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**MEMORANDUM**

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

December 7, 2004

To: All MUSC DEA and DHEC Registrants  
From: J. Paul Taylor, Director  
Tom Brown, Controlled Substance Investigator  
Subject: DEA and DHEC Registration Process and Record Keeping

The Drug Enforcement Administration requires that the Principal Investigator on a research project be the registrant of controlled substances, instead of the Department Chairman. We have been working closely with DEA and DHEC to comply. We agree with this change because it 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 DHEC Registrations.

**Registration Process (two part requirements):**

➤ **DHEC registration:**

**A. Reseachers:**

1. Complete and submit an application for new registration: NDC Form 225/227
2. Submit Curriculum Vitae
3. Submit Research Protocol **(You must include an explanation of security measures implemented and exact room location where controlled substances will be stored must be included) If using a Schedule I controlled substance please submit two copies of your protocol.**
4. Submit a current copy of your professional license (if applicable)
5. Submit Check for \$125.00 payable to:

S.C. Department of Health and Environmental Control  
Finance Division  
P.O. Box 100103  
Columbia, SC 29202-3103

## **B. Hospital Clinics:**

1. Complete and submit an application for new registration: NDC Form 225/227
2. Submit a current copy of your professional license (if applicable)
3. Submit Check for \$125.00 payable to:

S.C. Department of Health and Environmental Control  
Finance Division  
P.O. Box 100103  
Columbia, SC 29202-3103

### ➤ **DEA registration:**

1. Complete and submit an application for **new registration**: DEA Form 224  
**UPON COMPLETION, FORM 224 MUST BE FORWARDED TO THE INTERNAL AUDIT DEPARTMENT TO BE CERTIFIED FOR FEE EXEMPTION. INTERNAL AUDIT WILL MAIL THE FORM 224 TO DEA.**

Curriculum vitae and research protocol may be submitted to support registration. However, they are only required for a Schedule I registration.

2. Renewal of **existing registrations** DEA Form 225a should be mailed or delivered to Controlled Substances Services in Pharmacy Services, Main Hospital, Room 149.

### ➤ **Required Documents and Records:**

Regulations specify 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 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. 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 Drug Enforcement Agency and the South Carolina Bureau of Drug Control upon inspection or audit. **All controlled substances and controlled substance records should be located in the same area and should be maintained in a safe or in a cabinet with two separate locks requiring different keys.**

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.

1. **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.*
2. **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.*
3. **Federal 222 forms (unexecuted)**
  - A. 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 the Internal Audit Department during a scheduled audit or by contacting the Internal Audit Department.

- B. 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.
  - C. 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.
4. 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 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 in #5 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 given to Pharmacy Services, Controlled Substances Services, upon execution of the document.*
5. **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) authorize others to pick up the controlled substances from Pharmacy Services, and
  - 3) maintain the records of controlled substances obtained 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 and a copy should be maintained with your controlled substance records.

6. **Invoices and Executed DEA 222 forms**

- A. Invoices and executed DEA 222 forms must remain in the area where the controlled substances are stored.
- B. 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.
- C. 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.
- D. 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.

7. **Disposition Records (Control Sheets)**

- A. Disposition records (control sheets) must remain in the area where controlled substances are stored.
- B. 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.
- C. 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.

- D. 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.

8. **Inventory of Controlled Substances**

- A. 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.**
- B. All Registrants are required to perform an inventory count of all controlled substances at the **close of business on 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 sent to Pharmacy Services.

9. **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 Board of Pharmacy. This original permit must be publicly displayed on the wall. We recommend posting it next to the controlled substance storage area.

10. **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. The Drug Enforcement Administration has authorized the Controlled Substance Investigator in the Internal Audit Department to destroy expired, contaminated or unwanted controlled substances.

- A. 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.
- B. Destructions can be conducted during routine audits or by appointment. Contact Mr. Tom Brown at 2-4199 or pager 11283.

11. **Record Keeping Recommendations**

- A. Maintain all records in a three-ring binder clearly marked controlled substance records.
- B. Use clearly marked **TABS** for each type of record.
- C. Arrange in this order:
  - Tab Registrations: DHEC & DEA (Originals)
  - Tab Power of Attorney (Original)
  - Tab Authorization Sheets (for ordering and picking up controlled substances)
  - Tab Audit Letters/Reports
  - Tab Annual Inventory
  - Tabs for each Schedule I, Schedule II, OR Schedule III-V control sheets (whichever is appropriate)
  - Tabs for each Schedules I, Schedule II Invoices/Executed 222's (STAPLED) together
  - Tabs for each Schedule III Invoices
  - Tabs for each Schedule II Destructions/Discrepancies
  - Tab Schedule III-V Destructions/Discrepancies
  - Tab Policy and Procedures
  - Tab Miscellaneous Records

Unexecuted DEA 222 forms should be secured with controlled substances.

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

12. **Security Requirements**

- A. 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.
- B. Controlled Substances Services, in Pharmacy Services, has information and brochures regarding safes and storage cabinets that meet the requirements of DEA and DHEC regulations. They can be contacted at 792-7022.

13. **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 through Pharmacy Services; please copy Internal Audit. The letter must include the Registrants name, address including the P.O. Box 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  
Department of Justice  
P.O. Box 28083, Central Station  
Washington, DC 20005

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

14. **A. 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:

- 1) the registrant's name, address, and registration number as printed on the certificate of registration,
- 2) the substances and/or schedules to be added to his/her registration, and
- 3) 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:

The Registration Unit  
Drug Enforcement Administration Services  
Department of Justice  
P.O. Box 28083, Central Station  
Washington, DC 20005

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

**B. 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 for cancellation, and any unexecuted order forms in his/her possession. The registrant shall also return his/her DHEC certificate of registration to DHEC. The addresses are provided below.

The Registration Unit  
Drug Enforcement Administration Services  
Department of Justice  
P.O. Box 28083, Central Station  
Washington, DC 20005

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

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

Internal Audit Department  
166 Ashley Avenue  
P.O. Box 250206

Pharmacy Services  
169 Ashley Avenue  
Main Hospital, Room 149  
P.O. Box 250336

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

Ms. Susan Barnhart and myself are responsible for monitoring MUSC's compliance with Federal and State regulations regarding controlled substances. More specifically, we are responsible for monitoring the duties of Mr. Tom Brown, the Controlled Substances Investigator. If you have any concerns, please feel free to call me at 2-4570, Ms. Susan Barnhart (2-1316/pager 12540) or Mr. Tom Brown (2-4199/pager 11283).

If you have any questions concerning the information contained in this memorandum or need assistance in setting up your record system, please contact Mr. Brown or Ms. Barnhart.