64B16-26.300 Consultant Pharmacist Licensure.

(1) No person shall serve as consultant pharmacist as defined in Section 465.003(3), F.S., unless that person holds a license as a consultant pharmacist.

(2) Application for consultant pharmacist licensure shall be made on form DOH-MQA 1109, 02/09, Consultant Pharmacist Application and Information, which is hereby incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request an application or download the application from the board’s website at www.doh.state.fl.us/mqa/pharmacy. The application shall be accompanied by a non-refundable application fee.

(3) In order to be licensed as a consultant pharmacist, a person must meet the following requirements:
(a) Hold a license as a pharmacist which is active and in good standing,
(b) Successfully complete a consultant pharmacist course of no fewer than twelve (12) hours, sponsored by an accredited college of pharmacy located within the State of Florida, and approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and subject matter set forth in Rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.
(c) Successfully complete a period of assessment and evaluation under the supervision of a preceptor within one (1) year of completion of the course set forth in paragraph (b) above. This period of assessment and evaluation shall be completed over no more than three (3) consecutive months and shall include at least 40 hours of training in the following practice areas, 60% of which shall occur on-site at an institution that holds a pharmacy permit. The training shall include:

<table>
<thead>
<tr>
<th>Minimum Skills Required</th>
<th>Percent of Time</th>
<th>Hours</th>
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<tbody>
<tr>
<td>Minimum of 40 Hours in Maximum of Three Months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Regimen review, documentation and communication.</td>
<td>60%</td>
<td>24</td>
</tr>
<tr>
<td>a. Demonstrate ability to carry out process and understand documentation functions.</td>
<td></td>
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<tr>
<td>b. Understand and perform drug regimen review. Communicate findings to appropriate individuals or groups.</td>
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<tr>
<td>c. The applicant is responsible for learning other skills needed to perform in his/her type of facility where he/she is or will be the consultant Pharmacist of Record.</td>
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<tr>
<td>2. Facility review. Demonstrate areas that should be evaluated, documentation, and reporting procedures.</td>
<td>20%</td>
<td>8</td>
</tr>
<tr>
<td>3. Committee and Reports. Review quarterly Quality of Care Committee minutes and preparation and delivery of pharmacist quarterly report.</td>
<td>5%</td>
<td>2</td>
</tr>
<tr>
<td>4. Policy and Procedures. Preparation, review, updating Policy and Methods.</td>
<td>5%</td>
<td>2</td>
</tr>
<tr>
<td>5. Principles of formulary management. Demonstrate ability to manage formulary.</td>
<td>5%</td>
<td>2</td>
</tr>
<tr>
<td>6. Professional Relationships.</td>
<td>5%</td>
<td>2</td>
</tr>
</tbody>
</table>
Knowledge and interaction of facility
administration and professional staff.

(4) In order to act as a preceptor, a person shall:

(a) Be a consultant pharmacist of record at an institutional pharmacy which is required to have a consultant pharmacist under the provisions of Chapter 465, F.S., and these rules.

(b) Have a minimum of one (1) year of experience as a consultant pharmacist of record.

(c) Maintain all pharmacist licenses in good standing with the Board.

(d) Not act as a preceptor to more than two (2) applicants at the same time.

(5) Upon completion of the requirements set forth above, the applicant’s preceptor shall confirm that the applicant’s assessment and evaluation have met the requirements and that the applicant has successfully completed all required assignments under the preceptor’s guidance and supervision.

(6) After licensure a consultant pharmacist’s license shall be renewed biennially upon payment of the fee set forth in Rule 64B16-26.1003, F.A.C., and upon completing twenty-four (24) hours of board approved continuing education based upon the provisions of Rule 64B16-26.302, F.A.C.

(7) The number of hours earned in recertification programs by a consultant pharmacist, if applied to the twenty-four (24) hours required for consultant pharmacist license renewal, may not be used toward the thirty (30) hours of continued professional pharmaceutical education credits as set forth in Rule 64B16-26.103, F.A.C.

(8) An applicant who applies for a consultant pharmacist license after the effective date of this rule shall be required to complete the assessment and evaluation required in paragraph (3)(c) prior to being licensed as a consultant pharmacist.

64B16-26.301 Subject Matter for Consultant Pharmacist Training Program.

(1) Jurisprudence.
   (a) Laws and regulations, state and federal, pertaining to institutional pharmacy and health care facilities.
   (b) Laws and regulations, state and federal, pertaining to the safe and controlled storage of alcohol and other related substances, and relating to fire and health-hazard control.

(2) Policy and Procedures.
   (a) Written procedures for outlining the medication system in effect.
       1. Traditional systems.
       2. Unit-dose systems.
          a. Centralized.
          b. Decentralized.
          c. Automated medication systems.
       3. Routine and emergency use of drugs.
       4. After hours procedure for medication dispensing.
   (b) Record keeping and reports.
       1. Controlled substance control and record-of-usage.
       2. Alcohol inventory and record-of-usage.
       3. Patient drug use control and records.
          a. Recalls.
          b. Medication use evaluation.
          c. Medication errors.
   4. Drug charges, methods, accountability, and reports.
   5. Statistical reports of usage, volume, etc.

(3) Administrative Responsibilities.
   (a) Fiscal Control.
       1. Perpetual and traditional inventory systems.
       2. Application of EDP techniques.
   (b) Personnel Management, orientation and training.
   (c) Intra-professional relations pertaining to medication use.
   (d) Inter-professional relations with other members of the institutional health care team.
       1. Pharmacy & Therapeutic Committee.
          a. Rational drug therapy; review of medication use and prescribing.
          b. Formulary development — evaluation, appraisal, selection, procurement, storage, distribution, medication safety, criteria for use development and safety.
          c. Automatic stop orders on potent and dangerous drugs.
          d. Controls on storage and use of investigational drugs.
       2. In-service education of nurses and other health-related personnel.
       3. Infectious Disease Committee.
(4) Professional Responsibilities.
   (a) Drug information retrieval and methods of dispersal.
   (b) Development of pharmacy practice.
   (c) Development of an IV Admixture service.
   (d) Procedures to enhance medication safety.
      1. Availability of equipment, technique, etc., to prepare special dosage forms for pediatric
         and geriatric patients.
      2. Preparation of sterile dosage forms.
      3. Proper writing, transcribing and initiating and/or transferring patient medication orders;
         development of physician’s chart order copy system.
   5. Reporting and trending adverse drug reactions.
   6. Screening for potential drug interactions.
   7. Development and maintenance of up-to-date emergency kits.
   (e) Maintain drug quality and safe storage.
      1. Procedures for eliminating out-dated drugs.
      2. Requirements for safe and appropriate storage conditions.
   (f) Maintain drug identity.
      1. Procedures for labeling, transferring of bulk medications, etc.
      2. Manufacturing and packaging procedures.
      3. Pre-packaging control and supervision.
(5) The Institutional Environment.
   (a) The institution’s pharmacy function and purpose.
   (b) Interdepartmental relationships important to the institutional pharmacy.
   (c) Understanding of scope of service and in-patient care mission of the institution.
   (d) Special training with respect to the operation of nursing homes and Extended Care
       Facilities (ECF)/pharmacy relationship and special procurement procedures.
(6) Nuclear pharmacy.
   (a) Procurement.
   (b) Compounding.
   (c) Quality control procedures.
   (d) Dispensing.
   (e) Distribution.
   (f) Basic radiation protection and practices.
   (g) Consultation and education to the nuclear medicine community; including patients,
       pharmacists, other health professionals, and the general public.
   (h) Research and development of new formulations.
   (i) Record keeping.
   (j) Reporting adverse drug reactions and medication errors.
   (k) Screening for potential drug interaction.
64B16-26.302 Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education.

A Consultant Pharmacist License Renewal Continuing Education Program must contain at least three (3) hours of training in any of the subjects specified below. Duplicate courses are not acceptable.

   (a) Drug, Disease State Information – In-depth disclosure of the drug or therapeutic class of drugs or disease state including pharmacology, side effects and interaction.
   (b) New Therapeutic Modalities: Expansion of current drug therapy or treatment.
   (c) Patient Assessment: Assessment techniques by consultant pharmacist to determine the need and effectiveness of indicated drug therapy along with identification and assessment of side effects on patient’s well-being.
   (d) Pertinent Laboratory Tests.
   (e) Therapeutic Dosing.
2. Administrative Responsibilities.
   (a) Update on Administrative Responsibilities.
   1. Legal requirements including statutes, rules and regulation (Federal and State).
   2. The Joint Commission on the Accreditation of Healthcare Organizations.
   3. Personnel requirements.
   (b) Focus on Consultant Pharmacist Practice Issues/Concerns.
   1. How to get things accomplished in complex organizations.
   2. Key contacts to be effective as a consultant pharmacist.
   3. Considerations and preparation for site inspections.
3. Consultant Pharmacist Facility Responsibilities. This segment details the requirements in one of the facility types for which a consultant pharmacist is required. Only one practice setting may be included in each program.
   (a) Pharmacist-Medication Responsibilities – Assessment mechanism for delivery system, review procedures and monitoring processes.
   (b) Pharmacist-Patient Responsibilities – Patient assessment, laboratory test monitoring and therapeutic dosing.
   (c) Committee Responsibilities – Make-up and responsibilities for various facility committees.
   (d) Reporting requirements.

64B16-27.104 Conduct Governing Pharmacists and Pharmacy Permittees.

(1) A pharmacist or pharmacy shall be permitted to advertise medicinal drugs other than those controlled substances specified in Chapter 893, F.S., and patent and proprietary preparations so long as such advertising is not false, misleading or deceptive.

(2) No pharmacist, employer or employee of a pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Florida Board of Pharmacy, from which to solicit, accept or dispense prescriptions.

(3) No pharmacist or pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with any physician or other practitioner or nursing home or extended care facility for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement of any kind, whereby in any way a patient's free choice of a pharmacist or pharmacy is or may be limited.

(4) No pharmacist, employer or employee of a pharmacy may knowingly place in stock of any pharmacy any part of any prescription compounded for, or dispensed to, any customer of any pharmacy and returned by said customer, unless otherwise permitted by Rule 64B16-28.118, F.A.C.

(5) Pursuant to Section 465.018, F.S., a permit for a community pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy. The Board shall not register a prescription department manager as the manager of more than one pharmacy. The Board shall grant an exception to this requirement upon application by the permittee and the prescription department manager showing circumstances such as proximity of permits and limited pharmacist workload that would allow the manager to carry out all duties and responsibilities required of a prescription department manager.

64B16-27.1001 Practice of Pharmacy.

Those functions within the definition of the practice of the profession of pharmacy, as defined by Section 465.003(13), F.S., are specifically reserved to a pharmacist or a duly registered pharmacy intern in this state acting under the direct and immediate personal supervision of a pharmacist. The following subjects come solely within the purview of the pharmacist.

(1) A pharmacist or registered pharmacy intern must:
   (a) Supervise and be responsible for the controlled substance inventory.
   (b) Receive verbal prescriptions from a practitioner.
   (c) Interpret and identify prescription contents.
   (d) Engage in consultation with a practitioner regarding interpretation of the prescription and date in patient profile.
   (e) Engage in professional communication with practitioners, nurses or other health professionals.
   (f) Advise or consult with a patient, both as to the prescription and the patient profile record.

(2) When parenteral and bulk solutions of all sizes are prepared, regardless of the route of administration, the pharmacist must:
   (a) Interpret and identify all incoming orders.
   (b) Mix all extemporaneous compounding or be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parenteral solution.
   (c) Physically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation.
   (d) Systemize all records and documentation of processing in such a manner that professional responsibility can be easily traced to a pharmacist.

(3) Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.

(4) The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient’s agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.

(5) The pharmacist performing in this state any of the acts defined as “the practice of the profession of pharmacy” in Section 465.003(13), F.S., shall be actively licensed as a pharmacist in this state, regardless of whether the practice occurs in a permitted location (facility) or other location.

(6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:
   (a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day.
during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.

(b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist’s earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.

(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

(7) The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one registered pharmacy technician. In every pharmacy, the pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in the licensee’s employ or under the licensee’s supervision.

Consultant pharmacist license; application, renewal, fees; responsibilities; rules.

465.0125 Consultant pharmacist license; application, renewal, fees; responsibilities; rules.—

(1) The department shall issue or renew a consultant pharmacist license upon receipt of an initial or renewal application which conforms to the requirements for consultant pharmacist initial licensure or renewal as promulgated by the board by rule and a fee set by the board not to exceed $250. The consultant pharmacist shall be responsible for maintaining all drug records required by law and for establishing drug handling procedures for the safe handling and storage of drugs. The consultant pharmacist may also be responsible for ordering and evaluating any laboratory or clinical testing when, in the judgment of the consultant pharmacist, such activity is necessary for the proper performance of the consultant pharmacist's responsibilities. Such laboratory or clinical testing may be ordered only with regard to patients residing in a nursing home facility, and then only when authorized by the medical director of the nursing home facility. The consultant pharmacist must have completed such additional training and demonstrate such additional qualifications in the practice of institutional pharmacy as shall be required by the board in addition to licensure as a registered pharmacist.

(2) Notwithstanding the provisions of subsection (1), a consultant pharmacist or a doctor of pharmacy licensed in this state may also be responsible for ordering and evaluating any laboratory or clinical testing for persons under the care of a licensed home health agency when, in the judgment of the consultant pharmacist or doctor of pharmacy, such activity is necessary for the proper performance of his or her responsibilities and only when authorized by a practitioner licensed under chapter 458, chapter 459, chapter 461, or chapter 466. In order for the consultant pharmacist or doctor of pharmacy to qualify and accept this authority, he or she must receive 3 hours of continuing education relating to laboratory and clinical testing as established by the board.

(3) The board shall promulgate rules necessary to implement and administer this section.

History.—s. 31, ch. 83-329; s. 1, ch. 85-65; ss. 9, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 1, ch. 93-231; s. 89, ch. 97-264.
2013 Florida Statutes

Title XXXII REGULATION OF PROFESSIONS AND OCCUPATIONS
Chapter 465 PHARMACY Entire Chapter
SECTION 019
Institutional pharmacies; permits.

465.019 Institutional pharmacies; permits.—

(1) Any institution desiring to operate an institutional pharmacy shall apply to the department. If the board certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit.

(2) The following classes of institutional pharmacies are established:

(a) “Class I institutional pharmacies” are those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises, except that nursing homes licensed under part II of chapter 400 may purchase medical oxygen for administration to residents. No medicinal drugs may be dispensed in a Class I institutional pharmacy.

(b) “Class II institutional pharmacies” are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. However, an institutional pharmacy located in an area or county included in an emergency order or proclamation of a state of emergency declared by the Governor may provide dispensing and consulting services to individuals who are not patients of the institution. However, a single dose of a medicinal drug may be obtained and administered to a patient on a valid physician’s drug order under the supervision of a physician or charge nurse, consistent with good institutional practice procedures. The obtaining and administering of such single dose of a medicinal drug shall be pursuant to drug-handling procedures established by a consultant pharmacist. Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of this section.

(c) “Modified Class II institutional pharmacies” are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.

(3) Medicinal drugs shall be stocked, stored, compounded, dispensed, or administered in any health care institution only when that institution has secured an institutional pharmacy permit from the department.

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal
drug to any patient of an emergency department of a hospital that operates a Class II institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

(5) All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

(6) In a Class II institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs, proprietary preparations, biologics, biosimilars, and biosimilar interchangeables that may be dispensed by the pharmacists employed in such institution. A facility with a Class II institutional permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 2, ch. 83-101; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 29, ch. 93-211; s. 244, ch. 98-166; s. 36, ch. 99-397; s. 79, ch. 2001-277; s. 6, ch. 2008-216; s. 1, ch. 2013-102.
Title XLVI CRIMES
Chapter 893 DRUG ABUSE PREVENTION AND CONTROL Entire Chapter
SECTION 02
Definitions.

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

1. “Administer” means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person or animal.

2. “Analog” or “chemical analog” means a structural derivative of a parent compound that is a controlled substance.

3. “Cannabis” means all parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin.

4. “Controlled substance” means any substance named or described in Schedules I-V of s. 893.03. Laws controlling the manufacture, distribution, preparation, dispensing, or administration of such substances are drug abuse laws.

5. “Cultivating” means the preparation of any soil or hydroponic medium for the planting of a controlled substance or the tending and care or harvesting of a controlled substance.

6. “Deliver” or “delivery” means the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.

7. “Dispense” means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.

8. “Distribute” means to deliver, other than by administering or dispensing, a controlled substance.


11. “Homologue” means a chemical compound in a series in which each compound differs by one or more alkyl functional groups on an alkyl side chain.

12. “Hospital” means an institution for the care and treatment of the sick and injured, licensed pursuant to the provisions of chapter 395 or owned or operated by the state or Federal Government.

13. “Laboratory” means a laboratory approved by the Drug Enforcement Administration as proper to be entrusted with the custody of controlled substances for scientific, medical, or instructional
purposes or to aid law enforcement officers and prosecuting attorneys in the enforcement of this chapter.

(14) “Listed chemical” means any precursor chemical or essential chemical named or described in s. 893.033.

(15)(a) “Manufacture” means the production, preparation, propagation, compounding, cultivating, growing, conversion, or processing of a controlled substance, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging, or labeling of a controlled substance by:

1. A practitioner or pharmacist as an incident to his or her administering or delivering of a controlled substance in the course of his or her professional practice.

2. A practitioner, or by his or her authorized agent under the practitioner’s supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis, and not for sale.

(b) “Manufacturer” means and includes every person who prepares, derives, produces, compounds, or repackages any drug as defined by the Florida Drug and Cosmetic Act. However, this definition does not apply to manufacturers of patent or proprietary preparations as defined in the Florida Pharmacy Act. Pharmacies, and pharmacists employed thereby, are specifically excluded from this definition.

(16) “Mixture” means any physical combination of two or more substances.

(17) “Patient” means an individual to whom a controlled substance is lawfully dispensed or administered pursuant to the provisions of this chapter.

(18) “Pharmacist” means a person who is licensed pursuant to chapter 465 to practice the profession of pharmacy in this state.

(19) “Possession” includes temporary possession for the purpose of verification or testing, irrespective of dominion or control.

(20) “Potential for abuse” means that a substance has properties of a central nervous system stimulant or depressant or an hallucinogen that create a substantial likelihood of its being:

(a) Used in amounts that create a hazard to the user’s health or the safety of the community;

(b) Diverted from legal channels and distributed through illegal channels; or

(c) Taken on the user’s own initiative rather than on the basis of professional medical advice.

Proof of potential for abuse can be based upon a showing that these activities are already taking place, or upon a showing that the nature and properties of the substance make it reasonable to assume that there is a substantial likelihood that such activities will take place, in other than isolated or occasional instances.
(21) "Practitioner" means a physician licensed pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, a naturopath licensed pursuant to chapter 462, a certified optometrist licensed pursuant to chapter 463, or a podiatric physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

(22) "Prescription" means and includes an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of s. 893.04. The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state other than Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription. A prescription order for a controlled substance shall not be issued on the same prescription blank with another prescription order for a controlled substance which is named or described in a different schedule, nor shall any prescription order for a controlled substance be issued on the same prescription blank as a prescription order for a medicinal drug, as defined in s. 465.003(8), which does not fall within the definition of a controlled substance as defined in this act.

(23) "Wholesaler" means any person who acts as a jobber, wholesale merchant, or broker, or an agent thereof, who sells or distributes for resale any drug as defined by the Florida Drug and Cosmetic Act. However, this definition does not apply to persons who sell only patent or proprietary preparations as defined in the Florida Pharmacy Act. Pharmacies, and pharmacists employed thereby, are specifically excluded from this definition.

History.—s. 2, ch. 73-331; s. 1, ch. 75-18; s. 470, ch. 77-147; s. 1, ch. 77-174; s. 184, ch. 79-164; s. 1, ch. 79-325; s. 37, ch. 82-225; s. 169, ch. 83-216; s. 1, ch. 85-242; s. 1, ch. 91-279; s. 1, ch. 92-19; s. 1434, ch. 97-102; s. 104, ch. 97-264; s. 234, ch. 98-166; s. 300, ch. 99-8; s. 10, ch. 99-186; s. 1, ch. 2000-320; s. 3, ch. 2001-55; s. 10, ch. 2002-78; s. 13, ch. 2005-128; s. 1, ch. 2008-184; s. 18, ch. 2010-117; s. 1, ch. 2011-73; s. 12, ch. 2013-26.
Controlled Substances

Disclaimer

Section 812 of the Controlled Substances Act (21 U.S.C. §801 et seq.) (CSA) lists substances which were controlled in 1970 when the law was enacted. Since then, approximately 160 substances have been added, removed, or transferred from one schedule to another. The current official list of controlled substances can be found in section 1308 of the most recent issue of Title 21 Code of Federal Regulations (CFR) Part 1300 to end (21 CFR §1308) and the final rules which were published in the Federal Register subsequent to the issuance of the CFR.

This list describes the basic or parent chemical and do not describe the salts, isomers and salts of isomers, esters, ethers and derivatives which may be controlled substances. These lists are intended as general references and are not comprehensive listings of all controlled substances. Please note that a substance need not be listed as a controlled substance to be treated as a Schedule I substance for criminal prosecution. A controlled substance analogue is a substance which is intended for human consumption and is structurally or pharmacologically substantially similar to or is represented as being similar to a Schedule I or Schedule II substance and is not an approved medication in the United States. (See 21 U.S.C. §802(32)(A) for the definition of a controlled substance analogue and 21 U.S.C. §813 for the schedule.)
## Defined Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>2C-B</td>
<td>4-Bromo-2,5-dimethoxyphenethylamine</td>
</tr>
<tr>
<td>2C-T-7</td>
<td>2,5-Dimethoxy-4(n)-propylthiophenethylamine</td>
</tr>
<tr>
<td>BZP</td>
<td>N-Benzylpiperazine</td>
</tr>
<tr>
<td>DMT</td>
<td>Dimethyltryptamine</td>
</tr>
<tr>
<td>DOM</td>
<td>4-Methyl-2,5-dimethoxyamphetamine</td>
</tr>
<tr>
<td>GBL</td>
<td>Gamma butyrolactone</td>
</tr>
<tr>
<td>GHB</td>
<td>Gamma hydroxybutyric acid, gamma hydroxybutyrate, 4-hydroxybutanoic acid, sodium oxybate</td>
</tr>
<tr>
<td>LAAM</td>
<td>Levo-alphacetylmethadol</td>
</tr>
<tr>
<td>LSD</td>
<td>Lysergic acid diethylamide, lysergide</td>
</tr>
<tr>
<td>MDA</td>
<td>3,4-Methylenedioxyamphetamine</td>
</tr>
<tr>
<td>MDE</td>
<td>3,4-Methylenedioxy-N-ethylamphetamine</td>
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<td>MDMA</td>
<td>3,4-Methylenedioxymethamphetamine</td>
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<td>P2P</td>
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<td>PCC</td>
<td>1-Piperidinocyclohexanecarbonitrile</td>
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<td>PCE</td>
<td>N-Ethyl-1-phenylcyclohexylamine</td>
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<tr>
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<td>1-Phenylcyclohexylamine</td>
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<tr>
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<td>THG</td>
<td>Tetrahydrogestrinone</td>
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Definition of Controlled Substance Schedules

Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. An updated and complete list of the schedules is published annually in Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Some examples of the drugs in each schedule are listed below.

Schedule I Controlled Substances

Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Some examples of substances listed in Schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy").

Schedule II/IIN Controlled Substances (2/2N)

Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, and codeine.

Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).

Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital.

Schedule III/IIN Controlled Substances (3/3N)

Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples of Schedule III narcotics include: combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®), products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®, and buprenorphine (Suboxone®).

Examples of Schedule IIN non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.
**Schedule IV Controlled Substances**

Substances in this schedule have a low potential for abuse relative to substances in Schedule III.

Examples of Schedule IV substances include: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

**Schedule V Controlled Substances**

Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.
Preface

The Drug Enforcement Administration (DEA) was established in 1973 to serve as the primary agency responsible for the enforcement of federal drug laws. The Controlled Substances Act (CSA) and its implementing regulations establish federal requirements regarding both illicit and licit controlled substances. With respect to pharmaceutical controlled substances, DEA's responsibility is twofold: to prevent diversion and abuse of these substances while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. In carrying out this mission, DEA works closely with state and local authorities and other federal agencies.

Under the framework of the CSA, all controlled substance transactions take place within a "closed system" of distribution established by Congress. Within this "closed system" all legitimate handlers of controlled substances - manufacturers, distributors, physicians, pharmacies, and others, must be registered with DEA (unless exempt) and maintain strict accounting for all controlled substance transactions.

To carry out this mission effectively, DEA seeks to educate its registrants regarding their legal obligations. It is DEA's goal to maintain a positive working relationship with all of its registrants, including pharmacies. DEA understands that it can best serve the public interest by working with the pharmacy community to prevent the diversion of pharmaceutical controlled substances and scheduled listed chemical products (SLCPs) into the illicit market.

Federal controlled substance laws are designed to function in tandem with state controlled substance laws. DEA works in cooperation with state professional licensing boards and state and local law enforcement officials to make certain that pharmaceutical controlled substances are prescribed, administered, and dispensed for a legitimate medical purpose in the usual course of professional practice. Within this framework, the majority of investigations into possible violations of controlled substance laws are carried out by state authorities. DEA focuses its investigations on cases involving violators of the highest level or most significant impact.

In the event a state board revokes the license of a pharmacy, DEA will request a voluntary surrender of the pharmacy's DEA registration. If the pharmacy refuses to surrender its registration, DEA will seek administrative action to revoke its DEA registration based on lack of state authorization. Additional administrative remedies that may be utilized to correct a lack of compliance include a letter of admonition or an administrative hearing. DEA may also pursue civil or criminal sanctions if there is sufficient evidence to justify a prosecution. All such actions are designed to protect the public health and safety.

In addition to the diversion of controlled substances, DEA is concerned with the diversion of certain chemicals used in the clandestine manufacture of controlled substances. Chemicals such as ephedrine and pseudoephedrine contained in over the counter and prescription substances are immediate precursors used in the illicit manufacture of methamphetamine and amphetamine. These products may be purchased or stolen from retail outlets, including pharmacies, for use in clandestine laboratories.
SECTION II - SCHEDULES OF CONTROLLED SUBSTANCES

The drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. A listing of the substances and their schedules is found in the DEA regulations, 21 C.F.R. Sections 1308.11 through 1308.15. A controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence. Some examples of controlled substances in each schedule are outlined below.

NOTE: Drugs listed in schedule I have no currently accepted medical use in treatment in the United States and, therefore, may not be prescribed, administered, or dispensed for medical use. In contrast, drugs listed in schedules II-V have some accepted medical use and may be prescribed, administered, or dispensed for medical use.

Schedule I Controlled Substances

Substances in this schedule have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug or other substance under medical supervision.

Some examples of substances listed in schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("ecstasy").

Schedule II Controlled Substances

Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples of single entity schedule II narcotics include morphine and opium. Other schedule II narcotic substances and their common name brand products include: hydromorphone (Dilaudid®), methadone (Dolophine®, meperidine (Demerol®), oxycodone (OxyContin®), and fentanyl (Sublimaze® or Duragesic®).

Examples of schedule II stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Other schedule II substances include: cocaine, amobarbital, glutethimide, and pentobarbital.

Schedule III Controlled Substances

Substances in this schedule have a potential for abuse less than substances in schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples of schedule III narcotics include combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®) and products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with codeine®). Also included are buprenorphine products (Suboxone® and Subutex®) used to treat opioid addiction.

2010 Edition
Page 5
Examples of schedule III non-narcotics include benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as oxandrolone (Oxandrin®).

**Schedule IV Controlled Substances**

Substances in this schedule have a low potential for abuse relative to substances in schedule III.

An example of a schedule IV narcotic is propoxyphene (Darvon® and Darvocet-N 100®).

Other schedule IV substances include: alprazolam (Xanax®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

**Schedule V Controlled Substances**

Substances in this schedule have a low potential for abuse relative to substances listed in schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. These are generally used for antitussive, antidiarrheal, and analgesic purposes.

Examples include cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC® and Phenergan with Codeine®).

**Scheduled Listed Chemical Product (SLCP)**

An SLCP is defined as a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug.
SECTION III - REGISTRATION REQUIREMENTS

New Pharmacy Registration

Every pharmacy that dispenses a controlled substance must be registered with the DEA. First, a state license must be obtained.

To register as a new pharmacy, the DEA Form 224 must be completed. The cost of the application fee is indicated on the application form. The certificate of registration must be maintained at the registered location and kept available for official inspection. If a person owns and operates more than one pharmacy, each place of business must be registered.

The DEA Form 224 should be completed online (www.DEAdversion.usdoj.gov).

A paper version of the DEA Form 224 may be requested by writing to:

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

If a pharmacy needs a duplicate Certificate of Registration (DEA Form 223), a copy may be requested online via DEA's Diversion website, www.DEAdversion.usdoj.gov, or contact DEA Headquarters at 1-800-882-9539 or via e-mail at DEA.Registration.Help@usdoj.gov.
BLANK DEA FORM-363
APPLICATION FOR REGISTRATION
Under Narcotic Addict Treatment Act of 1974

READ INSTRUCTIONS BEFORE COMPLETING
USE BLACK INK

Name: Applicant or Program Name

(Last, First, Ml)

Tax Identification Number

Proposed Business Address (When using a P.O. Box you must also provide a street address)

City State Zip Code

Applicant’s Business Phone Number Applicant’s Fax Number

REGISTRATION CLASSIFICATION:

1. BUSINESS ACTIVITY:
   (X only one)
   [ ] Maintenance [ ] Detox [ ] Main & Detox [ ] Compounded/Maintenance [ ] Compounded/Detox
   [ ] Compounded/Detox

2. DRUG SCHEDULES:
   (X all that apply)
   [ ] Schedule II [ ] Schedule IV
   [ ] Schedule III [ ] Schedule V

3. INDICATE HERE IF YOU REQUIRE ORDER FORM BOOKS.

4. SUPPLY ANY OTHER CURRENT DEA REGISTRATION NUMBERS

5. FDA No.
   APPLIED FOR:
   [ ] Yes [ ] No

6. ALL APPLICANTS MUST ANSWER THE FOLLOWING:
   (X) Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate?
   [ ] Yes - State License No. [ ] N/A [ ] PENDING

By completing this application, you are applying for registration or renewal or registration as a narcotic treatment program pursuant to the Controlled Substances Act of 1970, (PL 91-513), Title 21, United States Code, Section 823(f) and (g).

Note: The graphic illustrated above is only a depiction of the DEA Form-363. It is not intended to be used as an actual application form.
BLANK DEA FORM-363
APPLICATION FOR REGISTRATION
Under Narcotic Addict Treatment Act of 1974

6. CONTINUED
   (a) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law? [YES] [NO]
   (b) Has the applicant ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation? [YES] [NO]
   (c) Has the applicant ever surrendered or had a federal controlled substance registration revoked, suspended, restricted or denied? [YES] [NO]
   (d) If the applicant is a corp, assoc, partnership or pharmacy has any person associated with the firm been convicted of a crime in connection with controlled substances under state or federal law, or ever surrendered or had a federal/state controlled substance registration revoked? [YES] [NO]

7. EXPLANATION FOR ANSWERING "YES" TO ITEMS 6(b), (c), (d), or (e)
   Applicants who have answered "yes" to items 6(b), (c), (d), or (e) are required to submit a statement explaining such response(s). The space provided below should be used for this purpose. If additional space is needed, use as a separate sheet and return with application.

8. PAYMENT METHOD (X only one)
   [ ] VISA  [ ] MASTER CARD  [ ] CHECK  [ ] U.S. MONEY ORDER
   Credit Card Number
   Expiration Date
   SIGNATURE OF CARD HOLDER

9. CERTIFICATION FOR FEE EXEMPTION
   [ ] MARK THIS BLOCK IF APPLICANT NAMED HEREON IS A FEDERAL, STATE, OR LOCAL GOVERNMENT OPERATED HOSPITAL, INSTITUTION, OR OFFICIAL.
   The undersigned hereby certifies that the applicant named herein is a federal, state, or local government operated hospital, institution, or official, and is exempt from payment of the application fee.
   Signature of Certifying Official (other than applicant)  Date
   Print or Type Name of Certifying Official
   Print or Type Title of Certifying Official

10. APPLICANT SIGNATURE (must be an original signature in ink)
    Signature  Date
    I hereby certify that the foregoing information furnished on this application is true and correct.
    Print or Type Name
    Print or Type Title (e.g., President, Dean, Procurement Officer, etc)

Note: The graphic illustrated above is only a depiction of the DEA Form-363. It is not intended to be used as an actual application form.
Renewal of Pharmacy Registration

A pharmacy registration must be renewed every three years utilizing DEA Form 224a, Renewal Application for DEA Registration. The cost of the application fee is indicated on the application form.

To renew a registration, the most current information from the pharmacy’s existing registration must be utilized. A registrant can renew online no more than 60 days prior to the current expiration date. The DEA Form 224a should be completed online and can be found at www.DEAdversion.usdoj.gov.

If the registrant has not renewed online approximately 50 days before the registration expiration date, a renewal application is sent to the registrant at the mailing address listed on the current registration. If the renewal form is not received by the 30th day before the expiration date of the current registration, the pharmacy should contact the local DEA Registration Specialist (Appendix J) or DEA Headquarters at 1-800-882-9539 and request a renewal registration form.
BLANK DEA FORM-363a

RENEWAL

APPLICATION FOR DEA REGISTRATION

Under Narcotic Addict Treatment Act of 1974

READ INSTRUCTIONS BEFORE COMPLETING

USE BLACK INK

1. DRUG SCHEDULES:
   (X all that apply)
   - Schedule II
   - Schedule III
   - Schedule IV

DRUG CODES (Must indicate below the Narcotic Code Number(s) for schedules checked)

2. INDICATE HERE IF YOU REQUIRE ORDER FORM BOOKS.

3. FDA NUMBER

4. ALL APPLICANTS MUST ANSWER THE FOLLOWING:
   (a) Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate?

   - Yes - State License No. [Blank]
   - No - [Blank] N/A - [Blank]

   If you have answered yes to the following question(s) on previous applications, you must continue to answer yes and provide a statement of explanation.

   (b) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law?

   - Yes [Blank]
   - No [Blank]

   (c) Has the applicant ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation?

   - Yes [Blank]
   - No [Blank]

   (d) If the applicant is a corp., assoc., partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substances under state or federal law, or ever surrendered or had a fed. Controlled substance registration revoked, suspended, denied, restricted, or placed on probation?

5. EXPLANATION FOR ANSWERING "YES" TO ITEM(S) 4(b), (c), (d), or (e).

Applicants who have answered "yes" to items 4(b), (c), (d), or (e) are required to submit a statement explaining such response(s). The space provided below should be used for this purpose. If additional space is needed, use a separate sheet and return with application.

By completing this application, you are applying for registration or renewal or registration as a narcotic treatment program pursuant to the Controlled Substances Act of 1970, (P.L. 91-513). Title 21, United States Code, Section 823(f) and (g).

DEA REGISTRATION
NUMBER

YOUR CURRENT
REGISTRATION
EXPIRES ON

ATTENTION

Note: The graphic illustrated above is only a depiction of the DEA Form-363a. It is not intended to be used as an actual application form.
SECTION IV - TRANSFER OR DISPOSAL OF CONTROLLED SUBSTANCES

Transfer of Controlled Substances

A pharmacy may hire an outside firm to inventory, package, and arrange for the transfer of its controlled substances to another pharmacy, the original supplier, or the original manufacturer. The pharmacy is responsible for the actual transfer of the controlled substances and for the accuracy of the inventory and records. The records involving the transfer of controlled substances must be kept readily available by the pharmacy for two years for inspection by the DEA.

To transfer schedule II substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

Transfer to a Pharmacy

If a pharmacy goes out of business or is acquired by a new pharmacy, it may transfer the controlled substances to another pharmacy. On the day the controlled substances are transferred, a complete inventory must be taken which documents the drug name, dosage form, strength, quantity, and date transferred. In addition, DEA Form 222 or the electronic equivalent must be prepared to document the transfer of schedule II controlled substances. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. A copy of the inventory must be included in the records of each pharmacy. It is not necessary to send a copy of the inventory to the DEA. The pharmacy acquiring the controlled substances must maintain all records involved in the transfer of the controlled substances for two years.

Transfer to the Original Supplier or Original Manufacturer

Any pharmacy may transfer controlled substances to the original supplier or the original manufacturer that is appropriately registered with the DEA. The pharmacist must maintain a written record showing:

1. The date of the transaction.
2. The name, strength, dosage form, and quantity of the controlled substance.
3. The supplier or manufacturer's name, address, and registration number.

The DEA Form 222 or the electronic equivalent will be the official record for the transfer of schedule II controlled substances.
### BLANK DEA FORM-222
#### U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

**TO:** (Name of Supplier)  
**STREET ADDRESS**

<table>
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<th>CITY and STATE</th>
<th>DATE</th>
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**TO BE FILLED IN BY SUPPLIER**

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**TO BE FILLED IN BY PURCHASER**

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LAST LINE COMPLETED  
(MUST BE 10 OR LESS)  
SIGNATURE OR PURCHASER  
OR ATTORNEY OR AGENT

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Registered as a  
No. of this Order Form

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**Note:** The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.
BLANK DEA FORM-222
U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

See Reverse of PURCHASER'S Copy of Instructions

No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).

TO: (Name of Supplier)  STREET ADDRESS

CITY and STATE  DATE  TO BE FILLED IN BY SUPPLIER

SUPPLIERS DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

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LAST LINE COMPLETED (MUST BE 10 OR LESS)

SIGNATURE OR PURCHASER OR ATTORNEY OR AGENT

Date Issued  DEA Registration No.  Name and Address of Registrant

Schedules

Registered as a  No. of this Order Form

Shaded areas are pre-printed by DEA prior to mailing to the registrant.

DEA Form-222  U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II  DRUG ENFORCEMENT ADMINISTRATION  SUPPLIER'S Copy 1

Note: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.
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SECTION V - SECURITY REQUIREMENTS

Requests for Employment Waivers for Certain Pharmacy Employees

Under 21 C.F.R. § 1301.76(a), a registrant must not employ in a position which allows access to controlled substances any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for DEA registration denied, revoked, or surrendered for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

However, 21 C.F.R. § 1307.03 does permit registrants desiring to employ an individual who meets this definition to request an exception to this requirement. The employer must have a waiver approved before allowing such an employee or prospective employee to have access to controlled substances. A waiver request should be sent by the employer to the following address:

Drug Enforcement Administration  
Attn: Regulatory Section/ODG  
8701 Morrissette Drive  
Springfield, Virginia 22152

A registrant that applies for such a waiver should understand that the following factors will be considered by the DEA in the approval process and should provide details relevant to each factor as part of the waiver request submitted, since a waiver will not be considered unless there are valid reasons to believe that diversion is unlikely to occur:

1. A detailed description of the nature and extent of the individual’s past controlled substances violations, including all pertinent documentation;
2. Current status of the individual’s state licensure;
3. Extent of individual’s proposed access to controlled substances. “Access” is not limited to only physical access to controlled substances, but includes any influence over the handling of controlled substances;
4. Registrant’s proposed physical and professional safeguards to prevent diversion by the individual;
5. Status of employing registrant regarding handling of controlled substances;
6. Other pertinent information uncovered by DEA in its investigation of the individual’s or registrant’s handling of controlled substances; and
7. All other relevant factors or materials.

Controlled Substance Theft or Significant Loss

Should a theft or significant loss of any controlled substance occur at a pharmacy, the following procedures must be implemented within one business day of the discovery of the theft or loss.
A. Notify DEA and Local Police

The theft of controlled substances from a registrant is a criminal act and a source of diversion that requires notification to DEA. A pharmacy must notify in writing the local DEA Diversion Field Office (Appendix K) within one business day of discovery of a theft or significant loss of a controlled substance. Although not specifically required by federal law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. Prompt notification to enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion. If there is a question as to whether a theft has occurred or a loss is significant, a registrant should err on the side of caution and report it to DEA and local law enforcement authorities.

DEA must be notified directly. This requirement is not satisfied by reporting the theft or significant loss in any other manner. For example, a corporation which owns or operates multiple registered sites and wishes to channel all notifications through corporate management or any other internal department responsible for security, must still provide notice directly to DEA in writing within one business day upon discovery and keep a copy of that notice for its records. The notice must be signed by an authorized individual of the registrant.

B. Complete DEA Form 106

A pharmacy must also complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances) which can be found online at www.DEAdiversion.usdoj.gov under the Quick Links section. The DEA Form 106 is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved. A paper version of the form can be obtained by writing to:

Drug Enforcement Administration  
Attn: Registration Section/ODR  
8701 Morrissette Drive  
Springfield, Virginia 22152

If completing the paper version, the pharmacy should send the original DEA Form 106 to the local DEA Diversion Field Office (Appendix K) and keep a copy for its records. Please see the Guidelines for Completing the DEA Form 106 (Appendix I) for additional guidance.

The DEA Form 106 must include the following information:

1. Name and address of the firm (pharmacy),
2. DEA registration number,
3. Date of theft or loss (or when discovered if not known),
4. Name and telephone number of local police department (if notified),
5. Type of theft (e.g., night break-in, armed robbery),
6. List of identifying marks, symbols, or price codes (if any) used by the pharmacy on the labels of the containers, and
7. A listing of controlled substances missing, including the strength, dosage form, and size of container (in milliliters if liquid form) or corresponding National Drug Code numbers.

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SECTION VI - RECORDKEEPING REQUIREMENTS

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

All required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials. Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant. All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records. Recordkeeping requirements for prescriptions are detailed in Section VI, Prescription Records.

Readily retrievable is defined as:

1. Records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or
2. Records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Required Records

The records which must be maintained by a pharmacy are:

1. Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
2. Power of Attorney authorization to sign order forms
3. Receipts and/or invoices for schedules III, IV, and V controlled substances
4. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
5. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
6. Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
7. Reports of Theft or Significant Loss (DEA Form 106), if applicable
8. Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
9. Records of transfers of controlled substances between pharmacies
10. DEA registration certificate
11. Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005
SECTION VII - INVENTORY REQUIREMENTS

An "inventory" is a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for schedule II controlled substances and an estimated count or measure of the contents of a schedule III, IV, or V controlled substance (unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents must be made). The CSA also requires that all inventory records be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection. In addition, the inventory records of schedule II controlled substances must be kept separate from all other controlled substances.

Initial Inventory

When issued a DEA registration, a registrant must take an initial inventory, which is an actual physical count of all controlled substances in their possession. If there are no stocks of controlled substances on hand, the registrant should make a record showing a zero inventory. There is no requirement to submit a copy of the inventory to the DEA. The C.F.R. requires that the inventory include:

1. The date of the inventory,
2. Whether the inventory was taken at the beginning or close of business,
3. The name of each controlled substance inventoried,
4. The finished form of each of the substances (e.g., 10 milligram tablet),
5. The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle),
6. The number of commercial containers of each finished form (e.g., four 100 tablet bottles), and
7. A count of the substance - if the substance is listed in schedule II, an exact count or measure of the contents or if the substance is listed in schedules III, IV, or V, an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case, an exact count of the contents is required.

DEA recommends, but does not require, an inventory record include the name, address, and DEA registration number of the registrant, and the signature of the person or persons responsible for taking the inventory.

Biennial Inventory

Following the initial inventory, the registrant is required to take a biennial inventory (every two years), which requires the same information as the initial inventory (see list above) of all controlled substances on hand. The biennial inventory may be taken on any date which is within two years of the previous inventory date. There is no requirement to submit a copy of the inventory to DEA.

Newly Scheduled Controlled Substance Inventory

When a drug not previously listed as a controlled substance is scheduled or a drug is rescheduled, the drug must be inventoried as of the effective date of scheduling or change in scheduling.
# REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration.

Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

<table>
<thead>
<tr>
<th>1. Name and Address of Registrant (include ZIP Code)</th>
<th>2. Phone No. (include Area Code)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZIP CODE</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. DEA Registration Number</th>
<th>4. Date of Theft or Loss</th>
<th>5. Principal Business of Registrant (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 digit prefix</td>
<td>7 digit suffix</td>
<td>1. Pharmacy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Practitioner</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Manufacturer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Hospital/Clinic</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. County in which Registrant is located</th>
<th>7. Was Theft reported to Police?</th>
<th>8. Name and Telephone Number of Police Department (include Area Code)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. Number of Thefts or Losses Registrant has experienced in the past 24 months</th>
<th>10. Type of Theft or Loss (Check one and complete items below as appropriate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Night break-in</td>
<td>3. Employee pilferage</td>
</tr>
<tr>
<td>6. Other (Explain)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>11. If Armed Robbery, was anyone:</th>
<th>12. Purchase value to registrant of Controlled Substances taken?</th>
<th>13. Were any pharmaceuticals or merchandise taken?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Killed? ☐ No ☐ Yes (how many)</td>
<td>☐ No ☐ Yes (est. value)</td>
<td>☐ No ☐ Yes</td>
</tr>
<tr>
<td>Injured? ☐ No ☐ Yes (how many)</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Name of Common Carrier</td>
</tr>
<tr>
<td>------------------------------</td>
</tr>
<tr>
<td>D. Was the carton received by the customer?</td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.</th>
</tr>
</thead>
</table>

| 17. What security measures have been taken to prevent future thefts or losses? |

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SECTION VIII - ORDERING CONTROLLED SUBSTANCES

Ordering Schedule II Controlled Substances

Only schedules I and II controlled substances are ordered with an official order form, DEA Form 222, or the electronic equivalent (see below, Controlled Substance Ordering System (CSOS) - Electronic Order Forms). A DEA Form 222 is required for each distribution, purchase, or transfer of a schedule II controlled substance.

When a controlled substance has been moved by DEA from schedule II to another schedule at the federal level, in many states it may remain a schedule II controlled substance pending any legislative or administrative action that may result from the federal action. Many states require transactions that involve substances they classify as schedule II be made via official order forms (DEA Form 222) or the electronic equivalent. When federal law or regulations differ from state law or regulations, a pharmacy is required to abide by the more stringent aspects of both the federal and state requirements. When the use of DEA Form 222 or the electronic equivalent for the transfer of a controlled substance is not required under federal law, its use as mandated by these states does not violate federal law and is therefore permitted.

Requesting Official Order Forms

The unexecuted DEA Form 222 can be requested initially by checking "block 3" on the application for a new registration (DEA Form 224). The DEA Form 224 can be found online at www.DEAdiversion.usdoj.gov.

Once a registrant has received a DEA registration number, additional DEA Forms 222 may be ordered online at www.DEAdiversion.usdoj.gov. When requesting additional DEA Forms 222 online, a valid DEA registration number, business name, and contact telephone number are required. The registrant may also request DEA Forms 222 by calling the DEA Headquarters Registration Section at 1-800-882-9539 or by contacting the local DEA Registration Specialist (Appendix J).

Each book of DEA Form 222 consists of seven sets of forms. Each pharmacy is provided a maximum of six books at one time unless its needs exceed this limit. In such a case, the pharmacy should contact the local DEA Registration Specialist (Appendix J) to request additional books.

Completing Official Order Forms

When ordering schedule II controlled substances, the purchaser is responsible for filling in the number of packages, the size of the package, and the name of the item. Each DEA Form 222 must be signed and dated by a person authorized to sign a registration application or a person granted power of attorney (see below, Power of Attorney to Sign an Official Order Form). When the items are received, the pharmacist must document on the purchaser's copy (copy three) the actual number of packages received and the date received.

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# SAMPLE DEA FORM-222

**SHADeD SECTIONS ARE Filled In BY THE NTP WHEN PLACING AN ORDER**

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**TO: (Name of Supplier)**

**STREET ADDRESS**: 21 Xyz Lane

**CITY and STATE**: Anytown, FL 22312

**DATE**: MM/DD/YYYY

**SUPPLIERS DEA REGISTRATION No.**

---

**TO BE FILLED IN BY PURCHASER**

<table>
<thead>
<tr>
<th>Line No.</th>
<th>No. of Packages</th>
<th>Size of Package</th>
<th>Name of Item</th>
<th>National Drug Code</th>
<th>Packages Shipped</th>
<th>Date Shipped</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>25</td>
<td>946 ml</td>
<td>Methadone HCl 10mg/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>100</td>
<td>Methadone HCl Tablets 10mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>20</td>
<td>4 x 25</td>
<td>Methadone HCl diskettes 40mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
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<td>6</td>
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<td>7</td>
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<td>8</td>
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<td>9</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**LAST LINE COMPLETED (MUST BE 10 OR LESS)**

**SIGNATURE OR PURCHASER OR ATTORNEY OR AGENT**: John Doe

**Date Issued**: MM/DD/YYYY

**DEA Registration No.**: RW0000000

**Name and Address of Registrant**:

Who Treatment Center
123 Whatever Lane
Whereami, FL 12345

**Schedules**: 2

**Registered as a**: NTP BOTH

**No. of this Order Form**: 1234567890

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**U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II**

**DRUG ENFORCEMENT ADMINISTRATION**

**SUPPLIER'S Copy 1**

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**Note**: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.
## SAMPLE DEA FORM-222

**SHAD ED SECTION S ARE FILLED IN BY THE NTP UPON RECEIPT OF AN ORDER**

### TO: (Name of Supplier)
**Methadone Supplier**

### STREET ADDRESS
21 Xyz Lane

## CITY and STATE
Anytown, FL  22312

### DATE
**MM/DD/YYYY**

<table>
<thead>
<tr>
<th>LINE</th>
<th>No. of Packages</th>
<th>Size of Package</th>
<th>Name of Item</th>
<th>National Drug Code</th>
<th>Packages Shipped</th>
<th>Date Shipped</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>25</td>
<td>946 ml</td>
<td>Methadone HCl 10mg/ml</td>
<td></td>
<td>25</td>
<td>M-D-Y</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>100</td>
<td>Methadone HCl Tablets 10mg</td>
<td></td>
<td>5</td>
<td>M-D-Y</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>4 x 25</td>
<td>Methadone HCl diskettes 40mg</td>
<td></td>
<td>20</td>
<td>M-D-Y</td>
</tr>
</tbody>
</table>

### LAST LINE COMPLETED
(MUST BE 10 OR LESS)

**John Doe**

### SIGNATURE OR PURCHASER OR ATTORNEY OR AGENT

### DEA Registration No.
RW0000000

### Name and Address of Registrant
Who Treatment Center  
123 Whatever Lane  
Whereami, FL 12345

### Date Issued
**MM/DD/YYYY**

### Schedules
2

### Registered as a
NTP BOTH

### No. of this Order Form
1234567890

### *** TO BE USED FOR METHADONE AND LAAM ONLY ***

### U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II

**DRUG ENFORCEMENT ADMINISTRATION**

**SUPPLIER'S Copy 1**

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### Note:
The graphic illustrated above is only a depiction of the DEA Form-222.  
It is not intended to be used as an actual order form.
Drug Enforcement Administration
Pharmacist’s Manual

The executed DEA Form 222 must be maintained separately from the pharmacy’s other business records. However, this does not preclude a registrant from attaching a copy of the supplier’s invoice to the related DEA Form 222.

Title 21 C.F.R. § 1305.15(a)(1) requires that, for orders using the DEA Form 222, an order must not be filled if the order is not complete, legible, or properly prepared, executed, or endorsed, or if the order shows any alteration, erasure, or change of any description. For a discussion of the circumstances in which an electronic order must not be filled see below, Controlled Substance Ordering System (CSOS) - Electronic Order Forms.

A supplier may refuse to accept an order for any reason as set forth under 21 C.F.R. § 1305.15(c). If a supplier refuses to accept an order, a statement that the order is not accepted is sufficient. If an order is refused, the supplier must return copies one and two of the DEA Form 222 to the purchaser with a statement explaining the reason the order was refused. For electronic orders, the supplier must notify the purchaser and provide a statement as to the reason (see below, Controlled Substance Ordering System (CSOS) - Electronic Order Forms).

DEA policy does not preclude the substitution of identical products differing in packaging size from those initially ordered, provided that the actual quantity received does not exceed the amount initially ordered and that the National Drug Code number reflected is that of the actual product shipped. For example, a distributor may substitute five bottles of 100, 2 milligram tablets for one bottle of 500, 2 milligram tablets or any variation thereof.

Cancellation and Voiding an Official Order Form

A purchaser may cancel an order (or partial order) on a DEA Form 222 by notifying the supplier in writing. The supplier must indicate the cancellation on Copies 1 and 2 of the DEA Form 222 by drawing a line through the cancelled item(s) and printing “cancelled” in the space provided for the number of items shipped.

A supplier may void part or all of an order on a DEA Form 222 by notifying the purchaser in writing. The supplier must indicate the voiding in Copies 1 and 2 of the DEA Form 222 by drawing a line through the cancelled item(s) and printing “void” in the space provided for the number of items shipped. For information regarding cancelled electronic orders, see below, Controlled Substance Ordering System (CSOS) - Electronic Order Forms.

Power of Attorney to Sign an Official Order Form

Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 by granting a power of attorney to each such individual. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute the DEA Forms 222.

The power of attorney may be revoked at any time by the person who granted and signed the power of attorney. Only if the renewal application is signed by a different person is it necessary to
grant a new power of attorney when the pharmacy completes a renewal registration. The power of attorney should be filed with executed DEA Forms 222 as a readily retrievable record. The power of attorney is not submitted to DEA.

Suggested formats for granting and revoking a power of attorney follow:

Power of Attorney for DEA Forms 222 and Electronic Orders

________________________ (Name of registrant)
________________________ (Address of registrant)
________________________ (DEA registration number)

I, ____________________________ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint ____________________________ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for schedule I and II controlled substances, in accordance with Section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

(Signature of person granting power)

I, ____________________________ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact)

Witnesses:
1. ____________________________
2. ____________________________

Signed and dated on the ___ day of ___________ in the year ___ at _____________.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act. Written notice of this revocation has been given to the attorney-in-fact ____________________________ this same day.

(Signature of person revoking power)
Suggested Format for the Power of Attorney Form
(see 21 CFR 1305.07)

____________________________________  (Name of registrant)
____________________________________  (Address of registrant)
____________________________________  (DEA registration number)

I, __________________________________ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint __________________ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

________________________________________________________
(Signature of person granting power)

I, __________________________________ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

________________________________________________________
(Signature of attorney-in-fact)

Witnesses:
1. ____________________________________________.
2. ____________________________________________.

Signed and dated on the _____ day of ________, (year), at ________.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act of the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _________ this same day.

________________________________________________________
(Signature of person revoking power)

Witnesses:
1. ____________________________________________.
2. ____________________________________________.

Signed and dated on the _____ day of ________, (year), at ________.
Disposal of Controlled Substances

A pharmacy may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. The pharmacy should contact the local DEA Diversion Field Office (Appendix K) for an updated list of DEA registered reverse distributors. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA. The DEA procedures established for the disposal of controlled substances must not be construed as altering in any way the state laws or regulations for the disposal of controlled substances.

Reverse Distributors Authorized to Dispose Controlled Substances

A pharmacy may forward controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. When a pharmacy transfers schedule II controlled substances to a reverse distributor for destruction, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the pharmacy. When schedules III-V controlled substances are transferred to a reverse distributor for destruction, the pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred. The DEA registered reverse distributor who will destroy the controlled substances is responsible for submitting a DEA Form 41 (Registrants Inventory of Drugs Surrendered) to the DEA when the controlled substances have been destroyed. A DEA Form 41 should not be used to record the transfer of controlled substances between the pharmacy and the reverse distributor disposing of the drugs.

A paper version of the DEA Form 41 may be requested by writing to:

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

Disposal of Controlled Substances by Persons Not Registered with DEA

On January 21, 2009, DEA published in the Federal Register an Advance Notice of Proposed Rulemaking (ANPRM), Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration. This ANPRM sought comments on how to address the issue of disposal of dispensed controlled substances held by DEA nonregistrants (i.e., ultimate users, long term care facilities). DEA was interested in the possible options that would enable nonregistrants to dispose of unwanted controlled substances, while also protecting public health and public safety, and minimizing the possibility of diversion. The public comment period for this ANPRM ended on March 23, 2009.
The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: (Include Name, Street, City, State and ZIP Code in space provided below.)

<table>
<thead>
<tr>
<th>Signature of applicant or authorized agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regrant's DEA Number</td>
</tr>
<tr>
<td>Regrant's Telephone Number</td>
</tr>
</tbody>
</table>

NOTE: CERTIFIED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse (page 2) of form.

<table>
<thead>
<tr>
<th>NAME OF DRUG OR PREPARATION</th>
<th>Number of Containers</th>
<th>CONTENTS (Number of grams, tablets, ounces or other units per container)</th>
<th>Controlled Substance Content (Each Unit)</th>
<th>FOR DEA USE ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DISPOSITION</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QUANTITY</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>GMS.</td>
</tr>
</tbody>
</table>

| Example: Methadone HCL Tablets, 10mg | 1 | 100mg | 10 |
| Example: Methadose 960 ml, 10mg/ml | 1 | 960ml | 10 |

Note: The graphic illustrated above is only a depiction of the DEA Form-41. It is not intended to be used as an actual Drug Disposal form.
<table>
<thead>
<tr>
<th>NAME OF DRUG OR PREPARATION</th>
<th>Number of Containers</th>
<th>CONTENTS (Number of grams, tablets, ounces or other units per container)</th>
<th>Controlled Substance Content (Each Unit)</th>
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</tr>
</thead>
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<tr>
<td></td>
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<td>QUANTITY</td>
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<tr>
<td></td>
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<td></td>
<td>GMS.</td>
</tr>
<tr>
<td>17</td>
<td>1</td>
<td></td>
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</tr>
<tr>
<td>18</td>
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<td>23</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The controlled substances surrendered in accordance with Title 21 of the Code of Federal Regulations, Section 1307.21, have been received in ________ packages purporting to contain the drugs listed on this inventory and have been: **(1) Forwards tape-sealed without opening; (2) Destroyed as indicated and the remainder forwarded tape-sealed after verifying the contents; (3) Forwarded tape-sealed after verifying contents.**

DATE ____________________________ DESTROYED BY: ____________________________

**Strike out lines not applicable.**

WITNESSED BY: ____________________________

**INSTRUCTIONS**

1. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit described in column 3; e.g., morphine sulfate tabs, 3 pills, 100 tabs, 1/4 gr (16 mg) or morphine sulfate tabs, 1 pill, 80 tabs, 1/5 gr (32 mg), etc.

2. All packages included on a single line should be identical in name, content, and controlled substance strength.

3. Prepare this form in duplicate. Mail two (2) copies of this form to the Special Agent in Charge, under separate cover. Enclose one additional copy in the shipments with the drugs. Retain one copy for your records. One copy will be returned to you as a receipt. No further receipt will be furnished to you unless specifically requested. Any further inquiries concerning these drugs should be addressed to the DEA District Office which serves your area.

4. There is no provision for payment of drugs surrendered. This is merely a service rendered to registrants enabling them to clear their stocks and records of unwanted items.

5. Drugs should be shipped tape-sealed via prepaid express or certified mail (return receipt requested) to Special Agent in Charge, Drug Enforcement Administration, of the DEA District Office which serves your area.

**PRIVACY ACT INFORMATION**

This section of the DEA-41 has been omitted due to space constraints.

Note: The graphic illustrated above is only a depiction of the DEA Form-41. It is not intended to be used as an actual Drug Disposal form.
APPENDIX A

This summary is provided as a quick reference to the provisions of the Controlled Substances Act. It is not intended to replace any statutory or regulatory requirement thereof. For complete guidance as to the provisions of each area indicated below, please check the appropriate section of this manual.

Summary of Controlled Substances Act Requirements

<table>
<thead>
<tr>
<th></th>
<th>Schedule II</th>
<th>Schedules III &amp; IV</th>
<th>Schedule V</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Registration</strong></td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td><strong>Receiving Records</strong></td>
<td>DEA Form 222</td>
<td>Invoices, readily</td>
<td>Invoices,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>retrievable</td>
<td>readily</td>
</tr>
<tr>
<td><strong>Prescriptions</strong></td>
<td>Written¹ prescriptions²</td>
<td>Written, oral, or fax</td>
<td>Written, oral, or fax</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>No more than 5 within 6 months</td>
<td>As authorized when prescription is issued or if renewed by a practitioner</td>
</tr>
<tr>
<td><strong>Refills</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Maintenance of</strong></td>
<td>Separate file</td>
<td>Separate file or readily retrievable</td>
<td>Separate file or readily retrievable³</td>
</tr>
<tr>
<td><strong>Prescriptions</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Distribution</strong></td>
<td>DEA Form 222</td>
<td>Invoices</td>
<td>Invoices</td>
</tr>
<tr>
<td><strong>Between Registrants</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Security</strong></td>
<td>Locked cabinet or dispersed among non-controlled pharmaceuticals</td>
<td>Locked cabinet or dispersed among non-controlled pharmaceuticals</td>
<td>Locked cabinet or dispersed among non-controlled pharmaceuticals</td>
</tr>
<tr>
<td><strong>Theft or Significant Loss</strong></td>
<td>Report to DEA and complete DEA Form 106</td>
<td>Report to DEA and complete DEA Form 106</td>
<td>Report to DEA and complete DEA Form 106</td>
</tr>
</tbody>
</table>

Note: *All records* must be maintained for 2 years, unless state law requires a longer period.

¹ Written prescriptions include paper prescriptions and electronic prescriptions that meet DEA’s requirements for such prescriptions.

² Emergency prescriptions require a signed follow-up prescription within seven days.

*Exceptions:* A facsimile prescription serves as the original prescription when issued to residents of Long Term Care Facilities, hospice patients, or patients with a diagnosed terminal illness, or for immediate administration (21 C.F.R. § 1306.11(e), (f) and (g)).

³ The record of dispensing can also be a schedule V logbook, if state law allows.
APPENDIX B

Definitions Based on the Controlled Substances Act
and the Code of Federal Regulations

Administer
The direct application of a controlled substance to the body of a patient or research subject by 1) a practitioner or (in his/her presence) by his/her authorized agent, or 2) the patient or research subject at the direction and in the presence of the practitioner, whether such application is by injection, inhalation, ingestion, or any other means.

Central Fill Pharmacy
A pharmacy which is permitted by the state in which it is located to prepare controlled substance orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed “authorized” to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

Chemicals
Please see the definitions for List I Chemical, Retail Distributor and Scheduled Listed Chemical Product.

Dispense
To deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

Individual Practitioner
A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

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

Inventory
All factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).
List I Chemical
A chemical specifically designated by the [DEA] Administrator in 21 C.F.R. § 1310.02(a)... that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the [Controlled Substances] Act and is important to the manufacture of a controlled substance.

Long Term Care Facility (LTCF)
A nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

Mid-level Practitioner (MLP)
An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of MLPs include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants who are authorized to dispense controlled substances by the state in which they practice. Because this authority varies greatly by state, check with the state licensing authority to determine which MLP disciplines are authorized to dispense controlled substances in a particular state or visit, www.DEAdversion.usdoj.gov (click on Registration Support, then Resources, then Mid-level Practitioners Authorization by State).

Online Pharmacy
An online pharmacy is a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet.

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

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).

Readily Retrievable
Certain records which are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

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