

Controlled Substances Regulation for Veterinarians Georgia and Florida

Abuse of controlled substances extends across all segments of society, including veterinarians and their staff members. The behavior of health care professionals is a reflection of the general behavior of society. Licensed health care providers and their staff members incur a somewhat greater abuse liability than the general population because of their legal access to controlled substances. It is appropriate to ***protect yourself and your coworkers*** by developing and maintaining a carefully designed system of security and accountability for controlled substances in your practice.

A voluminous set of state and federal laws, regulations and rules governs the manufacture, distribution, use and accountability of controlled substances in legitimate channels. These requirements sometimes contradict each other. The most stringent requirement must be met in such cases.

Federal controlled substance ***laws*** are found in Title 21 USC, §801-971. The ***regulations***, which are more detailed and somewhat more practical in nature, are contained in Title 21 CFR, §1300 et seq. Both of these sources are compiled periodically and recent changes may not appear in the most current bound volumes. Recent changes are published in the Federal Register. You can access these documents on the Web.

USC (United States Code) can be accessed at <http://www.gpoaccess.gov/uscode/index.html>.

CFR (Code of Federal Regulations) can be found at <http://www.gpoaccess.gov/cfr/index.html>.

The Federal Register (1995-present) can be found at <http://www.gpoaccess.gov/fr/index.html>.

DEA also has a web site at: <http://www.usdoj.gov/dea/>.

University of Georgia Veterinary Pharmacy website: <http://www.vet.uga.edu/pharmacy/index.php>

Georgia controlled substance laws are found in Title 16, Chapter 13, Articles 1-2 and Title 26, Chapter 4, Article 1. Veterinarians are also subject to the Rules of the Georgia State Board of Pharmacy, Chapter 480-26, and the Rules of the Georgia State Board of Veterinary Medicine, Chapter 700-8.

Of particular interest is the Georgia Veterinary rule (Chapter 700-8-.01) that states:

1. It shall be unprofessional conduct for a licentiate to:

- (i) Prescribe or dispense any controlled substance without having actually examined the animal;
- (ii) Prescribe or dispense than a thirty (30) day supply of a C-II controlled substance;
- (iii) Prescribe or dispense more than the usual dosage as set forth in published references or as determined by documented clinical need; or
- (iv) Refill any prescription for a C-II controlled substance without examining the animal.

Florida veterinarians are subject to the Comprehensive Drug Prevention and Control Act (Chapter 893) and the Rules of the Department of Professional Regulations, Board of Veterinary Medicine (Chapter 21X-15).

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. Although the term "potential for abuse" is not defined in CSA, there is much discussion of the term in the legislative history of the Act. According to the DEA web site:

The following items are indicators that a drug or other substance has a potential for abuse:

1. There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or
2. There is significant diversion of the drug or other substance from legitimate drug channels; or
3. Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or
4. The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has substantial capability of creating hazards to the health of the user or to the safety of the community. Of course, evidence of actual abuse of a substance is indicative that a drug has a potential for abuse.

Some drugs are designated as scheduled drugs due to international treaty considerations:

U.S. treaty obligations may require that a drug or other substance be controlled under the CSA, or rescheduled if existing controls are less stringent than those required by a treaty. The procedures for these scheduling actions are found in Section 201 (d) of the Act. [21 U.S.C. 811 (d)]

Generally, C-I substances are those that have a high potential for abuse, but lack approved medical uses in the United States. Examples of C-I substances are heroin and LSD. C-II substances also have a high potential for abuse, but have accepted medical uses in the United States. Examples are oxymorphone, meperidine and pentobarbital. C-II substances are of particular interest to law enforcement agencies. Discrepancies involving C-II agents may result in vigorous regulatory action.

C-III, IV and V substances have decreasing potential for abuse and accepted medical uses in the United States. Examples of C-III substances are acetaminophen with codeine, and the anabolic steroids. Diazepam, midazolam, butorphanol, and phenobarbital are examples of C-IV substances. C-V consists of buprenorphine and mixtures containing low concentrations of narcotic drugs. Although these classes of drugs do not usually elicit the same level of regulatory interest as the C-II agents, failure to comply with the laws, regulations and rules for these agents is not taken lightly.

Ketamine is a C-III controlled substance at the Federal level as of August, 1999. An inventory of all ketamine on hand must be recorded and stored with your biennial controlled substances inventory record. Ketamine is a highly abused substance and is associated with veterinary practice in many news publications. (Federal Register Vol 64, No 68, April 9, 1999)

The anabolic steroids were designated as C-III agents under federal public law 101-647, Title XIX-Anabolic Steroids Control Act of 1990 §1901-1907. This change went into effect as of February 1991. The term 'anabolic steroid' means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins and corticosteroids and dehydroepiandrosterone). The requirement that a drug be proven to promote muscle growth was removed from the definition of anabolic steroid as of January 20, 2005.

A list of drugs covered under the Act can be seen in the Federal Register: December 16, 2005 (Volume 70, Number 241) and includes any salt, ester, or ether of a drug or substance described in the list found in the list but does not include an **anabolic** steroid that is expressly intended for administration through implants to cattle or other nonhuman species and that has been approved by the Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, the person shall be considered to have prescribed, dispensed, or distributed an **anabolic** steroid within the meaning of this paragraph.

Anabolic steroids were designated C-IV under Florida state law in 1987. Human chorionic gonadotropin (HCG) was originally included. The anabolic steroids were moved to C-III when the federal law took effect, except HCG, which remained C-IV under Florida law. HCG has been removed from controlled substances regulation in Florida. Although control of HCG seems illogical, there has been evidence of abuse of HCG and corticotropin (ACTH) by certain sports enthusiasts. Neither agent is a controlled substance in Georgia.

Ephedrine, pseudoephedrine and phenylpropanolamine are classified as List I chemicals under the Domestic Chemical Diversion Control Act of 1993 (DCDCA) and the Comprehensive Methamphetamine Control Act of 1996 (MCA). These products have been used as precursors in illegal amphetamine manufacturing. **Distributors**, such as drug wholesalers are required to register with DEA and maintain inventory information. This does not extend to retail outlets or to dispensers such as pharmacists or veterinarians as long as sales are face to face to individual customers for personal use and do not exceed certain limits. List 1 articles are devices used in clandestine manufacture of methamphetamine, such as encapsulating or tableting machines. (21CFR1309 & 1310) List 2 chemicals are not direct precursors to amphetamines, but are used in manufacture, such as iodine.

Some states treat ephedrine and related compounds as controlled substances (Ohio). Georgia requires that pseudoephedrine be kept behind the counter, sold only in blister packaging with a 3 pack or 9 gram purchase limit. (OCGA 16-13-30.3).

http://www.legis.state.ga.us/legis/2005_06/fulltext/hb216.htm

The Georgia Meth Watch website has videos and information to help your practice avoid being used to support meth labs with drugs or other supplies. <http://www.gameth.com>

Registration:

Online DEA registration website: <http://www.deadiversion.usdoj.gov/>

Previously every veterinarian in private practice who administered, prescribed, distributed or dispensed controlled substances must have registered with the Drug Enforcement Agency (DEA). If a veterinarian dispensed or administered controlled substances at more than one location, then that veterinarian must have registered for each site. NOTE: under Federal law, administration of controlled substances is a form of dispensing (21 USC §802). The DEA has reinterpreted the regulations to allow practitioners to function as agents of a single registrant in a practice – but there are limitations. Agents can administer and dispense, but **cannot prescribe controlled substances**. If veterinarians function as agents of the registrant, the registrant may sign controlled substance prescriptions after carefully reviewing the medical record and becoming familiar with the case. Veterinarians who have more than one practice location are advised to contact the DEA for registration advice on a case-by-case basis.

A single practitioner must be designated "practitioner in charge" for each practice in Georgia and Florida. This person is charged with assuring compliance with all laws, regulations and rules governing the use of all drugs, including controlled substances. This individual will be held accountable for any breach in the controlled substance accountability system. All controlled substances may be administered and dispensed from a common stock.

Although the designated practitioner in charge will be targeted, all veterinarians registered with DEA are responsible for controlled substance security. All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances (21 CFR §1301.71(a)).

DEA has issued two letters regarding locum tenens practitioners. <http://www.vet.uga.edu/pharmacy/dea903.pdf>. These letters seem to contradict the “cannot prescribe” limitations of agents. For that reason it is wise to contact DEA for advisement if you do not hold your own DEA registration. Require that their answer be in writing and store the written replies in a safe place.

Drug Researcher Registration:

Each drug researcher in the State of Georgia is required by state law to be individually registered with the Georgia State Board of Pharmacy. (OCGA Title 26, Chapter 4, Section 49) Each registered researcher is solely responsible for maintaining all records pertaining to drugs used in their research, including disposal. Rules implementing the law can be found in the Georgia Board of Pharmacy Rules 480-7.04.

Use of Agents:

Nonpractitioners, such as technicians, can function as agents of practitioners, under Federal law, for ordering, administering or inventory control of scheduled drugs without individual registration if such agent is acting in the usual course of his business or employment. These agents can not dispense controlled substances in Georgia, except that they can measure quantities and type labels for dispensing if the practitioner is physically present and actually observing the actions of such person doing such measuring and typing. The label and contents must be checked by a licensed practitioner before it is provided to the client. No more than two such assistants shall assist a

practitioner at any time in Georgia.

Employee screening:

It is the position of DEA that the obtaining of certain information is a matter of business necessity for any employee who will have access to controlled substances. It is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry, in this regard. DEA assumes that the following questions will become a part of an employer's comprehensive employee screening program (21 CFR §1301.90):

Question: Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing any criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.

Question: In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

Advice: An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right to privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

DEA recommends that inquiries concerning employee's criminal records be made as follows (21 CFR §1301.93):

Local inquiries. Inquiries should be made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions. Local practice may require such inquiries to be made in person, rather than by mail, and a copy of an authorization from the employee may be required by certain law enforcement agencies.

DEA inquiries. Inquiries supplying identifying information should also be furnished to DEA Field Division Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check made by the Field Division Office.

The registrant shall not employ as an agent or employee who has access to controlled substances

any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked, or has surrendered a DEA registration for cause. For purposes of this subsection "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation or the individual's handling of controlled substances. (21 CFR §1301.76).

Note: The stated intent is to prevent a DEA registrant from hiring anyone with access to controlled substances who probably would be denied a DEA registration due to risk of diversion. DEA can revoke DEA registration if such registration is inconsistent with the public interest (21 USC 823(f) & 824(a)(4)). Conduct that has led to consideration of criminal charges, as well as misdemeanor or felony drug convictions are sufficient to deny or revoke registration (Federal Register Vol. 56, No. 148, August 1, 1991). The DEA office in Atlanta has stated that the term "employ" also means "use," therefore volunteers in your practice who have access to controlled substances would be subject to the same screening as hired employees.

Basic components of a distribution system:

- 1) Audit trails. A system of documents detailing the receipt, inventory and eventual legal disposition of controlled substances. This trail must be clear, concise and readily retrievable.
- 2) Security/accountability. The system must provide for secure storage and complete accountability for all controlled substances.
- 3) Valid uses. Justification for all uses of controlled substances should be clearly demonstrated in each patient's medical record. The data must support the use.
- 4) Common sense. Think about what you are doing. A well designed, well maintained system can be used to your advantage. A poorly designed or carelessly maintained system may not provide enough documentation to support your position if you come under suspicion. Protect yourself, your practice and your staff.

Receiving/ordering records:

DEA website to order 222 forms:

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

A DEA 222 form must be completed when ordering C-II drugs. Be sure to indicate the number of lines used and cross out the other lines to prevent anyone from altering the forms. Send the top two copies to the vendor. Retain the last (blue) copy for your records. Record the date and quantity received on the blue copy when the order is received. Orders for C-III, IV & V drugs do not require use of a 222 form. Note: Vendors require that 222 forms be completed using exact terms that may be unique for their firm. It is advisable to call the company for directions the first time a particular item is ordered from them. Note: ***You cannot use a prescription to obtain controlled substances for general purposes.***

Invoices for C-II items must be kept separate from other invoices. Invoices for C-III, IV or V items must either be filed separately or be marked with a red "C", one inch high in the lower right hand corner of the invoice. All invoices for controlled substances must be readily retrievable.

A centralized receiving log, with sections for each drug received, is advisable. Extensive documentation makes finding errors easier.

DEA has created the Controlled Substance Ordering System (CSOS) that takes allows for secure electronic transmission of controlled substance orders without the supporting paper Form 222. The adoption of CSOS standards is the only allowance for the electronic transmission of Schedule II controlled substance orders between controlled substance manufacturers, distributors, pharmacies, and other DEA authorized ordering entities.

CSOS uses Public Key Infrastructure (PKI) technology, which requires CSOS users to obtain a CSOS digital certificate for electronic ordering. To participate you must apply for a CSOS Digital Certificate as must your suppliers. For more information and online application see: <http://www.deacom.gov/csosmain.html>

Note: Drug enforcement agencies receive copies of your invoices and order forms for controlled substances. Orders for excessive quantities or unusual items may result in a site inspection.

Storage:

All controlled substances stored at a veterinary practice must be kept in a securely locked, substantially constructed cabinet. A metal cabinet with double locks is usually deemed to fit this requirement. The cabinet should be securely affixed to prevent the entire stock from being carried away. Some agents (such as carfentanil) require the use of a US government Class V security safe.

Institutional practices and pharmacies can disperse C-III, IV and V drugs among their other stocks. However, this allowance does not extend to veterinary, medical or dental practices. This technique would not be an effective deterrent to theft due to the limited quantities of drugs stocked in these practices.

Disposition records:

Consolidated records that clearly show the disposition of all doses of controlled substances must be maintained. The records should be easy to audit so that errors can be detected and corrected promptly. Errors are much easier to correct if found soon after they occur. Assigning a single signout sheet for each container of drug can be useful during the audit process.

Use of separate disposition forms for drugs used for administration as opposed to those dispensed from the practice may simplify audits. The utility of this practice will probably vary from one practice depending on volume and number of individuals with access to the controlled substances. Regardless of the method, you must keep records for all controlled drugs administered as well as those dispensed and the records must be easy to interpret.

Dispensing records:

A practitioner must write a prescription for each drug dispensed (GA laws) and that prescription

must include: (Florida requires a consolidated dispensing record, but not prescriptions, as such.)

- Full name & address of the patient
- Name, quantity & strength of drug
- Directions for taking
- Legal signature of practitioner
- Date prescription written
- Serial number of prescription
- For controlled substances:
 - name of dispenser
 - address of dispenser
 - DEA number of dispenser

The format of a prescription is not defined in GA or federal law, except that, in GA, a preprinted prescription blank may have only one signature line.

Dispensing records must be kept in one of three ways:

1. Maintain 3 files
 - a. C-II prescriptions
 - b. C-III, IV & V prescriptions
 - c. other drugs
2. Maintain 2 files
 - a. C-II prescriptions
 - b. all others (red "C" in lower right for C-III, IV & V)
3. Maintain 2 files
 - a. C-II, III, IV & V (red "C" in lower right for C-III, IV & V)
 - b. other drugs

Audit records:

Frequent audits should be performed to assure accountability and detect errors, diversion or theft. Daily audits (or even more frequent) may be advisable in an active practice, especially if several individuals have access to the controlled substances. Audit records should be retained for documentation purposes.

An inventory of all controlled substances stocked in a practice must be taken within two years of your last inventory. This inventory must be kept separate from other inventory records. DEA no longer requires that this be done on May 1st.

Medical records:

Documentation of all doses administered, dispensed or prescribed by a practice must appear in the medical record for that animal. Medical justification all uses of controlled substances must be documented in the record. DEA registration as a practitioner only permits use of controlled substances within the lawful course of your professional practice. The medical record is a key component of the controlled substances audit trail when determining whether that requirement has been met.

Computer generated records:

Federal regulations allow for the use of automated data processing systems, or other electronic or mechanized records systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are visually identified apart from other items appearing on the records (21 CFR §1304.01). Georgia State Board of Pharmacy Rules, which are binding for veterinarians, are more specific. The following is a version of Rule 480-27.05, edited to reflect the requirements of veterinarians who use these systems:

An automated data processing system (computer and software program) may be employed for the recordkeeping system if the following conditions are met:

- (a) All original written prescriptions must be retained as a permanent record for two years in the usual consecutively numbered prescription file
- (b) The system shall at a minimum produce sight readable printouts for all controlled substance prescriptions for each 24 hour period. The term sight-readable means that a regulatory agent shall be able to examine the record and read the information. These printouts must be generated at least weekly and maintained for two years.
- (c) Such information shall include, but not be limited to, the prescription requirements and records of dispensing controlled or dangerous (legend) drugs by other means
- (d) The individual responsible for completeness and accuracy of the entries to the system, must provide documentation of the fact that the prescription information entered into the computer is correct, by dating and signing the print-out in the same manner as signing a check or legal document.
- (e) An auxiliary record keeping system shall be established for the documentation of dispensing if the automated data processing system is inoperative for any reason. When the system is restored to operation the prescription information shall be entered into the system within 96 hours.
- (f) Any veterinary practice using an automated data processing system must comply with all applicable state and federal laws and regulations.
- (g) A veterinary practice shall make arrangements with the supplier of data processing services or materials to assure that the practice continues to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A practice shall assure continuity in the maintenance of records.

Duty to report loss or theft:

It is the position of DEA that an employee that has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information.

A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy. (21 CFR §1301.91) The registrant shall notify the Field Division Office of the DEA in his area of the theft or significant loss of any controlled substance

upon discovery of such loss or theft. The registrant shall also complete DEA (or BND) form 106 regarding such loss or theft (21 CFR §1301.76). The Drugs and Narcotics Agency must also be informed of such losses that take place in Georgia.(Title 26, Chapter 4, Article 112)

Disposal:

Expired drugs are considered adulterated. Their use is illegal. Out of date controlled substances should be pulled from active inventory and stored in a secure place until actual disposal. The practitioner must contact the local Field Division Office to obtain DEA form 41 and instructions for drug disposal. The DEA will no longer accept controlled substances for destruction. Destruction must be handled by "reverse distributors"and, in Georgia, these agents must be licensed by the Board of Pharmacy.

Capital Returns, Inc.
9101 N. 64th St
Milwaukee, WI 53218
800-950-5479

Guaranteed Returns Midwest Division
100 Teduke Ct
St Charles, MO 63301
800-473-2138

Maximum Rx Credit, Inc.
4765 Stone Mountain Highway, Suite C
Lilburn, GA 30047
770-985-2136

Pharmaceutical Credit Corporation
130 Seaboard Lane, Suite A-6
Franklin, TN 37067
800-487-4308

Return Logistics International
22 Antley Rd
Savannah, GA 31408
912-748-5100

Strong Pharmaceutical Services
6264 Crooked Creek Rd, Ste 11
Norcross, GA 3092
770-409-1500

Universal Rx Solutions of Georgia
2084-900 Lake Industrial Ct
Conyers, GA 30013

770-785-9710

Maintain copies of all approvals, forms, and communications involving disposal of controlled substances.

Retention of records:

State and federal law dictates retention of records for a minimum of 2 years. The statute of limitations under FDA law is 5 years, so retention for 5 years or longer may be advisable.

Overview:

A good record keeping system will track all controlled substances from acquisition, storage and final disposition. Remember: the function of this audit trail is to protect all persons who have access to the controlled substances. Knowledge that the system is being monitored may be sufficient to prevent a dishonest person from diverting drugs from your stocks.

Inspections:

If state or federal drug agents request, you must make your controlled substances records available to them. This authority does not extend to financial data; sales data, other than shipment data; or pricing data unless the owner, operator or practitioner in charge consents (21 USC §880). You have the right to refuse inspection by DEA agents if they do not present appropriate credentials and an administrative warrant, subpoena or search warrant. However, administrative warrants are simple to obtain. Refusal to permit an inspection is a felony under GA law (Title 16, Chapter 13, §42).

Distribution by a dispenser to another practitioner (21 CFR §1307.11):

(a) a practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to another practitioner for the purpose of general dispensing by the practitioner to his patients or its patients: Provided, That:

- (1) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;
- (2) The distribution is recorded by the distributing practitioner in accordance with §1304.24(e) of this chapter and by the receiving practitioner in accordance with §1304.24(c) of this chapter
- (3) If the substance is in Schedule I or II, an order form is used as required in part 1305 of this chapter;
- (4) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and §1301.28 of this chapter during each calendar year in which the practitioner is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to this section and §1304.28 of this chapter will exceed 5 percent of the total number of dosage units of all controlled

substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.

A registered practitioner can distribute controlled substances to another registered practitioner if the amount distributed per calendar year does not exceed 5% of the total volume. If the substance is a C-II agent, a DEA 222 form must be executed. (It is uncertain whether the electronic CSOS will allow such transfers.) All purchase and inventory records must be maintained by the buyer and the seller.

Filling of prescriptions written by another practitioner:

The Veterinarian-Client-Patient relationship has been accepted by AVMA, GVMA, FDA and the Georgia Board of Veterinary Medicine as the basis of veterinary practice. AMDUCA incorporated it into federal regulation, giving it the force of law. The act of filling another veterinarian's prescription falls outside that relationship.

Georgia laws allow a practitioner to fill prescriptions for the practitioner's own patients, but prohibits filling prescriptions written by others.

- (a) Except as otherwise provided in this chapter, it shall be unlawful for any individual to engage in the practice of pharmacy unless currently licensed to practice under the provisions of this chapter.
- (b) Practitioners authorized under the laws of this state to compound drugs and to dispense drugs to their patients in the practice of their respective professions shall not be required to be licensed under the provisions of this chapter; however, practitioners shall meet the same standards, record-keeping requirements, and all other requirements for the dispensing of drugs applicable to pharmacists.
- (c) Any individual who, after hearing, shall be found by the board to have unlawfully engaged in the practice of pharmacy shall be subject to a fine to be imposed by the board for each offense. Each violation of this chapter pertaining to unlawfully engaging in the practice of pharmacy shall also constitute a felony punishable upon conviction thereof by a fine of not less than \$500.00 nor more than \$1,000.00 or by imprisonment for not less than two nor more than five years, or both. Georgia Drug and Cosmetic Act: 26-4-40.

Federal law prohibits filling of controlled substances prescriptions by private practitioners.

A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner. (21 CFR §1306.6)

Under the **Criminal Fine Enforcement Act of 1984** fines for violations of any federal law, including FD&C, are:

Up to \$100,000 for a misdemeanor by a corporation or individual not resulting in death

Up to \$250,000 for a misdemeanor by an individual that results in death, or for a felony

Up to \$500,000 for a misdemeanor by a corporation that results in death, or for a felony

Maximum imprisonment for a misdemeanor violation of the Act is 1 year. Prison terms for felonies are up to 10 years.

Other penalties:

Forfeiture of property, including real estate, cars, planes, securities, etc. Double penalties (up to life

imprisonment) if within 1000 feet of a school, playground, video arcade, or other child-attracting facility.

Differing interpretations:

Interpretation of laws, rules and regulations sometimes differs according to the source of information used, reflecting the large volume of laws, regulations, rules, legal opinions and case law involved. The registrant should contact the agencies involved for guidance if there is any question as to how a registrant should proceed. You are advised to get written responses and store copies in a safe place for future reference.

Resources:

Georgia Drugs and Narcotics Agency
166 Pryor Street, Rm 503
Atlanta, GA 30303-3465
404-656-5100

Drug Enforcement Administration (Georgia and South Carolina)
The Entrusted Building
3420 Norman Berry Dr, Suite 302
Hapeville, GA 30354
404-893-7165

Doug Kemp, Pharm.D.
College of Veterinary Medicine
University of Georgia
Athens, GA 30602-7391
706-542-5511