Witness

Mala Cullipher, R.Ph.

Senior Pharmacist

Florida Department of Health

On August 15, 2024, SENIOR PHARMACIST MALA CULLIPHER accompanied by VERONICA GIBSON-RAY, MQAI conducted a routine inspection at OUSIA PHARMACY located at 5194 MARINER BOULEVARD, SPRING HILL, FL 34609, SSCP file number 29867 where A[redacted] H[redacted], [redacted], [redacted] was present for the inspection.

The pharmacy had failed their initial sterile compounding new business inspection on April 26, 2024, due to not having a properly certified hood to compound sterile products which would qualify as Category 2 or Category 3 compounded injectable solutions. The firm's owners or pharmacist were informed of the failure as neither had prior experience with sterile compounding or understood basic concepts for compounding injectable medications.

When the inspectors arrived, the front door of the pharmacy, 5194 MARINER BOULEVARD was not accessible, however, there was no prescription department sign displayed. Inspectors had to enter from 5196 MARINER BLVD, SPRING HILL, FL urine drug testing side owned by the same owner.

Exhibit 1 Locked Front Door of Pharmacy with no sign for the public to enter from the side.

There is a single pharmacist who works at the pharmacy located at 5194 Mariner Blvd. The entrance to the pharmacy is located at 5196 Mariner Blvd, Spring Hill, FL. The units are conjoined by doors at the front and back to the actual pharmacy. 5196 Mariner Blvd is the urine drug testing side, where the inspectors met with an IT person who also manages Best Rx, the firm's pharmacy computer system. There is also a former technician on the urine drug testing side of the firm where these doors can be used to access the pharmacy. The front door access to the pharmacy remains locked, leaving the pharmacy accessible by the urine testing side of the firm. Compounded product was confirmed to be stored in the refrigerator at 5196 Mariner Blvd, Spring Hill, FL, the urine testing side of the business.

The pharmacy has not received a license to be able to compound and dispense injectable compounded medications but had started compounding and dispensing since June 2024 as explained by the pharmacist, without following any regulations that pertain to the novel USP <797> chapter.

This is a violation of 64B16-28.802(1) Special Sterile Compounding Permits for Pharmacies and Outsourcing Facilities, which states**, "(1) A Special Sterile Compounding Permit (SSCP) is required before any pharmacy may engage in the preparation of compounded sterile products."** Per this rule, **"(3) All sterile compounding shall be done in strict compliance with the standards set forth in Rules 64B16-27.700 and 64B16-27.797, F.A.C."**

The firm informed the inspector on May 20th, 2024, that they had applied for an extension from the Board of Pharmacy and that construction was going to happen to build a cleanroom suite to comply with state regulations on sterile compounding. There is no indication of this extension being granted.

The pharmacist at the firm was unable to demonstrate basic hand hygiene or don personal protective equipment and still did not have adequate core skills and competency assessments documented to prove she can safely compound or sterilize non-sterile powders used to compound injectable compounds aseptically.

All required observational assessments and documentation of hand hygiene, garbing, cleaning, media fills representing aseptic technique, gloved fingertip sampling, or surface sampling has not been completed.

This is a failure to comply with USP <797>, which states**, "All personnel who compound or have direct oversight of compounding personnel must be initially trained and qualified by demonstrating knowledge and competency in compounding CSPs according to the requirements in this section before being allowed to perform their job functions independently. Designated person(s) are responsible for creating and implementing a training program for personnel and for ensuring that compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties are initially trained and qualified by demonstrating knowledge and competency in maintaining the quality of the sterile compounding environment before being allowed to perform their job functions independently."**

Regarding Section 3.3 of USP<797>**, "Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must be properly garbed. Garb must be donned and doffed in an order that reduces the risk of contamination. The required garb, manner of storage, and order of garbing must be determined by the facility and documented in the facility's SOPs. When preparing Category 2 or Category 3 CSPs, all garb should be donned in a classified area before entering the buffer room. If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb. Skin must not be exposed inside the ISO Class 5 PEC (e.g., gloves must not be donned or doffed inside the ISO Class 5 PEC exposing bare hands). Donning and doffing garb should not occur in the same area at the same time. The minimum garbing requirements for preparing Category 1 and Category 2**

**CSPs include the following:**

- **Low-lint garment with sleeves that fit snugly around the wrists**
- **and an enclosed neck (e.g., gown or coverall) Low-lint covers for shoes**
- **Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair**
- **Low-lint face mask**
- **Sterile powder-free gloves**
- **If using a RABS (i.e., a CAI or CACI), disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeve."**

Low-lint wipes used inside the CACI were not noted to be sterile if wiping items introduced into the PEC.


Exhibit 2 Non-sterile low lint wipes.

This violates USP <797> revised chapter which states, **"Just before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use."**

These are the same non-sterile wipes which are used to wipe and introduce the uncalibrated portable weighing scale into the ante-chamber of the CACI.

Equipment calibrations are deficient.

The pharmacy failed to calibrate a properly functioning sterile hood and has not classified their CACI in SCA but is compounding injectable medication such as Semaglutide, Tirzepatide and NAD plus injections without any sterility, endotoxin, or stability testing, as well as other required testing, in order to assign the vials a one year beyond use date which exceeds the requirements of USP <797>. Such compounds qualify as Category 3 compounds and require full garbing and a cleanroom suite. It was noted several prescriptions for Tirzepatide were filled and dispensed to patients and possibly physician clinics.

Exhibit 3 Negative pressure CACI in SCA uncertified and surrounded with cardboard.

USP <797> requires that, **"Equipment must be placed in a manner that facilitates sterile compounding operations. The equipment must be capable of operating properly and within required performance parameters. Compounding personnel must follow established SOPs for the calibration, maintenance, cleaning, and use of the equipment based on the manufacturer's recommendations. Personnel must maintain records from equipment calibration, verification, and maintenance in accordance with the requirements in 20. Documentation."**

The firm has released Tirzepatide 5mg/0.5ml to patients, specifically lot 159090, without ensuring that components, container closures that come into contact with the injectable is sterile. In-fact the use of non-sterile pipettes is not permitted by the USP.

USP<797> states, **"Supplies in direct contact with the CSP must be sterile and depyrogenated."**

Exhibit 4 Compounded unsterilized vials of Tirzepatide not tested prior to release.

The firm has compounded copies of commercially available drugs on an anticipatory basis in violation of 64B16-27.700 Definition of Compounding, which states, **"(c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist."**

These are serious violations of several sections of USP <797> as adopted in 64B16-27.797 (1) (a) Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

Per 2022/2023 USP <797>, **"The requirements in this chapter must be met to ensure the sterility of any CSP. Although the list below is not exhaustive, the following must be sterile:**
**• Injections, including infusions"**

Further, according to the chapter, **"Category 3 CSPs undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for personnel qualification, use of sterile garb, use of sporicidal disinfectants, frequency of environmental monitoring, and stability determination. Category 3 CSPs may be assigned longer BUDs than those set for Category 2 CSPs but not exceeding the limits in Table 14 (see 14. Establishing Beyond-Use Dates), if compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter (see 14.4 Additional Requirements for Category 3 CSPs)."**

Equipment that is supposed to be used to sterilize utensils, beakers, glassware used in compounding or rubber stoppers placed on vials are not sterilized as this type of equipment such as a dry heat oven is simply missing or not validated using endotoxin challenge vials to determine if heat is reaching the cold spots. Autoclave was not validated using biological indicators and instruments were not documented as having been sterilized.

Per USP <797>, **"The effectiveness of the dry heat depyrogenation cycle must be established initially and verified annually using ECVs to demonstrate that the cycle can achieve a ≥3-log reduction in endotoxins (see Bacterial Endotoxins Test <85>). The effectiveness of the depyrogenation cycle must be re-established if there are changes to the depyrogenation cycle described in SOPs (e.g., changes in load conditions, duration, or temperature). This verification must be documented."**

Further, per USP<797>, **"The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization <1229.9>)."**

Filtration as the method of sterilization could not be demonstrated, as the pharmacy, up to this point, did not have any sterilizing filters in stock.

Per USP <797>, **"Sterilizing filters must be sterile, dehydrogenated, have a nominal pore size of 0.22 µm or smaller, and be appropriate for pharmaceutical use. Sterilizing filters with labeling those states "for laboratory use only" or a similar statement must not be used for compounding CSPs. Sterilizing filters must be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (i.e., pressure, flow rate, and volume filtered)."**

Non-viable and viable air and surface sampling of the compounding environment has never been completed as the firm failed to get the hood certified initially or every 6 months. The segregated compounding area was cluttered with cardboard boxes (Exhibit 1) of supplies and the hood was switched off throughout the entire inspection with the door to the SCA that remained wide open. The externally ventilated negative pressure hood is not the appropriate environment to compound non-hazardous injectable drugs.

Exhibit 5 Unclassified PEC/CACI used to compound Semaglutide and Tirzepatide Injection.

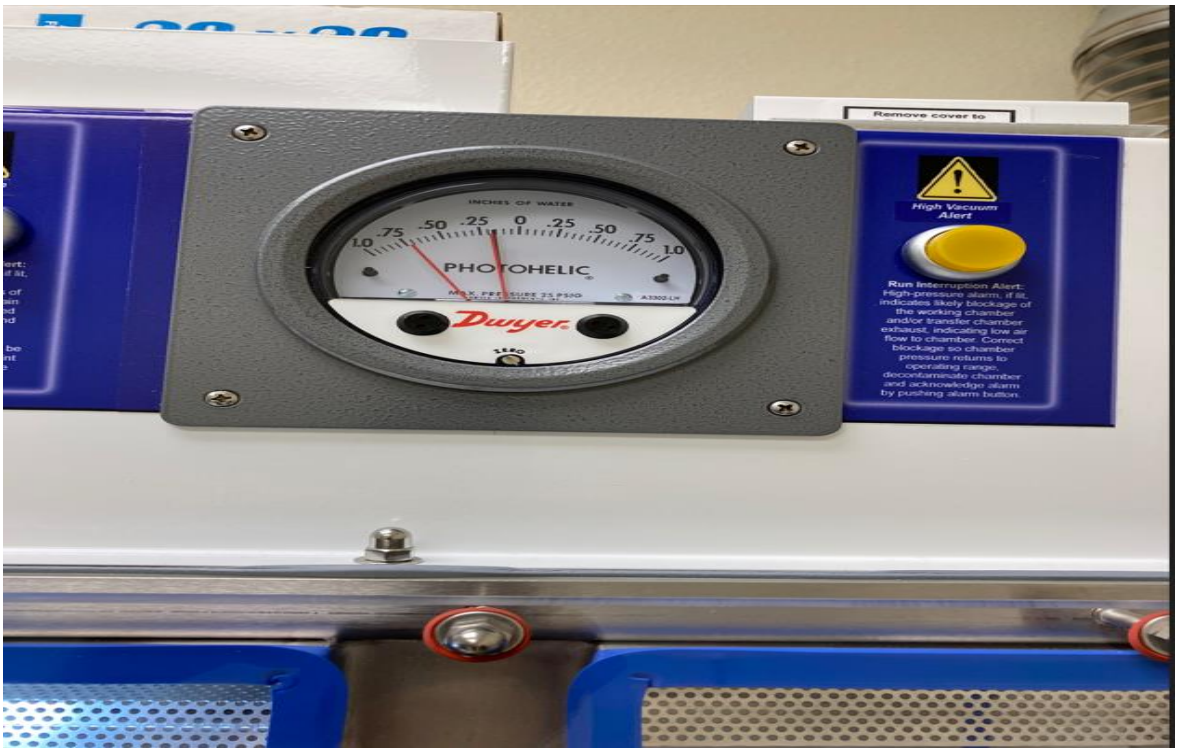

Exhibit 6 Negative Pressure Gauge incorrect PEC for compounding non-hazardous drugs.

Per USP <797>, **"Facilities used for compounding CSPs must be designed so that air quality improves with movement through separate operational areas to the PEC."** And per the chapter, **"Category 1, Category 2, and Category 3 CSPs must be compounded in an ISO Class 5 or better PEC."**

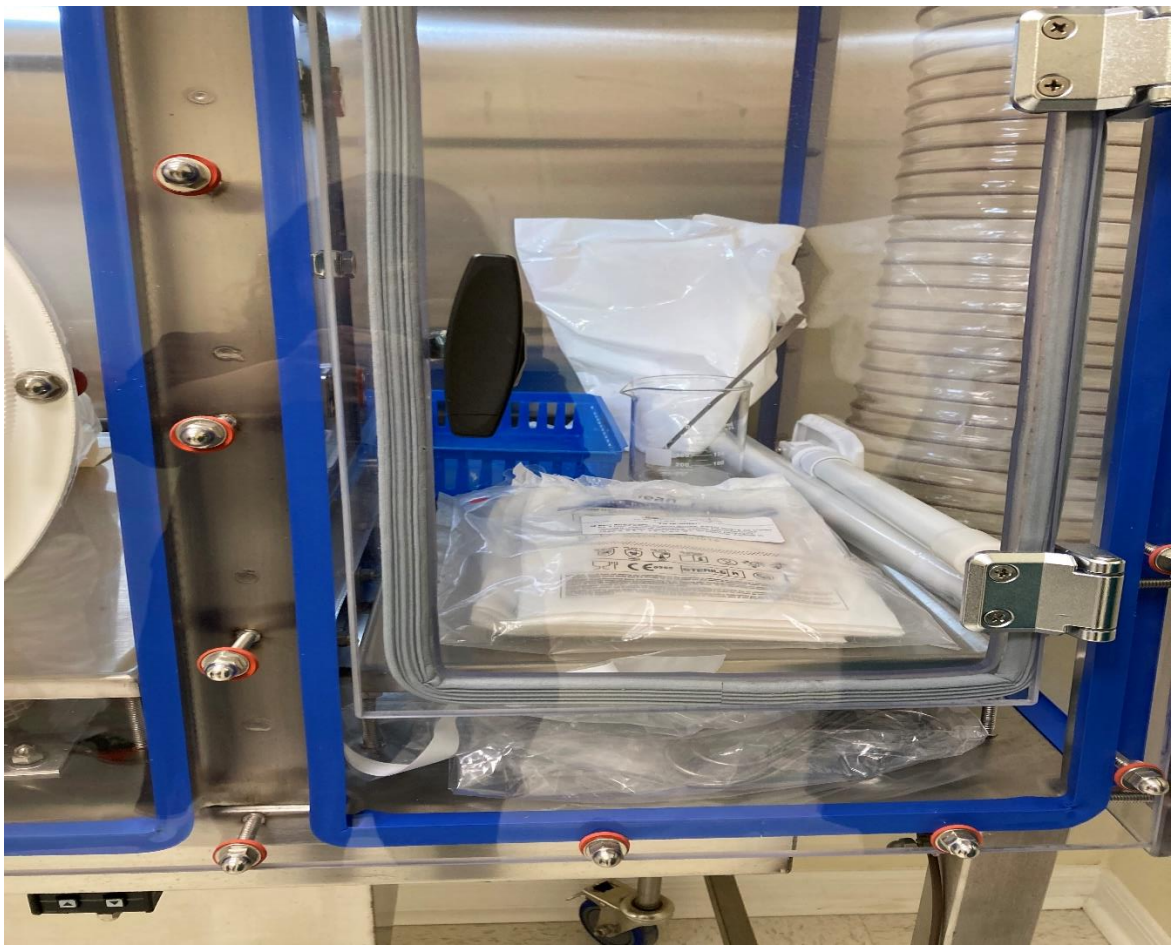

Exhibit 7 Cluttered Antechamber where Active Pharmaceutical Ingredient Powder is weighed in an uncertified hood.

Per USP <797>, **"Before a compounding area is used to compound either Category 1, Category 2, or Category 3 CSPs, it must be independently certified using the requirements in this chapter and when applicable, manufacturer specifications. Certification indicates that the compounding area is meeting its design and air quality specifications."** Also, per the chapter, **"Certification of the classified areas including the PEC must be performed initially, and recertification must be performed at least every 6 months and must include:**

- **Airflow testing: Airflow testing is performed to determine acceptability of the air velocity, the room air exchange rate, and the room, pressure differential in doorways between adjacent rooms to ensure consistent airflow and that the appropriate quality of air is maintained under dynamic operating conditions. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on the certification report.**
- **HEPA filter integrity testing: HEPA filters must be leak tested at the factory and then leak tested again after installation and as part of Total particle count testing: (See 5.1 Total Airborne Particle Sampling.) Total particle count testing must be performed under dynamic recertification, operating conditions using calibrated electronic equipment.**
- **Dynamic airflow smoke pattern test: Smoke pattern tests must be performed for**

**each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).**

**All certification and recertification records must be reviewed by the designated person(s) to ensure that the classified environments meet the minimum requirements in this chapter. The number of personnel present in each PEC and SEC during total particle-count tests and dynamic airflow smoke-pattern tests must be documented. Records must be maintained in accordance with the requirements in 20. Documentation."**

Labeling of compounds is inadequate and inaccurate based on F.A.C., 64B16-28.108 Labels and Labeling of Medicinal Drugs. The pharmacy assigns a one year beyond use date to compounded products and immediately releases these unsterilized injectables, without quarantine or testing confirmation after batching them in quantities of 50 articles. Release prior to testing to ensure injections have met the conditions of sterility or endotoxin testing and numerous other tests as required by USP, is a violation of 64B16.27.797 (1)(b) and (c) The Standards of Practice for Compounding Sterile Products which states,"

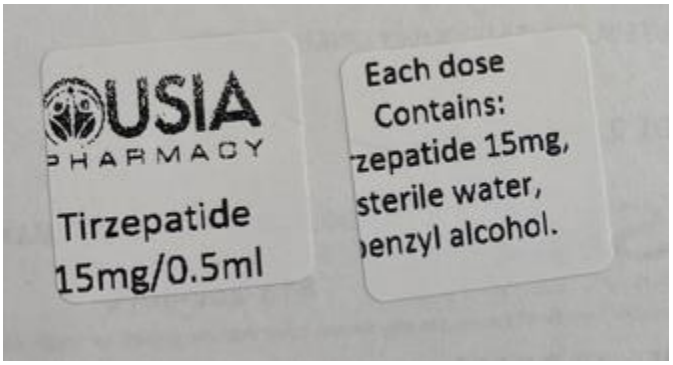


Exhibit 8 Incorrect immediate container label missing dosage form, route and several other elements.

Additionally, labels did not state the injection was a compounded drug. There was unlabeled active pharmaceutical ingredient saved in the refrigerator after weighing in an unclassified hood.

Compounded non-sterile injections were noted in the refrigerator, in an unlabeled condition which cannot prevent mix-ups. These vials were not even crimped.

Exhibit 9 Unlabeled vials in the refrigerator

Exhibit 10 Allegedly Tirzepatide powder unlabeled and pre-weighed in an uncertified, unclassified CACI.

According to USP<797>, **"The label on each immediate container of the CSP must, at a minimum, display prominently and legibly, the following information: Assigned internal identification number (e.g. barcode, prescription, order, or lot number)**

- **Active ingredient(s) and their amount(s), activity(ies), or concentration(s)**
- **Storage conditions if other than controlled room temperature**

- **BUD**
- **Dosage form**
- **Total amount or volume if it is not obvious from the container**
- **If it is a single-dose container, a statement stating such when space permits if it is a multiple-dose container, a statement stating such.**

**The labeling on the CSP must display the following information, as applicable:**

- **Route(s) of administration**
- **Special handling instructions**
- **Warning statement(s)**
- **Compounding facility name and contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded.**

**The labeling on the CSP should indicate that the preparation is compounded."**

Category 3 drugs are not labeled according to USP<797>, they are assigned a one year beyond use date without being aseptically processed in a cleanroom suite, which displays as follows**, "**

**Table 14: BUD Limits for Category 3 CSPs[a]**

| Preparation Characteristics | Storage Conditions | | |
|---|---|---|---|
| Compounding Method | Controlled Room Temperature (20°–25°) | Refrigerator (2°–8°) | Freezer (–25° to –10°) |
| Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs | 60 days | 90 days | 120 days |
| Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs | 90 days | 120 days | 180 days |

[a] A shorter BUD must be assigned when the physical and chemical stability of the CSP is less than the BUD limit stated in the table. **"**

This violates Section 4 of USP <797>, which states, **"Sterile compounding facilities must be designed, outfitted, and maintained properly to minimize the risk of contamination of CSPs. The required air quality must be achieved and maintained through PECs and secondary engineering controls (SECs)."**

The pharmacist stated that there are no compounding records maintained or master formulation record to guide the pharmacist how to compound. No documentation was provided upon several requests, except for saved certificates of analysis. The firm lacks the understanding and a license issued by the Board to be able to safely compound in the current environment.

This also violates 64B16-28.140 F.A.C. Record Maintenance Systems for all permits, which states**," 2. Data processing systems shall have a workable (electronic) data retention system which can produce an audit trail of drug usage for the preceding four (4) years as specified in Rule 64B16-27.800, F.A.C.**

**(g) Change or discontinuance of a data processing system.**

**1. Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:**

**a. Transfer the records of dispensing to the new data processing system, or**

**b. Purge the records of dispensing to a printout which contains the same information required on the daily printout as specified in paragraph (3)(b), of this section. The information on this hard-copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.**

**2. Other records. A pharmacy that changes or discontinues use of a data processing system**

**must:**

**a. Transfer the records to the new data processing system, or**

**b. Purge the records to a printout which contains all of the information required on the original document.**

**3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for four (4) years from the date of initial entry into the data processing system.**

**(h) Loss of Data. The prescription department manager shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss."**.

The pharmacist demonstrated that she uses pipettes which are non-sterile to draw up solution to place them into vials rather than sterile syringes. Components are not used according to requirements of 64B16-27.797(1)(a) F.A.C. The Standards of Practice for Compounding Sterile Products.

The Beyond use date assigned by the firm for Tirzepatide and Semaglutide, does not specify any lot # and is not supported by studies including stability, sterility, endotoxin testing, antimicrobial effectiveness testing, container closure integrity or subvisible particle testing according to USP <788>.

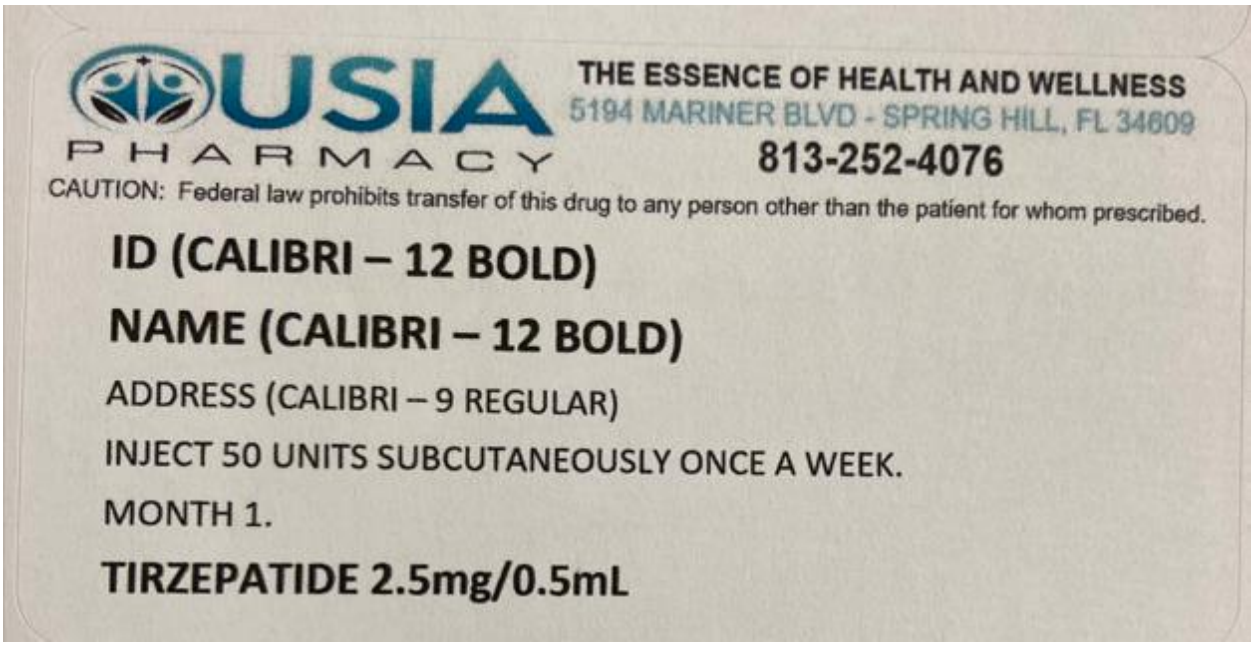


Exhibit 11 Tirzepatide Injection missing lot# and beyond use date.

The firm is compounding non-hazardous weight loss medication and stores the weighed API back in the freezer outside of a hood that qualifies as ISO 5. The hood was dirty and there were fibers inside of the hood.

The firm compounds in the most unsanitary conditions and has violated all the sterile compounding rules of the state of Florida and is dispensing non-sterile products as they are not even filtering the compounds to sterilize them. No cleaning documentation was provided to the inspectors. Please refer to the

inspection summary and Sections violated of 64B16-27.797 (1) (a), (b) and (c) The Standards of Practice for Compounding Sterile Products.

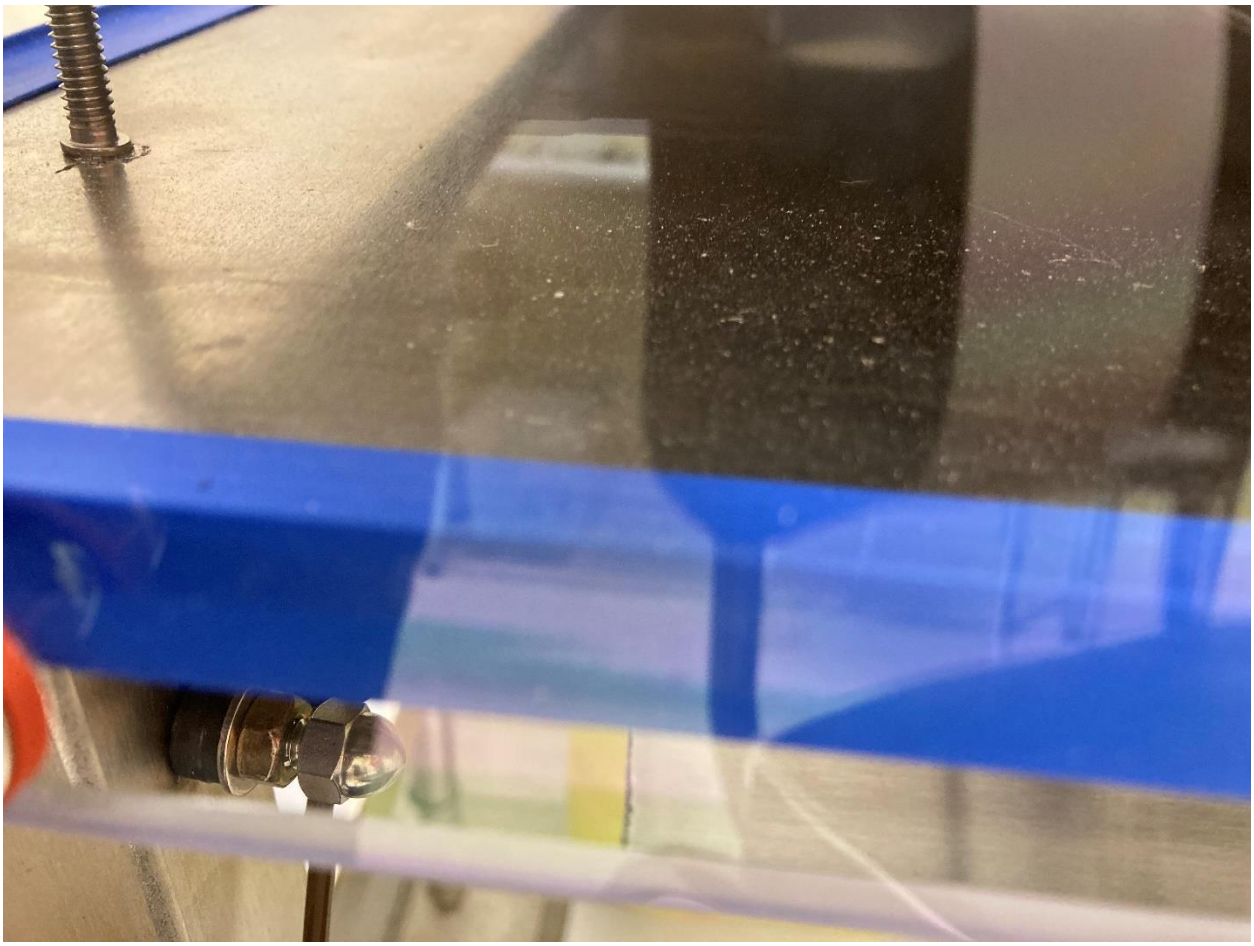

Exhibit 12 Dirt on undertray of CACI in SCA where Category 3 Compounding Occurs.

According to USP<797>, cleaning is deficient**, "Proper placement of the PEC is critical to ensuring an ISO Class 5 environment for preparing CSPs. Placement of the PEC must allow for cleaning around the PEC." How can the firm accomplish this when cardboard boxes appear on the staging cart. This will risk contaminants being introduced in the injections."**

Further, according to USP <797>, **"The SCA and all surfaces (e.g., walls, floors, counters, and equipment) in the SCA must be clean, uncluttered, and dedicated to compounding."**

The firm could not demonstrate compliance with cleaning requirements, considering they are extending the BUD to 1 year of injectable compounds released to patients. The pharmacy did not have any documented cleaning records creating non-compliance with Section 7 of USP<797> which states, **"Cleaning and disinfecting surfaces and applying a sporicidal disinfectant must occur at the minimum frequencies specified in Table 10:**

Table 10. Minimum Frequency for Cleaning and Disinfecting Surfaces and Applying Sporicidal Disinfectants in Classified Areas and in the SCA[a]

| Site | Cleaning | Disinfecting[b] | Applying Sporicidal Disinfectant |
|---|---|---|---|
| PEC(s) and equipment inside the PEC(s) | • Equipment and all interior surfaces of the PEC daily on days when compounding occurs and when surface contamination is known or suspected | • Equipment and all interior surfaces of the PEC daily on days when compounding occurs and when surface contamination is known or suspected | • Monthly for entities compounding Category 1 and/or Category 2 CSPs<br>• Weekly for entities compounding Category 3 CSPs |

| Site | Cleaning | Disinfecting[b] | Applying Sporicidal Disinfectant |
|---|---|---|---|
| Removable work tray of the PEC, when applicable | • Work surface of the tray daily on days when compounding occurs<br>• All surfaces and the area underneath the work tray monthly | • Work surface of the tray on days when compounding occurs<br>• All surfaces and the area underneath the work tray monthly | • Work surfaces of the tray monthly<br>• All surfaces and the area underneath the work tray monthly |
| Pass-through chambers | • Daily on days when compounding occurs | • Daily on days when compounding occurs | • Monthly for entities compounding Category 1 and/or Category 2 CSPs<br>• Weekly for entities compounding Category 3 CSPs |
| Work surface(s) outside the PEC | • Daily on days when compounding occurs | • Daily on days when compounding occurs | |
| Floor(s) | • Daily on days when compounding occurs | • Daily on days when compounding occurs | |
| Wall(s), door(s), and door frame(s) | • Monthly | • Monthly | • Monthly |
| Ceiling(s)[c] | | | |
| Storage shelving and bin(s) | | | |
| Equipment outside the PEC(s) | | | |

[a] Cleaning of sinks is described in *4.4 Water Sources*.

**Cleaning and disinfecting agents must be selected and used with careful consideration of compatibilities, effectiveness, and user safety. Considerations when selecting and using disinfectants include their antimicrobial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected. After the disinfectant or sporicidal disinfectant is applied to the surface, the agent must be allowed to dwell for the minimum contact time specified by the manufacturer."**

Products released by the pharmacy pose a danger to public health of all patients in Florida who have received these injectable medications.

The PDM stated they do not maintain compounding records. This seriously violates USP <797>, which states. **"A CR must be created for all Category 1, Category 2, and Category 3 CSPs."**

The pharmacy failed to provide proper records of dispensing or refills in violation of 64B16-28.140 Record Maintenance Systems for All Pharmacy Permits, which states, **"2. Data processing systems shall have a workable (electronic) data retention system which can produce an audit trail of drug usage for the preceding four (4) years as specified in Rule 64B16-27.800, F.A.C.**

**(g) Change or discontinuance of a data processing system.**

**1. Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:**

**a. Transfer the records of dispensing to the new data processing system, or**

**b. Purge the records of dispensing to a printout which contains the same information required on the daily printout as specified in paragraph (3)(b), of this section. The information on this hard-copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.**

**2. Other records. A pharmacy that changes or discontinues use of a data processing system must:**

**a. Transfer the records to the new data processing system, or**

**b. Purge the records to a printout which contains all of the information required on the original document.**

**3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for four (4) years from the date of initial entry into the data processing system.**

**(h) Loss of Data. The prescription department manager shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.**

**(2) All transfers of prescriptions must be strictly in accordance with the provisions of Section 465.026, F.S., and Rule 64B16-27.105, F.A.C.**

**(3) Records of dispensing.**

**(a) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.**

**(b) The data processing system shall have the capacity to produce a daily hard-copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:**

**1. Unique identification number of the prescription,**

**2. Date of dispensing,**

**3. Patient name,**

**4. Prescribing practitioner's name,**

**5. Name and strength of the drug product actually dispensed, if generic name, the brand name or manufacturer of drug dispensed,**

**6. Quantity dispensed,**

**7. Initials or an identification code of the dispensing pharmacist; and,**

**8. If not immediately retrievable via CRT display, the following shall also be included on the hard-copy printout:**

**a. Patient's address,**

**b. Prescribing practitioner's address,**

**c. Practitioner's DEA registration number, if the prescription drug order is for a controlled substance,**

**d. Quantity prescribed, if different from the quantity dispensed,**

**e. Date of issuance of the prescription drug order, if different from the date of dispensing; and,**

**f. Total number of refills dispensed to date for that prescription drug order.**

**(c) The daily hard-copy printout shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances."**

No visual inspections of compounded sterile products are completed or documented. According to USP <797>, **"At the completion of compounding, before release and dispensing, the CSP must be visually inspected to determine whether the physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects). The CSP label must be visually inspected to confirm that the CSP and its labeling match the prescription or medication order. The inspection also must include a visual inspection of container closure integrity (e.g., checking for leakage, cracks in the container, or improper seals). Any CSP found to be of unacceptable quality (e.g., observed defects) must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal."**

The pharmacy engages in office use compounding and had a vial labeled with the physician name.

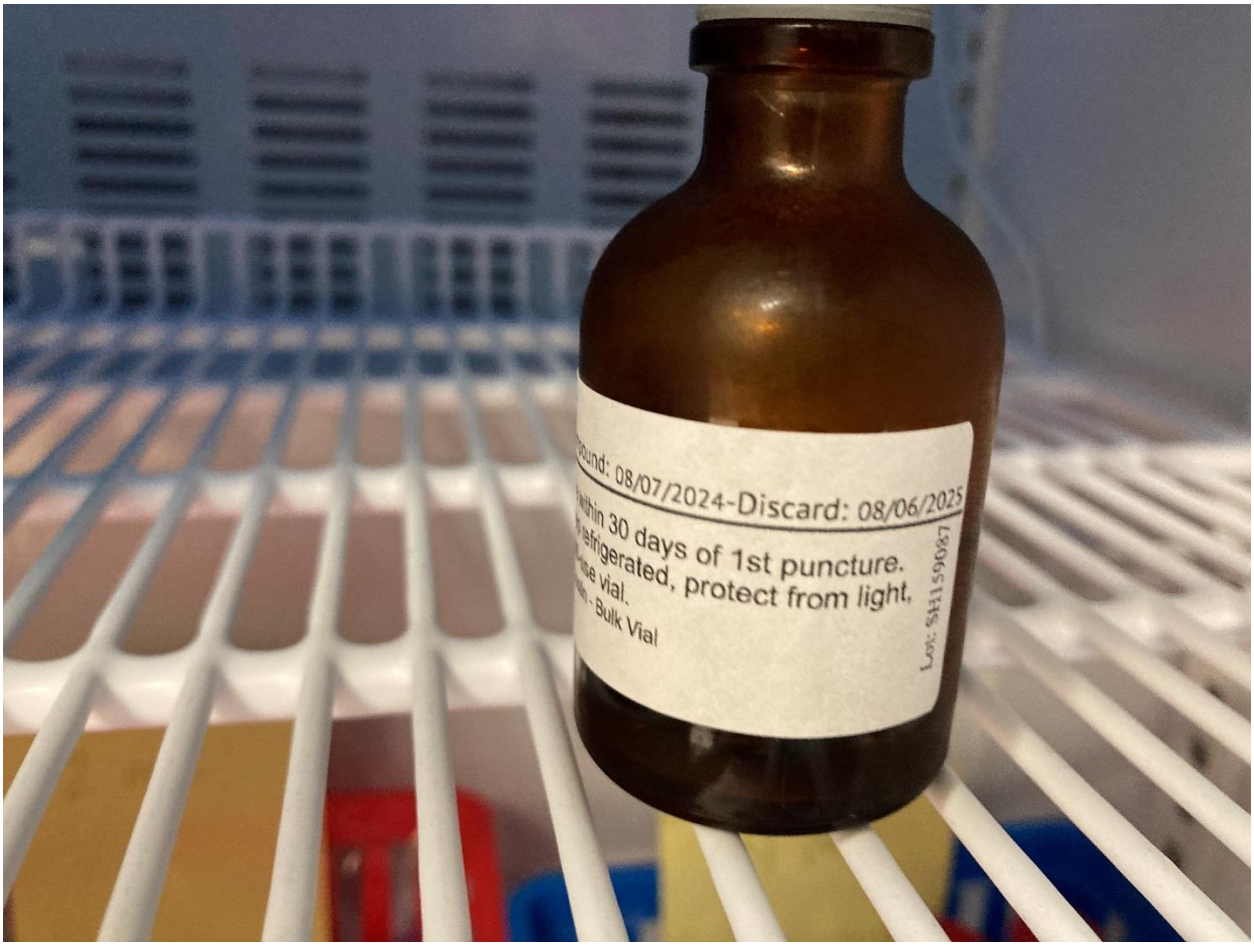


Exhibit 13 Dr Justin bulk vial to be used within 30 days of initial puncture instead of 28 days.

This violates the rule related to office use compounding, 64B16-27.700 (6)(g) Definition of Compounding which states, **"(g) In the case of compounded products intended for human use, the pharmacy must be in full compliance with 21 U.S.C. §353b, including being registered as an Outsourcing Facility. 21 U.S.C. §353b (eff. Nov. 27, 2013) is hereby adopted and incorporated by reference and available at** http://www.flrules.org/Gateway/reference.asp?No=Ref-04180"


Exhibit 14 Dr. Justin Bulk Vial of Semaglutide 2.5mg/1ml compounded 8-7-24.

Compounding personnel are not qualified by training or the completion of core observational assessment skills to compound and release safe injectable medications to the patients of Florida.

Exhibit 15 Improperly garbed personnel with no mask or hair bonnet demonstrating donning of gloves in the unclassified primary engineering control.

The pharmacy had a recall policy, "Recall of Dispensed CSP's", noted on the April 26, 2024 inspection, but has failed to issue a recall of all Category 3 injectable compounded vials not tested, or safely compounded in a proper cleanroom suite while maintaining certification and all requirements of 64B16-27.797, F.A..C. The Standards of Practice for Compounding Sterile Products.

Additional deficiencies are noted on the Inspection summary with their relevant sections.

Signature: _____ Date 10/31/24

(Required to file complaint)

Florida Statutes 837.06, False Official Statements: Whoever knowingly makes a false statement in writing with the intent to mislead a public servant in the performance of his official duty shall be guilty of a misdemeanor of the second degree.


Photo shows area outside of compounding room where a refrigerator housing compounding ingredients were being stored. Refrigerator has been removed from pharmacy.

Exhibit 7

Photo shows room where the compounding was being done. All compounding equipment has been removed.


Photo shows area were compounded products were being stored in refrigerators on 5196 side of pharmacy. Refrigerators have been removed.


Photo shows correct size human trafficking signage.

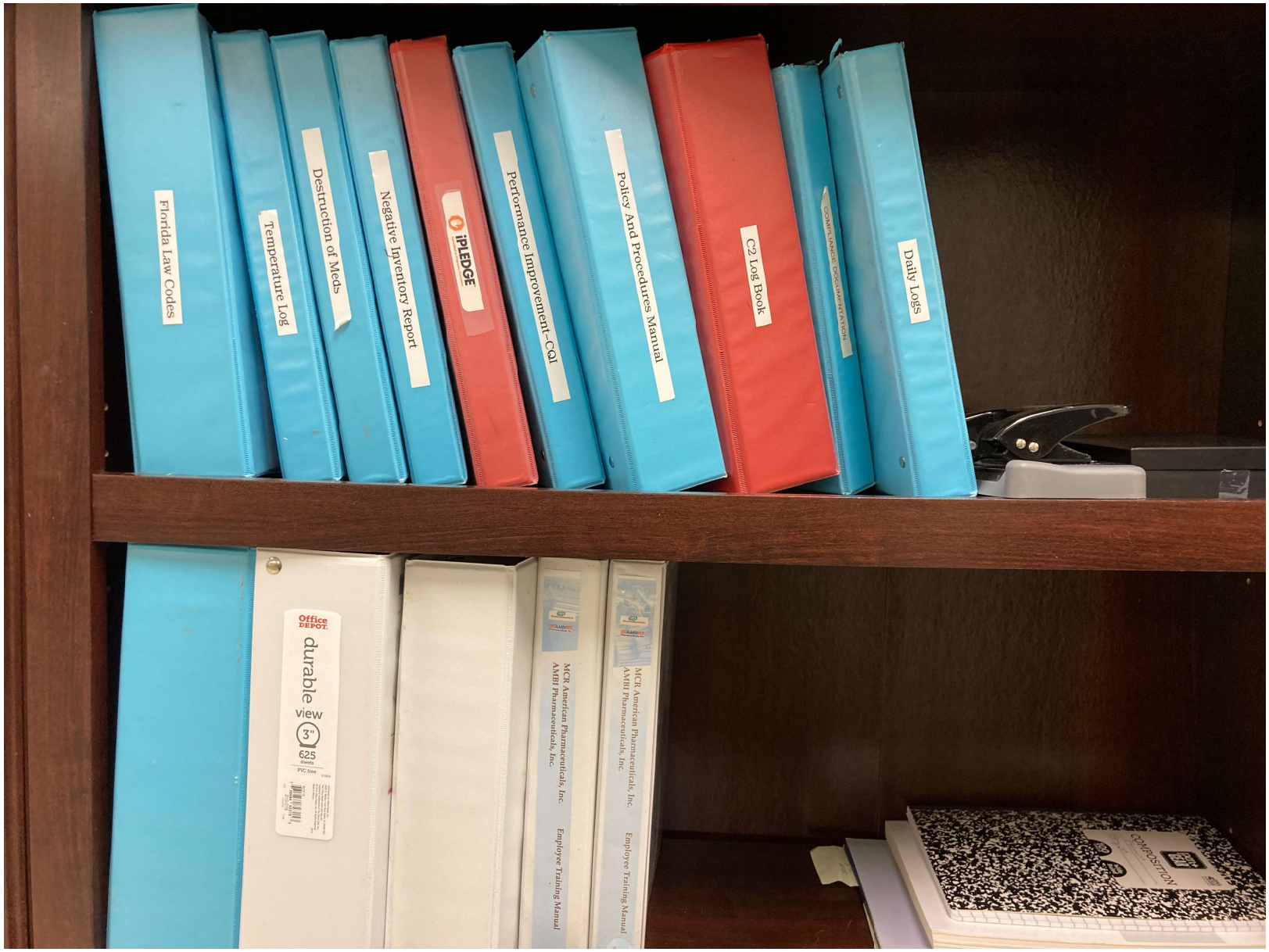


Photo shows dedicated area for manuals, policies and procedures.


Photo shows pharmacy has cleared out all of the boxes that were congesting the area.