Responsible Person Site Visit Sample Checklist

Updated 9/9/2026

This checklist is intended to assist terminal distributors of dangerous drugs in complying with the responsible person requirements of OAC 4729:5-2-01 (effective February 1, 2027). For more information about these requirements visit: www.pharmacy.ohio.gov/responsible.

Please be advised that this checklist is reference material for licensees and applicants and does not represent a specific or exhaustive list of requirements for each license type. For questions regarding this checklist, please consult your designated inspection guide: https://www.pharmacy.ohio.gov/Compliance/InspectionGuides

REMINDER: OAC 4729:5-2-01 (effective February 1, 2027) requires a copy of this documentation to be maintained at, or accessible by, the terminal distributor of dangerous drugs where the visit was conducted for immediate on-site inspection by an agent, officer, or inspector of the Board.

The use of this document does not bind the Ohio Board of Pharmacy, and does not confer any rights, privileges, benefits, or immunities for or on any person, applicant, or licensee.

Responsible Person Site Visit Checklist

Date of Visit: _____ **TDDD License Number: _____**

Yes	No	N/A	Drug Security and Storage
☐	☐	☐	Access to non-controlled drugs is limited to authorized personnel*.
☐	☐	☐	Access to controlled substances is limited to authorized personnel*.
☐	☐	☐	Controlled substances are stored in a securely locked, substantially constructed cabinet or safe to deter and detect unauthorized access.
☐	☐	☐	Prescription blanks used for writing prescriptions are limited to authorized personnel*.
☐	☐	☐	D.E.A. controlled substance order forms (Form 222) are secured when not in use.
☐	☐	☐	The licensee has completed a documented controlled substance inventory within the past 13 months in accordance with OAC 4729:5-3-07.
☐	☐	☐	All areas where dangerous drugs and devices are stored are dry, well-lit, well-ventilated, and maintained in a clean and orderly condition (e.g., free of personal items, including food and beverages).
☐	☐	☐	Drugs available in active inventory are within date (e.g., not expired).
☐	☐	☐	Hypodermics are either physically secured to prevent unauthorized access or stored in areas where members of the public are supervised by individuals authorized to administer injections.
☐	☐	☐	FOR ALTERNATE DISPENSING LOCATIONS: The location complies with the requirements of OAC 4729:5-3-24.

**Authorized personnel varies by license type. Please consult your respective Chapter of the Ohio Administrative Code and/or inspection guide.*

NOTES, OBSERVATIONS, OR REQUIRED CORRECTIONS (if applicable):

Yes	No	N/A	Storage and Disposal of Adulterated/Expired Drugs
☐	☐	☐	Adulterated/expired drugs are stored in a secure area that prohibits access by unauthorized persons and is separate from active drug stock (e.g., areas used for the storage of unexpired/unadulterated drugs).
☐	☐	☐	Adulterated/expired drugs are stored no longer than one year from the date of adulteration or expiration.
☐	☐	☐	Controlled substance inventory is disposed of in a non-retrievable manner in accordance with OAC 4729:5-3-01.
☐	☐	☐	Records documenting controlled substance inventory disposal (DEA Form 41) contain the required information.
☐	☐	☐	Records documenting the disposal of unused portions of controlled substances resulting from patient administration (i.e., waste) contain all the required information.
☐	☐	☐	Records documenting non-controlled substance inventory disposal contain the required information.

NOTES, OBSERVATIONS, OR REQUIRED CORRECTIONS (if applicable):

Yes	No	N/A	Drug Purchases, Sales & Recalls
☐	☐	☐	Records of receipt of drugs by a licensee contain all the required information.
☐	☐	☐	The licensee has conducted an annual, documented query of eLicense Ohio for each Board licensed facility from whom it purchases to ensure they have an active Ohio Board of Pharmacy license. This includes the purchase of active pharmaceutical ingredients or API.
☐	☐	☐	If the licensee receives patient-specific medication (e.g., acting an alternate location), the pharmacies providing those medications have an active Ohio Board of Pharmacy license.
☐	☐	☐	Only FDA-approved drugs are purchased (e.g., drugs purchased should not be labeled in a foreign language or indicate that the drug is "for research purposes only" or "for export only.")
☐	☐	☐	If permissible under 4729:5-3-09, records of transfer or sale by the licensee contain the required information.
☐	☐	☐	A written procedure to manage recalls (see OAC 4729:5-3-18) for the dangerous drugs stocked, dispensed, or personally furnished by the licensee has been implemented and is updated as necessary.

NOTES, OBSERVATIONS, OR REQUIRED CORRECTIONS (if applicable):

Yes	No	N/A	Compounding & Drug Preparation
☐	☐	☐	**For Prescriber Compounding ONLY:** The licensee complies with the immediate-use prescriber compounding rule (OAC 4729:7-3-04) when engaged in immediate-use compounding.
☐	☐	☐	The licensee complies with USP 797 for all sterile compounding activities that do not fall under the prescriber immediate-use provision (OAC 4729:7-3-04) or the pharmacy sterile compounding exemptions (OAC 4729:7-2-02).
☐	☐	☐	The licensee complies with USP 795 for all non-sterile compounding activities.
☐	☐	☐	The licensee complies with all applicable requirements for the preparation of hazardous drugs (for prescriber clinics see OAC 4729:7-3-05 | for pharmacies see OAC 4729:7-2-03).
☐	☐	☐	Reconstituted cosmetic neurotoxins (e.g., Botox®, Dysport®, XEOMIN®, etc.) are discarded in accordance with the manufacturer's labeling. If the label says, "use within 24 hours," then the product must be used within that timeframe. If no such beyond-use date or timeframe exists on the label, the drug may only be used for up to six hours following preparation.
☐	☐	☐	Compounded drugs are validated by a prescriber or pharmacist prior to administration*, personally furnishing, or dispensing. (*NOTE: Nurses may validate compounded drugs under certain conditions prior to administration.)
☐	☐	☐	The licensee complies with the applicable compounding record keeping requirements (for prescriber clinics see OAC 4729:7-3-06 | for pharmacies see OAC 4729:7-2-03).

NOTES, OBSERVATIONS, OR REQUIRED CORRECTIONS (if applicable):

Yes	No	N/A	Drug Administration
☐	☐	☐	Administration records for controlled substances contain the required information.
☐	☐	☐	Administration records for non-controlled substances contain the required information.
☐	☐	☐	Drugs administered by a health care professional, who is not a prescriber, have documentation of an order issued by a prescriber or protocol authorizing the administration of the drug.
☐	☐	☐	Administration of drugs is conducted in accordance with a health care professional's applicable scope of practice (e.g., are not administering drugs outside of the professional's scope of practice).
☐	☐	☐	Patient-specific drugs are only administered to the patient for whom the drug was dispensed.
☐	☐	☐	Multi-dose vials are labeled with the date opened and/or the beyond-use date (e.g. 28 days, unless otherwise specified by the manufacturer).
☐	☐	☐	Use of protocols for drug administration complies with requirements of OAC 4729:5-3-12.

NOTES, OBSERVATIONS, OR REQUIRED CORRECTIONS (if applicable):

Yes	No	N/A	Dispensing (Applicable to Pharmacies ONLY)
☐	☐	☐	Records of dispensing by a pharmacist contain the required information.
☐	☐	☐	Drugs that are dispensed contain all the required labeling.
☐	☐	☐	Dispensing of drugs is documented by a pharmacist using positive identification.
☐	☐	☐	Prospective drug utilization review is conducted by a pharmacist prior to dispensing (OAC 4729:5-5-08).
☐	☐	☐	The pharmacy operates or participates in a quality assurance program that documents and assesses dispensing errors to determine cause and an appropriate response to improve the quality of pharmacy service and prevent errors in accordance with OAC 4729:5-3-22.
☐	☐	☐	Patient counseling is offered to patients or caregivers either in writing or verbally in accordance with OAC 4729:5-5-09.

NOTES, OBSERVATIONS, OR REQUIRED CORRECTIONS (if applicable):

Yes	No	N/A	Personally Furnishing (NOT Applicable to Pharmacies)
☐	☐	☐	Records of personally furnishing by a prescriber contain the required information.
☐	☐	☐	Drugs that are personally furnished contain all the required labeling.
☐	☐	☐	Personally furnishing drugs is documented by a prescriber using positive identification.
☐	☐	☐	Patient counseling is offered to patients or caregivers either in writing or verbally.

NOTES, OBSERVATIONS, OR REQUIRED CORRECTIONS (if applicable):

Yes	No	N/A	General Record Keeping and Theft or Significant Loss Reporting
☐	☐	☐	All required records are maintained for a period of three years.
☐	☐	☐	All theft and significant losses of drugs or drug documents to the Ohio Board of Pharmacy in the required timeframe.

NOTES, OBSERVATIONS, OR REQUIRED CORRECTIONS (if applicable):

Yes	No	N/A	Temperature Monitoring
☐	☐	☐	Refrigerators and freezers used for the storage of drugs and devices are monitored with temperature logs (with daily observations, even on days the licensee is closed) or a temperature monitoring system capable of detecting and alerting staff of a temperature excursion.
☐	☐	☐	Temperature control monitoring records contain the required information.
☐	☐	☐	The licensee has implemented policies and procedures to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs.
☐	☐	☐	No food or beverage products are stored in refrigerators or freezers used to store drugs. **NOTE:** Licensees may keep unopened bottled water in the refrigerator doors to help maintain consistent temperatures.

NOTES, OBSERVATIONS, OR REQUIRED CORRECTIONS (if applicable):

Yes	No	N/A	Other Requirements (TDDD Specific)
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NOTES, OBSERVATIONS, OR REQUIRED CORRECTIONS (if applicable):

Acknowledgement	
I hereby attest that a site visit in accordance with OAC 4729:5-2-01 has been completed on the date listed in this form. I acknowledge that any deficiencies or potential violations will be corrected in a timely manner in accordance with OAC 4729:5-2-01 (G)(5).	
Signature of the Responsible Person (RP)	*Date of Site Visit Completion*
Full Name of RP	