



## Resolutions – September 2022

**\*Approval authorized by the Board President pursuant to resolution R-2022-0128.**

### **1) Responsible Person Requirements for Licensure**

The Board hereby makes the following additions to the Responsible Person Requirements for Licensure resolution last amended on January 10, 2022 (R-2022-0341) and publicly posted at [www.pharmacy.ohio.gov/RP](http://www.pharmacy.ohio.gov/RP):

- To the Terminal – Facility – Non-Limited license types:

TERMINAL - FACILITY - <b>NON-LIMITED</b>				
Business Type	Business Type Definition	Approved Credentials for Responsible Person	Special Requirements	Applicable Inspection Guide
IC	Infusion Center	DO, MD, RPH, <b>APRN, PA</b>		<a href="#">Non-Limited Facility</a> (OAC <a href="#">4729:5-22</a> )

### **2) Approval of Compliance Team for Non-Resident Compounding Pharmacy Inspections**

The Board hereby adds the Compliance Team (<https://thecomplianceteam.org/>) to the list of approved providers of non-resident pharmacy compounding inspections in accordance with paragraph (H) of OAC 4729:5-8-04. The Board further authorizes the amended filing of OAC 4729:5-8-04(H) to add the Compliance Team to the list of organizations approved in the rule.



### **3) Naloxone for Emergency Use (MetroHealth / ADAMHS Board of Cuyahoga County)\***

*The Board hereby finds it permissible to deploy naloxone for emergency use in accordance with the following standards:*

- *Naloxone for emergency use shall be maintained in insulated boxes that protects the medication from moisture.*
- *Excursions for naloxone stored for emergency use shall be permitted between 39°F – 101°F.*
- *Naloxone shall be replaced if it has experienced temperatures below -5°F or over 104°F for more than 48 hours.*
- *Where applicable, the naloxone should be stored in a shaded area of the park.*
- *Each box shall utilize a device or time temperature indicator (for an example, please see: <https://multimedia.3m.com/mws/media/2155060/3mtm-monitormarktm-time-temperature-indicators-brochure.pdf>)*
- *Each box shall prominently display the following warning on the box that includes all the following elements:*
  - *Naloxone freezes at temperatures below 5°F (-15°C).*
  - *If this happens, the device will not spray.*
  - *If naloxone is frozen and is needed in an emergency, do NOT wait for the naloxone to thaw. Get emergency medical help right away.*

*Studies utilized to authorize the proposal:*

- [\*Effect of Extreme Temperature on Naloxone Nasal Spray Dispensing Device Performance - PubMed \(nih.gov\)\*](#)
- [\*The effects of heat and freeze-thaw cycling on naloxone stability | Harm Reduction Journal | Full Text \(biomedcentral.com\)\*](#)
- [\*Effect of Extreme Temperature on Naloxone Nasal Spray Dispensing Device Performance | Prehospital and Disaster Medicine | Cambridge Core\*](#)

### **4) Wholesale Sales of Non-Controlled Dangerous Drugs Conducted Local Health Departments\***

*Pursuant to division (A)(3)(c) of section 4729.51 of the Revised Code, the Board authorized amendments to rule 4729:5-3-09 of the Administrative Code to permit occasional wholesale sales of non-controlled dangerous drugs by a local health department licensed as a terminal distributor of dangerous drugs for the purpose of improving or promoting public health within the department's jurisdiction and to exempt such authorization from the current limitations set forth in paragraph (B) of the rule. The Board hereby finds it is in the public interest to authorize this practice while the rule is pending. Licensees shall comply with all required recordkeeping requirements to conduct a sale of dangerous drugs in accordance with rule 4729:5-3-09 of the Administrative Code.*