SPECIAL NOTICE:
To
PHYSICIANS, DENTISTS, VETERINARIANS AND PODIATRISTS

From

NEW HAMPSHIRE BOARD OF PHARMACY
Compliance Division

SUBJECT:  DEA “Technical Violation” Inspections

It has come to our attention that Drug Enforcement Administration investigators have been involved in “Technical Violation” inspections in some of our neighboring states. We believe that our random inspection activities have addressed many issues and that we have minimal problems here in New Hampshire. We have developed this document to include some pertinent information. If you need any assistance or have any questions, please feel free to contact the Board of Pharmacy office at any time (603) 271-2350. The investigators will be happy to assist you in any way that they can.

1.  CORRECT ADDRESS ON YOUR DEA REGISTRATION

   Have you moved your office location and not changed the address on your DEA registration?

   Have you opened a second or third place of practice and have controlled drugs on the premises at each of these locations?

   DEA registers by location and you must notify them of any change of location or addition of location of practice if different from the original location listed on your registration.

2.  Have you changed your name?

3.  Is your primary office in another state and you only practice in NH on a part-time basis?

   If your DEA registration is assigned to an address in another state, you need to complete a separate registration for EACH STATE in which you practice.

4.  ARE YOU REGISTERED FOR THE APPROPRIATE SCHEDULES?

   Almost ALL practitioners (very few exceptions) should be registered for schedule 2,2N,3,3N,4&5.

   If your registration does not indicate the above, you may unknowingly be engaging in illegal distribution. PLEASE take a moment to check your registration certificate. If you have a question, please call the Board of Pharmacy for assistance.
CONTROLLED SUBSTANCES IN THE OFFICE:

Should you possess ANY controlled substances in your office (samples included), please take a minute to review the following:

1. RECORDS OF RECEIPT

   CII= These drugs are obtained by using DEA Form 222 (triplicate narcotic order blank) and completed order forms must be filed separately and readily retrievable.

   BOTH FEDERAL AND STATE LAW PROHIBIT THE USE OF “PRESCRIPTIONS” IN ORDER TO OBTAIN ANY CONTROLLED SUBSTANCES FOR OFFICE USE OR GENERAL DISPENSING.

   CIII-V= These drugs are obtained via an invoice and upon receipt, should be filed separately and readily retrievable. This includes obtaining and filing receipts for ANY controlled drug samples left by manufacturers representatives.

2. RECORDS OF DISTRIBUTION

   DEA has ruled that “patient histories” do not constitute readily retrievable records. We suggest a log book with a separate page for each controlled substance on hand. Each page would indicate the following:

   Date of dispensing
   Patient’s name
   Patient’s address
   Quantity of drug dispensed
   Number of dosage units left on hand
   (See sample on page 10)

   Maintaining these distribution records will also assist you in monitoring any suspected or potential internal employee diversion.
3. **BIENNIAL INVENTORY**

Both Drug Enforcement and the New Hampshire Controlled Substance Act requires that a complete inventory of controlled substances on hand be conducted on May 1, 1991 and repeated on May 1\textsuperscript{st} of each odd numbered year thereafter (biennially). This should be completed on the required date and filed in such a fashion that it is separate and readily retrievable.

(See sample on page 11)

Each practitioner's office (that engages in the possession of controlled drugs) should have THREE separate file folders for the following receipt records:

1. All records of receipt of Class II drugs (CII)
2. All records of receipt of Class III-V drugs (CIII-V)
3. The biennial inventory

Again, we hope that this information will be of assistance to you. Should you have any questions or require any assistance, please, call the Board of Pharmacy office (6030 271-2350. Remember, Drug Enforcement applies civil fines to violations in the amount of $25,000 per violation. A telephone call for assistance can save you time and money.
LEGAL REQUIREMENTS FOR NEW HAMPSHIRE PRACTITIONERS
ADMINISTRATION/DISPENSING CONTROLLED SUBSTANCES FROM THEIR OFFICES
(SUMMARY OF FEDERAL & STATE REGULATIONS)

The licensed practitioner is given the authority to dispense legend drugs to meet the “immediate needs” of their patients, by law. In the case of a “controlled drug”, dispensing is limited to a Bona Fide EMERGENCY. This authority is granted by law and CANNOT be delegated to other office personnel. The authorized prescriber is responsible for ALL drugs dispensed and NO drugs may be dispensed except By or Under the DIRECT SUPERVISION of the practitioner. “Direct Supervision” is defined by law as, “Under the direct charge or direction and does not contemplate any absence of the person responsible for providing such supervision.
RSA318:1,XIX
RSA318:42,II
RSA318-B:10,1

Records to be Kept: Confidentiality:

Practitioners including physicians, podiatrists, dentists, veterinarians, optometrists, advanced registered nurse practitioners, manufacturers, wholesalers, pharmacists, clinics, hospitals and laboratories shall keep separate records, so as not to breach the confidentiality of patient records, to show the receipt and disposition of all controlled drugs. Such records shall meet the requirements of the department of Health and Human Services and federal laws and regulations relative to the receipt, manufacture, inventory, distributions, sale, dispensing, loss, theft, and any other disposition of controlled drugs. The records shall indicate at least the name, dosage form, strength, and quantity of the controlled drug; the name and address of any person to whom the drug was administered, dispensed, sold or transferred and the date of any and all transactions involved with the controlled drug.
RSA318-B:12,1

INVENTORY REQUIREMENT:

All practitioners, registered with the US Drug Enforcement Administration, engaging in possession, administration or dispensing of controlled substances, are required to conduct and maintain inventories of these substances.
21 CFR 1304.11
21 CFR 1304.21

Practitioners including physicians, podiatrists, dentists, veterinarians, optometrists, advanced registered nurse practitioners, manufacturers, wholesalers, pharmacies, clinics, hospitals, laboratories, and any other person required by federal law to conduct biennial controlled substance inventories, shall do so beginning May 1, 1991, and thereafter on May 1st of every odd-numbered year.
RSA 318-B:12, III

INVENTORY CONTENT:

1. The name, address and DEA registration number of the registrant
2. The date and time that the inventory was taken (open or close of business)
3. Signed by the person or persons responsible for taking the inventory
4. An exact count of ALL Schedule II controlled substances on hand
5. Schedule II controlled substance inventories shall be separate from inventories of Schedule III - V controlled substances.
All inventories and records of receipt and distribution of controlled substances listed in Schedule II shall be separate from all inventories and records of receipt and distribution of Schedule III-V controlled substances.

21 CFR 1304.04

Records of receipt and distribution of controlled substances shall be maintained by the registrant and available for inspection for a period of 4 years.

All inventories and records of receipt and distribution for all controlled substances must be maintained separately or must be in such a form that they are “readily retrievable” from the ordinary professional and business record of the practitioner.

*Note: DEA has taken the position that patient records or charts that reflect orders for controlled substance are not readily retrievable within the meaning of the Act. An agency statement has the same legal effect as a rule.

5 USC 551(4)

PURCHASE RECORDS:

A practitioner may NOT issue a prescription order in order to obtain controlled substances (any schedule) for the purposes of general dispensing or administration.

21 CFR 1306.04 (b)

Schedule II Controlled Substances:
All scheduled controlled substance must be purchased (transferred from registrant to registrant) via execution of DEA Form 222 (triplicate narcotic order form).

*Note: After receiving the order, the invoice and the executed DEA Form 222 should be attached to each other and kept that way in order to substantiate the receipt of the items. Also the purchaser must complete the far right hand side of the form, indicating the number of packages and the date received.

Schedule 111-V Controlled Substances:
Practitioners receiving controlled substances in these schedules (samples included) must maintain records of transactions by filing “suppliers” invoices in a separate, readily retrievable fashion. The date of receipt and any difference from the quantity ordered should be noted on the invoice. These records must be maintained at the registered location for a period of four (4) years.

21CFR 1304.04
21CFR 1305.03
21CFR 1306.21

SECURITY REQUIREMENTS:
Controlled substances in schedules II - V shall be stored in a securely locked, substantially constructed cabinet.

21CFR 1301.75(b)

CONTROLLED SUBSTANCE LOSSES:
Any and all controlled substance losses, (including theft or tampering) must be reported to local police, Board of Pharmacy, and the US Drug Enforcement Administration, retaining one copy with the registrant’s controlled substance records. The report to the DEA is made by completing a DEA form 106, available at the Board of Pharmacy office.
OUTDATED/UNWANTED CONTROLLED SUBSTANCES:
Disposal of these items must be documented on the official DEA form 41, retaining one copy with the registrant’s controlled substance records. This is accomplished either by agents of the Board of Pharmacy or retaining the services of an approved “reverse distributor”. Under NO circumstances should practitioners take it upon themselves to independently destroy controlled substances from their inventory.

DISPENSING LIMITATIONS FOR CONTROLLED SUBSTANCES:
A practitioner other than a veterinarian, in good faith, in the course of his professional practice, and for a legitimate medical purpose, may administer and prescribe controlled drugs, or the practitioner may cause the same to be administered by a nurse or intern under his direction and supervision. In a bona fide emergency situation, the practitioner may dispense a controlled drug to a patient under his care but only in a quantity not to exceed a 48 hour supply for all schedule II substances or 7 day supply of schedule III-V substances.
RSA 318-B:10, I

A veterinarian, in good faith, in the course of his professional practice only, and not for use by a human being, may administer and prescribe controlled drugs, and the veterinarian may cause them to be administered to an animal under his care, but only in a quantity not to exceed a 48-hour supply of a schedule II substance or a 7 day supply of schedule III-V substances.
RSA 318-B:10, II

Practitioners maintaining inventories of controlled substances, for either administration or dispensing, would be well served by maintaining “perpetual” inventory documents, specifically for the purposes of readily identifying possible internal diversion problems.

LABELING REQUIREMENTS:
When a practitioner, other than a pharmacist, but including a physician, dentist, podiatrist, optometrist, veterinarian or advanced registered nurse practitioner dispenses a controlled drug, he/she shall indicate on the label the following:

1. Name of the practitioner
2. Name & address of patient
3. Date dispensed
4. Name of drug dispensed
5. Strength of the drug
6. Quantity of drug dispensed
7. Directions for administration
RSA 318-B:13, III

ENFORCEMENT:
Enforcement of all provisions of Chapter 318 & 318-B shall be the duty of the Board of Pharmacy. Its inspectors and investigators shall have free access during normal business hours to all places where drugs, medicines, poisons or hypodermic devices are held, stored or offered for sale and to all records pertaining to the sale and disposition of such.
RSA 318-8, RSA 318-8-a, R-A 318-B:12, II, and RSA 318-8:25

Assistance in compliance with these regulations may be obtained from:

OPLC-Board of Pharmacy
121 South Fruit Street
Concord, NH 03301

U.S. Dept. of Justice
Drug Enforcement Administration
JFK Federal Bldg, Room E-400
15 New Sudbury Street
Boston, MA 02203
(617)557-2200
Ph 704.02 Pre-signed Prescription Blanks. No person shall possess, and no pharmacy shall have within it, any document signed by a prescriber which, if completed, would be usable as a prescription.

Ph 704.14 Prescription Refill Limitations.
   a) Prescriptions bearing "PRN", "Ad lib" or other similar prescription refill designation permitting the pharmacist to refill the prescription as needed by the patient, shall be refilled only in keeping with the number of doses ordered and according to the directions for use, and in no instance shall such prescription be refilled beyond one year from the date of issue. If additional medication is needed thereafter, the original prescription shall be voided and a new prescription obtained.

   b) No prescription containing either specific or "PRN" refill authorization shall be refilled after the prescribing practitioner ceases to practice:

1. Due to license suspension or revocation;
2. If he/she no longer maintains a valid NH license;
3. If prescribing limitations are placed on a practitioner’s license by any state or federal licensing agency: which impact on certain previously refillable prescriptions; or
4. Due to death.

   c) Notwithstanding (a) and (b) above, the pharmacist may dispense an additional refill supply according to the provisions of Ph 704.15
STATE OF NEW HAMPSHIRE

BOARD OF PHARMACY

SAMPLES

We recognize for many practitioners, manufacturer's samples are an integral part of your practice. It is NOT our intention to disrupt your normal course of practice. However, we would like to make you aware of some VERY IMPORTANT issues pertaining to medications that are possessed and dispensed (samples and stock medications) at the practitioner level.

1. Records of RECEIPT and DISTRIBUTION must be available for all the transactions involving controlled substances. (There are NO state requirements for NON-controlled substances)

2. All controlled substances dispensed, must be in child resistant containers and PROPERLY LABELED prior to dispensing.

3. If you have outdated/unwanted controlled substances, you must call the Board of Pharmacy office to request a "drug destruction". DO NOT DESTROY THESE DRUGS ON YOU OWN. THERE ARE SPECIAL DEA FORMS THAT MUST BE COMPLETED IN ORDER TO AVOID POTENTIAL VIOLATIONS OF THE CONTROLLED SUBSTANCE ACT. Please contact the Board of Pharmacy at (603) 271-2350.

Upon receiving your call, we shall attempt to complete the drug destruction at our earliest convenience. Most of the time, the destruction can be completed on site. If there is a large volume of drugs, they may need to be removed for incineration. As of July 1, 1992 we no longer have access to an incineration site and we are asking that you request or accept a supply of samples that you will use prior to their expiration dates. Thank you for assistance in this matter.
III. Prescriptions written by practitioners for controlled drugs shall be executed in clear, concise, readable form and may be typewritten. Each prescription shall contain the following information and comply with the following requirements:

a) The full name and complete address of the patient or of the owner of the animal for which the drug is prescribed.
b) The day, month, and year the prescription is issued.
c) The name of the controlled drug prescribed. Only, one controlled drug shall appear on a prescription blank.
d) The strength of the controlled drug prescribed.
e) The specific directions for use of the controlled drug by the patient.
f) No refills shall be authorized for controlled drugs in schedule II of the current chapter 21, Code of Federal Regulations.
g) The Federal Drug Enforcement Administration registration number of the practitioner.
h) The practitioner shall sign the prescription in ink on the date of issuance.
i) The practitioner’s full name shall be printed, rubber stamped, or typewritten above or below the hand-written signature.
j) A practitioner shall not issue a prescription in order to obtain controlled substances for the purpose of general dispensing to his patients.
k) A practitioner shall not issue a prescription to himself or his immediate family which includes a spouse, children or parents.
l) A prescription shall be deemed invalid if it is not filled within 6 months from the date prescribed.

IV. No prescription shall be filled for more than a 34-day supply upon any single filling for controlled drugs of schedules II or III; provided, however, that for controlled drugs, in schedules II or III, that are commercially packaged for dispensing directly to the patient, such as metered sprays and inhalers, liquids packaged in bottles with calibrated droppers, and certain topical preparations packaged with metered dispensing pumps may be filled for greater than a 34-day supply, but not more than 60 days, utilizing the smallest available product size, in order to maintain the dosing integrity of the commercially packaged containers; and, provided that with regard to amphetamines and methylphenidate hydrochloride, a prescription may be filled for up to a 60-day supply if either such prescription specifies it is being used for the treatment of attention deficit disorder, attention deficit disorder with hyperactivity, or narcolepsy.

V. Notwithstanding the provisions of RSA 318-B:26, it shall be a misdemeanor for a practitioner to issue or a pharmacist to fill a prescription that does not meet the requirements of this section.
# DEA CONTROLLED SUBSTANCE DAILY LOG

Perpetual Inventory Form

<table>
<thead>
<tr>
<th>Date</th>
<th>Patient</th>
<th>Address</th>
<th>Quantity</th>
<th>Bal. O/H</th>
<th>Practitioner</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-05-2000</td>
<td>Starting inventory</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10-09-2000</td>
<td>John Doe</td>
<td>6 Elm, Nashua</td>
<td>8</td>
<td>92</td>
<td>E. Brooks</td>
</tr>
</tbody>
</table>

Date this page started: 10-5-2000

*(SAMPLE FORM)*

See description on page 2
BIENNIAL INVENTORY

JOHN M. DOE, M.D.
393 Center Street
Anytown, N.H. 03800
DEA# 12345678

SCHEDULE II

PERCOCET TABLETS 5mg/325mg   21 TABLETS
TYLOX CAPSULES               9 CAPSULES

SCHEDULE III, IV, AND V

VALIUM TABLETS 5MG   15 TABLETS
VICODIN ES TABLETS   11 TABLETS
DIAZEPAM INJECTION 5MG/ML 10 ml

(SAMPLE FORM)
See description on page 3

INVENTORY TAKEN BY ____________________________________________
DATE TAKEN ____________________________________________
TIME OF INVENTORY _________ OPEN OR CLOSE OF BUSINESS (CIRCLE)