NSU | NOVA SOUTHEASTERN UNIVERSITY Florida	
POLICY TITLE: Health Care Clinic Establishment ("HCCE") Management of Prescriptions and Controlled Substances Policy	
POLICY OWNER: Environmental Health & Safety Department	
FUNCTION: EHS	**POLICY CODE NO:**
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LAST REVIEW: N/A	

Health Care Clinic Establishment ("HCCE") Management of Prescriptions and Controlled Substances Policy

Table of Contents

I. Purpose

This policy applies to all faculty, healthcare providers, employees, researchers, and students in **Florida** who procure, store, or use Prescription Items ("RX Items"), including prescription drug items, and controlled substances for NSU patient care, NSU research, and NSU teaching purposes in accordance with NSU's policies and procedures. It is the policy of NSU Health and NSU Environmental Health and Safety Department ("EHS") on behalf of NSU to ensure that there are proper monitoring and control measures in place for ordering, receiving, storing, dispensing, administering, and disposing of RX Items.

Items classified under the category of Professional Use items ("PU") require a medical license for procurement, and these items are distinct from those classified as RX items. The specific criteria for designating items as PU are determined by individual vendors and may vary among different vendors.

It is the policy of NSU that the purchasing, receiving, storing, dispensing, administering, and documenting of all prescription drugs and controlled substances must be in accordance with current Federal, Florida, and local laws and regulations. Florida law provides that any entity purchasing RX Items in the name of or on behalf of NSU must do so either pursuant to a Health Care Clinic Establishment ("HCCE") permit or exemption.

- An HCCE permit is required if RX Items are purchased and used **for patient care**.
- An HCCE exemption is required if RX Items are purchased and used **for research or educational purposes only**.

Each NSU Location ordering RX Items must have either an HCCE permit or exemption. The HCCE permits and exemptions allow NSU Locations to purchase RX Items in the name of NSU for use by NSU practitioner(s) instead of having each practitioner within NSU purchase the RX Items under his/her individual license for use with his/her patients. If controlled substances are proposed to be administered as part of a research protocol, the practitioner must ensure that all DEA requirements, including registration, inspection, and certification, as applicable, are met.

Each NSU Location with an HCCE permit or exemption must identify a Designated Qualifying Practitioner ("DQP"), who will be listed on the permit or exemption. The DQP must ensure that appropriate recordkeeping accompanies each RX Item and is responsible for the purchasing, storing, monitoring, dispensing, administering, and disposing of all RX Items at their NSU Location.

To the extent that any NSU Location has any policy or procedure outlining requirements different from this Policy, such policy or procedure must be available to the DQP and Authorized Users, and readily available for inspection. (Any such location-specific policy or procedure will be reviewed during the **Compliance Check** by the HCCE Team Lead.)

Licensed practitioners, such as physicians, are responsible for all medications ordered or administered for their patients. The HCCE permit and exemption do not replace any permits required by any other state or federal government agency, such as the U.S. Drug Enforcement Agency ("DEA"), the Florida Department of Health, Florida professional licensing boards, and the Florida Agency for Healthcare Administration.

II. Scope

This policy applies to NSU Health, NSU Research, NSU DQPs, faculty, healthcare providers, employees, researchers, and students, whether or not employees of NSU Health, NSU Research, or EHS. All such persons shall comply with this policy. The DQP is responsible for ensuring compliance by all persons acting under his/ her supervision, including Authorized Users. All personnel who are authorized to handle RX Items, including prescriptions and controlled substances, must receive training on the procedures for acquiring, storing, using, and disposing of those items.

III. Definitions

1. **Authorized Users**: The DQP and their designated faculty, healthcare providers, employees, researchers, or students who have been given authority and engage in approved activities under the direction of the DQP when handling prescription drugs and/or controlled substances. The DQP must establish, maintain, and update a roster of Authorized Users for each location within NSU. This roster should include a description of the Authorized Users' responsibilities and qualifications in purchasing, receiving, storing, dispensing, quarantining, or disposing of RX Items.

2. **Controlled Substance ("CS"):** A drug, substance, or chemical for which manufacture, possession, or use is regulated by the U.S. DEA. Controlled Substances include behavior-altering, addictive, and illicitly used drugs, or prescription medications that are designated as controlled drugs. Not all RX Items are Controlled Substances. Controlled substances are divided into five categories, or "Schedules", based on the use for medicinal purposes as defined in the U.S. Controlled Substances Act and Florida Drug Abuse Prevention and Control Act.

3. **Designated Qualifying Practitioner (DQP):** The term "qualifying practitioner" means a licensed health care practitioner defined in Section 456.001, F.S., or a veterinarian licensed under chapter 474, F.S., who is authorized under the appropriate practice act to prescribe and administer RX Items, including prescription drugs or CS. The DQP is legally responsible for the NSU Location's compliance with legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of RX Items, including prescription drugs and CS, outlined in the Florida Drug and Cosmetic Act, the U.S. Controlled Substances Act, and the Florida Drug Abuse Prevention and Control Act. The DQP must also be the DEA registrant for

any CS. Any person licensed under the following chapters below may be designated as a DQP. See each chapter for a complete list of licensees.

Chapter	Licensees
457	Acupuncturist
458	Medical physician (M.D.), resident, intern, fellow, physician assistant (PA), anesthesiologist assistant
459	Osteopathic Medicine – Osteopathic Physician (D.O.), Physician Assistant (PA), Anesthesiologist Assistant
460	Chiropractor
461	Podiatric Medicine – Podiatrist
462	Naturopathy: practice of psychological, mechanical, and material health sciences
463	Optometrist (O.D.)
464	Nursing, Certified Nursing Assistant (CNA), Advanced Practice Registered Nurse ("APRN") including Certified Nurse Midwives ("CNM"), Certified Nurse Practitioner ("CNP"), Certified Registered Nurse Anesthetists ("CRNA"), Clinical Nurse Specialist ("CNS"), and Psychiatric Nurses, Registered Nurse ("RN"), Licensed Practical Nurse ("LPN"), and psychiatric nurse
465	Pharmacist
466	Dentist and Dental Hygienist
467	Midwife
468	Part I: Speech Language Pathologist and Audiologist; Part II: Nursing Home Administrator; Part III: Occupational Therapist; Part V: Respiratory Therapist; Part X: dietician/ nutritionist; Part XIII: athletic trainer; Part XIV: orthotist, pedorthist, prosthetist, and prosthetist-orthotist
478	Electrolysis
480	Massage Therapist
483	Part I: Clinical Lab Personnel; Part II: Medical Physicist; Part III: Genetic Counselor
484	Optician/ Optical Practitioner
486	Physical Therapist (DPT)
490	Psychologist
491	Clinical, Counseling and Psychotherapy

4. **Dispenser:** Means a pharmacy, dispensing pharmacist, or dispensing healthcare practitioner who is subject to licensure or regulation by the Florida Department of Health (DOH) under chapters 458, 459, or 461-466, Florida Statutes, and is authorized to dispense controlled substances.

5. **Drug Sample:** A human prescription drug that is labeled "sample," "not to be sold," "complimentary," or other words to that effect, that is provided as a courtesy, which is not intended to be sold, and that is intended to promote the sale of the drug.

6. **E-FORCSE:** The Electronic-Florida Online Reporting of Controlled Substances Evaluation program (E-FORCSE) is Florida's Prescription Drug Monitoring Program (PDMP). The purpose of E-FORCSE is to collect and store dispensing information for controlled substances listed in schedules II, III, IV, and V, as defined in section 893.03, Florida Statutes, and provide the information maintained in the system to healthcare practitioners to guide their clinical decision making.

7. **HCCE Team Lead**: The NSU employee responsible for managing the HCCE permits and exemptions for all NSU Locations. This person can be reached in the EHS department at **HCCEassist@nova.edu**.

8. **NSU Health Clinics** include but are not limited to the following:
    - NSU Health, Audiology Clinic
    - NSU Health, Dental Clinic(s)
    - NSU Health, E.M. Papper Laboratory of Clinical Immunology
    - NSU Health, Family Therapy, Brief Therapy Institute
    - NSU Health, Eye Care
    - NSU Health, Medicine
    - NSU Health, Institute for Neuro Immune Medicine
    - NSU Health, Neuroscience Institute
    - NSU Health, Psychology Services Center
    - NSU Health, Rehabilitation Facility
    - NSU Health, Speech-Language and Communication Clinic
    - NSU Health, Sports Neuropsychology and Performance Enhancement Clinic
    - NSU Health, Student Medical Center
    - * Any new NSU Health Clinic

9. **NSU Location**: Any Florida location within NSU that orders, receives, stores, dispenses, administers, or disposes of RX Items. These locations may include clinics as well as academic programs.

10. **NSU Research**: Includes all research conducted on or for NSU whether or not through the Division of Research and Economic Development, including but not limited to Center for Collaborative Research, Sponsored Programs, Clinical Research, Technology Transfer, and Grant Writing. This includes but is not limited to:
    - AutoNation Institute for Breast and Solid Tumor Cancer Research
    - Broward County Sea Turtle Conservation Program and NSU's Marine Environmental Education Center
    - Deep Pelagic Nekton Dynamics of the Gulf of Mexico (DEEPEND) Consortium
    - Guy Harvey Research Institute
    - Institute for Neuro-Immune Medicine
    - Neuroscience Institute

- Marilyn Segal Early Childhood Studies Center
- Rumbaugh-Goodwin Institute for Cancer Research
- National Coral Reef Institute
- Save Our Seas Shark Research Center
- Cell Therapy Institute
- * Any new NSU center, institute, or other research organization

11. **Prescription Drug:** Means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients as defined by the Florida Drug and Cosmetic Act.

12. **Prescription Item (RX Item):** any drug (including prescription and controlled substances) or device that requires a written prescription from a licensed healthcare professional.

13. **Professional Use Item**: Professional Use items ("PU") require a medical license to procure items not classified as RX items. Note: Vendors establish their criteria for designating items as PU, and these criteria may vary from one vendor to another.

14. **Registrant**: A person who is licensed and registered with the U.S. DEA to possess and handle CS. This person is responsible to ensure compliance with state and federal laws for recordkeeping, storage, and security of the CS.

15. **Schedule I Controlled Substances**: Drugs, substances, or chemicals with no currently accepted medical use and a high potential for abuse.

16. **Schedule II Controlled Substances**: Drugs, substances, or chemicals with a high potential for abuse, with use potentially leading to severe psychological or physical dependence.

17. **Schedule III Controlled Substances**: Drugs, substances, or chemicals with a moderate to low potential for physical and psychological dependence.

18. **Schedule IV Controlled Substances**: Drugs, substances, or chemicals with a low potential for abuse and low risk of dependence.

19. **Schedule V Controlled Substances**: Drugs, substances, or chemicals with a lower potential for abuse relative to substances listed in Schedule IV and that consist of preparations containing limited quantities of certain narcotics.

20. **Student**: Includes any NSU student involved in providing NSU patient care under appropriate faculty supervision or conducting NSU research. This includes all NSU students in NSU Health Clinics and in Research, under appropriate faculty supervision, and includes health care trainees, residents, fellows, and interns. Each NSU Location may have different rules regarding who is allowed to order, inventory, handle, and/or use RX items. If so, these policies/rules must be communicated to the DQP and all Authorized Users and will be reviewed during the **Compliance Check** by the HCCE Team Lead.

IV. Procedures

A. HCCE Permit or Exemption Application, and Amendment Process

1. Prior to ordering RX items, practitioners, employees, and staff are required to confirm whether there is a valid HCCE permit or exemption for the respective location. If the person is uncertain, the individual must contact the HCCE Team Lead to confirm at HCCEassist@nova.edu.
2. If the NSU Location has an HCCE permit or exemption in place, any RX Items must be handled through the DQP, and the Authorized User must proceed only under the supervision of the DQP for that NSU Location.
3. If an HCCE permit or exemption is not in place for the practitioner's NSU Location, the practitioner must work with the HCCE Team Lead to obtain a permit or exemption.
   3.1. The HCCE Team Lead will prepare and submit the HCCE permit or exemption application via the Florida Department of Business & Professional Regulation ("DBPR") online licensing portal. An individual practitioner or NSU Location **SHOULD NOT** independently submit applications for HCCE permit or exemption to DBPR.
   3.2. **Clinics**: Clinics and any NSU Locations using RX Items for patient care will require an HCCE permit. The HCCE Team Lead will require the following information for the HCCE permit from the NSU Location:
      3.2.1. Name of DQP, medical license number and DEA license number (if applicable) of the DQP, exact physical and mailing address of the NSU Location where the RX Items will be stored, items being ordered, amount and frequency of order, as well as disciplinary and permitting background of the DQP.
   3.3. **Academic Programs**: Academic instructors and researchers using RX Items only for research or educational purposes will require an HCCE exemption. The HCCE Team Lead will require the following information for the HCCE exemption from the NSU Location:
      3.3.1. Name of DQP, medical license number and DEA license number (if applicable) of the DQP, exact physical and mailing address of the NSU location, a summary of the RX Items to be used, and the purposes for which the RX Items will be used.
4. The HCCE permit or exemption for each NSU Location shall not exceed two (2) years from the effective date. The HCCE Team Lead will be responsible for submitting the HCCE permit or exemption for reapplication before its expiration date.
   4.1. The DQPs will be responsible for providing any updated or revised information, differing from the initially received to submit the HCCE permit or exemption (the information mentioned above in 3.2.1 and 3.3.1).
      4.1.1. Failure to provide the necessary information may result in delay or denial of processing the permit or exemption.
   4.2. **E-Contracts:** The HCCE Team Lead must maintain copies of the HCCE permits and exemptions for each NSU Location within E-Contracts. E-Contracts will have the following information for each NSU Location:
      1. Practitioner's name on the license (the DQP)
      2. NSU Location name listed on the HCCE permit or exemption
      3. Practitioner's license number (DEA license if applicable)

4. Customer number assigned by Henry Schein
5. Additional notes to include a section for change in DQP (includes name and date) in case the appointed DQP is no longer employed at NSU or change of address.
6. Drop down menu to select the permit type (HCCE permit or exemption)
7. Start date (Date HCCE permit or exemption was approved by DBPR)
8. Term Period/End Date (Expiration date of the HCCE permit)
9. 3-month reminder of the HCCE's permit or exemption upcoming expiration date
10. Compliance Check Form

5. **Change in DQP:** When a DQP leaves NSU, the DQP must contact the HCCE Team Lead in writing to advise who will be the subsequent DQP. The DQP must notify the Florida DBPR within **ten (10) days** of the DQP's departure from employment with NSU.
   5.1. The HCCE Team Lead will assist with completing of the "Notice of Designated Qualifying Practitioner Change" for HCCE permitholders and initiate a new HCCE exemption application for eligible entities.
   5.2. During semesterly **Compliance Checks**, the HCCE Team Lead will ensure the DQP information for each NSU Location is current and process any DQP changes as necessary.
   5.3. After notifying the Florida DBPR of the DQP change, the HCCE Team Lead will inform the vendor(s) (e.g., Henry Schein) of the DQP changes in writing.

B. Purchasing, Ordering, and Receiving

1. The DQP (and Authorized Users) are responsible for any purchasing, ordering, and receiving of RX Items at the NSU Location. Unauthorized personnel must not be involved in purchasing, ordering, or receiving RX Items.
   1.1. DQPs are responsible for providing and maintaining a current list of Authorized Users on file with the HCCE Team Lead.
2. **Purchasing Prescription Items and Controlled Substances through ARIBA**:
   2.1. All purchases of RX Items must comply with NSU's Office of Procurement Services Policies (available at nova.edu/procurement/policies.html). The DQP (and Authorized Users) will be referred to as "Requester" within ARIBA. Requesters must procure RX Items from approved suppliers, commonly referred to as ARIBA catalog suppliers. (A list of approved suppliers can be found at https://www.nova.edu/procurement/vendors.html.) Approved suppliers should be used to procure items and services whenever possible.
      2.1.1. **Controlled substances must be ordered through a purchase order via Ariba and not a check request**. If a DQP or Authorized User encounters challenges in the procurement process using a purchase order, they are required to contact the Office of Procurement Services for assistance.
   2.2. When specific RX Items are not listed or preferred suppliers cannot meet a requester's requirements, requesters **MUST** contact the Office of Procurement Services to identify an appropriate supplier. Purchase requisitions (PR) for all non-catalog items require approval from the Office of Procurement Services. The Office of Procurement Services may deny any unapproved orders. (For more information, see Office of Procurement

Services Policies and Procedures and click the Competitive Bid Thresholds dropdown. https://www.nova.edu/procurement/policies.html

3. **Important ARIBA Ordering Reminders**:
   3.1. The DQP (or Authorized Users) must ensure that the NSU Location "Requester" and "ship-to-location" are the same as those on the HCCE permit or exemption.
   3.2. The DQP (or Authorized Users) for the NSU Location must be the practitioner whose name, establishment address, and license number are used on all distribution documents for RX Items purchased or returned by the NSU Location.
   3.3. If a supplier or vendor cancels or delays any RX Item order due to a question about the HCCE permit or exemption status, the requester (either the DQP or Authorized User) must immediately notify the HCCE Team Lead to resolve any concerns.
4. **Requesting Drug Samples**
   4.1. A written request from a practitioner for a drug sample that is required must contain:
      4.1.1. The name, address, professional designation, and signature of the practitioner who makes the request;
      4.1.2. The name, strength, and dosage form of the drug sample requested and the quantity requested;
      4.1.3. The name of the manufacturer of the drug sample requested; and
      4.1.4. The date of the request.
5. **Receipt of RX Items**
   5.1. Upon receipt, the RX Items must be marked as received in Ariba for each corresponding PO. This will indicate to accounts payable that the invoice is approved for payment.
   5.2. The DQP must visually examine each outside shipping container for identity and to prevent the acceptance of misbranded, adulterated, or otherwise contaminated RX Items. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
   5.3. The DQP must reconcile any RX Items received against the packing slip or invoice accompanying the order, as well as any DEA ordering form(s), where applicable.
   5.4. The DQP must compare the contents of the shipment against the shipping invoice by carefully reviewing the quantities, lot numbers, and expiration dates.
   5.5. The DQP must record the following information about the RX Items on the applicable log sheet, pursuant to Section C-2.7 of this policy:
      5.5.1. Drug Enforcement Administration (DEA) form information, if applicable:
         5.5.1.1. Accuracy of quantity, strength, and medication type.
         5.5.1.2. Date of receipt and number received as documented on the DEA form.
         5.5.1.3. The DEA form is filed at the ordering center for a period of two years.
      5.5.2. When a DEA form is not applicable:
         5.5.2.1. Brand and/or/generic/chemical name,
         5.5.2.2. Strength
         5.5.2.3. Quantity
         5.5.2.4. Date received
         5.5.2.5. Signature of receiving party
         5.5.2.6. Lot number
         5.5.2.7. Expiration date; and

5.5.2.8. Manufacturer name.

5.6. The DQP must maintain a receipt log for recording RX Items received, pursuant to Section C-2.7 of this policy. Only an Authorized User (responsible for the receipt of the RX Items) may sign and date the log entry.

5.7. The DQP must take appropriate action with any RX Items that are compromised due to inappropriate storage or shipment. The RX Item may be returned to the shipping vendor, or otherwise wasted or disposed. Any wasted or disposed RX Items must be recorded on the applicable log, pursuant to Section C-2.7 of this policy.

5.8. For all RX Items that must be returned, the RX Items must be marked as rejected in Ariba with a note explaining the reason for rejection. The rejection note will indicate to accounts payable that an invoice should not be approved for payment.

C. Security and Storage

1. Facility Security

1.1. An NSU Location at which RX Items are stored, warehoused, handled, held, offered, marketed, or displayed must:

1.1.1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations including:

1.1.1.1. The NSU Location must be large enough to store the estimated quantity of RX Items. The Location's estimated quantity must be based on the Location's prior year's volume of activity with RX Items that required storage. The Location must also consider the type of RX Items possessed, the size of any containers used, as well as any other products that are, or are intended to be, possessed.

1.1.1.2. The NSU Location must have a refrigeration and/or freezer capacity large enough to store the estimated quantity of RX Items that might require refrigeration or freezing. The Location's estimated quantity must be based on the Location's prior year's volume of activity with RX Items that required refrigeration or freezing. The Location must also consider the type of RX Items possessed, the size of the containers used, as well as any other products that are, or are intended to be, possessed.

1.1.2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

1.1.3. Have a quarantine area for storage of RX Items that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened.

1.1.3.1. A quarantine section shall be clearly marked and designated separate and apart from any other place where RX Items are stored so that quarantined products are not confused with usable products being held for dispensing or administering. Any RX Item stored outside the quarantine area is a product held for dispensing or administering.

1.1.3.2. RX Items must be quarantined if obvious damage, determined by a visual inspection of the exterior of the product's packaging, has occurred to any part of the packaging that is or may be in direct contact with the dosage form of the prescription drugs or any additional part of the packaging which is provided to prevent adulteration of the prescription drugs in addition to "containing" the product.

1.1.4. Be maintained in a clean and orderly condition.

1.1.5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

1.2. An NSU Location that is used for RX Item storage must be secure from unauthorized entry.

1.2.1. Access from outside the premises must be kept to a minimum and be well controlled.

1.2.2. The outside perimeter of the premises must be well lit.

1.2.3. Entry into areas where RX Items are held must be limited to Authorized Users.

1.3. An NSU Location that is used for RX Item storage must be equipped with:

1.3.1. An alarm system to detect entry after hours.

1.3.2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

2. **Storage of all RX Items**

2.1. RX Items must be kept in a secure, locked cabinet. Keys that open the medication cabinets are issued to authorized medically licensed personnel. The DQP must maintain a list of all employees who were issued keys. Authorized Users are expected to maintain possession of the keys and return them when no longer working for the NSU Location. If a key goes missing, the DQP will take steps to change the lock within 72 business hours, or the earliest possible time period, and all keys will be reissued with the assistance of the PSD-Locksmith Operations. An incident report needs to be completed by contacting the NSU Public Safety Department at 954-262-8999.

2.1.1. Locking hardware, needed changes, and key requests services must be provided by NSU's PSD-Locksmith Operations. NSU's Office of Facilities Management – Public Safety Department - Locksmith Operations request forms, standards, and policies can be found online at: NSU Public Safety Locksmith | Nova Southeastern University.

2.2. RX Items must be stored in accordance with the manufacturer's label, including single-use vials and disposal of expired drugs.

2.3. Expired, contaminated, or deteriorated RX Items must be quarantined pursuant to Section D of this policy (i.e., not stored with other products so that these expired, contaminated, or deteriorated RX Items are not available for use).

2.4. All RX Items shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such products or the current U.S.P. temperature range.

2.4.1. If no storage requirements are established for an RX Item, then it may be held at "controlled" room temperature to help ensure that its identity, strength, quality, and purity is not adversely affected.

2.4.2. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs must be used to document proper storage of RX Items.

2.4.2.1. In the absence of electronic monitoring devices, there must be two mounted thermometers in the immediate area of the stored Rx Items. The immediate area of the stored RX Items is within six (6) feet of the products in storage. One thermometer will be mounted in the warmest area of the stored RX Items and the other thermometer will be mounted in the coolest immediate area of the stored RX Items.

2.4.3. A temperature record log must be maintained recording the date; time; thermometer one temperature; thermometer two temperature; and the initials of the Authorized User recording the data or reviewing the data if electronically monitored. This record and temperature reading must be recorded at least five (5) days each week with the temperature readings taken between 2:00 p.m. and 4:00 p.m. (EST). **This record must be kept on file for at least two years, as further detailed in the NSU Records Management and Destruction Policy and NSU Record Retention Schedule. See "Medical and Scientific Equipment Records" on page 7 of the NSU Record Retention Schedule available at https://www.nova.edu/records/forms/secure/records-and-destruction-policy.pdf**.

2.5. **Secure Storage of Controlled Substances**

2.5.1. Schedule I and II controlled substances (e.g., Pentobarbital and Fentanyl are Schedule II drugs): Must be stored in a safe or steel cabinet of substantial construction. If the safe or cabinet is less than 750 lbs., it must be mounted or secured to something of substantial construction (e.g., bolted to a wall or the floor, or the base imbedded in concrete). The safe/cabinet should have an inner and outer door with the locks for each door keyed differently. Standard "narcotics cabinets" can be purchased through a variety of resources with PSD-Locksmith Operations review and assistance.

2.5.2. Schedule III, IV, and V controlled substances (e.g., Ketamine and Buprenorphine are Schedule III controlled substances): Should be stored using one of the following methods:

2.5.2.1. Preferred method: a wall mountable controlled substance lockbox with two doors and two locks (each lock is keyed differently).

2.5.2.2. A single-lock lockbox that is stored in a drawer or cabinet that is secured at all times with an eye hasp or locking bar with a padlock. The drawer and cabinet should be substantially constructed such as in a drawer that is part of either a bench or cabinet that is mounted to the wall or floor.

2.5.2.3. If a lab is not accessible to the public, then an option is to use a single-lock lockbox, stored in a drawer or cabinet in a room that is kept locked

at all times. NSU's Office of Facilities Management – Public Safety Department - Locksmith Operations request forms, standards, and policies can be found online at: NSU Public Safety Locksmith | Nova Southeastern University.

2.5.3. Schedule III, IV and V substances can also be stored with Schedule I and II substances.

2.5.4. Cold storage for controlled substances: For storage at 4°C or colder, a single-lock lockbox in a refrigerator or freezer that can also be locked is permitted. The room must also be lockable and locked after hours.

2.6. **Inventory and Record-Keeping**

2.6.1. **Annual Inspection**: The DQP must conduct an annual inspection of all stored RX Items (at least every 12 months) and must remove and quarantine any RX Items for which the expiration date has passed.

2.6.2. **Quarantine:** The DQP must examine all stored RX Items and must identify and quarantine any RX Items of which the immediate or sealed outer containers or sealed secondary containers have been opened or used, or damaged, deteriorated, misbranded, or adulterated. Such RX Items must be identified as such and must be quarantined and physically separated from other RX Items until they are destroyed or returned to the supplier.

2.6.2.1. A quarantine section must be separate and apart from other sections where RX Items are stored so that prescription drugs in this section are not confused with usable prescription drugs.

2.6.3. **Inventory System**: The DQP must maintain an inventory system that assures the accuracy of all RX Items. The inventory system must document the movement of RX Items and provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component.

2.6.3.1. The inventory system may be manual or computerized as long as the system accurately tracks the disposition of all RX Items, including the purchase, storage, quarantine, dispensing, administering, and disposing of each RX Item Florida law requires all NSU Locations storing RX Items to take inventory of all such items on hand every year. This is different from the federal DEA requirement that requires a controlled substance inventory every two years. NSU requires a complete inventory to be taken at least every 12 months.

Exhibit 1: Inventory Log Template

1-A: List of Authorized Users for Prescription Items
1-B: Initial Inventory or Periodic Inventory for Prescription Items
1-C: Purchase and Receiving Records for Prescription Items
1-D: Controlled Substances Use Log

2.6.3.2. The inventory may be taken on any date which is within thirteen months of the previous inventory date.

2.6.3.3. Each inventory must contain a complete and accurate record of all RX Items on hand on the date the inventory is taken, including:

2.6.3.3.1. The name of the substance.

2.6.3.3.2. The total quantity of the substance, including: Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter); The number of units or volume of each finished form in each commercial container (e.g., one-hundred-tablet bottle or ten-milliliter vial); The number of commercial containers of each such finished form (e.g., three one hundred-tablet bottles or ten one-milliliter vials).

2.6.3.3.3. For any Schedule I or II CS, the DQP must make an exact count or measure of the contents.

2.6.3.3.4. For any Schedule III, IV, or V CS, the DQP may make an estimated count or measure of the contents, unless the container holds more than one thousand tablets or capsules in which an exact count of the contents must be made.

2.6.3.3.5. If there are no stocks of RX Items on hand, the DQP should make a record showing a zero inventory.

2.6.3.3.6. A separate inventory must be made for each NSU Location where RX Items are in the possession or under the control of the DQP.

2.6.3.3.7. All inventory records must be kept for a period of three years at the NSU Location. The annual inventory must comply with the same requirements as a DEA inventory. For more information on DEA inventory requirements visit:

https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.htm#7

2.7. **Logs for All RX Items**

2.7.1. A separate log must be maintained for all RX Items.

2.7.2. All logs must be organized by each individual medication by brand and/or generic/chemical name.

2.7.3. Upon the receipt of RX Items, the Authorized User must make a log entry containing:

2.7.3.1. The vendor's name and address.

2.7.3.2. The HCCE permit or HCCE exemption number as applicable.

2.7.3.3. The address of the location where the RX Items were shipped from.

2.7.3.4. The distribution date.

2.7.3.5. The name, strength, and quantity, and the National Drug Code, if applicable.

2.7.3.6. The name, Florida license number, and DEA license number, if applicable, of the DQP or any other person or NSU entity that purchased the RX Items.

2.7.3.7. The financial data, including the unit type and unit price, for the distributions involving the RX Items.

2.7.4. Entries in logs must be made any time an RX Item is purchased, stored, monitored, quarantined, dispensed, administered, disposed, lost, stolen, or significantly handled in a way that would require an entry be made.

2.7.5. If any discrepancy is identified in any log or inventory, the DQP must be immediately notified.

2.7.6. Every record required by this subsection, including prescription records, shall be maintained separately from all other records.

2.7.7. Records required to be kept pursuant to this subsection must be maintained for the time periods specified in the NSU Records management & Destruction Policy and NSU Record Retention Schedule. See Section P. ("Patient Care Records") of the NSU Record Retention Schedule.

2.8. **Recordkeeping/ E-FORCSE Reporting of Controlled Substances**

2.8.1. Records relating to Schedule III, IV, or V CS kept at an NSU Location must be immediately retrievable, including by computer or other electronic means. Records maintained at a central location within Florida, other than an NSU Location, must be readily available for inspection. Records kept at a central location outside of Florida, which are not electronically retrievable, must be made available for inspection within two (2) working days after a request by an authorized official of a federal, state, or local law enforcement agency.

2.8.2. Practitioners who dispense CS to patients must report specific information to E-FORCSE each time a controlled substance is dispensed to an individual. Additional information on E-FORCSE can be found on the Florida Department of Health website. **Disclaimer**: This policy pertains to the requirements for storing and monitoring prescriptions related to HCCE locations, as defined by Florida Statute 499. The E-FORCSE requirements listed here do not encompass all requirements by E-FORCSE. For additional information on E-FORCSE requirements, visit the Florida Department of Health website.

2.8.3. For each CS dispensed, the DQP or Authorized User shall report the following information to E-FORCSE as soon as possible, but no later than the close of the next business day after the day the CS is dispensed:

2.8.3.1. The name of the prescribing practitioner, the practitioner's federal DEA registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.

2.8.3.2. The date the prescription was filled and the method of payment.

2.8.3.3. The full name, address, telephone number and date of birth of the person for whom the prescription was written.

2.8.3.4. The name, national drug code, quantity, and strength of the CS dispensed.

2.8.3.5. The full name, federal DEA registration number, and the address of the pharmacy or other location from which the CS was dispensed.

2.8.3.6. The name of the pharmacy, or practitioner, other than a pharmacist, dispensing the CS and the practitioner's National Provider Identification number.

2.8.4. A dispenser must file a zero report no later than the close of the next business day if the dispenser usually dispenses CSs in or into Florida and has created an account to report to E-FORCSE® but has no dispensing transactions to report for that day. This includes a dispenser that is closed on Saturday or Sunday.

2.8.5. Not all CS prescriptions dispensed are required to be reported to E-FORCSE. Acts of dispensing or administration are exempt from reporting to E-FORCSE when:

2.8.5.1. A CS is administered directly to a patient if the amount is adequate to treat the patient during that treatment session;

2.8.5.2. A CS is administered or dispensed to a patient under the age of 16; or

2.8.5.3. A one-time 72-hour re-supply of CSs is dispensed.

D. Dispensing and Disposal

1. RX Items must be administered in accordance with the manufacturer's label, including single-use vials and disposal of expired drugs.
2. Each dispensing or outgoing shipment of RX Items must be carefully inspected for identity of the RX Item and to ensure that there is no delivery of RX Items that have been expired, damaged, misbranded, adulterated, or otherwise contaminated in storage.
3. **Controlled Substances**
   - 3.1. Damaged, expired, unused, or otherwise unwanted CS shall be promptly disposed of as follows:
   - 3.2. The CS must be delivered to a reverse distributor as a first choice. This can be done by delivery by common or contract carrier pick-up, or by reverse distributor pick-up at the registrant's registered location.
   - 3.3. If a reverse distributor is not available or feasible, the CS must be disposed of onsite using a Cactus Sink. Cactus Sinks are available in multiple locations throughout NSU.
   - 3.4. If neither a reverse distributor nor a Cactus Sink is available, please contact the HCCE Team Lead immediately for proper disposal of the CS.
   - 3.5. Recalled or returned CS shall be promptly delivered by common or contract carrier pick-up or pick-up by other registrants at the registrant's registered location to the registered person from whom it was obtained (the vendor), the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf.
4. **All RX Items**
   - 4.1. Unopened RX Items that do not qualify as CS are returned to the vendor.
   - 4.2. Opened RX Items that do not qualify as CS are disposed of thirty (30) days after opening, in accordance with the process recommended by the vendor and/or local authorities. Disposal must be witnessed by two Authorized Users and must be recorded in the inventory log.
   - 4.3. All expired RX Items should be recorded on the applicable log, pursuant to Section C-2.7 of this Policy.
   - 4.4. No later than thirty (30) days after being quarantined or opened but unused, RX Items should be disposed of in accordance with the recommendations of the vendor and/or Federal, State, or Local authorities depending on the RX Items to be disposed.

E. Theft or Loss

1. All RX Items: If any RX Item (that is not a CS) is lost or stolen, the DQP must notify the HCCE Team Lead and contact the Nova Southeastern Public Safety Department — an incident report needs to be completed by contacting NSU Public Safety at 954-262-8999.
2. Controlled Substances: If any CS is lost or stolen, the NSU Location must contact the Nova Southeastern Public Safety Department — an incident report needs to be completed by contacting NSU Public Safety at 954-262-8999 and notify the DEA Field Division Office, in writing, using DEA Form 106, immediately. The NSU Location must also contact the Department Chair, and the HCCE Team Lead, within one business day of discovery of such loss or theft.
   Where any RX Items is lost or stolen, a record shall be maintained by the NSU Location which contains a detailed list of the RX Item(s) lost or stolen; the kind and quantity of such RX Item(s); and the date of discovering of such loss, destruction, or theft.

F. Inspection and Auditing

1. The NSU Location must allow authorized federal, state, and local officials to enter and inspect any premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.
2. The DQP will be the point of contact for the DBPR regarding any questions about the purchase, recordkeeping, storage, and handling of prescription drugs, including providing contacts outside of business hours.
3. The DQP must immediately notify the HCCE Team Lead of any requests for inspection or auditing of any NSU Location by any government official.
4. Further, EHS may conduct inspections as necessary to ensure university compliance with Florida and DEA regulations. All records regarding the purchase, recordkeeping, storage, and handling of RX Items must be immediately available to EHS for review.

V. Enforcement

1. All individuals having roles or responsibilities covered under this policy are expected to be thoroughly familiar with the policy and its procedures and obligations as they pertain to the employee's role. Failure to comply with this policy may result in disciplinary action pursuant to all applicable university policies and procedures.
2. The DQP is aware that violations of any state or federal law or this policy by the NSU Location or DQP constitutes grounds for discipline of the DQP's license by NSU or the appropriate professional licensing board.
3. **Compliance Check**: (See **Exhibit 2: Compliance Checklist**.) **On a semester basis**, the DQP is required to provide confirmation to the HCCE Team Lead for each NSU Location under his/her supervision the following:
   1) DQP has completed any required training for the HCCE Permit or Exemption;

2) DQP is knowledgeable about the HCCE permit or exemption that he/she is utilizing to order and use RX Items; any Change in DQP must be submitted to the DBPR through the HCCE Team Lead;
3) DQP is knowledgeable about any policies or procedures specific to each NSU Location under his/ her supervision;
4) DQP reviewed the status of the HCCE permit or exemption to determine whether it must be renewed or amended;
5) DQP has maintained and provided to the HCCE Team Lead a list of Authorized Users;
6) DQP must affirm that in the event any RX Items orders are being put on hold or canceled due to an issue with the HCCE permit or exemption, the DQP must contact the HCCE Team Lead immediately to resolve the problem; and
7) DQP has conducted and maintained an accurate inventory log of all RX Items; and
8) DQP has conducted a self-inspection using this policy and taken steps to correct any concerns identified therein; and
9) Authorized Users have completed any required training provided by EHS.

4. A review of a DQP's policy on managing RX items may be initiated by EHS due to concerns about compliance with this Policy and the law, and also may be requested by a DQP, or a DQP's supervisor or Dean, if there are concerns about compliance with this policy.

VI. Relevant Statutes and Rules

- Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes
- Florida Drug Abuse Prevention and Control Act, Chapter 893, Florida Statutes
- Chapters 61N-1 and 61N-2, Florida Administrative Code
- U.S. Controlled Substances Act, Title 21 U.S. Code, Chapters 1-29

EXHIBIT 1: INVENTORY LOG TEMPLATE

1-A: List of Authorized Users for Prescription Items
1-B: Initial Inventory or Periodic Inventory for Prescription Items
1-C: Purchase and Receiving Records for Prescription Items
1-D: Controlled Substances Use Log

EXHIBIT 2: COMPLIANCE CHECKLIST

Compliance Contact

If you would like further information on the NSU Environmental Health and Safety Department's Management of Prescription Items, Including Prescription Drugs and Controlled Substances, or have additional questions, please contact us via email to the HCCE Team Lead compliance point-of-contact at HCCEassist@nova.edu.

Enforcement

All employees having roles or responsibilities covered under this policy are expected to be thoroughly familiar with the policy and its procedures and obligations as they pertain to the employee's role. Failure to comply with this policy may result in disciplinary action pursuant to all applicable university policies and procedures.

Environmental Health and Safety Department should report non-compliance with this policy to the NSU Executive Vice President and Chief Operating Officer, the DCO-VP, the DCO–FD, the Vice President for Compliance, and any other appropriate University official.

EXHIBIT 1: INVENTORY LOG TEMPLATES

1-A: LIST OF AUTHORIZED USERS FOR PRESCRIPTION ITEMS

NSU LOCATION NAME:	
NSU LOCATION ADDRESS: (Building and Room Number)	
HCCE PERMIT OR EXEMPTION NUMBER:	
DESIGNATED QUALIFYING PRACTITIONER:	

Name of Authorized User	Job Title	Date of Birth	Signature of Authorized User	Initials (as used in Inventory Records)	Date Departed*	Designated Qualifying Practitioner Initials

* Once a person has departed NSU, that person is no longer an Authorized User.

DQP Signature: _____
(to be completed as part of Compliance Check each semester)

1-B: INITIAL INVENTORY or PERIODOC INVENTORY FOR PRESCRIPTION ITEMS

NSU LOCATION NAME:	
NSU LOCATION ADDRESS: (Building and Room Number)	
HCCE PERMIT OR EXEMPTION NUMBER:	
DESIGNATED QUALIFYING PRACTITIONER:	
DEA REGISTRANT NAME AND REGISTRATION NUMBER (if the inventory includes any Schedule II or III controlled substances)	

The inventory of Prescription Items (including prescription drugs, controlled substances and items that require a practitioner's license to order) was prepared as set forth below. I verify that the substances listed below were received and secured appropriately in a locked safe/ cabinet at the below location.

Name of Drug (and strength)	Lot #	Schedule	Bulk or Finished Form	Total Units	NDC # (if available)

Inventory Date and Time: _____
Inventory Conducted by: _____
Inventory Witnessed by: _____
DQP Signature: _____
(to be completed as part of Compliance Check each semester)

1-C: PURCHASE AND RECEIVING RECORDS FOR PRESCRIPTION ITEMS

NSU LOCATION NAME:	
NSU LOCATION ADDRESS: (Building and Room Number)	
HCCE PERMIT OR EXEMPTION NUMBER:	
DESIGNATED QUALIFYING PRACTITIONER:	
DEA REGISTRANT NAME AND REGISTRATION NUMBER (if the inventory includes any Schedule II or III controlled substances)	

DQP/Authorized User who Placed Order	**Product Name**	**Amount Purchased**	**Date Received**	**Supplier/ Vendor**	**Schedule of Drug**	**DEA Form 222 # (if applicable)**	**PR # / PO # and Invoice #**	**Initials**	**Materials received intact with container unopened, in original condition (Y/N)**

DQP Signature: _____
(to be verified as part of Compliance Check each semester)

1-D: CONTROLLED SUBSTANCES USE LOG

NSU LOCATION NAME:	
NSU LOCATION ADDRESS: (Building and Room Number)	
HCCE PERMIT OR EXEMPTION NUMBER:	
DESIGNATED QUALIFYING PRACTITIONER:	
DEA REGISTRANT NAME AND REGISTRATION NUMBER (if the inventory includes any Schedule II or III controlled substances)	

1) One log sheet must be completed for each container of Controlled Substance. If the material is converted or diluted, start a new log form to track that usage. Reference the original container's Lot or Serial Number and original bottle number assigned by lab.
2) Controlled Substance usage must be tracked on a per-dose (use) basis and only by an Authorized User. Record total quantity of the substance to the nearest metric unit weight/ volume or the total number of units finished form.
3) Minor loss occurring in routine use and handling should be recorded when noticed to maintain an accurate inventory.

Date/ Time	Amount Removed (weight, mL, units)	Starting Amount	Ending Amount	Activity Type (prepare solution, tablet)	New log form created (Y/N)	Name of Authorized User	Initials

DQP Signature: _____
(to be verified as part of Compliance Check each semester)

Exhibit 2: Health Care Clinic Establishment (HCCE) Compliance Checklist

NSU LOCATION NAME:	
NSU LOCATION ADDRESS: (Building and Room Number)	
HCCE PERMIT OR EXEMPTION NUMBER:	
DESIGNATED QUALIFYING PRACTITIONER:	
DEA REGISTRANT NAME AND REGISTRATION NUMBER (if the inventory includes any Schedule II or III controlled substance)	

I, the Designated Qualifying Practitioner ("DQP") for this NSU Location, have reviewed this Compliance Checklist to maintain compliance with NSU's Policy on Management of Prescription Items, Including Prescription Drugs, Controlled Substances, and Professional Use Items.

1. As the DQP, I am aware of this Location's HCCE permit or exemption.
    a. If this Location has an HCCE exemption, I have reviewed the items listed on the HCCE Exemption letter, and they correspond with the Prescription Items used by this Location. YES/ NO

2. As the DQP, I am aware of my responsibility to maintain compliance with NSU policy and all legal and regulatory requirements relating to the purchase, recordkeeping, storage, and handling of Prescription Items. YES/ NO

3. I have reviewed any written policy and procedures specific to this Location and confirm that such policy and procedures are consistent with NSU's Policy on Management of Prescription Items. (If any such policy or procedures are written, a copy must be provided to the HCCE Team Lead.) YES/ NO

4. Has there been a change in DQP from the previous semester?
    a. If NO, go to the next question.
    b. If YES, has this NSU Location notified the HCCE Team Lead and the Florida Department of Business & Professional Regulation of the change in DQP? YES? NO

5. The DQP's state board license number: _____.

6. I have reviewed this Location's practices involving Prescription Items, and confirm that this Location's practices are consistent with NSU's Policy on Management of Prescription Items, relating to the following:
    a. Receipt of prescription drugs, and controlled substances if applicable. YES/NO
    b. Inventory of prescription drug, and controlled substances if applicable. YES/NO
    c. Storage of prescription drugs, and controlled substances if applicable. YES/NO

d. Recordkeeping of prescription drugs, and controlled substances if applicable. YES/NO
e. Disposal of prescription drugs, and controlled substances if applicable. YES/NO
f. Recall of prescription drugs, and controlled substances if applicable. YES/NO
g. Security of prescription drugs, and controlled substances if applicable. YES/NO

7. I have reviewed this Location's alarm / security system, and it is functioning as required in NSU's Policy on Management of Prescription Items. YES/NO

8. I have reviewed the Purchasing and Receiving Records of Prescription Items ordered or purchased by this Location, and those documents include the DQP's name, establishment address, and license number, as required in NSU's Policy on Management of Prescription Items. YES/NO

9. I have reviewed the Inventory Records of Prescription Items used, returned, or disposed of by this Location, and those documents include the DQP's name, establishment address, and license number, as required in NSU's Policy on Management of Prescription Items. YES/NO

10. I have reviewed the List of Authorized Users for Prescription Items for this Location and confirm that the list accurately reflects the individuals personally involved with Prescription Items for this Location. YES/NO

11. The Authorized Users have completed any required training provided by EHS.

DQP Signature: _____
(to be verified by HCCE Team Lead as part of Compliance Check each semester)