

CONTROLLED SUBSTANCES INFORMATION SHEET FOR RESEARCHERS

UMMC faculty and staff conducting research or teaching activities with controlled substances must comply with the federal regulations regarding the handling and safeguarding of controlled substances (Title 21, Code of Federal Regulations). It is the responsibility of UMMC to assure that employees maintain adequate records on the acquisition, use, and disposal of controlled substances and that adequate control is established to prevent unauthorized use or diversion of controlled substances.

Information for researchers who dispense controlled substances to patients in the course of professional practice as authorized by his/her registration is not included in this document.

REGISTRATION - OBTAINING A MS BOARD OF PHARMACY / DEA REGISTRATION

According to the Drug Enforcement Agency (DEA), as of 10/14/2009, all researchers who hold a current DEA registration certificate or researchers wishing to obtain a DEA registration certificate must also obtain a Mississippi Board of Pharmacy Controlled Substance Registration.

- **Process to Apply for MS Board of Pharmacy CS Registration:**

1. Locate the Application Form and Fee Schedule at the web address below:
[http://www.mbp.state.ms.us/mbop/Pharmacy.nsf/webpageedit/apLN_apPage_csrfSub/\\$FILE/csfacilityappfinal.pdf?OpenElement](http://www.mbp.state.ms.us/mbop/Pharmacy.nsf/webpageedit/apLN_apPage_csrfSub/$FILE/csfacilityappfinal.pdf?OpenElement)
2. Print the form and complete:
 - Business Name: UMMC – “Your Departmental Affiliation”
 - Principle Business Owners: State of Mississippi
 - Check Proper Blank: Other – Researcher
 - Check Appropriate Schedules: “Drug schedules that will be handled should match the drug schedules you have listed on the DEA Registration application.”
3. Submit completed form with the fee – funding source of payment is left up to the researcher.
4. Mail the completed form and the fee to the physical address below:
***MS Board of Pharmacy
204 Key Drive, Suite D
Madison, MS 39110
Phone: (601) 605-5388***

- **Process to Apply for a DEA Registration:**

1. Apply for DEA Registration as a Researcher using DEA-225 Application
2. DEA-225 Applications are available online at www.deadiversion.usdoj.gov
3. Can submit application online if registration fee is paid by credit card
4. Include Mississippi Board of Pharmacy Controlled Substance Registration number on application
5. Once you are registered, a DEA Certificate of Registration will be mailed to you, or you can go online and download a copy of your certificate.

For information on applicable fees, please visit the DEA website:

<http://www.deadiversion.usdoj.gov/drugreg/categories.htm>

- **DEA Registration Renewals**

1. Researcher registrations must be renewed every three years. Renewal registrations use DEA Form 224a, Renewal Application for DEA Registration. The cost of the registration is indicated on the application form.
2. A renewal application is sent to the registrant approximately 45 days before the registration expiration date. The renewal application is sent to the address listed on the current registration certificate. If the renewal form is not received within 30 days before the expiration date of the current registration, the researcher should contact the DEA registration office for their state, or DEA Headquarters at 1-800-882-9539, and request a renewal registration form.
3. The registration renewal application may be completed online at www.deadiversion.usdoj.gov or in hard copy and mailed to:

**Drug Enforcement Administration
Registration Unit
Central Station
P.O. Box 28083
Washington, D.C. 20038-8083**

- **Termination of Registration:**

1. Any researcher desiring to discontinue business activities with respect to controlled substances must notify the nearest DEA field office in writing or by calling the number below to receive a Voluntary Surrender of Controlled Substance Privilege Form.
2. Along with the form, the researcher should send their DEA Certificate of Registration and any unused Official Order Forms (DEA Form-222) to the physical address below:

**JACKSON DEA DISTRICT OFFICE
100 W. Capitol Street, Suite 1100
Jackson, MS 39269
Diversion Number: (601) 965-4400
Diversion Fax: (601) 965-4401**

3. If the registration of a researcher is terminated, expires, is suspended or revoked or if the address of registration is changed, all unused order forms should be returned to the nearest DEA office.

NOTE: All controlled substances must be properly disposed of prior to requesting termination of registration.

REPORTS AND RECORDS OF THEFT OR LOSS

- **Drugs** - Should a theft or significant loss of any controlled substance occur, a registrant should implement the following procedure within one business day of the discovery of the theft or loss:
 - **Notify DEA and Campus Police** – The theft of controlled substances from a registrant is a criminal act and a source of diversion that requires notification to DEA. Thefts must be reported to the DEA whether or not the controlled drugs are recovered or the responsible parties are identified.
 - **Complete DEA FORM 106 (Report of Theft or Loss of Controlled Substance)** – This form is used to document the actual circumstances of the theft or loss and the quantities of controlled substance involved.
- **Order forms** - whenever any used or unused order forms are stolen or lost, the registrant must notify the DEA promptly.

RECORD KEEPING AND REPORTING

- Persons registered and authorized to conduct research with controlled substances (all schedules) are required to maintain the following information in their "Proof of Use" records:
 1. The name of the substance
 2. Each finished form and the number of units or volume of finished form in each commercial container
 3. The number of commercial containers of each drug received
 4. The number of units or volume administered or otherwise used including the date and time used, the number of units or volume used and the initials of the individual administering
 5. The number of units or volume of drug disposed of including the date and time, manner of disposal and the quantity of drug disposed of
- All documents pertaining to controlled substances must be readily retrievable. Readily retrievable means that documents required must be maintained in such a manner that they can be separated out from other records and verified by the DEA inspectors.
- All records including used order forms, inventory records, proof of use records, and proof of destruction must be maintained for two years.
- Inventories and records of controlled substances in Schedules I and II shall be maintained separately from all of the records of the registrant.
- Inventories and records of controlled substances in Schedules III, IV and V shall 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.

INVENTORY REQUIREMENTS

- The DEA requires an initial inventory and a biennial inventory.
 - ***Initial inventory*** - persons who are newly registered should do an initial inventory taken on the date activities with controlled substances begin.
 - ***Biennial inventory*** - an inventory on the second anniversary of the original inventory date must be made, and thereafter the registrant should continue to take another inventory on that same date every two years.
- The Inventory Record must include:
 1. The name, address and DEA registration number of the registrant
 2. The date and the time the inventory is taken
 3. The signature of the person or persons responsible for taking the inventory
 4. The name of each controlled substance
 5. Each finished form of the substance (e.g., 10mg tablet or 10mg per milliliter)
 6. The number of units or volume of each finished form in each commercial container (e.g., 100 tablet bottle or 3 milliliter vial)
 7. The number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3 milliliter vials)
- Inventory records of each controlled substance must be kept separate from all other records.

ACQUISITION AND DISPOSITION OF CONTROLLED SUBSTANCES FROM THE UNIVERSITY HOSPITAL AND HEALTH SYSTEMS DEPARTMENT OF PHARMACY

- Schedule II drugs may be requested in research areas by properly completing a UMC store order and DEA form #222 and submitting it to the University Hospital and Clinics Pharmacy.
- The DEA Form #222 must be completed appropriately according to federal law:
 1. ***Name of Supplier:*** University Hospital and Clinics Department of Pharmacy
 2. ***The Address:*** "2500 North State Street, Jackson, MS."
 3. ***The Order Date:*** Must be clear and unaltered.
 4. ***The Item Name:*** The line entries must be clear and unaltered. The "name of item" needs to be specific. Include drug name, strength, units, or concentration.
 5. ***Number of items ordered:*** Must be completed with the number of lines used, not number of containers ordered.
 6. ***Signature of purchaser or his attorney or agent:*** Must be signed before filling the order. Each order form must be signed and dated by the person who is named on the form unless a power of attorney is used. When a power of attorney is used, pharmacy must have a list of those given power of attorney before filling the Stores Order. The registrant must file the list of those with power of attorney with the registrant's copies of DEA Form #222.

- Registrant must complete DEA Form #222 with no alterations or change. The pharmacy cannot fill altered or incomplete DEA order forms.
- Pharmacy retains the top two copies of the DEA Form. The requestor retains the bottom copy for his records. This copy must be stored separately from other records of the requestor and kept available for inspection for two years.
- Schedule III-V drug requests will require only a completed stores order with an authorized signature. Only personnel registered and authorized to conduct research with controlled substances may request controlled substances.
- **Dispensing Controlled Substances to Research Areas** - Controlled substances shall be dispensed to research areas by the narcotic quality assurance assistant or the narcotic pharmacist for that shift. Authorized pharmacy personnel will properly complete the DEA form and stores order. Copy #2 of the completed DEA form #222 will be sent to the DEA office and the original will be appropriately filed for a period of at least two years.
- **Disposal of Unwanted/Out of Date Controlled Substances** - The Pharmacy Department cannot accept unwanted or out of date controlled substances for disposal. To dispose of any unwanted or out of date controlled substances the registrant should complete the following:
 1. Complete DEA Form 41
 2. Obtain copies of the original DEA Form 222 and active inventory for the drug to be disposed of.
 1. Contact the Department of Environmental Health and Safety who will arrange disposal. Contact Information: Yolanda Griffin, Biological Safety Officer email: ygriffin@umc.edu or call (601)815-5074.

ACQUISITION AND DISPOSITION OF CONTROLLED SUBSTANCES UNDER INDIVIDUAL REGISTRATION

- Ordering from your individual supplier may require further ordering requirements.
- In addition, Schedule II drugs may be requested by properly completing a DEA form #222.
- The DEA Form #222 must be completed appropriately according to federal law:
 1. Name of Supplier: (Name of researcher holding DEA registration)
 2. The Address: "2500 North State Street, Jackson, MS."
 3. The Order Date: Must be clear and unaltered.
 4. The Item Name: The line entries must be clear and unaltered. The "name of item" needs to be specific. Include drug name, strength, units, or concentration.
 5. Number of items ordered: Must be completed with the number of lines used, not number of containers ordered.
 6. Signature of purchaser or his attorney or agent: Must be signed before filling the order. Each order form must be signed and dated by the person who is named on the form. The registrant must file the list of those with power of attorney with the registrant's copies of DEA Form #222, if applicable.

- The requestor retains copies of the DEA Form for his records. This copy must be stored separately from other records of the requestor and kept available for inspection for two years.
- Only personnel registered and authorized to conduct research with controlled substances may request controlled substances.
- **Receiving Controlled Substances in Research Areas** – The registrant must open and verify the contents when receiving controlled substances. Any discrepancies should be rectified with the supplier. Purchase and shipment receipts should also be maintained by the registrant.
- **Disposal of Unwanted/Out of Date Controlled Substances** - To dispose of any unwanted or out of date controlled substances the registrant should complete the following:
 2. Complete DEA Form 41 (Registrants Inventory of Drugs Surrendered)
 3. Obtain copies of the original DEA Form 222 and active inventory for the drug to be disposed of.
 4. Contact the Department of Environmental Health and Safety who will arrange disposal. Contact Information: Yolanda Griffin, Biological Safety Officer email: ygriffin@umc.edu or call (601)815-5074.

STORAGE AND SECURITY

- The DEA requires controlled substances be stored in "securely locked, substantially constructed cabinet" to guard against theft and diversion.
 - Controlled Substances in Schedule I or II must be kept separate from other drugs and materials.

FOR FURTHER REFERENCE:

DEA Drug Diversion website: <http://www.deadiversion.usdoj.gov/>

Title 21, Code of Federal Regulations, Part 1300: <http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>