

Controlled Substance Registration Process and Record Keeping

**IMPORTANT INFORMATION REGARDING CONTROLLED SUBSTANCES
PLEASE FILE WITH YOUR CONTROLLED SUBSTANCE RECORDS**

The Drug Enforcement Administration (DEA) requires that the Principal Investigator on a research project be the registrant of controlled substances. This requirement increases accountability and places the responsibility for record keeping and inventory on the individual who holds the registrations. **Registrants may not provide Controlled Substances to Researchers in other laboratories or locations.** Each Principal Investigator using controlled substances must have their own DEA and SC Department of Health and Environmental Control (SC DHEC) Registrations.

I. How to obtain new state and federal controlled substance registrations

A. SC DHEC registration

RESEARCHERS	HOSPITAL CLINICS
1. Complete and submit an application for new registration: Form 1026 http://www.scdhec.gov/administration/library/d-1026.pdf	1. Complete and submit an application for new registration: Form 1026 http://www.scdhec.gov/administration/library/d-1026.pdf
2. Attach to the application a copy of: <ul style="list-style-type: none"> • The Registrant’s Curriculum Vitae • The Research Protocol (You must include an explanation of security measures implemented and <u>exact</u> room location where controlled substances will be stored. If applying for a Schedule I controlled substance, please submit <u>two</u> copies of your protocol.) • A current copy of the registrant’s professional license (if applicable) 	2. Attach a current copy of the registrant’s professional license (if applicable)
3. Complete credit card information or submit a check for specified amount payable with the complete application to: S.C. Department of Health & Environmental Control Finance Division P.O. Box 100103 Columbia, SC 29202-3103	3. Complete credit card information or submit a check for specified amount payable with the complete application to: S.C. Department of Health & Environmental Control Finance Division P.O. Box 100103 Columbia, SC 29202-3103

B. DEA registration

1. Complete a paper application for **new registration**: DEA Form 225
(http://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_form.pdf)
Upon completion, form 225 should be mailed or delivered to Internal Audit to be certified for fee exemption.
(<http://academicdepartments.musc.edu/provost/pdf/DEAexemptionFee.pdf>). Internal Audit will electronically submit or mail the form 225 to DEA.

Curriculum vitae and research protocol should be submitted to support registration.
2. Renewal of **existing registrations** DEA Form 225a should be mailed, or delivered to Internal Audit for fee exemption. Internal Audit will electronically submit the renewal application.

II. Required Documents and Records

Regulations require that all controlled substance records be kept separate from all other records and marked in a manner making them readily available. Records for Schedules I and II controlled substances should be kept separate from records for Schedules III through V. For example, Schedule I 222 forms, invoices and disposition records should be separated with clearly marked dividers from Schedule II 222 forms, invoices and disposition records. Records for Schedules III through V can be kept together. We recommend organizing all controlled substance records in a three-ring binder with clearly marked dividers separating each type of record. This system will provide easier access for the DEA and the SC DHEC upon inspection or audit. All controlled substances should be maintained in a safe or in a cabinet with two separate locks requiring different keys. The records should be kept in the same area.

Certain records are required by the State and Federal Controlled Substances Act. Each area with a registration to handle controlled substances is required to maintain the following list of documents. Information concerning the State regulations governing controlled substances may be found under DHEC Regulation, Section R61-4.

A. **DEA Registration** to maintain controlled substances

This original document must be kept in the area where controlled substances are maintained. It does not have to be posted on a wall, however, it must be readily available.

B. **South Carolina DHEC Registration** to maintain controlled substances

This original document must be kept in the area where controlled substances are maintained. It does not have to be posted on a wall, however, it must be readily available.

C. **Federal 222 forms (unexecuted)**

1. All unexecuted 222 forms for MUSC registered areas are kept by the registrant or Pharmacy Services. The forms are mailed from DEA to the registrant immediately after registration is completed and each time a change is made to the registration. Excess forms may be surrendered to a representative of Internal Audit during a scheduled audit or by contacting Internal Audit.
2. Unexecuted 222 forms for Schedule I controlled substances must be maintained separately from all other records of the registrant. They may be secured in the safe or double lock security cabinet with the controlled substances.
3. Unexecuted 222 forms for Schedule II controlled substances must be maintained separately from all other records of the registrant. They may be secured in the safe or double lock security cabinet with the controlled substances.

D. The **Power of Attorney** form allows Pharmacy Services representatives to sign 222 forms to order drugs under your registration.

The original Power of Attorney form should be kept with your controlled substance records. If the records are maintained in folders, we recommend keeping it in the same folder as the signature sheets discussed below. If the records are maintained in a binder, it may be kept in the same section as the signature sheets. A copy of the Power of Attorney form must be forwarded to the Controlled Substances Services division of Pharmacy Services and University Compliance upon execution of the document.

Pharmacy Services, Controlled Substances
169 Ashley Avenue
Main Hospital, Room 149
MSC 336
Fax 792-7564

University Compliance
49 Bee Street
MSC 857
Fax 792-7066

E. **Signature/Authorization Sheets** authorize specific people to order and pick up controlled substances and to keep the records of controlled substance usage. Each Registrant may authorize individuals in their area to:

1. Place orders for controlled substances with Pharmacy Services,
2. Pick up the controlled substances from Pharmacy Services, and
3. Maintain the records of controlled substances obtained and administered under the Registrant's DEA number.

We recommend identifying no more than three authorized individuals for each task. The original is filed with Pharmacy Services, a copy should be maintained with your controlled substance records, and a copy sent to University Compliance.

Pharmacy Services, Controlled Substances
169 Ashley Avenue
Main Hospital, Room 149
MSC 336

University Compliance
49 Bee Street
MSC 857
Fax 792-7066

F. Invoices and Executed DEA 222 forms

1. Invoices and executed DEA 222 forms must remain in the area where the controlled substances are stored.
2. Related Invoices and executed 222 forms for Schedule I controlled substances should be stapled together and kept with other Schedule I records separated from other records by a clearly marked divider. Schedule I records are to be retained separate from all other controlled substance records.
3. Related Invoices and executed 222 forms for Schedule II controlled substances should be stapled together and kept with other Schedule II records separated from other records by a clearly marked divider. Schedule II records are to be retained separate from all other controlled substance records.
4. Invoices for Schedule III-V controlled substances are to be kept with other Schedule III-V records separated from other records by a clearly marked divider.

G. Disposition Records (Control Sheets)

1. Disposition records (control sheets) must remain in the area where controlled substances are stored.
2. Disposition records (control sheets) for Schedule I controlled substances should be kept with other Schedule I records separated from other records by a clearly marked divider.
3. Disposition records (control sheets) for Schedule II controlled substances should be kept with other Schedule II records separated from other records by a clearly marked divider.
4. Disposition records (control sheets) for Schedule III-V controlled substances should be kept with other Schedule III-V records separated from other records by a clearly marked divider.

H. Annual June 30 Inventory of Controlled Substances

1. Federal and State regulations require a bi-annual inventory on May 1 of every odd year. **MUSC is exempt from this regulation and elects to take annual inventories of all controlled substances on June 30 to coincide with our fiscal year end inventory.**
2. All Registrants are required to perform an inventory count of all controlled substances at the **close of business on June 30** (or the last workday before June 30) every year. The time the inventory is taken must be indicated on the form. A Registrant's Inventory of Controlled Substances form must be completed even if there are no controlled substances on hand. The original form is to be retained with the Registrant's controlled substance records and a copy mailed or faxed to:

University Compliance
49 Bee Street
MSC 857
Fax 792-7066

I. Pharmacy Permit or Drug Outlet Permit issued by the Board of Pharmacy

All Registrants of pharmacy or clinic areas must also have a Pharmacy Permit or a Drug Outlet Permit issued by the SC Board of Pharmacy. This original permit must be publicly displayed on the wall. We recommend posting it next to the controlled substance storage area.

J. Destruction of Controlled Substances

Federal and State regulations require disposition of all expired, contaminated or unwanted controlled substances in accordance to **Section 1307.21** of the Code of Federal Regulations. SC DHEC has authorized Internal Audit to destroy expired, contaminated or unwanted controlled substances.

1. Destruction of controlled substances must be documented using the **DEA Form 41**, Registrant's Inventory of Drugs Surrendered. The original copy of the form must be filed with the registrant's controlled substances records.
2. Destrutions can be conducted during routine audits or by appointment. Contact the Controlled Substance Investigator at 792-4199, 792-4561 or pager 11283.

K. Record Keeping Recommendations

1. Maintain all records in a three-ring binder clearly marked controlled substance records.
2. Use clearly marked **TABS** for each type of record.
3. Arrange in the following order:

1 st Tab	Registrations: DHEC & DEA (Originals)
2 nd Tab	Power of Attorney (Original)
3 rd Tab	Authorization Sheets (for ordering and picking up controlled substances)
4 th Tab	Audit Letters/Reports
5 th Tab	Annual Inventory
Tabs for each	Schedule I, Schedule II, and/or Schedule III-V control sheets (whichever is appropriate)
Tabs for each	Schedule I and/or Schedule II Invoices and Executed 222's (STAPLED) together
Tabs for each	Schedule III-V Invoices
Tabs for each	Schedule I and/or II Destrutions/Discrepancies
Tab	Schedule III-V Destrutions/Discrepancies
Tab	Policy and Procedures
Tab	Miscellaneous Records

Unexecuted DEA 222 forms should be secured with controlled substances.

4. When possible, Internal Audit will provide three ring binders, document separators, and pre-printed labels to assure uniform record keeping and compliance with DEA and DHEC regulations.

III. Security Requirements

All applicants and registrants shall provide effective controls and procedures to guard against theft or diversion of controlled substances. Where small quantities of controlled substances are stored, a combination safe or securely mounted double locked steel cabinet is suitable. Each lock on the steel cabinet must be keyed separately.

Internal Audit has information and brochures regarding safes and storage cabinets that meet the requirements of DEA and DHEC regulations.

IV. Relocation of Controlled Substances

If controlled substances are moved from the initial location identified on the DEA and DHEC registration, a letter to DEA and DHEC must be submitted by the registrant. The letter must include the Registrants name, address including the mail stop code (MSC) number, registration number as printed on the certificate of registration and room number where the Controlled Substances are stored. The mailing addresses are:

Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

SC DHEC
Bureau of Drug Control
Controlled Substance Services
2600 Bull Street
Columbia, SC 29201

Please send a copy of the letters to Internal Audit and Pharmacy Services at the following addresses:

Internal Audit
45 Bee Street, MSC 206
Fax 792-1204

Pharmacy Services
169 Ashley Avenue
Main Hospital, Room 149, MSC 336
Fax 792-7564

V. Modification in Registration

Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address. The letter shall:

- Contain the registrant's name, address, and registration number as printed on the certificate of registration,
- List the substances and/or schedules to be added to his/her registration, and
- Shall be signed in accordance with 1301.13(j) for DEA and signed in accordance with Regulation 116(f) with DHEC.

The letter of request should be mailed to the following addresses:

Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

SCDHEC
Bureau of Drug Control
Controlled Substances Services
2600 Bull Street
Columbia, SC 29201

Please send a copy of the letters to Internal Audit and Pharmacy Services at the following addresses:

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Fax 792-1204

Pharmacy Services, Controlled Substances
169 Ashley Avenue
Main Hospital, Room 149, MSC 336
792-7564

VI. Termination of Registration

Any registrant desiring to discontinue business activities altogether or with respect to controlled substances shall return to DEA his/her DEA certificate of registration and any unexecuted order forms in his/her possession for cancellation. The registrant shall also return his/her DHEC certificate of registration to DHEC. The addresses are provided below.

Drug Enforcement Administration
Attn: Office of Diversion/OD
8701 Morrisette Drive
Springfield, VA 22152

SC DHEC
Bureau of Drug Control
Controlled Substances Services
2600 Bull Street
Columbia, SC 29201

Please send a copy of the letters to Internal Audit and Pharmacy Services.

Internal Audit
45 Bee Street, MSC 206
Fax 792-1204

Pharmacy Services, Controlled Substances
169 Ashley Avenue
Main Hospital, Room 149, MSC 336
Fax 792-7564

ALL CONTROLLED SUBSTANCE RECORDS MUST BE RETAINED FOR THREE FULL YEARS AND STORED IN THE AREA IN WHICH THE CONTROLLED SUBSTANCES ARE KEPT.

VII. Internal Audit Contact Information

Internal Audit monitors MUSC's compliance with Federal and State regulations regarding controlled substances. If you have any concerns, please contact us.

Office: 792-4561
Office: 792-4199
Pager: 792-0590 ID 11283 or 12540
Fax: 792-1204

Address: 45 Bee Street
MSC 206