacy hereby authorizes a long-term care facility or other institutional facility, as defined under agency 4729 of the Ohio Administrative Code, to possess and administer COVID-19 or other vaccines to patients and staff under the terminal distributor of dangerous drugs license issued to the facility's servicing pharmacy (e.g., contingency stock license). This resolution shall also permit the use of the servicing pharmacy's contingency stock license to maintain dangerous drugs used to treat adverse reactions to vaccines stored at the facility.



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3) Expedited Licensure of Drug Distributors COVID Resolution Update

The Board is temporarily waiving the requirement for the submission of ownership/officer and responsible person criminal records checks prior to the initial issuance of a drug distributor license or processing of an application resulting from a change in the description of a distributor of dangerous drugs pursuant to rule 4729:6-2-05 of the Administrative Code received on or after March 2, 2020.

4) Non-Resident Pharmacy Inspection Reports for Compounding Pharmacies*

To address operational issues relating to the COVID-19 pandemic, the State of Ohio Board of Pharmacy temporarily authorizes the following waiver to OAC 4729-16-08 (E)(2):

- For non-resident compounding pharmacies renewing a terminal distributor of dangerous drugs license, the pharmacy shall submit the most recent inspection report from any entity listed in paragraph (E)(2) of rule 4729-16-08.*
- For non-resident compounding pharmacies applying for initial licensure or renewal, the Board will also accept the results of a virtual inspection that is less than two years from any entity listed in paragraph (E)(2) of rule 4729-16-08.*

This resolution shall also apply to rule 4729:5-8-04 once effective and shall remain in effect until December 31, 2021.

5) Verification of Prescriber Compounded Drug Products

To address operational concerns, a prescriber who engages in drug compounding may also use a pharmacist, in lieu of a nurse, to assist in the verification of compounded products prior to administration to a patient in accordance with OAC 4729:7-3-03 (H), 4729:7-3-04 (M), and 4729:7-3-05(G).

6) Updated Responsible Person Resolution (see next page)

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RESPONSIBLE PERSON REQUIREMENTS FOR LICENSURE

Updated 14/6XX/2021

Pursuant to rules [4729:5-2-01](#) and [4729:6-2-01](#) 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 meet 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 11](#) 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.



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Effective, January 6, 2020, the Board hereby adopts the following responsible person requirements:

TERMINAL - CLINIC				
Business Type	Business Type Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
AS	Ambulatory Surgery	DO, MD, RPH		Institutional (Coming Soon)
CI	Correctional Institution - clinic or med room that is located within a correctional facility or jail.	DO, MD, RPH, APRN, PA		Institutional (Coming Soon)
CL	Clinic - Health Dept., Free Clinic, Specialty Clinic	DO, MD, RPH, APRN, PA, DDS, DPM	<u>*If possessing RU-486 (mifepristone) must be MD or DO</u>	<u>Clinic and Prescriber Office</u> (OAC <u>4729:5-19</u>)
CT	Chemical Treatment	DO, MD, RPH, APRN, PA		<u>Clinic and Prescriber Office</u> (OAC <u>4729:5-19</u>) or Institutional (Coming Soon)
ED	Free Standing Emergency Department	DO, MD, RPH		Institutional (Coming Soon)
MC	Mobile Clinic - Drugs stored on a truck, aircraft, bus, etc.; includes non-emergent helicopters and aircraft.	DO, MD, RPH, DVM, APRN, PA, DDS		<u>Limited Facility</u> (OAC <u>4729:5-23</u>) or <u>Non-Limited Facility</u> (OAC <u>4729:5-22</u>)
MH	Mental Health	DO, MD, RPH, APRN, PA		<u>Clinic and Prescriber Office</u> (OAC <u>4729:5-19</u>) or

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				Institutional (Coming Soon)
ONC	Oncology Clinic	DO, MD, RPH		Clinic and Prescriber Office (OAC 4729:5-19)
PC	Prescriber Practice	DO, MD, APRN, PA, DDS, 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 (Coming Soon)
RT	Clinical Trials	DO, MD, RPH, DVM, OD, DDS, 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

Business Type	Business Type Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
PC	Prescriber Practice - general medical provider	DO, MD, APRN, PA, DDS, 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

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Business Type	Business Type Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
OTP	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

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

TERMINAL - PAIN MANAGEMENT CLINIC

Business Type	Business Type Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
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)
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 4729:5-11)

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

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

TERMINAL - FACILITY - NON-LIMITED				
Business Type	Business Type 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)
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)

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HC	Hospice	DO, MD, RPH		Non-Limited Facility (OAC 4729:5-22)
IC	Infusion Center	DO, MD, RPH		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	* 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.	Laboratory (OAC 4729:5-16)

TERMINAL - FACILITY - LIMITED

Business Type	Business Type 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 4729:5-15)
DG	Dog Trainer	Management + LENA	Law Enforcement Affiliation or contract required.	Limited Facility (OAC 4729:5-23)
FA	First Aid Room/Department	DO, MD, APRN, PA, RN	RN only if medication is delivered patient specific or for the purposes of	First Aid Department (OAC 4729:5-13)

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			personal furnishing naloxone.	
HH	Home Health Care - providing services to the patient's homes or vaccinations off-site	DO, MD, RPH		Limited Facility (OAC 4729:5-23)
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		Limited Facility (OAC 4729:5-23)
TE	Teaching Institution	DDS, DO, MD, HEAD OF PROGRAM (RN), RPH, APRN, PA, OD, DVM	If injecting into humans, must be - DDS, DO, MD, DDS, OD, RPH, PA or APRN.	Limited Facility (OAC 4729:5-23)

TERMINAL - MEDICAL GAS - LIMITED

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

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TERMINAL - NON-RESIDENT PHARMACY - **NON-LIMITED**

Business Type	Business Type 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.	Non-Resident (Coming Soon) (OAC 4729:5-8)
IP	Pharmacy Servicing Institutions	RPH	Must hold pharmacist license in state where pharmacy is located. May included Mental Health Pharmacies & Nursing Home Inpatient Pharmacies	Non-Resident (Coming Soon) (OAC 4729:5-8)
MO	Mail Order Pharmacy	RPH	Must hold pharmacist license in state where pharmacy is located.	Non-Resident (Coming Soon) (OAC 4729:5-8)
NU	Nuclear Pharmacy	RPH	Must hold pharmacist license in state where pharmacy is located.	Non-Resident (Coming Soon) (OAC 4729:5-8)
SP	Specialty Pharmacy - High \$ Drugs	RPH	Must hold pharmacist license in state where pharmacy is located. May include compounding	Non-Resident (Coming Soon) (OAC 4729:5-8)

TERMINAL - PHARMACY - **NON-LIMITED**

Business Type	Business Type Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
CF	Central Fill Pharmacy	RPH		Outpatient Pharmacy (OAC 4729:5-5)

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CH	Charitable Pharmacy	RPH	Must provide tax exempt paperwork.	Outpatient Pharmacy (OAC 4729:5-5)
CP	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		Institutional (Coming Soon)
II	Independent Community Retail (1 Outlet)	RPH		Outpatient Pharmacy (OAC 4729:5-5)
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 (Coming Soon)
IS	Small Chain Retail (2-11 Outlets)	RPH		Outpatient Pharmacy (OAC 4729:5-5)
KI	Kiosk	RPH		Institutional (Coming Soon)
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)

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ONC	Oncology Pharmacy	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

Business Type	Business Type Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
CR	Consulting Pharmacy	RPH	*Category II only	Outpatient Pharmacy (OAC 4729:5-5) or Institutional (Coming Soon)
CRP	Contract Remote Order Entry	RPH	*Category II only	Outpatient/Institutional (Coming Soon) - Specifically Remote Order Entry Requirements
MTM	Medication Therapy Management	RPH	*Category II only	Medication Therapy Management (Coming Soon) (OAC 4729:5-12)

TERMINAL - NON-RESIDENT PHARMACY - LIMITED

Business Type	Business Type Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
CR	Consulting Pharmacy	RPH	*Category II only Must hold pharmacist license in state where pharmacy is located.	Non-Resident (Coming Soon) (OAC 4729:5-8)

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CRP	Contract Remote Order Entry	RPH	*Category II only Must hold pharmacist license in state where pharmacy is located.	Outpatient/Institutional (Coming Soon) - Specifically Remote Order Entry Requirements
MTM	Medication Therapy Management	RPH	*Category II only Must hold pharmacist license in state where pharmacy is located.	Medication Therapy Management (Coming Soon) (OAC 4729:5-12)

TERMINAL - PHARMACY SUPPLIED CONTINGENCY STOCK - **UNLIMITED**

Business Type	Business Type Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
CI	Correctional Institution	RPH		Institutional (Coming Soon)
CS	Community Pharmacy	RPH		Outpatient (Coming Soon)
HC	Hospice Facility	RPH		Institutional (Coming Soon)
HS	Hospital	RPH		Institutional (Coming Soon)
MH	Mental Health Institution	RPH		Institutional (Coming Soon)
NH	Nursing Home	RPH		Institutional (Coming Soon)

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DISTRIBUTOR OF DANGEROUS DRUGS – MANUFACTURER, OUTSOURCING FACILITY, REPACKAGER, AND THIRD-PARTY LOGISTICS PROVIDER				
Business Type	Business Type 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 4729:6-10)
RE	Repackager	Management	Must provide FDA registration	Repackager (Coming Soon) (OAC 4729:6-9)
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 4729:6-11)

WHOLESALE				
BC	Bulk Pharmaceutical Chemical Seller	Management		Wholesale Distributor (Coming Soon) (OAC 4729:6-5)
BG	Buying Group - A group of wholesalers/stores that leverage for better pricing	Management		Wholesale Distributor (Coming Soon) (OAC 4729:6-5)
BR	Broker	Management	If out of state, must have licensure from home state.	Wholesale Distributor (Coming Soon) (OAC 4729:6-7)

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CM	Compressed Medical Gases	Management		
CN	Clinic Wholesaler: Blood Banks, Health Departments	Management		Wholesale Distributor (Coming Soon) (OAC 4729:6-5)
FS	Full Service	Management		Wholesale Distributor (Coming Soon) (OAC 4729:6-5)
IE	Import/Export - importing drugs from in/out of the country	Management		Wholesale Distributor (Coming Soon) (OAC 4729:6-5)
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 4729:6-5)
SD	Samples Distributor	Management		Wholesale Distributor (Coming Soon) (OAC 4729:6-5)
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 4729:6-6)

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WD	Waste Disposal/Reverse Distributor	Management	Must provide DEA & EPA registration	Wholesale Distributor (Coming Soon) (OAC 4729:6-5)
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