

# Regulation 61-4

## Controlled Substances

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**PART 100. Purpose and Scope; Definitions, Information, Payment of Fees, Certain Exemptions, Separate Registrations, Out-of-State Dispensing of Prescriptions.**

**101. Purpose and Scope.**

This regulation implements the provisions of Section 44-53-10, et seq., of the S.C. Code of Laws, 1976, as amended. It establishes the requirements necessary to ensure the appropriate security, authority and accountability with regard to the possession, manufacture, dispensing, administering, use and distribution of controlled substances in South Carolina.

**102. Definitions.**

As used in this regulation, the following terms shall have the meaning specified:

(a) Act. Article 3 of Chapter 53 of Title 44 of the 1976 S.C. Code of Laws, including all amendments thereto.

(b) Administration and the Abbreviation DEA. Refer to Drug Enforcement Administration, United States Department of Justice, the successor agency to the Bureau of Narcotics and Dangerous Drugs as defined in the Act.

(c) Automated Storage Machine. A mechanical system that performs operations, other than compounding or administration, that allow medications to be provided to the patient and stored near the point of care while controlling and tracking drug distribution under the control of a licensed pharmacist.

(d) Bureau Director. The Director of the Bureau of Drug Control, DHEC.

(e) Code. The Code of Laws of South Carolina, 1976, including all amendments thereto.

(f) Commercial Container. Any bottle, jar, tube, ampoule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and, in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term "commercial container" does not include any package liner, package insert, or other material kept with or within a commercial container, nor any carton, crate, box, or other package in which commercial containers are stored or are used for shipment of controlled substances.

(g) Compounder. Any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages, or changes the dosage forms of a narcotic drug listed in Schedules II, III, IV, or V for use in maintenance or detoxification treatment by another narcotic treatment program. The term "compounder" as the content requires, includes any lawfully authorized person who changes the dosage forms, mixes, or prepares any controlled substance for use by the ultimate user pursuant to the legitimate and lawful order of a practitioner acting in the regular course of professional practice or by the practitioner personally, if authorized by law to compound and dispense controlled substances.

(h) Controlled Premises:

(1) Places where original or other records or documents required under the Act are required to be kept, and

(2) Places, including factories, warehouses, or other establishments, and conveyances, where persons registered under the Act or exempted from registration under the Act may lawfully hold, manufacture, dispense, distribute, administer, or otherwise dispose of controlled substances.

(i) Controlled Substance. A drug, substance, or immediate precursor in Schedules I through V as described in S.C. Code Sections 44-53-190, 44-53-210, 44-53-230, 44-53-250, and 44-53-270.

(j) DHEC. The South Carolina Department of Health and Environmental Control.

(k) Director. Unless otherwise specified, the Director of the Department of Health and Environmental Control.

(l) Dispenser. An individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

(m) Detoxification Treatment. The dispensing for a period not in excess of twenty-one days, of a narcotic or narcotics drugs in decreasing dosages to an individual in order to alleviate adverse physiological or psychological effects incidental to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time. SEE ALSO §§ 1007 through 1011 inclusive.

(n) Emergency Situation. For the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the Act, the term "emergency situation" means those situations in which the prescribing practitioner determines:

(1) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

(2) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Act; and

(3) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

(o) Hearing. Any hearing held pursuant to the provisions of the Act or of this regulation, including, but not limited to, hearings for the granting, denial, revocation, or suspension of a registration pursuant to the Act.

(p) Home Infusion Pharmacy. A pharmacy which compounds solutions for direct administration to a patient in a private residence, Long Term Care Facility or hospice setting by means of parenteral, intravenous, intra-muscular, subcutaneous or intra-spinal infusion.

(q) Individual Practitioner. A physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States or the State of South Carolina, or by other jurisdiction, or otherwise permitted by the United States or the State of South Carolina, or by any other jurisdiction in which he practices to dispense a controlled substance in the regular course of professional practice, but does not include a pharmacist, a pharmacy, or any institutional practitioner.

(r) Inspector or Drug Inspector. An officer or employee of the Bureau of Drug Control authorized by the Bureau Director to make inspections under the Act, and to conduct audit procedures in relation to controlled substances, and includes the Director of the Bureau of Drug Control.

(s) Institutional Practitioner. A hospital or other person (other than an individual) licensed, registered, or otherwise permitted by the United States, the State of South Carolina, or other jurisdiction in which it practices, to dispense a controlled substance in the regular course of professional practice, but does not include a pharmacy.

(t) Interested Person. Any person adversely affected or aggrieved by any rule or proposed rule issued or issuable pursuant to the Act.

(u) Long Term Care Facility (LTCF). Nursing home, intermediate care, mental care, or other facility or institution which provides extended health care to resident patients and is licensed as such by DHEC or other appropriate State agency, which may further define the term for licensing and certification purposes.

(v) Name. The official name, common or usual name, chemical name, or brand name of a substance.

(w) Person. Includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(x) Pharmacist. Any pharmacist licensed by a state to dispense controlled substances, and shall include any person (e.g., pharmacy intern) authorized by the State to dispense controlled substances under the supervision of a pharmacist licensed by the State.

(y) Prescription. An order for medication which is dispensed to or for an ultimate user, but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

(z) Proceeding. All actions taken for the issuance, amendment, or repeal of any rules and regulations issued pursuant to the Act, commencing with the publication by the Bureau Director of the proposed rule, amended rule, or appeal.

(aa) Readily Retrievable. Certain records are kept by automatic data processing systems or other electronic or mechanized record keeping 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 asterisked, red-lined, or in some other manner visually identifiable apart from other items appearing on the records; when the term is not applicable to data processing systems, the term also means that a registrant is able to produce controlled substances records in a timely manner (usually within one hour) and that such records are segregated, sorted, or filed in such a manner that the controlled substances information may be derived from the material within a reasonable time (usually with a few hours) by an inspector.

(bb) Register and Registration. Refer only to registration required and permitted by the Act; (cc)

Registrant. Any person who is registered pursuant to the Act.

(dd) Scheduling of a Controlled Substance. Controlled substances are scheduled in accordance with provisions set forth in state law. Changes in the schedule of a controlled substance are made as set forth in S.C. Code Ann. § 44-53-160.

(ee) Any term not defined in this section shall have the definition set forth in the Act, or amendments thereto.

### **103. Information; Special Instructions.**

Information regarding procedures under these rules and special instructions supplementing these rules will be furnished upon request by writing to the Bureau of Drug Control DHEC, 2600 Bull Street, Columbia, SC 29201.

### **104. Time and Method of Payment of Fees; Refund.**

Registration and re-registration fees shall be paid at the time when the application for registration is submitted for filing. Payment shall be made in the form of a personal, certified or cashier's check, money order, credit card or online electronic payment, made payable to DHEC. Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. In the event that the application is not accepted for filing or is denied, the payment shall be refunded to the applicant.

### **105. Registrants Exempt from Fee.**

(a) Any federal agency, installation or official authorized by law to procure or purchase controlled substances for official use shall be exempt from payment of a fee for registration or re-registration.

(b) In order to claim exemption from the payment of fees for registration or re-registration, the registrant shall have completed the certification on the appropriate application form, wherein the applicant's superior or the agency head certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess or handle controlled substances.

(c) Exemption from payment of a registration fee does not relieve the registrant of any other requirements or duties prescribed by law.

### **106. Persons Required to Register.**

Every person who manufactures, distributes, prescribes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance shall obtain annually a registration unless exempted by law. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

### **107. Separate Registration for Independent Activities.**

(a) The following groups of activities are deemed to be independent of each other:

(1) Manufacturing controlled substances;

(2) Distributing controlled substances;

(3) Dispensing controlled substances listed in schedules II through V;

(4) Conducting research (other than research described in paragraph (a) (6) of this section) with controlled substances listed in schedules II through V;

(5) Conducting instructional activities with controlled substances listed in schedule II through V;

(6) Conducting a narcotic treatment program using any drug listed in Schedules II through V: however, pursuant to §109, employees, agents or affiliated practitioners, in programs, need not register separately. Each program site located away from the principal location and at which place narcotic drugs are stored or dispensed shall be separately registered and obtain narcotic drugs by use of order forms pursuant to §§ 901 and 902;

(7) Conducting research and instructional activities with controlled substances listed in schedule I;

(8) Conducting chemical analysis with controlled substances listed in any schedules;

(9) Importing controlled substances;

(10) Exporting controlled substances listed in schedules I through IV;

(11) A compounder as defined by § 102(g); and

(12) Automated storage machines at long term care facilities.

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:

(1) A person registered to manufacture or import any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture or import;

(2) A person registered to manufacture any controlled substance listed in schedules II through V shall be authorized to conduct chemical analysis and pre-clinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person registered to conduct research with a basic class of controlled substance listed in schedule I shall be authorized to manufacture or import such class if and to the extent that such manufacture and importation is set forth in the research protocol filed with the application for registration which shall conform with the provisions of 21 CFR § 1301.33, and to distribute such class to other persons registered or authorized to conduct research with such class, or registered or authorized to conduct chemical analysis with controlled substances;

(4) A person registered to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes, to distribute such substances to other persons registered to conduct chemical analysis or instructional activities and to persons exempted from registration pursuant to § 111, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances;

(5) A person registered or authorized to conduct research (other than research described in paragraph (a)(6) of this section) with controlled substances listed in those schedules in which he or she is authorized to conduct research, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, to import such substances for research purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 111, and to conduct instructional activities with controlled substances; and

(6) A person registered to dispense controlled substances listed in Schedules II through V may conduct research (other than research described in paragraph (a) (6) of this section) in conformity with the provisions of S.C. Code Ann. § 44-53-300(c) and conduct instructional activities with those substances.

(c) A single registration to engage in any group of independent activities may include one or more substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substance listed in Schedule I for which he or she has filed and had approved a research protocol.

#### **108. Separate Registrations for Separate Locations.**

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registrants other than the registered person or to persons not required to register by the Act;

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances for display purposes or lawful distribution as samples only nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office and where no supplies of controlled substances are maintained.

## **109. Exemption of Agents and Employees; Affiliated Practitioners.**

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his or her business or employment. (For example, a pharmacist employed by a pharmacy need not be individually registered to conduct lawful business activity in preparing and dispensing of controlled substances if the pharmacy in which he or she is employed is properly registered under the Act; a manufacturer's sales representative may lawfully distribute samples of controlled substances manufactured by his or her employer, provided the manufacturer-employer is lawfully registered and the distribution is made to a registrant authorized to possess controlled substances and not to a non-registrant employee of the recipient of the sample.)

(b) An individual practitioner who is affiliated with one or more other individual practitioners in any legitimate and lawful form of business arrangement (i.e., partnership, professional association, etc.) shall be registered individually with DHEC prior to engaging in any form of controlled substances activity, pursuant to the provisions of S.C. Code Ann. §§ 44-53-290 and 44-53-370(a)(1). With the written Power of Attorney of another affiliated practitioner within the group, any other affiliate individual practitioner may administer or dispense (other than by prescribing) controlled substances within the regular course of professional practice if and to the extent the practitioner granting the power of attorney has authorized. (For example, Dr. X and Dr. Y are partners; they shall be individually registered in order to utilize controlled substances in their practice; if Dr. X desired, he or she could issue Dr. Y a power of attorney to utilize Dr. X's office stock of controlled substances to administer an injection of product CRx to Dr. Y's Patient, Mrs. A. while she is in the office. Dr. Y may not, however, sign Dr. X's name to prescriptions, nor may Dr. Y use Dr. X's registration number to obtain stocks of controlled substances for himself or herself or his or her own office stock.) Any power of attorney, once granted, may be revoked by the grantor in writing. Nothing in this Section shall be construed to relieve the grantor of any power of attorney of any responsibility for the proper storage, record keeping, handling, or legitimate use of any controlled substances acquired by the grantor; nor shall anything be construed as relieving the grantee practitioner from full and complete responsibility for his or her actions conducted pursuant to the power of attorney or for controlled substances acquired or utilized pursuant to this paragraph.

(c) Pharmacists listed with the S.C. Board of Pharmacy as the "pharmacist-in-charge" of a pharmacy holding a permit issued by that Board to operate as a retail pharmacy, shall be considered as a "registrant" within the meaning of the Act and this Regulation, and shall be primarily responsible for the controlled substances activity at the registered location of the pharmacy. Nothing in this paragraph shall be construed as relieving an owner, partner, corporate officer, or any other person who may be a registrant-in-fact (due to his or her position within the business entity) from any direct or vicarious liability which may be incurred due to unlawful or ultra vires activity, nor shall it be construed to relieve any employee of the business entity from direct responsibility for his or her own unlawful acts.

(d) Individual practitioners permitted under the provisions of Federal Regulation 21 CFR § 1301.24 to dispense, administer, or prescribe controlled substances under the registration of a hospital or other institution which is registered, in lieu of personal registration, are prohibited from this practice by the provisions of S.C. Code Ann. §§ 44-53-290 and 44-53-370(a)(1). No prescriptions issued within this State shall be dispensed by any person registered with DHEC unless the individual practitioner issuing the prescription holds a valid individual practitioner registration with DEA. Nothing shall prevent the dispensing of such prescriptions if they are co-signed by an individual practitioner holding a valid individual registration with the DEA and DHEC, providing that the co-signing practitioner has established a valid practitioner-patient relationship as set forth

by §§ 1103 and 1204 of this Regulation prior to the dispensing of the controlled substance. Nothing in this paragraph shall preclude any pharmacy or dispensary operated by the Federal government on any property or enclave not subject to State jurisdiction from any act permitted under Federal law or regulation, nor shall it preclude the dispensing of out-of-state prescriptions as permitted by § 114 of this Regulation.

#### **110. Exemption of Certain Military and Other Personnel.**

(a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service or Bureau of Prisons who is authorized to prescribe, dispense or administer, but not procure or purchase controlled substances in the course of his or her official duties, provided such prescribing, dispensing, and administering of controlled substances takes place upon a military reservation or other Federal enclave. Practitioners who issue prescriptions for controlled substances which are to be dispensed from governmental stocks shall be exempt from registration. Any practitioner who issues prescriptions for controlled substances which are to be dispensed from non-governmental pharmacies or dispensaries shall register with DHEC prior to issuing such prescriptions.

(b) Practitioners who issue prescriptions for controlled substances which are dispensed from non-governmental pharmacies or dispensaries must complete a controlled substances registration application annually;

(c) Practitioners who register annually with DHEC are granted an exemption to the fee requirement pursuant to Section 1303 of this regulation, provided that the request for exemption to the fee requirement is filed in writing with the Bureau Director. The written request must contain a military picture ID of the requestor, as well as documentation of the name and location of the military installation or hospital facility where the practitioner is located.

(d) This registration requirement and fee exemption applies only to practitioners and officials of the United States military service organizations, including the Army, Navy, Marine Corp, Air Force, and Coast Guard, and the Public Health Service, Bureau of Prisons, and Veteran's Administration, who are based on military installations or other Federal hospital facilities, providing healthcare on behalf of the Federal government.

(e) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities.

#### **111. Exemption of Law Enforcement Officials.**

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any official or employee of the DEA, U.S. Department of Justice, any officer of the U.S. Bureau of Customs, any officer or employee of the United States Food and Drug Administration, and any other federal officer who is lawfully engaged in the law enforcement of any federal law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his or her official duties; and

(2) Any officer or employee of any state, or any political subdivision or agency thereof, who is engaged in the enforcement of any state or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his or her official duties.

(b) Any official exempted by this section may when acting in the course of his or her official duties, possess any controlled substances and distribute any such substance to any other official who is also exempted by this section and acting in the course of his or her official duties.

(c) Any official exempted by this section may procure any controlled substance in the course of an inspection, in accordance with the Act or in the course of any criminal investigation involving the person from whom the substance was procured.

(d) In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use in chemical analysis, such laboratories shall obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this section and within the activity described. For purposes of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section.

#### **112. Exemption of Civil Defense Officials.**

(a) The requirement of registration is waived for any official of a civil defense or disaster relief organization who, in the course of his or her official duties, is authorized to:

(1) Maintain, and distribute for such maintenance, controlled substances held for emergency use; or

(2) Procure controlled substances for the purpose of maintaining supplies for emergency use, provided that all of such procurement is from the U.S. General Services Administration and in accordance with the rules of the U.S. Office of Emergency Preparedness.

(b) The requirement of registration is waived for any official of a civil defense or relief organization during a state of emergency or disaster within his or her jurisdiction proclaimed by the President or by a concurrent resolution of the Congress, which official, in the course of his or her official duties, during such emergency or disaster, is authorized to:

(1) Dispense controlled substances; or

(2) Procure or distribute controlled substances, provided that all such procurement is on a special "Civil Defense Emergency Order Form" as prescribed in the Federal Regulations (21 CFR § 1301.27(c)).

#### **113. Registration Regarding Ocean Vessels and Aircrafts.**

Registration of masters of ocean vessels and aircraft or the medical officers thereof shall be deemed sufficient if they are properly registered with the U.S. Department of Justice, DEA.

#### **114. Dispensing of Out-of-State Prescriptions and Orders.**

(a) Prescriptions or orders for controlled substances from out-of-state practitioners may be filled in good faith by dispensers provided:

(1) The dispenser knows the recipient; or requires proper ID and notes such on the prescription;

(2) The dispenser makes a good faith inquiry concerning whether the order or prescription is legitimate;

(3) The prescription or order meets all of the requirements of this regulation and the Act, including whether the order or prescription is for legitimate medical purposes, and is within the regular course of practice of the practitioner;

(4) The practitioner who issued the prescription would ordinarily be entitled to issue prescriptions under SC law (i.e., physicians, dentists, veterinarians, and podiatrists are authorized to issue prescriptions; chiropractors, psychologists, etc. are not authorized to prescribe drugs); and

(5) The prescribing practitioner holds a valid individual Federal [D.E.A.] controlled substance registration number in the state, district, or territory of origin of the prescription, or is exempt from such registration requirement under the provisions of Federal Regulation 21 CFR § 1301.24.

(b) Out-of-State prescriptions which do not conform to South Carolina law and which are not otherwise exempted shall not be dispensed.

#### **PART 200. Application for Registration.**

##### **201. Time for Application for Registration; Expiration Date.**

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Bureau Director to such person.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his or her registration.

(c) Fees for registration for a physician shall be from October 2nd of the year until October 1st of the succeeding year. Fees for registration for any other person required to be registered shall be from April 2nd of the year until April 1st of the succeeding year. In the event any physician shall become registered subsequent to October 1st of any year, the entire registration fee shall be due and no pro-rata of fees will be allowed. In the event any other person required to be registered shall become registered subsequent to April 1st of any year, the entire registration fee shall be due and no pro-rata of fees will be allowed.

##### **202. Application Forms; Content; Signature.**

(a) If the person is required to be registered, and is not so registered and is applying for registration;

(1) As a practitioner, pharmacy, mid-level practitioner, animal control, animal shelter, health clinic, EMS, rescue squad, or hospice, he or she shall apply on the applicable DHEC form or its

electronic equivalent;

(2) As a narcotic treatment program, he or she shall apply on the applicable DHEC form or its electronic equivalent;

(3) As a distributor, canine unit, researcher, exporter, importer, broker, analytical or forensic laboratory, manufacturer or hospital, he or she shall apply on the applicable DHEC form or its electronic equivalent.

(b) Each application for registration to handle any basic class of controlled substances listed in schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in schedule II, or to conduct research with any Narcotic controlled substance listed in schedule II, shall include the Controlled Substances Control Number for each basic class or substance to be covered by such registration.

(c) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(d) Each application, attachment, or other document files as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. Another person may be authorized to sign for the applicant, if proof of authority (e.g. general power of attorney) accompanies the application.

### **203. Research Protocols.**

(a) Applicants for “Researcher” registration in Schedule I shall submit a research protocol containing all the information required for Federal Schedule I research protocol set forth under 21 CFR § 1301.32.

(b) Practitioners registered with DHEC desiring to perform incidental research on or with controlled substances under the provisions of S.C. Code Ann. § 44-53-300(c) are not required to furnish the formal protocol (except for narcotic substances as is required under Federal law), but shall instead provide a written summary of the proposed research, including the scope, the substance to be utilized, the number of research subjects (and their identity if protection from prosecution is desired), the duration of the research and the estimated usage of the controlled substance. Insofar as is practical, the dispensing of the controlled substance utilized in a valid research project shall be performed by the researcher or a particular dispenser or small group of dispensers in order to maintain adequate control. While not imperative to DHEC, notice of any participating dispensaries or pharmacies should be made to the Bureau of Drug Control in order that inadvertent and unnecessary investigations of normally unusual dispensing practices may be avoided.

(c) DHEC may require additional information or updating of protocols from time to time, but not more often than annually, unless a major change or deviation from previously submitted protocols or summaries is discovered. It is the responsibility of the person conducting the research project to notify to Department prior to any change in a protocol.

#### **204. Additional Information.**

The Bureau Director may request an applicant to submit such documents or written statements of fact relevant to the application as he or she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after having been requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Bureau Director in granting or denying the application.

#### **205. Amendments to and Withdrawal of Applications.**

(a) An application may be amended or withdrawn without permission of the Bureau Director at any time before the date on which the applicant receives an order to show cause pursuant to § 309 or before the date on which a notice of hearing on the application is published pursuant to § 309 whichever is sooner. An application may be amended or withdrawn with permission of the Bureau Director at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

### **PART 300. Action on Applications for Registration; Revocation or Suspension of Registration.**

#### **301. Administrative Review Generally.**

The Bureau Director may inspect, or cause to be inspected the establishment of an applicant or registrant, pursuant to the Act or this Regulation. The Bureau Director shall review the application for registration and other information gathered by the Bureau of Drug Control regarding an applicant in order to determine whether the applicable standards of the Act have been met by the applicant.

#### **302. Applications for Research in Controlled Schedule I Substances.**

(a) In the case of an application for registration to conduct research with controlled substances, the Bureau Director shall refer such application to the Director who shall determine the qualifications and competency of the applicant as well as the merits of the research protocol. The Bureau Director, in determining the merits of a research protocol, shall consider procedures to effectively safeguard against diversion of such controlled substances from legitimate medical or scientific use. If the Bureau Director finds the applicant qualified and competent and the research protocol meritorious and adequately safeguarded, he shall register the applicant unless he finds registration should be denied on a ground specified in the Act.

(b) If the Bureau Director is unable to find the applicant qualified or finds that grounds exist for the denial of the application, the Bureau Director shall issue an order to show cause pursuant to § 309 and, if requested by the applicant, hold a hearing on the application pursuant to § 310.

#### **303. Application for Bulk Manufacture of Schedules I and II Substances.**

The Bureau Director shall coordinate applications for bulk manufacture of schedules I and II controlled substances with the DEA of the U.S. Department of Justice. Applications may be received

by the Bureau Director for such bulk manufacture, but shall not be acted upon until tentative or conditional approval is made by the appropriate federal agency, and after such notifications, publications, and other actions required by Chapter II, Title 21, Code of Federal Regulations [21 CFR §1301, ff.] are effected by the applicant.

#### **304. Provisional Registration.**

(a) The Bureau Director, in his or her discretion, may grant provisional registration as a Researcher, Manufacturer, Distributor, Importer, or Exporter to any applicant, pending such applicant's obtaining a registration under Federal law. The duration of such provisional registration shall not exceed one year, and may not be renewed. Upon the granting of Federal registration, the provisional registration may be converted to a permanent registration by DHEC, which may renew such registration in the same manner as any other regular registration. If the Bureau Director does not find it in the public interest to grant a provisional registration, or to convert a provisional registration into a regular registration in the manner provided above, procedures set forth in S.C. Code Ann. § 44-53-320 for denial of registration shall be followed.

(b) Provisional registration does not entitle the applicant (i.e., the provisional registrant) to conduct any controlled substances activity within this State until such time as the applicant obtains a valid federal [DEA] registration for the identical activity at the same registered location.

#### **305. Certificate of Registration; Denial of Registration.**

(a) The Bureau Director shall issue a Certificate of Registration to an applicant if the issuance of registration or re-registration is required under the applicable provisions of the Act. In the event that the issuance of registration or re-registration is not required, the Bureau Director shall deny the application. Before denying any application, the Bureau Director shall issue an order to show cause pursuant to § 309 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 310.

(b) The Certificate of Registration shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or Controlled Substances Code Number of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration. The registrant shall maintain the Certificate of Registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the DEA or of any federal, state, or local agency engaged in enforcement of laws relating to controlled substances.

#### **306. Suspension or Revocation of Registration.**

(a) The Bureau Director may suspend any registration pursuant to the Act for any period of time he determines.

(b) The Bureau Director may revoke any registration pursuant to the Act.

(c) Before revoking or suspending any registration, the Bureau Director shall issue an order to show cause pursuant to § 309 and, if requested by the registrant shall hold a hearing pursuant to § 310. Notwithstanding the requirements of this section, however, the Director may suspend any registration pending a final order pursuant to § 307.

(d) Upon service of the order of the Bureau Director suspending or revoking registration, the registrant shall immediately deliver his or her Certificate of Registration and any forms to his or her possession to the office of the Bureau of Drug Control. The suspension or revocation of a registration shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant. Also, upon service of the order of the Bureau Director suspending or revoking registration, the registrant shall:

(1) Deliver all controlled substances in his or her possession to the office of the Bureau of Drug Control or to authorized agents of the Bureau of Drug Control; or

(2) Place all controlled substances in his or her possession under seal as described in the Act.

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration and, if appropriate, any order forms in his or her possession to the office of the Bureau of Drug Control. The suspension or revocation of a registration, when limited to a particular basic class or classes of controlled substances, shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant for such class or classes. Also, upon service of the order of the Bureau Director revoking or suspending registration, the registrant shall:

(1) Deliver to the office of the Bureau of Drug Control or to authorized agents of the Bureau of Drug Control all of the particular controlled substances or substances affected by the revocation or suspension which are in his or her possession; or

(2) Place all of such substances under seal as described in the Act.

### **307. Suspension of Registration Pending Final Order.**

(a) The Bureau Director may suspend any registration simultaneously with or at any time subsequent to the service upon the registration of an order to show cause why such registration should not be revoked or suspended, in any case where he or she finds there is an imminent danger to the public health or safety. If the Bureau Director so suspends, he or she shall serve with the order to show cause pursuant to § 309 an order of immediate suspension, which shall contain a statement of his or her findings regarding the danger in public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his or her Certificate of Registration and any order forms in his or her possession to the office of the Bureau of Drug Control. The suspension of any registration under this section shall suspend any quota fixed for the registrant. Also, upon service of the order of the Bureau Director immediately suspending registration, the registrant shall, as instructed by the Bureau Director:

(1) Deliver all affected controlled substances in his or her possession to the office of the Bureau of Drug Control or to authorized agents of the Bureau of Drug Control; or

(2) Place all of such substances under seal as described in the Act.

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Bureau Director or dissolved by a court of competent jurisdiction. Any registrant whose registration

is suspended under this section may request a hearing on the revocation or suspension of his or her registration at a time earlier than specified in the order to show cause pursuant to § 309, which request shall be granted by the Bureau Director, who shall fix a date for such hearing as early as reasonably possible.

### **308. Extension of Registration Pending Final Order.**

(a) In the event that an applicant for re-registration (who is doing business under a registration previously granted and not revoked or suspended) has applied for re-registration of at least 45 days before the date on which the existing registration is due to expire, and the Bureau Director has issued an order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue to effect until the date on which the Bureau Director so issues his or her order.

(b) The Bureau Director may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for re-registration; at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Bureau Director finds that such extension is not inconsistent with the public health and safety.

### **309. Order to Show Cause.**

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Bureau of Drug Control regarding the applicant, the Bureau Director is unable to make the determinations required by the applicable provisions of the Act to register the applicant, the Bureau Director shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Bureau of Drug Control regarding any registrant, the Bureau Director determines that the registration of such registrant is subject to suspension or revocation to the Act, the Bureau Director shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before a hearing officer at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant shall, if he or she desires a hearing, file a request for a hearing in writing. If a hearing is requested, the hearing officer shall hold a hearing at the time and place stated in the order, pursuant to § 311.

(e) When authorized by the Bureau Director, any agent of the Bureau of Drug Control may serve the order to show cause, or service may be effected by registered or certified mail.

### **310. Hearing Generally.**

(a) In any case where the hearing officer shall hold a hearing on any registration or application therefore, the procedures for such hearing shall be governed generally by the adjudication procedures set forth by statute or by the Attorney General's Office.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act of any other law of this State or the United States.

### **311. Purpose of Hearing.**

If requested by a person entitled to a hearing the hearing officer shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration, and the granting of any application for registration to manufacture in bulk a basic class of controlled substances listed in schedules I or II. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

### **312. Waiver and Modification of Rules.**

The Director or the presiding officer (with respect to matters pending before him or her) may modify or waive any rules in this part by notice in advance of the hearing, if he or she determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

### **313. Request for Hearing or Appearance; Waiver.**

(a) Any person entitled to a hearing pursuant to §§ 302-306 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause, file with the Director a written notice for a hearing.

(b) Any person entitled to and desiring to participate in a hearing pursuant to § 309 shall, within 10 days of the date of the hearing, file with the Director a written notice of his or her intention to participate in such hearing.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to §§ 302-306 may, within the period permitted for filing a request for a hearing or a notice of appearance, file with the Director a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his or her position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to §§ 302-306 fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his or her opportunity for the hearing or to participate in the hearing, unless he show good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Director may cancel the hearing if scheduled, and issue his or her final order pursuant to § 316 without a hearing.

### **314. Burden of Proof.**

(a) At any hearing on an application to manufacture any controlled substance listed in schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to the Act are satisfied. Any other person participating in the hearing pursuant to § 313 shall have the burden of proving any proposition of fact or law asserted to him or her in the hearing.

(b) At any hearing on the granting or denial of an application to be registered to conduct a narcotic treatment program or as a compounder, the applicant shall have the burden of proving that the requirements for each registration pursuant to S.C. Code Ann. § 44-53-290(i) are satisfied.

(c) At any other hearing for the denial of a registration, DHEC shall have the burden of proving that the requirements for such registration pursuant to the Act are not satisfied.

(d) At any hearing for the revocation or suspension of a registration, DHEC shall have the burden of proving that the requirements of the Act for such suspension or revocation are satisfied.

### **315. Time and Place of Hearing.**

The hearing will commence at the place and time designated in the order to show cause or notice of hearing (unless expedited pursuant to § 307) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

### **316. Final Order and Appeals.**

(a) Final order. As soon as practicable after the hearing officer has certified the record to the Director, the Director shall certify his or her order on the granting, denial, revocation, or suspension of registration.

(b) Appeals. A Department decision involving the issuance, denial, renewal, suspension, or revocation of a permit, license, certificate or certification may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Chapter 53; and Title 1, Chapter 23. Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Chapter 53; and Title 1, Chapter 23.

### **317. Modification in Registration.**

Any registrant may apply to modify his or her registration to authorize the handling of additional controlled substances or to change his or her name or address, by submitting a letter of request to the Bureau of Drug Control, DHEC, 2600 Bull Street, Columbia, SC 29201. The letter shall contain the registrant's name, address, and registration number as printed on the Certificate of Registration, and the substances and/or schedules to be added to his or her registration or the new name or address and shall be signed in accordance with § 202(d). If the modification in registration is approved, the Bureau Director shall issue a new Certificate of Registration to the registrant, who shall maintain it with the old Certificate of Registration until expiration.

### **318. Termination of Registration.**

The registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Bureau Director promptly of such fact.

### **319. Termination of Registration; Partnerships and Corporations; Other Business Entities.**

(a) Upon the transfer of ownership of a controlling interest in any partnership, corporation, holding company, association, or other business entity holding a registration under the Act, which

is not a personal registration as an individual or a proprietorship registration involving a single individual registrant, the registration held prior to any transfer of any controlling interest or controlling ownership shall terminate upon the effective date of the transfer, and a new registration shall be obtained if the business entity is to continue controlled substances activity. DHEC may, in its discretion, permit a transferor-registrant to permit the transferee to continue operation pursuant to a written power of attorney for a period of not more than 60 days, during the pendency of obtaining a new registration for the transferee.

(b) If the control of a corporation already registered under the Act shall be acquired by another corporation not registered under the Act, the acquiring corporation need not obtain a separate registration for itself, unless merger takes place; the corporation acquired shall, however, obtain a new registration even if there is no change in corporate officers if it intends to continue controlled substances activity. In the event a merger is effected between the acquiring corporation and the acquired corporation (regardless of the surviving or ensuing name) the acquiring corporation shall obtain a new registration in its own name, or in the name of the successor or ensuing corporation (if different) prior to engaging in controlled substances activity. Successor corporations shall be deemed to be new business entities, and shall obtain new registration prior to conducting controlled substances activity.

### **320. Transfer of Registration.**

No registration or authority conferred thereby shall be assigned or otherwise transferred except upon conditions as the Bureau Director may specifically designate and then only pursuant to his or her written consent.

## **PART 400. Security Requirements.**

### **401. Security Requirements Generally.**

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Bureau Director shall use the security requirements set forth in §§ 402-406 as standards for the physical security controls and operating procedures necessary to diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§ 402, 403, and 405 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in §§ 402-406 may be deemed sufficient by the Bureau Director after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Bureau Director may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or non-usable powders);

(3) The quantity of controlled substances handled;

- (4) The location of the premises and the relationship such location bears on security needs;
  - (5) The type of building construction comprising the facility and the general characteristics of the building or buildings;
  - (6) The type of vault, safe, and secure enclosures or other storage systems (e.g., automatic storage and retrieval system) used;
  - (7) The type of closures on vaults, safes, and secure enclosures;
  - (8) The adequacy of key control systems and/or combination lock control system;
  - (9) The adequacy of electric detection and alarm systems if any, including use of supervised transmittal lines and standby power sources;
  - (10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
  - (11) The adequacy of supervision over employees having access to manufacturing and storage area;
  - (12) The procedures for handling business guests, visitors, maintenance personnel, and non-employees service personnel;
  - (13) The availability of local police protection or of the registrant's or applicant's security personnel; and
  - (14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.
- (c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different scientific schedule, or as a result of a non-controlled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in §§ 402-406 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.
- (d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§ 402-406 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Bureau Director or to the Compliance Investigations Division, DEA, Department of Justice, Washington, DC 20537.
- (e) Physical security controls of locations registered under the Harrison Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in §§ 402, 403, and 405. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Bureau of Drug Control, shall not necessarily be deemed to comply

substantially with the standards set forth in §§ 402, 403, and 405 notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved.

#### **402. Physical Security Controls for Non-practitioners; Storage Areas.**

(a) Schedules I and II. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in schedules I and II shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe or steel cabinet:

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-minutes against lock manipulation, and 20 man-minutes against radiological techniques.

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Bureau Director may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system and

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vaults are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½ inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors and ceilings;

(ii) The door and frame of which vault shall conform to the following specifications or the equivalent; 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against local manipulation, and 20 man-hours against radiological techniques.

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a “day-gate” which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant as the Bureau of Drug Control may approve and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) Which vault has one of the following: complete electrical lacing of the

walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Bureau of Drug Control.

(b) Schedules III, IV and V. Raw materials, bulk materials awaiting further processing and finished products which are controlled substances listed in schedules III, IV, and V shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe which complies with the requirements set forth in paragraph (a)(1) of this section;

(2) A vault which complies with the requirements set forth in either paragraph (a)(2) or (3) of this section; equipped with an alarm system as described in paragraph (b) (4) (v) of this section; or

(3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

(i) Has an electronic alarm system as described in paragraph (b) (4) (v) of this section;

(ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use, and when in use is kept under direct observation of a responsible employee of the agent or registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded, or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;

(4) A cage, located within a building on the premises, meeting the following specifications:

(i) Having walls constructed of not less than No. 10 gauge steel posts, which posts are:

(a) At least one inch in diameter;

(b) Set in concrete or installed with lag bolts that are pinned or brazed; and

(c) Which are placed no more than 10 feet apart with horizontal one and one-half inch reinforcements every sixty inches;

(ii) Having a mesh construction with openings of not more than two and one-half inches across the square;

(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height;

(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all of the requirements of subparagraph (b)(3)(ii) of this section; and

(v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency, or a local or state police agency, each having a legal duty to respond, or a 24-hour control station operated by the registrant, or to such other source of protection that the Bureau Director may approve;

(5) An enclosure of masonry or other material, approved in writing by the Bureau Director as providing security comparable to a cage;

(6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor, agency, BNDD, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment from DEA (BNDD) has been received for the area in which such building or enclosure is situated;

(7) Such other secure storage areas as may be approved by the Bureau Director after consulting with DEA and the factors listed in § 401(b)(1) through (14) of this regulation;

(8)(i) Schedule III through V controlled substances may be stored with Schedules I and II controlled substances under security measures provided by paragraph (a) of this section;

(ii) Non-controlled drugs, substances, and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by this section, provided, that permission for such storage of non-controlled substances has been obtained in advance, in writing, from both the Bureau Director and the DEA agent in charge of the area in which such storage area is situated [See 21 CFR § 1301.72 (b)(8)(ii)]. Any such permission shall be based upon the determination that the storage of such items does not diminish security for the controlled substances.

(a) Multiple store areas. Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g. returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(b) Accessibility to storage areas. The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

#### **403. Physical Security Controls for Non-practitioners; Manufacturing Areas.**

All manufacturing activities (including processing, packaging, and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance

with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. "Limited access" may be provided in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted, provided, that he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his or her knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

#### **404. Other Security Controls for Non-practitioners; Narcotic Treatment Programs and Compounders for Narcotic Treatment Programs.**

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the DEA or with the state controlled registration agency to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to alert the registrant of suspicious orders of controlled substances. The registrant shall inform the Bureau of Drug Control of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the office of the Bureau of Drug Control of any theft or loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the contract or common carrier pursuant to subparagraph (e) of this section, upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts shall be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substances in schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer and (3) only in reasonable quantities. Such request shall contain the name, address, and

registration number of the customer and the name and quantity of the specific controlled substances desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of Part 900 of the Regulation shall be complied with for any distribution of a controlled substance listed in schedule II. For purposes of this paragraph, the term "customer" includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance to the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers, which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 402. In addition, the registrant shall employ precautions (e.g. assuring that shipping containers do not indicate the contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detail men), a registrant is responsible for providing adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of etorphine hydrochloride and/or diprenorphine to any person, the registrant shall verify that the person is authorized to handle the substance(s) by contacting the Bureau of Drug Control and DEA.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his or her specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse (LPN) under the direction of the licensed practitioner, or (4) a pharmacist acting under a prescription or an order issued by the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs shall comply with standards established by the appropriate Federal authorities [see 21 CFR § 1301.74(k)] and the Bureau of Drug Control, and the provisions of S.C. Code Ann. §§ 44-53-710 through 44-53-760 respecting the quantities of narcotic drugs that may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA and the Bureau of Drug Control may exercise discretion regarding the degree of security required in narcotic treatment programs based upon such factors as the location of the program, the number of patients enrolled in a program, and the number of physicians, staff members, and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

#### **405. Physical Security Controls for Practitioners.**

(a) Controlled substances listed in schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) This section shall also apply to non-practitioners authorized to conduct research or chemical analysis under another registration.

(d) Etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

#### **406. Other Security Controls of Practitioners.**

(a) The registrant shall not knowingly 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 denied, or has had his or her registration revoked, at any time.

(b) The registrant shall notify the Bureau of Drug Control, DHEC, of the loss or theft of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DEA Form 106 regarding such loss or theft.

(c) The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to 21 CFR § 1301.74(e), upon discovery of such theft or loss.

(d) Whenever the registrant distributes a controlled substance (without being registered as a distributor, as permitted by § 107(b) and/or §§ 1401 through 1404 of this Regulation) he or she shall comply with the requirements imposed on non-practitioners in § 404(a), (b), and (e).

#### **407. Loss by Diversion Due to Repeated Thefts.**

(a) Any registrant who suffers repeated losses of controlled substances by theft due to break-ins, employee theft, mysterious disappearance, or other than through an armed robbery shall be deemed to be providing inadequate security for such controlled substances.

(b) Upon the first such diversion, the registrant shall cause such physical security measures to be instituted to prevent reoccurrence.

(c) Upon the second such diversion, the registrant shall be required to appear before the designated hearing officer of DHEC to provide, under oath, the security measures that the registrant has effected and plans to effect in the future to prevent further diversion by theft.

(d) Upon the third such diversion, the registrant shall be cited to show cause, if any he or she

may have, why his or her registration under the Controlled Substances Act should not be revoked, suspended, or denied pursuant to the provisions of S.C. Code Ann. § 44-53-310(e).

#### **408. Filing of Theft Reports.**

Theft reports (DEA Form 106) as required by this regulation shall be filed with the Bureau of Drug Control not later than 30 days following the discovery of the theft. Failure to file theft reports within the thirty-day period shall result in the issuance of an order to show cause for revocation or suspension of registration under the Act.

#### **409. Employee Screening Procedures.**

Registrants are required to screen all employees for criminal convictions and/or unauthorized use of controlled substances. An employer's comprehensive employee screening program will include the following inquiries:

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

(2) In the past three years, have you ever knowingly used any narcotic, barbiturates, or amphetamines, other than prescribed to you by a physician or other practitioner? If the answer is yes, furnish details.

Employers should obtain an authorization, in writing, that allows inquires to be made of courts and law enforcement agencies for possible pending charges or convictions. This authorization shall be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person shall 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. This person must also be informed that the information contained in the application and any information disclosed as a result of the authorization will be available to the Bureau of Drug Control in the event of inquiry or investigation.

#### **410. Employee Responsibility to Report Drug Diversion.**

An employee who has knowledge or suspicion of drug diversion from his or her employer by a fellow employee shall report such information to a responsible security official of the employer, or to a person in a management position with 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, or with access to controlled substances. The employer shall inform all employees concerning this policy.

#### **411. Illicit Activities by Employees.**

Employees who sell, possess, use, or divert controlled substances will subject themselves not only to state and federal criminal prosecution for any illicit activity, but shall also immediately become

the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, and the past record of employment. in determining whether to suspend, transfer, terminate, or take other action against the employee.

#### **412. Separate Registration by Permitted Pharmacies for Installation and Operation of Automated Storage Machines at Long Term Care Facilities.**

(a) A permitted pharmacy may install and operate automated storage machines, as defined in § 102(c) of this Regulation, at long term care facilities. No person other than a permitted pharmacy may install and operate an automated storage machine at a long term care facility.

(b) Permitted pharmacies installing and operating automated storage machines at long term care facilities must maintain a separate registration at the location of each long term care facility at which automated storage machines are located.

(c) A permitted pharmacy applying for a separate registration to operate automated storage machines which contain controlled substances at a long term care facility is exempt from application fees for any such additional registrations.

### **PART 500. Labeling and Packaging Requirements for Controlled Substances.**

#### **501. Symbol Required; Exceptions.**

(a) Each commercial container of a controlled substance shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, shall bear a label complying with the requirement of this part.

(b) Each manufacturer shall print upon the labeling of each controlled substance distributed by him or her the symbol designating the schedule in which such controlled substance is listed.

(c) The following symbols shall designate the schedule corresponding thereto:

Schedule	Symbol
Schedule I	I or C-I
Schedule II	II or C-II
Schedule III	III or C-III
Schedule IV	IV or C-IV
Schedule V	V or C-V

The word "schedule" need not be used. No distinction need be made between narcotic and non-narcotic substances.

(d) The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.

(e) The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.

(f) The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind and double blind studies.

(g) The symbol is not required on a commercial container containing, or on labeling of, a controlled substance intended for export from the United States.

#### **502. Location and Size of Symbol on Label.**

(a) The symbol shall be prominently located on the right upper corner of the principal panel of the label of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance listed in schedules I through V. The symbol shall be at least two times as large as the largest type otherwise printed on the label.

(b) In lieu of locating the symbol in the corner of the label, as prescribed in paragraph (a) of this section, the symbol may be overprinted on the label, in which case the symbol shall be printed at least one-half the height of the label and in a contrasting color providing clear visibility against the background color of the label.

(c) In all cases the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf.

#### **503. Location and Size of Symbol on Labeling.**

The symbol shall be prominently located on all labeling other than labels covered by Regulation 203. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

(a) All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on July 1, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of § 501.

(b) All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on July 1, 1971, and thereafter transferred to another schedule or is added to any schedule after July 1, 1971, and which is packaged more than 180 days following the dates on which the transfer or addition becomes effective shall comply with the requirements of § 501.

(c) The Bureau Director may, in the case of any controlled substance, require compliance with the requirements of § 501 within a period of time shorter than required by this section if he or she finds that public health or safety necessitates an earlier effective date.

(d) Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under federal or state law as to labels of such containers and as to labeling of such substances existing prior to the effective date prescribed in this section.

#### **504. Effective Dates of Labeling Requirements.**

(a) All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on July 1, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of § 501.

(b) All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on July 1, 1971, and thereafter transferred to another schedule or is added to any schedule after July 1, 1971, and which is packaged more than 180 days following the dates on which the transfer or addition becomes effective shall comply with the requirements of § 501.

(c) The Bureau Director may, in the case of any controlled substance, require compliance with the requirements of § 501 within a period of time shorter than required by this section if he or she finds that public health or safety necessitates an earlier effective date.

(d) Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under federal or state law as to labels of such containers and as to labeling of such substances existing prior to the effective date prescribed in this section.

#### **505. Sealing of Controlled Substances.**

(a) On each bottle, multiple dose vial, other commercial container of any controlled substance listed in schedules I and/or II, and of any narcotic controlled substance listed in schedule III or IV, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper of such container a seal to disclose upon inspection any tampering or opening of the container.

(b) Any seal accepted for use, under federal law prior to July 1, 1971, shall be deemed acceptable for use under this section.

#### **506. Labeling for Controlled Substances Dispensed Directly to Ultimate Users.**

Controlled substances which are dispensed directly to an ultimate user other than by a prescription dispensed by a pharmacy or by direct administration or application of the substance into or upon the person for whom it is intended, shall bear a label or labeling containing the drug name, the quantity dispensed, the name and address of the dispenser, the name of the ultimate user (i.e., the “patient”), specific directions for use, and the date of the dispensing. The label or labeling shall include any necessary cautionary statement, whether customary or required by state or federal law. A serial number may be utilized at the discretion of the dispenser. The act of dispensing controlled substances shall be performed by the registrant, and shall not be delegated to any person other than a pharmacist acting in the regular course of professional activity. Prescriptions shall be labeled pursuant to the provisions of Part 1000 of this Regulation, unless specifically exempted. No practitioner shall directly dispense more than a thirty-one day supply.

### **PART 600. Records and Reports of Registrants.**

#### **601. Scope of Part 600.**

Inventory and other records and reports required under the Act shall be in accordance with, and contain the information required by, those sections and by the sections of this Part.

#### **602. Persons Required to Keep Records and File Reports.**

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this Part, except as exempted by this Section. Any registrant who is authorized to conduct other activities without being registered to conduct these activities, either pursuant to § 107(b) or to §§

1401 through 1404, shall maintain the records and inventories and shall file the reports required by this Part for persons registered to conduct such activities. The latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately, nor that separate records are required for each activity. The intent of the Bureau of Drug Control is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled substances used in any activity. The Bureau of Drug Control does not wish to require separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled item, he or she shall keep a record of the quantity manufactured; when he or she distributes a quantity of the item, he or she shall use and keep invoices or order forms to document the transfer; when he or she imports a substance, he or she keeps as part of his or her records the documentation required to an importer; and when substances are used in chemical analysis, he or she need not keep a record of this because such a record would not be required of him or her under a registration to do chemical analysis. All of those records may be maintained in one consolidated record system. Similarly, the researcher may store all of his or her controlled items in one place, and every year take inventory of all items in hand, regardless of whether the substances were manufactured by him or her, imported by him or her, or purchased domestically by him or her, or whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.

(b) A registered individual practitioner is not required to keep specific records with respect to controlled substances for which he or she issues prescriptions, or orders for administration within an institutional practitioner setting (e.g., hospital "orders"), in the lawful course of his or her professional practice; provided, that a complete record or memorandum of such prescription or order be maintained upon regular patient records.

(c) A registered individual practitioner is required to maintain a readily retrievable record, separate from patient charts, of all controlled substances acquired, dispensed, administered (other than by the issuance of an institutional order or a prescription) distributed, or otherwise disposed of by the practitioner, his or her employees or agents, whether the controlled substance is separately charged for, included in other charges, or is provided at no charge. Practitioners who personally administer narcotic controlled substances in an emergency need only keep a simple record of the date, kind, quantity, and strength of the controlled substance administered in such emergency, and the name of the recipient. Within 72 hours of the emergency administration, a permanent record shall be constituted and included in the readily retrievable records of dispensing required herein. Repeated or excessive emergency administrations will require the registrant to notify the Bureau of Drug Control of such happenstance.

(d) A registered person using any controlled substance in research conducted in conformity with an exemption granted under § 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) as a registered establishment which maintains records in accordance with either of those sections is not required to keep records if he notified the Bureau of Drug Control of the name, address, and registration number of the establishment maintaining such records.

(e) A registered person using any controlled substance in pre-clinical research or in teaching at a registered establishment, which maintains records with respect to such substance, is not required to keep records if he notifies the Bureau of Drug Control of the name, address, and registration number of the establishment maintaining such records.

(f) Notice required by paragraphs (d) and (e) of this section shall be given at the time the person applies for registration or re-registration and shall be made in the form of an attachment to the application, which shall be filed with the application.

### **603. Maintenance of Records and Inventories.**

(a) Every inventory and other record required to be kept under this Part shall be kept by the registrant and be available, for at least two years from the date of such inventory or record, for inspecting and copying by authorized employees of the Bureau of Drug Control, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to 21 CFR § 1305.13) may be kept at a central location rather than at the registered location if the registrant has notified the Bureau of Drug Control of its intention to keep central records. Written notification shall be submitted by registered or certified mail, return receipt requested, in triplicate to the Bureau Director. Unless the registrant is informed by the Bureau Director that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of the return receipt accompanying the notification. All notifications shall include:

(1) The nature of the records to be kept centrally and the exact location where the records will be kept;

(2) The name, address, state and DEA registration numbers, and type of registration of the registrant whose records are being maintained centrally;

(3) Whether central records will be maintained in a manual, or computer readable form.

(b) Each registered manufacturer, distributor, importer, and exporter shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in schedules I and II shall be maintained separately from all of the records of the registrants, and

(2) Inventories and records of controlled substances listed 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.

(c) Each registered individual practitioner required to keep records and each institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (b) of this section.

(d) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained as a separate prescription file.

(2) Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

(3) Prescriptions for controlled substances shall be maintained in separate files from prescriptions for non-controlled substances. Prescriptions for schedule II controlled substances shall be filed separately from prescriptions for schedules III, IV, and V controlled substances. Compliance with this Section will be deemed proper if the pharmacy maintains not less than three files, those being:

File No. 1-Schedule II Controlled Substances only.

File No. 2-Schedules III, IV, and V Controlled Substances only. File No.

3- Non-controlled Substances.

Sequential numbering systems of the files shall be at the discretion of the dispenser.

(e) All registrants that are authorized to maintain a central record keeping system shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms, prescriptions, and/or inventories which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information) a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within 2 business days upon receipt of a written request from the Bureau of Drug Control, and if the Bureau of Drug Control chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Bureau of Drug Control to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Bureau Director may cancel such central record keeping authorization, and all other central record keeping authorization held by the registrant without a hearing or other procedures. In the event of cancellation of central record keeping authorization under this paragraph, the registrant shall, within the time specified by the Bureau Director, comply with the requirements of this section that all records be kept at the registered location.

(f) Original documents shall be maintained in addition to those which are stored in computer media for a period of two years from the date of the origination of the document, or from the last transaction contained therein or entered thereupon, whichever is the later date.

## **PART 700. Inventory Requirements.**

### **701. General Requirements for Inventories.**

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a

warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(b) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(c) A separate inventory shall be made by a registrant for each independent activity for which he is registered, except as provided in § 707.

(d) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business, and the date and time the inventory is taken.

(e) An inventory shall be maintained in an indelibly written, typewritten, or printed form. An inventory taken by use of an oral recording device shall be promptly transcribed. Such inventory shall be signed by a responsible individual, who attests to the completeness and accuracy of the inventory.

#### **702. Inventory upon Transfer of Business; Change of Pharmacist-in-Charge.**

(a) Inventory upon transfer of business.

(1) Any registrant transferring his or her business to another person who shall become registered to continue such business shall inventory all controlled substances on hand at the close of business on the day of transfer. The receiving registrant shall either (a) certify the inventory taken as being correct, or (b) shall affect his or her own inventory at the start of business on the date of transfer. Any discrepancy in the inventory shall be reported within 5 days to the Bureau Director.

(2) A new establishment, never before having been registered, and having no prior inventory of controlled substances, shall be deemed to have a zero inventory as of the first day of business.

(3) A registrant discontinuing business shall upon the date of discontinuance inventory all controlled substances and place said controlled substances in sealed containers under adequate protection from theft, until such time as the controlled substances are transferred to another registrant. A copy of this inventory shall be placed with the controlled substances, and a copy retained by the discontinuing registrant.

(b) A complete inventory of all controlled substances on hand shall be performed at the time of a change in pharmacist-in charge.

#### **703. Annual Inventory Date.**

Inventories shall be taken on May 1st of each year unless written permission for another date is granted by the Bureau of Drug Control. If permission for another date is granted, the registrant shall maintain documentation of such permission for a period of two (2) years. In the event that a person

commences business with no controlled substances on hand, he or she shall record this fact as his or her initial inventory.

#### **704. Inventories of Manufacturers.**

Each registered manufacturer shall include the following information in his or her inventory:

(a) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form:

(1) The name of the substance; and

(2) The total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971), avoirdupois weights may be utilized where metric weights are not readily available)

(b) For each controlled substance in the process of manufacture on the inventory date:

(1) The name of the substance;

(2) The quantity of the substance in each batch and/or state of manufacture, identified by the batch number or other appropriate identifying number;

(3) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of volume thereof.

(c) For each controlled substance in finished form:

(1) The name of the substance;

(2) Each finished form of the substance (e.g. 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(3) The number of units or volume of each finished form in each commercial container (e.g. 100-tablet bottle or 3-milliliter vial); and

(4) The number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials).

(d) For each controlled substance not included in paragraphs (a), (b), or (c) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compounding):

(1) The name of the substance;

(2) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(3) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

#### **705. Inventories for Distributors.**

Each registered distributor shall include in his or her inventory the same information required of manufacturers pursuant to §§ 704(c) and (d).

#### **706. Inventories of Dispensers and Researchers.**

Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to § 601 shall include in his or her inventory the same information required of manufacturers pursuant to §§ 704 (c) and (d). In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(a) If the substance is listed in schedule I or II, he or she shall make an exact count or measure of the contents; and

(b) If the substance is listed in schedule III, IV, V, he or she shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he or she shall make an exact count of the contents. If estimated counts are utilized, quantities shall be recorded as number of finished doses per container. Fractions of containers may not be utilized.

(c) It is the responsibility of the registrant to determine that any estimates are accurate, as audit procedures will be based upon the inventories maintained by the registrant. The Bureau of Drug Control utilizes exact counts in all audit procedures, and will allow only minor leeway for estimated inventories.

#### **707. Inventories of Importers and Exporters.**

Each registered importer or exporter shall include in his or her inventory the same information required of manufacturers pursuant to §§ 704(a), (c), and (d). Each registered importer or exporter who is also registered as a manufacturer or as a distributor shall include in his or her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his or her stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

#### **708. Inventories for Chemical Analysis.**

Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers pursuant to §§ 704 (a), (c), and (d) as to substances which have been manufactured, imported, or received by the laboratory conducting the inventory. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in schedule I), or less than 20 grams of a hallucinogenic substance listed in schedule I (other than lysergic acid diethylamide), or less than 0.5 grams of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory.

## **PART 800. Continuing Records.**

### **801. General Requirements for Continuing Records.**

(a) On and after June 17, 1971 every registrant required to keep records pursuant to § 602 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him or her, except that no registrant shall be required to maintain a perpetual inventory, except as provided in paragraph (e) of this section.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 602. In the event controlled substances are in the possession or under the control of a registrant at a location for which he or she is not registered, the substance shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he or she is registered, except as provided in § 804.

(d) In recording dates of receipt, importation, distribution, exportation or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred shall be used as the date of receipt or distribution of any packing slips.

(e) DHEC, upon a finding that a registrant has maintained inadequate records, or upon a finding that the registrant has a history of poor or inadequate record keeping, may, in its discretion, require perpetual inventories of all or a part on the controlled substances possessed or otherwise utilized or handled by such registrant (or an applicant for new registration having a history of record keeping deficiencies) as a condition for granting or renewing controlled substances registration. DHEC, upon a finding that adequate record keeping has been maintained for two or more years, pursuant to a perpetual inventory requirement, may remove the requirement and permit the registrant to resume standard record keeping activities with or without a probationary period of registration, as DHEC deems proper.

### **802. Records of Manufacture.**

Each registered manufacturer shall maintain records with the following information.

(a) For each controlled substance in bulk form to be used, or capable of use in, or being used in, the manufacture of the same or other controlled or non-controlled substance in finished form:

(1) The name of the substance;

(2) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(4) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him or her, including the date, quantity, and import permit or declaration number for each importation;

(5) The quantity used to manufacture the same substance in finished form, including:

(i) The date and batch or other identifying number of each manufacturer;

(ii) The quantity used in the manufacture;

(iii) The finished form (e.g., 10-milligram tablets or 10 milligram concentrate per fluid ounce or milliliter);

(iv) The number of units of finished form manufactured;

(v) The quantity used in quality control;

(vi) The quantity lost during manufacturing and the causes thereof, if known;

(vii) The total quantity of the substance contained in the finished form;

(viii) The theoretical and actual yields; and

(ix) Such other information as is necessary to account for all controlled substances used in the manufacturing process.

(6) The quantity used to manufacture other controlled and non-controlled substances, including the name of each substance manufactured and the information required in subparagraph (5) of this paragraph;

(7) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

(8) The quantity exported directly the registrant (under a registration as an exporter), including the date quantity, and export permit or declaration number of each exportation;

(9) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed.

(b) For each controlled substance in finished form:

(1) The name of the substance;

(2) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(3) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to subparagraph (5) of paragraph (a) of this section;

(4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address, and registration number of the person from whom the units were received;

(5) The number of units of finished forms and/or commercial containers imported directly by the registrant (under a registration as an importer), including the date of and the number of units and for commercial containers to each importation;

(6) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

(i) The date and batch or other identifying number of each manufacturer;

(ii) The operation performed (e.g., repackaging or re-labeling);

(iii) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes therefore, if known; and

(iv) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(7) The number of commercial containers distributed to other persons, including the date and number of containers in each distribution, and the name, address, and registration number of the person to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

### **803. Records for Distributors.**

Each registered distributor shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) Each finished form (e.g. 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration of the person from whom the containers were received;

(d) The number of commercial containers of each such finished form imported directly by the registrant (under a registration as an importer), including the date of and the number of containers in each importation;

(e) The number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

(f) The number of commercial containers of such finished form exported directly by the registrant (under a registration as an exporter), including the date of and the number of containers of each exportation; and

(g) The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution as complimentary samples), including the date and manner of distribution or disposal, the name and address, and registration number of the person to whom distributed or disposed.

#### **804. Records for Dispensers and Researchers.**

Each person registered to dispense or conduct research with controlled substances required to keep records pursuant to § 602 shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received;

(d) The number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the dispenser; and

(e) The number of units or volume of such finished form and/or commercial containers disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

#### **805. Records for Importers.**

Each registered importer shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume), and import permit or declaration number for each importation;

(c) The quantity (or number of units or volume in finished form) distributed to other persons, including the date and quantity (or number of units or volume) of each distribution and the name, address, and registration number of each person to whom a distribution was made; and

(d) The quantity disposed of in any other manner by the registrant, except quantities used for manufacturing by an importer under a registration as a manufacturer, which quantities are to be recorded pursuant to § 802(a)(4) or (b)(5) including the date and manner of disposal and the quantities disposed.

#### **806. Records of Exporters.**

Each registered exporter shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) The quantity or number of units (or volume in finished form) received from other persons, including the date and quantity (or number of units or volume) of each receipt and the name, address, and registration number of each person from whom the substance was received;

(c) The quantity (or number of units or volume in finished form) exported, including the date, quantity or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and numbers of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to § 802 (a)(8) or (b)(8); and

(d) The quantity disposed of in any other manner by the registrant including the date and manner of disposal and the quantity disposed.

#### **807. Records for Chemical Analysis.**

(a) Each person registered to conduct chemical analysis with controlled substances shall maintain records, with the following information (to the extent known and reasonably ascertainable by him or her) for each controlled substance:

(1) The name of the substance;

(2) The form or forms in which the substance is received, imported, or manufactured by the registrant (e.g., powder, granulation, tablet, capsules, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., 10-milligram concentration per milliliter);

(3) The total number of the forms received, imported, or manufactured (e.g., 100 tablets, thirty 1- milliliter vials, or 10 grams of powder), including the date and quantity of each receipt, importation, or manufacture and the name, address, and registration number, if any, of the person from whom the substance was received;

(4) The quantity distributed, exported, or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation or destruction, and the name, address, and registration number, if any, of each person to whom the substance was distributed or exported.

(b) Order forms, import and export permits, import invoices, and export declarations, relating to controlled substances shall be maintained separately from all other records of the registrant.

(c) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(d) Records relating to known or suspected controlled substances received as samples for analysis are not required under paragraph (a) of this section.

### **808. Reports.**

Manufacturers, re-packers, re-labelers, importers, exporters, and distributors who are required to report to ARCOS systems of the DEA, U.S. Department of Justice, need not file copies of such reports with the Bureau of Drug Control, but such registrants shall make copies of the reports available to the Bureau of Drug Control upon its written or oral request. Substantial compliance with the provisions of 21 CFR §§ 1304.31 through 1304.33 shall be deemed sufficient compliance with state reporting requirements.

### **809. Records for Maintenance Treatment Programs and Detoxification Treatment Programs.**

(a) Each person registered or authorized by DHEC to maintain and/or detoxify controlled substances users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

- (1) Name of substance;
- (2) Strength of substance;
- (3) Dosage form;
- (4) Date dispensed;
- (5) Adequate identification of the patient (consumer);
- (6) Amount consumed;
- (7) Amount and dosage form taken home by patient; and
- (8) Dispenser's initials.

(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with § 804 without reference to § 602.

(c) All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use, shall keep a separate batch record of the compounding.

(d) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except

that such records may be disclosed for purposes and under the circumstances authorized by this regulation and any other state or federal law or regulation.

#### **810. Records for Treatment Programs Which Compound Narcotics for Treatment Programs and Other Locations.**

Each person registered or authorized under the provisions of Section 107 of this Regulation to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information for each narcotic drug:

(a) For each narcotic controlled substance in bulk form to be used in, or capable of being used in, or being used in the compounding of the same or other non-controlled substances in finished form:

(1) The name of the substance;

(2) The quantity compounded in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch compounded;

(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(4) The quantity imported directly by the registrant (under a registration as an importer) for use in compounding by him or her, including the date, quantity, and import permit or declaration number of each importation;

(5) The quantity used to compound the same substance in finished form, including:

(i) The date and batch or other identifying number of each compounding;

(ii) The quantity used in the compound;

(iii) The finished form (e.g., 10-milligram tablets; 10 mg/ml per fluidounce, etc.);

(iv) The number of units of finished form compounded;

(v) The quantity used in quality control;

(vi) The quantity lost through compounding and the causes therefore, if known;

(vii) The total quantity of the substance contained in the finished form;

(viii) The theoretical and actual yields;

(ix) Such other information as is necessary to account for all controlled substances used in the compounding process;

(6) The quantity used to manufacture other controlled and non-controlled substances, including the name of each substance manufactured and the information required in paragraph (a) (5) of this section;

(7) The quantity distributed in bulk form to other programs, including the date and quantity of each distribution, and the name, address, and registration number of each program to whom a distribution was made;

(8) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation; and

(9) The quantity disposed of by destruction, including the reason, date, and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1501.

(b) For each narcotic controlled substance in finished form:

(1) The name of the substance;

(2) Each finished form and the number of units or volume or finished form in each commercial container (e.g., 100-tablet bottle or 3 ml. ampoule, etc.);

(3) The number of containers of each such commercial finished form compounded from bulk form by the registrant, including the information required by paragraph (a) (5) of this section;

(4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address, and registration number of the person from whom the units were received;

(5) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

(6) The number of units and/or commercial containers compounded by the registrant from units in finished form received from others or imported, including:

(i) The date and batch or other identifying number of each compounding.

(ii) The operation performed (e.g., repackaging or re-labeling);

(iii) The number of units of finished form used in the compound, the number compounded, and the number lost during compounding, with the causes for such losses, if known;

(iv) Such other information as is necessary to account for all controlled substances used in the compounding process.

(7) The number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address, and registration number of the program to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers, and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date, and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1501.

## **PART 900. Order Forms.**

### **901. Execution of Order Forms.**

DEA Form 222 as issued by the DEA, U.S. Department of Justice, as required by the Federal Controlled Substances Act (21 USC 828) when properly executed and filed will be deemed a sufficient order form as required by the Act.

### **902. Handling and Filing.**

Handling and filing of order forms, and electronic orders, shall be accomplished in the manner provided under Part 1305, 21 C.F.R. (Regulations of the DEA, United States Department of Justice.)

### **903. Power of Attorney.**

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his or her behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed (or was authorized to sign) the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of attorney shall be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked. The forms are available from Director of the Bureau of Drug Control, DHEC, 2600 Bull Street, Columbia, SC 29201.

## **PART 1000. Prescriptions.**

### **1001. Persons Entitled to Issue Prescriptions.**

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) Licensed by the S.C. Board of Medical Examiners, S.C. Board of Dentistry, S.C. Board of Veterinary Medicine Examiners, S.C. Board of Nursing, S.C. Board of Examiners in Optometry, or the S.C. Board of Podiatry Examiners, and is authorized to prescribe under the type of license issued by the pertinent Board to the individual practitioner; and

(2) Acting in the regular course of professional practice, e.g., a veterinarian prescribing for a human is not within the regular course of professional practice, nor is a dentist when prescribing for illnesses or disease other than those of the oral cavity and adjacent tissues, nor is a podiatrist when prescribing for treatment of disease other than those manifesting themselves in the foot; and

(3) Registered with DHEC under the provisions of the Act.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner. The individual practitioner may not delegate the act of prescribing (i.e., the decision-making process whether to issue a prescription, what drug or substance to prescribe, what dosage, what frequency, and whether to refill the prescription) to a person not authorized to issue a prescription in his or her own right as an individual practitioner.

Example: A nurse or other employee of a physician may transmit an oral prescription (if permissible as a Schedule III, IV, or V substance) to a pharmacist if authorized to do so by the prescribing physician; the transmitting person has no authority to make any change whatsoever in the order of the practitioner, nor to add or delete any information to be transmitted.

### **1002. Purpose of Issue of Prescription.**

(a) A prescription for a controlled substance to be effective shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his or her dependence upon such drugs whether or not in the course of conducting an authorized clinical investigation in the development of a narcotic rehabilitation program.

### **1003. Manner of Issuance of Prescription.**

All prescriptions for controlled substances shall be dated as of the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address, and registration number of the practitioner.

(a) Written prescriptions. A practitioner shall sign a prescription on the day when issued and in the same manner as he or she would sign a check or legal document (e.g., J. H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter, or other mechanical means of printing, and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this regulation. See also § 1001(b).

(b) Electronic prescriptions. Existing DEA regulations provide practitioners with the option of transmitting electronic prescriptions for controlled substances in lieu of paper prescriptions. In an effort to ensure the integrity of these electronic prescriptions, the electronic application shall comply with the current DEA regulations prior to use.

#### **1004. Registration Number Required on Prescriptions.**

All prescriptions for controlled substances, whether written by the practitioner or telephoned and subsequently reduced to writing, shall bear the Federal Controlled Substances Registration Number (DEA Number) of the prescribing practitioner.

#### **1005. Persons Entitled to Fill Prescriptions.**

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

#### **1006. Information Required for Filled Prescriptions.**

A notation shall be placed upon any prescription for controlled substances when originally filled that shall indicate the date filled, the identity or initials of the pharmacist dispensing the prescription and, if different from the quantity prescribed, the quantity dispensed.

#### **1007. Dispensing of Narcotic Drugs for Maintenance Purposes.**

The administering or dispensing directly (but not prescribing of) narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his or her dependence upon such drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his or her professional practice or research" in the Act, provided, that approval is obtained prior to the initiation of such a program by submission of a Notice of Claimed Investigational Exemption for a New Drug to the Food and Drug Administration which will be reviewed concurrently by the Food and Drug Administration for scientific merit and by the DEA for drug control requirements, and that the clinical investigation thereafter accords with such approval.

#### **1008. Federal Approval of Maintenance Programs Required.**

DHEC will not register any person to conduct an authorized maintenance program for drug dependent persons until approval of such program has been made by the appropriate federal agencies. Upon approval by these agencies, the Bureau of Drug Control shall accept the application for registration as complete.

#### **1009. Withdrawal of Drug Dependent Persons by Use of Methadone or Other Narcotic Controlled Substances.**

Practitioners desiring to withdraw, but not maintain, drug dependent persons addicted to narcotic controlled substances from such substances by the use of methadone or any other schedule II narcotic controlled substance, may do so provided that all of the following criteria are met:

- (a) The drug dependent person shall be a narcotic addict.

(b) The drug dependent person shall be confined to a hospital, clinic, rest home, or other appropriate location that properly segregates the drug dependent person from contact with possible illicit suppliers.

(c) The withdrawal program shall be on a reducing dosage basis, preferably through use of oral administration of the narcotic controlled substance used for withdrawal.

(d) Withdrawal treatment shall not exceed 21 days in length and shall not be available to any drug dependent person more often than once every six months. If, in the opinion of the withdrawing practitioner, longer periods of withdrawal treatment are necessary, application for such longer treatment shall be made to the Director stating the reasons therefore, along with pertinent medical facts including, but not limited to, the following:

(1) Medical condition of subject at onset of withdrawal treatment;

(2) Amount of drug intake and name of drug at onset of treatment;

(3) Initial withdrawal dosage of methadone (or other narcotic controlled substance);

(4) Reduction schedule of withdrawal substance;

(5) Current medical evaluation of withdrawal regimen;

(6) Statement concerning presence or absence from urine sample of drug dependent person of the drug to which he or she was addicted; and

(7) Any other pertinent facts deemed necessary by the withdrawing practitioner or by the Director.

(e) Any maintenance facility shall be approved by DHEC and the appropriate federal agencies.

**1010. Approved Uses of Methadone in Hospitals. Methadone is Approved for the Following Uses for Inpatients of Hospitals Licensed by DHEC:**

(a) Analgesia;

(b) Pertussis;

(c) Detoxification (withdrawal) of drug dependent persons under conditions set forth in Section 1009 of this regulation; or

(d) Temporary maintenance of methadone treatment of a drug dependent person enrolled in a methadone maintenance program licensed by any state or the federal government while such person is institutionalized within a licensed hospital for medical treatment of an illness or malady medically unrelated to drug dependence.

**1011. Departmental Approval; When Required.**

(a) Prior approval by DHEC for methadone use as set forth in § 1010 of this regulation is not required.

(b) Prior approval of DHEC and registration as provided by Title 21, § 1301.22(a)(6) of the Code of Federal Regulations and S.C. Code Ann. § 44-53-290(i), is required of all persons desiring to operate a treatment program utilizing methadone (i.e., a "methadone maintenance program").

(c) Prior approval by DHEC in the manner set forth by § 1012 of this regulation is not required to dispense methadone to outpatients of a hospital licensed by DHEC. Prior approval of DHEC is not required for "take home" methadone preparations which are lawfully dispensed by a methadone maintenance treatment facility.

(d) Approvals by DHEC, as required by §§ 1009 through 1012 of this regulation, may be granted by the Bureau of Drug Control in its discretion. If the Bureau finds that it cannot approve a request, the request shall be submitted to the Director, along with the Bureau's reasons for non-approval. The Director, in his or her discretion, may then approve or deny the request, but if he or she shall deny such request, the person making the request shall be entitled to a hearing to determine the public interest, in the manner provided for "contested cases" in the South Carolina Administrative Procedures Act.

(e) DHEC may require further information from any applicant in order to obtain sufficient information to be utilized in approving or denying any request.

#### **1012. Treatment of Outpatients with Methadone.**

(a) If a physician determines that methadone would be the drug of choice as an analgesic for a particular patient, the physician may issue prescriptions for methadone to the patient. Such prescriptions may be dispensed by any pharmacy that has agreed to perform such dispensing function.

(b) The treating physician shall agree to maintain adequate records to substantiate the use of methadone as an analgesic for the patient and shall make such records available to DHEC upon request.

### **PART 1100. Controlled Substances Listed in Schedule II.**

#### **1101. Requirement of Prescription.**

(a) A pharmacist may dispense directly a controlled substance listed in schedule II, which is a prescription drug as determined under the Act, pursuant to one of the following methods:

- (1) As a written prescription signed by the prescribing individual practitioner;
- (2) As an electronic prescription transmitted in accordance with § 1003(b); or
- (3) As provided in paragraphs (d) through (g) of this section.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule II in the course of his or her professional practice without a prescription subject to § 1006.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule II only pursuant to a written prescription signed by the

prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period shall be pursuant to a written prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information requested in § 1003 except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual practitioner is not known to the pharmacist, he or she shall make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his or her phone number as listed in the telephone directory and/or other good faith efforts to insure his or her identity; and

(4) Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1003, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it shall be postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Bureau Director if the prescribing individual practitioner fails to deliver a written prescription to him or her; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(e) A prescription prepared in accordance with § 1003 written for a Schedule II narcotic controlled substance, to be compounded for the direct administration to a patient by parenteral, intravenous, intra-muscular, subcutaneous or intra-spinal infusion, may be transmitted by the practitioner or the practitioner's agent by facsimile to a home infusion pharmacy. The facsimile serves as the original prescription for the purposes of this paragraph (e) and it shall be maintained in accordance with § 603. The written, signed prescription shall be maintained in the medical record of the patient.

(f) A prescription prepared in accordance with § 1003 written for a Schedule II substance for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with Section 603 (d). The written, signed and voided prescription shall be maintained in the medical record of the patient. This paragraph (f) is not applicable to prescriptions issued for residents of community residential care facilities or assisted living facilities.

(g) A prescription prepared in accordance with § 1003 written for a Schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by

Medicare under Title XVIII of the Social Security Act, or a hospice program which is licensed by DHEC may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and shall be maintained in accordance with § 603 (d). The written, signed, and voided prescription shall be maintained in the medical record of the patient.

#### **1102. Limitations on Prescriptions for Schedule II Substances.**

Prescriptions for schedule II controlled substances shall not be issued for more than a thirty-one day supply of the substance. No prescription for schedule II controlled substances shall be dispensed later than 90 days from the date of issue.

#### **1103. Practitioner-Patient Relationship Required.**

Prior to the issuance of a prescription for, or the direct dispensing of any schedule II controlled substances, the prescribing practitioner shall have a valid practitioner-patient relationship established with the recipient of the prescription, such relationship to include, but not be limited to, a sufficient knowledge of the medical need of the patient for such schedule II controlled substance, determination of the benefit to risk ratio of the use of such substance, good faith determination of the identity and address of the patient, a determination of the physical condition of the patient, and such practitioner shall be in personal attendance of the patient at the time of issuance of the prescription. Any prescription issued by any practitioner for any person outside of the reasonable bounds of a practitioner-patient relationship shall be deemed issued other than in the course of professional practice required by the Act. A practitioner cannot usually acquire a valid patient-practitioner relationship with himself or herself, or with a member of his or her immediate family, due to the likelihood of the loss of or the vitiation of the objectivity required in making the necessary medical decisions in order to properly prescribe or dispense controlled substances. The practitioner may not be able to acquire a sufficient practitioner-patient relationship with non-family members (i.e., fiancé or fiancée, close personal friend, paramour, etc.) if total objectivity in deciding to prescribe or dispense controlled substances cannot be maintained due to such factors as extreme compassion, ardor, extortion, etc. which would vitiate such objectivity. In the event of a bona fide emergency situation, where great detriment to the health or safety of a patient may be involved, a practitioner may administer, dispense or prescribe limited amounts of controlled substances to any person, notwithstanding the provisions of this Section, until such time as another objective practitioner can be contacted.

#### **1104. Refilling Prescription.**

The refilling of a prescription for a controlled substance listed in schedule II is prohibited.

#### **1105. Partial Filling of Prescription.**

(a) The partial filling of a prescription for a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(b) Prescriptions for schedule II controlled substances issued for patients in long term care facilities (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities, to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription whether the patient is "terminally ill" or LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial dispensing, the pharmacist shall record on the back of the prescription the date of the partial dispensing, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial dispensings shall not exceed the total quantity prescribed. Schedule II prescriptions, for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication. This paragraph (b) is not applicable to prescriptions issued for residents of community residential care facilities or assisted living facilities.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, identification of LTCF, identification of medication authorized (to include dosage form, strength and quantity), listing of partial dispensings that have been dispensed under each prescription and the information required in paragraph (b) of this section.

(2) Immediate (real time) updating of the prescription record each time a partial dispensing of the prescription is conducted.

(3) Retrieval of partially dispensed Schedule II prescription information is the same as required by §§ 1202(b)(4) and (5) for Schedule III, IV, and V prescription refill information.

#### **1106. Labeling of Substance.**

The pharmacist filling a written or emergency oral prescription for a controlled substance listed in schedule II shall affix to the package a label showing the drug name, the quantity dispensed, the date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law. See also § 1918.

#### **1107. Filing of Prescriptions.**

All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of § 603.

## **PART 1200. Controlled Substances Listed in Schedules III, IV, and V.**

### **1201. Requirement of Prescription.**

(a) A pharmacist may dispense a controlled substance listed in schedule III, IV, or V which is a prescription drug as determined under the Act, only pursuant to one of the following methods:

(1) A written prescription signed by a prescribing individual practitioner;

(2) An electronic prescription transmitted in accordance with § 1003(b);

(3) An oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1003, except for the signature of the prescribing individual practitioner; or

(4) A facsimile of a written, signed prescription, transmitted by the practitioner or the practitioner's agent to the pharmacy. A prescription transmitted by facsimile must be received at the pharmacy as it was originally transmitted by facsimile and must include the name and address of the practitioner, the phone number for verbal confirmation, the time and date of transmission, and the name of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law.

(b) An individual practitioner may administer or dispense a controlled substance listed in schedule III, IV, or V in the regular course of his or her professional practice without a prescription.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule III, IV, or V pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 1003 except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

### **1202. Refilling of Prescriptions.**

(a) No prescription for a controlled substance listed in schedule III, IV, or V shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription may be refilled more than five times. Additional quantities of controlled substances listed in schedule III, IV, or V may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in § 1201 which shall be a new and separate prescription.

(b) An automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedules III, IV, and V, subject to the following conditions:

(1) Any such proposed computerized system shall provide online retrieval (via CRT display or hard-copy printout information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing

practitioner.

(2) Any such proposed computerized system shall also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III, IV, or V controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV, or V controlled substance is correct shall be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy of each day's controlled substance prescription order refill data, that print-out shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist shall verify that the data indicated is correct and then sign this document in the same manner as he or she would sign a check or legal document (e.g. J.H. Smith or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data shall be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It shall be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him or her and is correct as shown. Such a book or file shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized system shall have the capability of producing a print-out of any refill data which the user pharmacy is responsible for maintaining under the Act and its implementing regulation. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both.) Such a print-out shall indicate name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist and the number of the original prescription order. In any computerized system employed by a user pharmacy the central record-keeping location shall be capable of sending the print-out to the pharmacy within 48 hours, and if a DEA Special Agent or compliance Investigator or an Inspector from DHEC requests a copy of such print-out from the user pharmacy it shall, if requested to do so by the Agent, Investigator, or Inspector verify the print-out transmittal capability of its system by documentation (e.g. postmark).

(5) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy shall have an auxiliary procedure which will be used for the documentation of refills of Schedule III, IV, and V controlled substance prescription orders. This auxiliary procedure shall insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(c) When filing refill information for original prescription orders for Schedule III, IV, or V controlled substances, a pharmacy may use the system described in either paragraph (a) or (b) of this section.

### **1203. Limitations on Prescriptions for Schedules III, IV, and V Substances.**

Prescriptions for controlled substances listed in Schedules III, IV, and V shall not be issued for more than a 90 day supply of the substance. If authorized for refill, no prescription shall be refilled sooner than 48 hours prior to the time that the prescription should be consumed if the prescribed daily dosage is divided into the total prescribed amount. (Example: 4 daily divided into 100 dosage units = 25 days.) Carry over time shall not accrue between refills. In the event that the practitioner does not specify an exact daily dosage, the dispenser shall calculate date of refill from the usual daily dosage recommended by the manufacturer of the controlled substance.

### **1204. Practitioner-Patient Relationship Required.**

Prior to the issuance of a prescription for controlled substances listed in Schedule III, IV, or V the prescribing practitioner shall have a valid practitioner-patient relationship established with the recipient of the prescription, such relationship to include, but not be limited to, a sufficient knowledge of the medical need of the patient for such schedule III, IV, or V controlled substance, determination of the benefit to risk ratio of the use of such substance, good faith determination of the identity and address of the patient, a determination of the physical condition of the patient, and such practitioner shall be in personal attendance of the patient at the time of issuance of the prescription. Any prescription issued by any practitioner for any person outside of the reasonable bounds of a practitioner-patient relationship shall be deemed issued other than in the course of professional practice required by the Act. A practitioner cannot usually acquire a valid patient-practitioner relationship with himself or herself, now with a member of his or her immediate family, due to the likelihood of the loss or vitiation of the objectivity required in making the necessary medical decisions in order to properly prescribe or dispense controlled substances. The practitioner may not be able to acquire a sufficient practitioner-patient relationship with non-family members (i.e., fiancé or fiancée, close personal friend, paramour, etc.) if total objectivity in deciding to prescribe or dispense controlled substances cannot be maintained due to such factors as extreme compassion, ardor, extortion, etc. which would vitiate such objectivity. In the event of a bona fide emergency situation, where great detriment to the health or safety of a patient may be involved, a practitioner may administer, dispense or prescribe limited amounts of controlled substances to any person, notwithstanding the provisions of this Section, until such time as another objective practitioner can be contacted.

### **1205. Partial Filling of Prescriptions.**

The partial filling (dispensing) of a prescription for a controlled substance listed in Schedules III, IV, or V is permissible, provided that:

- (a) Each partial filling is recorded in the same manner as a refilling;
- (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
- (c) No dispensing occurs after six months from the date on which the prescription was issued.

### **1206. Labeling of Substances.**

The pharmacist filling a prescription for a controlled substance listed in schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the drug name, the quantity dispensed, the serial number of the prescription and the date of the initial filling, the name

of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescriptions as required by law.

#### **1207. Filing Prescriptions.**

All prescriptions for controlled substances listed in schedules III, IV, and V shall be kept in accordance with § 603.

#### **1208. Controlled Substances Listed in Schedule V – Dispensing Without a Prescription.**

A controlled substance in Schedule V, which is not a prescription drug as determined under the Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such distribution is made only by a pharmacist and not by a non-pharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his or her professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist):

(b) Not more than 120 ml. (4 ounces) of any controlled substance listed in Schedule V may be distributed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least 18 years of age;

(d) The pharmacist requires every purchaser of a controlled substance listed in Schedule V not known to him or her to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for distributions of controlled substances listed in Schedule V (other than by prescription) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who distributed the substance to the purchaser (the book shall be maintained in accordance with the record keeping requirement of § 603 of this chapter); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to the Act or any other law.

(g) Repetitive sales without prescription of Schedule V controlled substances without positive determination of medical need by the pharmacist selling the non-prescription controlled substance shall be deemed dispensing for other than medical purposes, and shall be prima facie evidence of detriment to the public health and safety.

### **PART 1300. Miscellaneous.**

#### **1301. Severability.**

If a provision of any section of Part 100 through 1900 of this regulation is held invalid, all valid provisions that are severable shall remain in effect. If a provision of any of this regulation is held invalid in one or more of its applications, the provision shall remain in effect in all its valid applications that are severable.

### **1302. Application of Other Laws.**

Nothing in this regulation shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under federal laws or obligations under international treaties, conventions or protocols, or under the law of the state in which he desires to do such act nor shall compliance with such Parts be construed as compliance with other federal or state laws unless expressly provided in such other laws.

### **1303. Exceptions in Regulations.**

Any person may apply for an exception to the application of any provision of these regulations by filing a written request stating the reasons for such exception. Requests shall be filed with the Bureau Director. The Bureau Director may grant an exception in his or her discretion, but in no case shall he or she be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

## **PART 1400. Special Exceptions for Manufacture and Distribution of Controlled Substances.**

### **1401. Distribution by Dispenser to Another Practitioner.**

(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 or her 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 § 804(e) of this regulation and by the receiving practitioner in accordance with § 804(c) of this regulation;

(3) If the substance is listed in Schedule I or II, an order form (DEA Form 222) is used as required by Part 4 of this regulation;

(4) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section during any 12 month period does not exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the twelve month period. Registrants in existence less than 12 months shall prorate the time period, and shall not distribute more than five percent of the dispensings for any monthly period.

(b) If, at any time during any consecutive 12 month period during which the practitioner is registered to dispense, there is reason to believe that the total number of dosage units of all controlled substance which will be distributed by him or her pursuant to this section will exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by him or her during the 12 month period, the practitioner shall obtain a registration to distribute controlled substances.

### **1402. Manufacture and Distribution of Narcotic Solutions and Compounds by a Pharmacist.**

As an incident to a distribution under § 1401, a pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion not exceeding 20 percent of the complete solution, compound, or mixture.

### **1403. Distribution to Supplier.**

Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he or she obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if know, of the supplier or manufacturer. In the case of returning a controlled substance listed in schedule I or II, an order form shall be used in the manner prescribed in Part 900 of these regulations and be maintained as the written record of the transaction.

### **1404. Distribution upon Discontinuance or Transfer of Business.**

(a) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his or her South Carolina Controlled Substances Certificate of Registration to the Bureau of Drug Control, DHEC, 2600 Bull Street, Columbia, SC 29201. His or her Federal Controlled Substances Certificate of Registration and any un-executed order forms shall be returned to the DEA, 1835 Assembly Street, Suite 1229, Columbia, SC 29201.

(b) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (by transferring such business activities to another person) shall submit in person or by registered or certified mail, return receipt requested, to the Bureau Director at least 14 days in advance of the date of the proposed transfer (unless the Bureau Director waives this time limitation in individual instances), the following information:

(1) The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);

(2) The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);

(3) Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed);

(4) Whether the registrant-transferor has a quota to manufacture or procure any controlled substance listed in schedule I or II (if so, the basic class or class of the substance should be indicated); and

(5) The date on which the transfer of controlled substances will occur.

(c) Unless the registrant-transferor is informed by the Bureau Director, before the date on which the transfer was stated to occur, that the transfer may not occur, the registrant-transferor may distribute (without being registered to distribute) controlled substances in his or her possession to the registrant-transferee in accordance with the following:

(1) On the date of transfer of the controlled substances, a complete inventory of all controlled substances being transferred shall be taken in accordance with Part 700 of this Regulation. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It

shall not be necessary to file a copy of the inventory with the Bureau of Drug Control unless requested by the Bureau Director. Transfers of any substances listed in schedules I or II shall require the use of order forms in accordance with Part 1305 of the Federal Regulations.

(2) On the date of transfer of the controlled substances, all records required to be kept by the registrant-transferor with reference to the controlled substances being transferred, under Parts 600 through 800 of this Regulation, shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

(3) In the case of registrants required to make reports pursuant to Parts 600 through 800 of this Regulation, a report marked "Final" will be prepared and submitted by the registrant-transferor showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him or her, if no further transactions involving controlled substances are consummated by him or her. The initial report of the registrant-transferee shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor-registrant, and the substances transferred to him or her shall be reported as receipts in his or her initial report.

## **PART 1500. Disposal of Controlled Substances.**

### **1501. Procedure for Disposing of Controlled Substances.**

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Bureau Director for authority and instructions to dispose of such substance.

(b) The Bureau Director shall authorize and instruct the individual in possession to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By destruction in the presence of an agent of the Bureau of Drug Control or other authorized person, or

(3) By such other means as the Bureau Director may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Bureau Director may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Bureau of Drug Control in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Bureau Director summarizing the disposals made by the registrant. In granting such authority, the Bureau Director may place such condition as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

## **PART 1600. Inspections.**

### **1601. Authority to Make Inspections.**

In carrying out his or her functions under the Act, the Bureau Director, through his or her inspectors, is authorized in accordance with the Act to enter controlled premises and conduct administrative inspections thereof, for the purpose of:

(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and any regulations promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to Parts 600 through 800 of this chapter, order form records required to be kept pursuant to Part 900 of this chapter, prescription and distribution records required to be kept pursuant to Part Parts 1000 through 1200 of this chapter, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage;

(b) Inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to this Act;

(c) Making a physical inventory of all controlled substances on hand at the premises;

(d) Collecting samples of controlled substances or precursors (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 84 to the owner, operator, or agent in charge of the premises);

(e) Checking of records and information on distribution of controlled substances by the registrant as they relate to total distribution of the registrant (i.e., has the distribution in controlled substances increased markedly within the past year, and if so, why); and

(f) Except as provided in § 1602, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the regulations thereunder.

### **1602. Exclusion from Inspection.**

(a) Unless the owner, operator, or agent in charge of the controlled premises so consents, no inspection authorized by the regulations shall extend to:

(1) Financial data;

(2) Sales data other than shipping data; or

(3) Pricing data.

### **1603. Entry.**

An inspection shall be carried out by an inspector. Any such inspector, upon:

(a) Stating his or her purpose and

(b) Presenting to the owner, operator, or agent in charge of the premises to be inspected:

(1) Appropriate credentials, or

(2) Written notice of his or her inspection authority under § 1601 and the Act, or

(c) Receiving informed consent under § 1605 of this Regulation or through the use of administrative warrant issued under the Act shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

#### **1604. Notice of Inspection.**

The notice of inspection shall contain:

(a) The name and title of the owner, operator, or agent in charge of the controlled premises;

(b) The controlled premises name;

(c) The address of the controlled premises to be inspected;

(d) The date and time of the inspection;

(e) A statement that a notice of inspection is given pursuant to the Act;

(f) A reproduction of the pertinent parts of the Act; and

(g) The signature of the inspector.

#### **1605. Consent to Inspection.**

(a) An administrative inspection warrant shall not be required if informed consent is obtained from the owner, operator, or agent in charge of the controlled premises to be inspected.

(b) Wherever possible, informed consent obtained by the inspector shall consist of a written statement signed by the owner, operator or agent in charge of the premises to be inspected.

(c) After August 17, 1974, informed consent may be shown by the production of a completed registration application or certificate, which shall contain printed thereon a preamble and conditions of registration.

#### **1606. Application for Administrative Inspection Warrant.**

(a) An administrative inspection warrant application shall be submitted to any judge or any magistrate and shall contain the following information:

(1) The name and address of the controlled premises to be inspected;

(2) A statement of statutory authority for the administrative inspection warrant, and that the fact that the particular inspection in question is designed to insure compliance with the regulations promulgated under those acts;

(3) A statement relating to the nature and extent of the administrative inspection, including,

where necessary, a request to seize specified items and/or to collect samples of finished or unfinished controlled substances;

(4) A statement that the establishment either:

- (i) Has not been previously inspected, or
- (ii) Was last inspected on a particular date.

(b) The application shall be submitted under oath to an appropriate judge or magistrate.

#### **1607. Administrative Probable Cause.**

If the judge or magistrate is satisfied that "administrative probable cause" exists, he shall issue an administrative warrant. Administrative probable cause shall not mean criminal probable cause as defined by federal or state statute or case law.

#### **1608. Execution of Warrants.**

An administrative inspection warrant shall be executed and returned as required by, and any inventory or seizure made shall comply with the requirements of the Act. The inspection shall begin as soon as is practicable after the issuance of the administrative inspection warrant and shall be completed with reasonable promptness. The inspection shall be conducted during regular business hours and shall be completed in a reasonable manner.

#### **1609. Refusal to Allow Inspection with an Administrative Warrant.**

If a registrant or any person subject to the Act refuses to permit execution of an administrative warrant or impedes the inspector in the execution of that warrant, he shall be advised that such refusal or action constitutes a violation of the Act. If the individual persists and the circumstances warrant, he or she shall be arrested and the inspection shall commence or continue.

### **PART 1700. Protection of Researchers and Research Subjects.**

#### **1701. Confidentiality of Research Subjects.**

(a) Any person registered to conduct a bona fide research project with controlled substances under the Act who intends to maintain the confidentiality of those persons who are the subjects of such research, shall, upon registration or within a reasonable time thereafter, submit to the Bureau of Drug Control, DHEC, 2600 Bull Street, Columbia, SC 29201, a separate request for each research project involving controlled substances, which shall contain the following:

- (1) The researcher's registration number for that project;
- (2) The location of the research project;
- (3) A general description of the research or a copy of the research protocol;
- (4) A specific request to withhold the names and/or any other identifying characteristics of the research subjects; and
- (5) The reasons supporting the request.

(b) Within 60 days from the date of receipt of the request, the Bureau Director shall issue a letter, either granting confidentiality, requesting additional information or denying confidentiality, in which case the reasons for the denial shall be included. A grant of confidentiality shall be limited solely to the specific research project indicated in the request.

(c) Within 30 days after the date of completion of the research project, the researcher shall so notify the Bureau Director.

(d) In addition to the requirements set forth in paragraphs (a), (b), and (c) of this Section, the person requesting confidentiality of research subjects shall also provide the Bureau of Drug Control with a copy of the petition to the Attorney General of the United States required pursuant to the provisions of 21 CFR § 1316.23. In the event that the federal petition for confidentiality is not granted, or is withdrawn by the Attorney General of the United States, the Bureau of Drug Control shall, after notice to the researcher, remove its grant of confidentiality, if previously granted.

### **1702. Exemption from Prosecution for Researcher.**

(a) Upon registration of a practitioner to engage in research in controlled substances under the Act, the Bureau of Drug Control, DHEC, on its own motion or upon request in writing from the Director or from the practitioner, may exempt the registrant when acting within the scope of his or her registration, from prosecution under State or local laws for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his or her exemption. However, this exemption does not diminish any requirement of compliance with the Federal Food, Drug and Cosmetic Act (21 USC 301, et seq.) or with the Federal Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801, et seq.).

(b) All petitions for Grants of Exemption from Prosecution for the Researcher shall be addressed to the Director, Bureau of Drug Control, SCDHEC, 2600 Bull Street, Columbia, SC 29201, and shall contain the following:

(1) The researcher's registration number, if any, for the project;

(2) The location of the research of the research project;

(3) The qualifications of the principal investigator;

(4) A general description of the research or a copy of the research protocol;

(5) The source of funding for the research project;

(6) A statement as to the risks posed to the research subjects by the research procedures and what measures of protection will be afforded to the research subjects;

(7) A statement as to the risks posed to society in general by the research procedures and what measures will be taken to protect the interests of society;

(8) A specific request for exemption from prosecution by Federal, State, or local authorities for offenses related to the possession, distribution, and dispensing of controlled substances in accord with the procedures described in the research protocol;

(9) A statement establishing that a grant of exemption from prosecution is necessary to the successful completion of the research project;

(c) Any researcher or practitioner proposing to engage in research requesting both exemption from prosecution and confidentiality of identity of research subjects may submit a single petition incorporating the information required in §§ 1701 and 1702.

(d) The exemption shall consist of a letter issued by the Bureau Director, which shall include:

(1) The researcher's name and address;

(2) The researcher's registration number for the research project;

(3) The location of the research project;

(4) A concise statement of the scope of the researcher's registration; and

(5) The limits of the exemption;

(6) The exemption shall apply to all acts done in the scope of the exemption while the exemption is in effect. The exemption shall remain in effect until completion of the research project or until the registration of the researcher is either revoked or suspended or his or her removal of registration is denied. However, the protection afforded by the grant of exemption from prosecution during the research period shall be perpetual.

(e) Within 30 days of the date of completion of the research project, the researcher shall so notify the Bureau Director. The Bureau Director shall issue another letter including the information required in paragraph (d) of this section and stating the date on which the period of exemption concluded; upon receipt of this letter, the researcher shall return the original letter of exemption.

## **PART 1800. Administrative Conferences.**

### **1801. Authority for Administrative Conferences.**

An administrative conference may be ordered or granted by the Director of the Bureau of Drug Control, at his or her discretion, to permit any person against whom criminal and/or civil action is contemplated under the Act an opportunity to present his or her views and his or her proposals for bringing his or her alleged violations into compliance with the law. Such administrative conference will also permit him or her to show cause why prosecution should not be instituted, or to present his or her views on the contemplated proceeding.

### **1802. Notice; Time and Place.**

Appropriate notice designating the time and place for the administrative conference shall be given to the person. Upon request, timely and properly made, by the person to whom notice has been given, the time and place of the administrative conference, or both, may be changed if the request states reasonable grounds for such change. Such request shall be addressed to the Bureau Director who issued the notice.

### **1803. Conduct of Administrative Conferences.**

Presentation of views at an administrative conference under this Subpart shall be private and informal. The views presented shall be confined to matters relevant to bringing violations into compliance with the Act or to other contemplated proceedings under the Act. These views may be presented orally or in writing by the person to whom the notice was given, or by his or her authorized representative.

## **PART 1900. Handling and Administering Controlled Substances in Hospitals. 1901.**

### **1901. Hospital Registration.**

All hospitals (except those owned and operated by the federal government) shall be registered with DHEC in controlled substances schedules II through V inclusive.

### **1902. Practitioners' Registration.**

Physicians and other practitioners who prescribe or order controlled substances for, or administer controlled substances to, patients in a hospital, shall be registered under the provisions of Article 3 of Chapter 53 of Title 44 of the 1976 Code.

### **1903. Residents' Registration.**

A resident may prescribe or order the administration of controlled substances for patients within a hospital or residency training program, provided, that such resident has completed his or her course of study in a recognized college of medicine and has been duly licensed by the Board of Medical Examiners of South Carolina to practice medicine within this state, and has duly registered with DHEC and the DEA under the respective Controlled Substances Acts.

### **1904. Responsibility for Controlled Substances.**

The administrative head of the hospital as a registrant under the Controlled Substances Act is responsible for the proper safeguarding and handling of controlled substances within the hospital. Responsibility for storage, accountability, and proper dispensing of controlled substances from the pharmacy may be delegated to a pharmacist employed by the hospital. Likewise, the Director of Nursing is usually delegated the authority for proper storage at nursing stations, and use, as directed by physician orders. However, delegation of authority does not relieve the administrator of the hospital of supervisory responsibility to insure detection and correction or any diversion or mishandling. The administrator shall be certain that all possible control measures are observed, and that any suspected diversion or mishandling of controlled substances is reported immediately to the Bureau of Drug Control for investigation. The administrator is ultimately responsible that all thefts be reported to DHEC pursuant to §§ 410 through 411 of this Regulation.

### **1905. Prescriptions not Required on Floor-Stocked Controlled Substances.**

(a) Physicians and other practitioners who may be authorized according to state law, and who may be privileged and credentialed to place orders for patients within the hospital, shall enter such orders in the patient's medical record and no prescription shall be required. The nursing station floor stock used in administering controlled substances in any schedule shall be accounted for in a readily retrievable format. The practitioner's order shall be checked against the medication administration record (MAR) and the controlled substances control sheet or hospital-specific record periodically by pharmacy personnel.

(b) Due to finite limits of nursing unit controlled substances storage areas, controlled substances that are not kept as floor stock will be occasionally ordered. Proper accountability for these controlled substances not included in floor stock require that they be issued on an individual demand basis with an accompanying sign-out control sheet. Any amount of these controlled substances which are not administered to or ingested by the patient shall be returned to the pharmacy within 72 hours after the medication order is discontinued by the individual practitioner treating the patient.

(c) Controlled substances secured from or obtained by prescription from retail sources outside the hospital are to be stored securely with all other controlled substances on the nursing unit. These controlled substances are to be monitored as to their administration to the patient by a supplemental controlled substances disposition sheet. This sheet should be designated with a control number or an identifying mark in order to distinguish it from regular hospital stock. If the patient is discharged before all of these controlled substances are administered, the amount sent home with the patient (if any) shall be noted on the disposition sheet and signed and dated by a registered nurse involved in the discharge process, who shall cause the sheet to be transmitted to the hospital pharmacy. In the event there are controlled substances obtained from outside sources which are not to be sent home with the patient, or if the patient expires and there are unutilized controlled substances from these sources, the balance of the medication shall be noted on the sheet by the Registered Nurse, and the sheet and the medication shall be returned to the hospital pharmacy for disposition.

(d) All non-electronic orders shall be manually signed by the practitioner.

(e) All controlled substances within a hospital that are not located within the hospital pharmacy shall be accompanied by either an electronic documentation, a disposition sheet, or a sign-out sheet upon which to record the administration of the substance, whether the substance originated as hospital stock, from a retail source outside the hospital, or was brought into the hospital by the patient with the consent of the hospital and the patient's practitioner.

#### **1906. Registry Number.**

The physician's full name shall appear on the physician's order sheet. The physician's registry number is not required on the sheet, but shall be recorded within the pharmacy or drug room.

#### **1907. Telephone Orders.**

Telephone orders for patients are permissible only in absolute necessity. The nurse receiving the order shall enter it into the patient's medical record, authenticate the practitioner's name, and the nurse's signature. The order for the controlled substance shall be authenticated according to hospital policy.

#### **1908. Verbal Orders.**

Verbal (oral) orders for hospital patients are permitted in a bona fide emergency. Such orders shall be handled in the same manner as telephone orders.

#### **1909. Controlled Substances Records.**

All non-electronic orders and non-electronic records of controlled substances shall be in ink, typed, or indelible pencil. Mechanical or electronic systems may be used to collect and store this data. All data shall be kept in a readily retrievable manner as set forth in §§ 601, 602, 603, 801, and

804 of this regulation. Any mechanical or electronic system shall be designed to retrieve data in such a manner as to show individual controlled substance activity per nursing unit as well as individual controlled substance volume in its entirety. This shall include, but is not limited to, control numbers, date dispensed, identity of the controlled substance, strength, quantity dispensed, and location within the hospital.

#### **1910. Procedure in Case of Waste, Destruction, Contamination, etc.**

(a) Aliquot part of solutions used for drugs: The nurse shall use the proper number of tablets or ampoules from nursing unit stock. The nurse shall record the number of tablets or ampoules used and the dose given in the proper columns of the controlled substances disposition sheet, in the automated storage machine, or in a hospital-specified format. The nurse shall properly dispose of that portion of the solution not used. The aliquot shall be witnessed and recorded by the witness according to hospital policy. This information must be readily retrievable by hospital staff.

(b) Prepared dose refused by patient or canceled by physician: When a dose of a controlled substance has been prepared for a patient but not used due to refusal by the patient or cancellation by the physician, or has been accidentally contaminated during the regular course of administering the drug to the patient for whom it has been ordered (e.g., blood aspirated into a syringe when beginning the administration of an intra-muscular medication) the nurse shall properly dispose of the solution, and record on the back of the disposition sheet, in the automated storage machine, or in a hospital-specified format the reason why the controlled substance was not administered. This information must be readily retrievable by hospital staff.

(c) Accidental destruction of controlled substance: When a solution, tablet, ampoule or substance is accidentally destroyed on a nursing unit, the person responsible shall indicate the accidental loss by writing "wasted; see waste report" on the line allowed for the record on the controlled substances disposition sheet, in the automated storage machine, or in a hospital-specified format. The responsible person shall record a complete report of the accident and sign the statement.

(d) Contaminated or broken hypodermic tablets and contaminated controlled substance solutions: When a controlled substance hypodermic tablet is contaminated or broken or a controlled substance solution is contaminated, the person responsible or the head nurse shall place the tablets, particles, or solution in a suitable container and label. The person responsible, or the head nurse, shall record on the disposition sheet, in the automated storage machine, or in a hospital-specified format the wastage. He or she shall write and sign a complete report, or document the situation electronically with an electronic signature. Regardless of which system is used, a witness shall co-sign the report. The container with the contaminated controlled substance shall be returned to the pharmacy or medication room. The pharmacist or person in charge of the medication room will receive it and note on the controlled substances disposition sheet covering the particular substance that it has been returned. The hospital shall properly dispose of the material.

#### **1911. Procedures in Case of Loss, Theft, etc.**

(a) Discrepancies in controlled substances count: Those involving small amounts (such as single doses) shall be reported to a responsible supervisory official. An investigation should be made to determine the cause of the loss. A copy of the report of the investigation, signed by the responsible supervisor shall be filed with the hospital controlled substance records, and appropriate action taken to prevent recurrence.

(b) Recurring shortages: In cases of recurring shortages or loss of significant quantities of controlled substances (several doses), a thorough investigation shall be made, making every effort to determine the reason for the shortages, and the person responsible for the shortage, if possible. A complete report of the incident and findings shall be made to the administrative authority of the hospital. Appropriate action shall be taken immediately to prevent recurrence. A copy of the report, including any findings resulting from the local investigations, and a theft report, as required by §408, shall be forwarded to the Bureau of Drug Control, DHEC, 2600 Bull Street, Columbia, SC 29201.

#### **1912. Controlled Substances of Physician's Office or Bag.**

It is unlawful for a physician to obtain substances for his or her office or bag use from the controlled substances stock of the hospital. A physician may obtain his or her controlled substances from a drug wholesaler by invoice; Schedule II substances shall be acquired through the use of order forms supplied by the DEA, U. S. Department of Justice (DEA Forms 222). Those hospitals maintaining permitted retail pharmacies, or otherwise licensed as a "drug outlet" by the S.C. Board of Pharmacy, may at their option, furnish controlled substances to practitioners pursuant to the provisions of § 1401 of this Regulation.

#### **1913. Dispensing to Outpatients.**

It is unlawful for a hospital to dispense controlled substances to outpatients on physicians' orders. Such dispensing shall be done only on the prescription of a duly licensed physician and only from the pharmacy holding a permit as a retail pharmacy of a hospital registered under Article 3 of Chapter 53 of Title 44 of the 1976 Code, and by or under the immediate supervision of a registered pharmacist. With the permission of the hospital, a practitioner may personally dispense limited quantities of controlled substances to their patients for take-home purposes, provided that such substances are properly packaged and labeled as required by provisions elsewhere within this regulation, and in compliance with statutory provisions.

#### **1914. Administering to Outpatients.**

Controlled substances may be administered to outpatients or emergency patients when admitted to the emergency room of the hospital when ordered by the physician in charge of the case, provided a record is kept showing the name and address of the patient, kind and quantity of controlled substance administered, date and physician's order. Under no conditions may the patient be given controlled substances to take out of the hospital except as provided in § 1913.

#### **1915. Emergency Rooms.**

The stock of controlled substances maintained in hospital emergency rooms or outpatient facilities is kept for the use by or at the direction of physicians in the emergency room. Therefore, in order to receive such medication, a patient shall be examined by a physician in the emergency room or outpatient facility and the need for the particular controlled substance determined by such physician. It is not possible under federal requirements for the use of controlled substances for a physician to see a patient outside of the emergency room setting, or talk to the patient over a telephone, and then call the emergency room and order the administration of a stocked controlled substance upon the patient's arrival at the emergency facility. Cf., S.C. Code Ann. § 44-53-110, "administer" ['...in his presence...']; §§ 1103 and 1204 of this Regulation, requiring personal attendance, etc.

### **1916. Storage of Controlled Substances.**

All controlled substances shall be kept in a locked, secure place. Large reserve stocks should be kept in a strong safe, substantial enough to deter entry and heavy enough to prevent being carried away. Other valuable property may be kept in the safe provided adequate security of the controlled substances contained therein is maintained. See also §§ 401 through 406, inclusive.

(a) Nursing station controlled drug box: Responsibility: Only a very limited number of persons should possess the key to the controlled substances on the nursing station. When such person(s) are relieved from duty, the person(s) taking charge should count and transfer the controlled substances in the presence of the person(s) being relieved, and all controlled substances should be accounted for. The responsibility rests with the person(s) assigned to possession of the key on each shift. The administrator shall be responsible for control of these keys. This responsibility may be delegated to the Director of Nursing. Written documentation of accountability of controlled substances (i.e., shift change nurses' signatures) shall be stored in a readily retrievable manner and maintained for a period of not less than two years, after which they may be destroyed.

(b) Responsibility of drug room: In those hospitals not maintaining a pharmacy under the supervision of a registered pharmacist, the drug room shall be restricted to the Director of Nurses, a designated assistant, or a designated registered nurse, not more than one of whom shall be in possession of the key to the drug room at the same time. The nurse in possession of the key to the drug room shall be responsible for all transactions in the drug room on his or her respective shift. (Observance of (a) and (b) does not relieve the Administrator of his or her responsibilities.)

### **1917. Availability of Records for Inspectors.**

The administrative head of the hospital shall, upon service of an inspection warrant by an inspector of the Bureau of Drug Control, DHEC, or if such administrative head chooses, voluntarily without inspection warrant, (acting pursuant to the informed consent to inspection delineated as a condition of registration upon the application for registration and the registration certificate issued to the registrant by DHEC) make available to such inspector all dispensing and administering records of controlled substances, for the purpose of audit of said controlled substances, as well as records of receipt and disposition of all controlled substances acquired by the hospital. Inspectors shall not divulge information contained on patient records that do not concern controlled substances or other drugs restricted to prescription use only.

### **1918. Labeling of Substances. (Schedule II)**

The requirements of § 1106 do not apply when a controlled substance listed in schedule II is prescribed for administration to an ultimate user who is institutionalized; Provided, that:

- (1) Not more than 7-day supply of the controlled substance listed in schedule II is dispensed at one time;
- (2) The controlled substance listed in schedule II is not in the possession of the ultimate user prior to the administration;
- (3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substances listed in schedule II; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

**1919. Labeling of Substances. (Schedules III, IV, V).**

The requirements of §1201 do not apply when a controlled substance listed in schedule III or IV is prescribed for administration to an ultimate user who is institutionalized; Provided, that:

(1) Not more than a 30-day supply or 100 dosage units, whichever is less, of the controlled substance listed in schedule III, IV or V is dispensed at one time.

(2) The controlled substance listed in schedule III, IV or V is not in the possession of the ultimate user prior to administration;

(3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing and storage of the controlled substance listed in schedule III, IV or V; and

(4) The system employed by the pharmacist in dispensing a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

**1920. Clarification and Intent.**

These regulations are considered to be a general but minimal required control level in the opinion of the Bureau of Drug Control, DHEC. More stringent control for the institution in question or special interpretations of these regulations may be approved by a special meeting with the Bureau of Drug Control, and the administrator or designated pharmacy and therapeutics committee of the respective hospital every 3 to 5 years when the need is felt for such clarification. The intent of Part 1900 of this regulation is to insure adequate control and accountability of controlled substances utilized in health care without duly hindering or restraining the delivery of such care. Accountability and an accurate audit at periodic intervals are the crux of the adequate control system.

**1921. Consultation Procedure.**

At the request of the institution under examination and/or the Bureau of Drug Control, DHEC, the S.C. Society of Hospital Pharmacists may furnish a recognized local authority on Institutional Medication Delivery and Control Systems to accompany the agent/or inspector and act as a consultant to the institution in question on rectifying flaws in the system under scrutiny.