

Marquette University

Controlled Substances Policy and Procedure

Policy: *It is the policy of Marquette University to properly license, manage, handle, store, and dispose of controlled substances in accordance with State and US Department of Justice Drug Enforcement Administration (DEA) Regulations.*

Objectives: To license, manage, store, and dispose of controlled substances in accordance to regulatory requirements.

Responsibility: *Increased oversight on the part of state and federal authorities has resulted in the requirement for researchers to obtain their own licenses to purchase, possess, and administer controlled substances. In Wisconsin, researchers must have both a Drug Enforcement Administration (DEA) registration (federal) and a Controlled Substance Special Use Authorization (SUA) issued by the State of Wisconsin Controlled Substances Board.*

Procedure:

WI Dept. of Safety and Professional Services (DSPS) Controlled Substance SUA

- WI Controlled Substance SUA must be obtained FIRST, before applying for DEA registration.
- Forms can be obtained from the WI Dept. of Safety and Professional Services (WI DSPS) under Controlled Substances or Controlled Substances Board Application forms. The direct link is: <http://dsps.wi.gov/Default.aspx?Page=4629c414-43ce-4f3d-b1d3-7365d37e4a50>
- Researchers must use Form # 2184 "Application for Research, Analytical Laboratory, Industrial/Commercial Procession, Instructional Activities and Other for Controlled Substances".
- Application forms must be printed out, completed, and

mailed in hard copy.

- Form #2275 provides instructions for filing a new application or amendment. Form #2277 outlines the physical security requirements for storage of controlled substances.
- A complete WI Controlled Substances SUA application will include:
 - ✓ Completed Form # 2184
 - ✓ Signed checklist Form #2836 (you must mail the initialed checklist back to DSPS)
 - ✓ Detailed 1-page layman's description of approved study that places drug use in context. (do not send entire protocol)
 - ✓ Copy of the approval, which can be sent directly to WI DSPS by the Office of Research Compliance upon email request from PI on protocol.

Federal Drug Enforcement Administration (DEA) Registration

- Researchers can only apply for DEA registration once a WI SUA number has been issued.
- Researchers apply for DEA registration from the DEA Office of Diversion Control. The direct link for the online application is: <http://www.deadiversion.usdoj.gov/drugreg/#1>
- DEA applications are better submitted online, but the forms can also be printed and completed in hard copy. Do not submit both online and hard copies.
- Researchers need to complete DEA Form # 225 "Manufacturers, Import/Export, Distributors, Researchers, Dog Handlers, and Labs".

Documentation Needed for the Non-Practitioner Application Process:

- Applicant will need to verify their identity by providing their social security number.
- Applicants curriculum vitae.
- Copy of Marquette's Institutional Care and Use Committee (IACUC) or Institutional Biosafety Committee (IBC) Protocol including signed copy of the approval letter. If not applicable, a

one page summary listing the procedures to be performed for using the controlled substances; the types and quantities to be stored on site; specific protocols for monitoring drug usage, inventory control, destruction, security, storage of the controlled substance inventory and/or records.

Renewal of Registration

- Both the state and Federal Agency responsible for controlled substance registration send notices via the U.S. Postal Service prior to expiration of registration.

Controlled Substances Schedules

- Controlled substances are designated as Schedule I-V (C-I, C-II, C-III, C-IV, and C-V) according to their medical use, potential for abuse, and safety or dependence liability. Use the following link to find and Federal DEA schedules.
 - DEA Schedules_
<http://www.deadiversion.usdoj.gov/schedules/index.html>

Records and Forms

A. Records of Registrants

Every registrant shall maintain records and inventories and shall file reports required by 21 CFR 1304.03.

http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_03.htm

Registered individual practitioner is required to keep records of controlled substances in schedule II, III, IV, and V which are administered in the lawful course of professional practice if they regularly engage in dispensing or administering.

All records required shall be maintained for at least two years for the date of such inventory or records, for inspection and copying by authorized employees of the DEA. Retaining records for five years is advisable due to the statute of limitations. These records must be in conformance with the record keeping and inventory requirements of federal law. This includes all purchasing records, all administering and dispensing records, all Controlled Substance Ordering Forms (DEA Form 222), and all physical inventories. Schedule I and II must be maintained separately from all other records of the registrant, and Schedule III, IV, and V must be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of

the registrant. The phrase "*readily retrievable*" means they can be separated out from other records in a reasonable time.

B. Purchasing Records

Purchasing records can be:

- A copy of the invoice
- A copy of the shipping document
- A copy of the packing slip

Purchasing records must contain:

- The name, address, and DEA number of the company from which the controlled substance was purchased
- The name of the controlled substance purchased
- The size and strength of the controlled substance purchased
- The amount purchased (which should match the amount received)
- preserved animal waste means:

The purchasing record (invoice, shipping document, or packing slip) must be annotated with the handwritten date of receipt. The date written on this document must match the date entered in the "Date Received" Column on your Record of Controlled Substances Purchases (CS Form 2)

C. Administering and Dispensing Records

Administering records must contain:

- Your DEA number, name, and address
- The recipient's DEA number, name, and address
- A complete description of the product and the quantity distributed
- The date of distribution by the selling registrant
- The handwritten date received by the receiving registrant

Dispensing records must contain:

- The name and address of person (research subject) to whom administered /dispensed
- The date administered/dispensed
- The initials of person administering or dispensing on behalf of registrant
- The name of the controlled substance
- The strength and size of the controlled substance
- The amount administered/dispensed (number of units or volume)

Use the Record of Controlled Substance Administered/Dispensed (CS Form 3). This form meets the DEA requirements for recording the amounts of administered/dispensed controlled substances.

D. Inventory Records

Controlled substance inventory is one of the most important aspects of the DEA program. Inventory maintenance is the key to the loss detection, theft, and the diversion of controlled substances. The Controlled Substance Physical Inventory (CS Form 1) meets the DEA requirements for a Controlled Substance inventory record. Complete inventory requirements can be found at the following link:

http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm

E. Security and Employee Authorization Documentation

Schedule I, II, III, IV, and V controlled substances must be properly stored. Security depends greatly on the type, quantity, and form of controlled substances being used in the research project.

- Both the State of WI and Federal DEA have physical security requirements but the State of WI DRL is more stringent. Compliance with WI DSPS ensures compliance with the DEA.
- WI DRL requires a wall-mounted or floor-bolted lockbox. Locked drawers or cabinetry are NOT adequate. The security requirements from WI DSPS can be found as Form #2277, "Physical Security Requirements". Direct link is:

http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm

Researchers must provide effective controls to guard against theft of controlled substances. This includes limiting the number of keys and the number of employees who have access to these keys. Developing a key accountability standard operating procedure is recommended. When possible, only authorized personnel should be allowed in the laboratory where controlled substances are used or stored. Authorized users names must be documented on the Controlled Substances Authorized User List (CS Form 5). A copy should be kept with the controlled substance inventory.

Note: Always ask visitors or individuals entering for identification and why they are there. When maintenance work is done in the controlled substance storage area the research staff must maintain adequate observation.

F. DEA Ordering Forms

To order a controlled substance you must first have a DEA license. The Controlled Substance Ordering Form (DEA Form 222) is a paper-based form

used to order controlled substances. It is requisitioned directly from the DEA and is required to be filled out in triplicate. The DEA Form 222 allows the exchange of controlled substances from the registrant to another party registered with the DEA (typically used when a controlled substance is sent to a reverse distributor for credit or disposal).

Schedule I and II registrants can request official DEA Form 222 on-line at:

- <https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>

You will receive the maximum number of order form books allowed for your business activity.

Schedule III, IV, and V drug orders do not require a DEA Form 222. These drugs can be ordered directly for the manufacturer. However, you may be asked to provide a copy of your DEA Registration before your order will be prepared and shipped.

Use the Record of DEA Form 222 Use (CS Form 4) to maintain accountability of all DEA Form 222's. This form meets the DEA requirement for accountability of all DEA form 222's.

Note: If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes his/her name or address as shown on his/her registration) or is suspended or revoked as to all controlled substances listed in Schedules I and II for which he/she is registered shall relinquish all unused controlled substances and order forms for such substances. EH&S must be contacted to determine the proper procedure to follow for surrendering the registration and relinquishing the order forms and controlled substances in inventory.

G. Disposal and Loss Records

To minimize waste, DEA registrants should only purchase quantities they intend to use. Damaged, expired, unwanted, unusable, or non-returnable Controlled Substances must be accounted for, retained, and disposed of in accordance with applicable State and Federal regulations.

A Registrant's Inventory of Drugs Surrendered (DEA Form 41)

http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_blank.pdf

must be completed prior to disposing of any DEA controlled substance. Two (2) copies of the form must be sent to the local Wisconsin DEA branch and one (1) copy should be retained by the registrant for at least 2 years.

Disposal records must contain:

- Your DEA number, name, and address
- The reverse distributor's DEA number, name, and address
- The number of units (in finished forms and/or commercial container) disposed of in any manner, including the manner of disposal.

The disposal record must be dated to reflect when the products were sent for destruction and left your inventory.

There are three disposal options for expired or unwanted controlled substances recommended by EH&S

1. Supplier Disposal:
Some suppliers will take back pharmaceuticals for credit.
2. On-site Disposal;
Small quantities (less than 1 pound) can be disposed on-site by the DEA registrant using the following six-step controlled substance disposal procedure:
 - I. Contact EH&S ext. 8-8411 with a controlled substance disposal request.
 - II. Complete the Registrants Inventory of Drugs Surrendered (DEA Form 41)
http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_blank.pdf prior to disposal.
 - III. Inform EH&S when DEA Form 41 is complete and ready for review
 - IV. EH&S will forward this form to the DEA with a projected two week disposal date.
 - V. At the end of the waiting period arrangements will be made for a Marquette Public Safety Officer and EH&S representative to be present as witnesses to the disposal, and verify the DEA Form 41 and inventory records.
 - VI. The Registrant shall forward two copies of the DEA Form 41 to the Agent in charge of Wisconsin DEA and retain one copy for their inventory records.
3. Reverse Distribution:
For large quantities (greater than 1 pound), contact a Reverse Distributor. This option transfers ownership of the controlled substance to a DEA-approved Pharmaceutical Returns Processor for re-us, re-sale, or destruction at a hazardous waste incinerator. This process may involve the completion of DEA Form 222 or DEA Form 41.

H. Spills

Breakage, spill, or other witnessed controlled substance losses do not need to be reported as lost. This type of loss must be documented by the registrant and witnessed on the inventory record. Controlled Substances that can be recovered after a spill, but cannot be used because of contamination (tablets), must be placed in the disposal/destruction waste stream. (Completion of DEA Form 41 required). If the spilled controlled substance is not recoverable (liquids); the registrant must document the circumstances in their inventory records and the witnesses must sign.

I. Theft of or Missing Controlled Substance Reporting

The DEA license holder must have complete accountability of all controlled substances stored or used in their area. This makes keeping good records essential so that any shortages or missing controlled substances will not go unnoticed. Theft or misuse of a controlled substance is a criminal act that must be reported to the following agencies:

Marquette Public Safety (414) 288-6800

Wisconsin Dept. of Safety and Professional Services (608) 266-2112

Nearest DEA Office:

Milwaukee DEA District Office
4725 West Electric Ave.
Milwaukee, WI 5319-1627
Tel: (414) 336-7370
Fax (414) 727-5454

In addition to the immediate phone reporting, a Report of Theft or Loss of Controlled Substances (DEA Form 106) <http://www.deadiversion.usdoj.gov/> must be completed and submitted to the DEA Wisconsin office.

Reporting is also necessary if small quantities of controlled substances become unaccounted for on a basis. Keep copies of DEA Form 106 in your inventory records.

J. Other Pertinent Record Information

Maintain current, complete and accurate records to reflect substances:

- Received (purchased)
- Sold (Administered & Dispensed)
- Delivered to another registrant

- Otherwise disposed of
- Theft or loss

Separate records are required for each location

Separate records are required for each independent activity for which he/she is registered

When recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution on any documents of transfer (e.g. invoice or packing slips).

Forms:

These forms will be used to log the purchasing, administration, dispensing, and inventory of controlled substances possessed by DEA registrants.

- Controlled Substance Physical Inventory (CS Form 1)
- Record of Controlled Substance Purchases (CS Form 2)
- Record of Controlled Substances Administration/Dispensed (CS Form 3)
- Record of DEA Form 222 Use (CS Form 4)
- Controlled Substance Authorized User List (CS Form 5)
- Controlled Substance Program Social Security Release (CS Form 6)
- Registrants Inventory of Drugs surrendered (DEA Form 41)
http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_blank.pdf
- Report of Theft or Loss of Controlled Substances (DEA Form 106)
<http://www.deadiversion.usdoj.gov/>
- DEA Applications, Registration Tools, and Resources
<http://www.deadiversion.usdoj.gov/drugreg/index.html>
- DEA Order Forms, Request (for DEA Form 222)
<https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>

Controlled Substance Links:

Code of Federal Regulations Schedule of Controlled Substances

<http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm>

US Department of Justice Drug Enforcement Administration Office of Diversion Control, <http://www.deadiversion.usdoj.gov/index.html>

DEA Security Regulations (21 CFR 1301.71 thru CFR 1301.76)
<http://www.deadiversion.usdoj.gov/index.html>