How to Maintain Compliance of your DEA license

Each UM researcher DEA license holder is responsible for understanding and complying with all regulations of the DEA regarding registration, purchase, use, and proper disposal of controlled drugs used in their research. The PI retains all liabilities for loss, theft, or misuse of any controlled substance acquired through their registration.

In brief, the license holder will:

- Ensure compliance with all federal laws
- Ensure safe, secure storage of controlled drugs
- Ensure that all employees/students with access to controlled drugs are appropriately screened
- Ensure that all required records for inventory, dispensing, and disposal of controlled drugs are maintained
- Report significant losses or theft of controlled drugs to the DEA
- Assure legal and proper disposal of controlled drugs
- Ensure that appropriate procedures are followed when performing a drug transfer

Storage and Security

DEA License holders must keep controlled drugs in a substantially constructed, securely locked cabinet (safe) that meets DEA requirements.

For Schedule I, the controlled substance must be stored in a substantially constructed, securely locked cabinet (safe), separate from other scheduled controlled drugs, with the cabinet secured to a wall or otherwise not removable, as per Federal regulations.

For Schedule II, the controlled substance must be stored in a substantially constructed, securely locked cabinet (safe), separate from other scheduled Controlled drugs, with the cabinet secured to a wall or otherwise not removable, as per Federal regulations

For Schedules III-V, the controlled substance must be in a locked cabinet or safe.

All controlled drugs shall be kept locked in their storage location except for the actual time required to remove, legitimately work with, and replace them. You can find standard narcotic cabinets by searching for “narcotic cabinets” on the internet. Please be aware that DEA regulations require that the cabinet be secured so that it cannot be removed. A locked drawer in a lab bench that is bolted to the floor or wall is generally sufficient.

Access to locked rooms and locked storage cabinets containing controlled drugs shall be restricted by the DEA license holder.

Each license holder must determine how their authorized users will access drugs. Authorized users must store controlled drugs in an individual lockbox, marked with the individual’s name, in a locked cabinet when not being legitimately worked with or at the license holder’s location for overnight storage. For Finished Form only drugs, laboratory-wide lockboxes, can be established and utilized but must be stored at the License holder’s location for overnight storage. Usage logs must be completed for each lockbox and returned to the DEA license holder upon completion.

Personnel Security-Background Checks & Employee Screening:

Authorized Agent: An individual who has the complete trust of a DEA license holder. An authorized agent can be given power of attorney authorization (POA) by a licensed researcher to oversee the ordering, dispensing and management of controlled substances in their absence. To reduce the risk of drug diversion, only 1-2 individuals in a laboratory should be provided the status of an authorized agent. Regardless of POA authorization, the licensed researcher remains ultimately responsible for the management of all controlled substances acquired under their DEA registration. Only a licensed researcher and their authorized agent(s) should have access to the safe or locked cabinet where significant inventories of controlled substances are stored. Only authorized agents are permitted to know the licensed researcher’s registration number and to order controlled substances on their behalf.

Authorized personnel: are research staff, including graduate students and postdoctoral scholars under the direct supervision of a researcher. In addition to the researcher and authorized agent(s), authorized laboratory personnel may use controlled substances during experiments or treatments of research animals. Authorized laboratory personnel can perform these functions

but without access to the safe or cabinet where bulk quantities of controlled substances are stored. Licensed researchers or their authorized agent(s) must take responsibility for dispensing limited quantities of controlled substances to authorized personnel for daily use and maintaining unused substances in an appropriate safe or locked cabinet for proper storage. Each licensed researcher is responsible for authorizing specific roles and providing required training for the proper handling of controlled substances. The registrant must also screen all authorized personnel by having them complete a DEA Authorized Personnel Screening Form.

Inventory Procedures

When issued a DEA registration, a license holder shall take an initial inventory, which is an actual physical count of all Controlled drugs in their possession. The license holder should make a record showing a zero inventory upon initial receipt of registration.

Each person registered to handle controlled drugs must maintain an inventory. The inventory should be:

- Maintained at the registered location (unless a notification has been sent to DEA notifying that records will be maintained at a specified central location).
- Available for 2 years after the substance is used or is disposed.
- Completed every 2 years (biennial) to meet DEA regulations (21 CFR 1304.11). The inventory may be taken on any date which is within two years of the previous biennial inventory date and must indicate whether it was performed at the opening or closing of the day.
- Updated on the effective date of a rule (from the DEA) when a substance is added to the Schedule (list of controlled drugs).

The inventory should have the following information:

- Name, address, and DEA registration number.
- Date the inventory was taken and whether it was at the beginning or end of the day.
- Sign and date form.

For Controlled drugs in Bulk Form

Name of substance;
The total quantity of the substance to the nearest metric unit weight consistent with unit size.

For Controlled drugs in Finished Form

- the name of the substance;
- Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
- The number of units or volume of each finished form in each container (e.g., 100-tablet bottle or 3-milliliter vial); and
- The number of containers of each such finished form (e.g. four 100-tablet bottles or six 3- milliliter vials).

For each substance that is expired, damaged, defective or impure drugs awaiting disposal, or drugs held for quality control purposes, or drugs maintained for extemporaneous compoundings):

- Name of substance;
- Total quantity of the substance to the nearest metric unit weight or the total number of units of finished form (i.e. fifty 10 mg tablets or 10 ml of 50 mg/ml);
- Reason for the substance being maintained by the License holder and whether such substance is capable of use in the manufacture of any Controlled Substance in finished form;
- Best practice is to maintain drugs in this category separately within your inventory, i.e., a separate compartment, box, or bag within the storage area

Labeling Requirements

All containers of controlled drugs must be properly labeled. If the laboratory re-packages, compounds or dilutes controlled

drugs, appropriately label the repackaged, compounded or diluted substance and store it in the safe. The label on diluted or combined Controlled drugs that will be stored at least overnight in the safe must include the following information:

- Name of controlled substance
- Lot number from the supplier
- Final concentration of controlled substance
- Volume per container
- Expiration date

Transporting Controlled drugs between University Buildings

Controlled drugs cannot be transported between buildings. A license holder cannot walk down the sidewalk or across the street to another building with controlled drugs in his/her pocket.

Disposal

Expired, damaged or otherwise unusable or unneeded controlled drugs can be disposed of by transferring them to a License holder who is authorized to receive such materials. These License holders are referred to as Reverse Distributors. A DEA authorized reverse distributor to assist license holders with the proper disposal of controlled drugs can be found through DVR ext. 6-9608.

Schedule I and II controlled drugs must be disposed of via DEA Form 222 with the Reverse Distributor. Schedule III-V controlled drugs may be transferred via invoice.

Expired or unusable drugs must be labeled, separated, and stored in a cabinet or safe that meets DEA requirements for the highest level Schedule, until ready for disposal. Maintaining these drugs in a separate box, or container, within the same cabinet where inventory is stored is acceptable.

The controlled drugs Inventory Record must be updated and copies of the records documenting the transfer and disposal of controlled drugs must be maintained for a period of two years. A controlled drugs disposal log can assist with this documentation.

Theft or Significant Loss

If theft is suspected, the DEA License holder shall immediately notify the Office of the Vice Provost for Research, UM Police, and the DEA. The DEA requires that theft or loss of controlled drugs be reported on DEA Form-106, Report of Theft or Loss of controlled drugs. A copy of Form-106 must be kept in the disposition records.

If a container of a controlled drugs is spilled/broken, it must be documented in the record and a witness must sign and date it.

Institutional Monitoring

The Office of the Vice Provost for Research office will provide guidance for License holders regarding DEA expectations, including reviewing inventory records, and acting as a UM representative at all DEA site inspections.

Employee Responsibilities to Report Drug Diversion

From 21 CFR 1301.91:
"Reports of drug diversion by fellow employees are not only a necessary part of an overall employee security program but also serve the public interest at large. It is, therefore, the position of DEA than an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information."

An employee who has knowledge of drug diversion associated with the actions of a fellow employee, student, or supervisor has an obligation to report such information to the Office of the Vice provost for Research or UM Canewatch.

Close Out of Registration

License holders wishing to terminate their registration(s) should prepare a letter to the DEA providing a date of termination. The original registration certificate should be included in the letter to each agency.

Under no circumstances are controlled drugs to be abandoned by a DEA License holder. License holders are expected to properly transfer or dispose of Controlled Substance inventory when controlled drugs are no longer required or prior to departure from their university position. Contact ekapsali@med.miami.edu when preparing to close out.

Any person who is registered with the DEA who violates record-keeping requirements or abandons controlled drugs will be subject to the civil penalties outlined in the United States Code (USC): 21 USC Sec. 842. Please note that abandoning drugs is equivalent to distributing a controlled drug to an unauthorized person.

Forms

A spreadsheet of forms can be found on the DEA website