NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

August 5, 2020
10:00 a.m. Central Time
Nebraska State Office Building – Lower Level A
301 Centennial Mall South, Lincoln, Nebraska
Phone call information: 888-820-1398; Participant code: 3213662#

The purpose of this hearing is to receive comments on proposed changes to Title 175, Chapter 8 of the Nebraska Administrative Code (NAC) – *Pharmacies.* The proposed changes update storage requirements to reflect industry best practices; clarify the scope and authority for the regulations; update definitions; update the licensing process; update the process for permanently closing a pharmacy; update the inspection process; update the roles and responsibilities of pharmacies, pharmacists, and practitioners in the dispensing process; and removed statutory duplication from the regulations.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

Due to the current public health crisis, the agency will enforce any Directed Health Measure Order on the size of gatherings that is in effect at the time of the hearing. In order to encourage participation in this public hearing, a phone conference line will be set up for any member of the public to call in and provide oral comments.

Interested persons may provide verbal comments by participating via phone conference line by calling 888-820-1398; Participant code: 3213662#.

A copy of the proposed changes is available online at http://www.sos.ne.gov, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: **Department of Health and Human Services**	
Title:175	Prepared by: Jesse Cushman
Chapter: 8	Date prepared: 6-26-20
Subject: Pharmacy Facility Licensure	Telephone: (402) 471-4915

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(☒)	(☒)	(☒)
Increased Costs	(☐)	(☐)	(☐)
Decreased Costs	(☐)	(☐)	(☐)
Increased Revenue	(☐)	(☐)	(☐)
Decreased Revenue	(☐)	(☐)	(☐)
Indeterminable	(☐)	(☐)	(☐)

Provide an Estimated Cost & Description of Impact:

State Agency: No Change

Political Subdivision: No Change

Regulated Public: There is no change in fees to the regulated public.

If indeterminable, explain why:

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 8 PHARMACIES

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ATTACHMENT

CODE OF FEDERAL REGULATIONS (CFR)

PARTS 1304 to 1307

4/1/06 EDITION

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 8 PHARMACIES

~~8-~~001. SCOPE AND AUTHORITY.~~:~~ These regulations govern licensure of Pharmacies. The regulations are authorized under~~by and implement~~ the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-475~~59~~; the Pharmacy Practice Act, Neb. Rev. Stat. §§ 38-2801 to 38-28,116; the Uniform Credentialing Act, Neb. Rev. Stat. §§ 38-101 to 38-1,142; and the Prescription Drug Safety Act, Neb. Rev. Stat. §§ 71-2457 to 71-2483.

~~8-~~002. DEFINITIONS. Definitions set out in the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-475; the Pharmacy Practice Act, Neb. Rev. Stat. §§ 38-2801 to 38-28,116; the Uniform Credentialing Act, Neb. Rev. Stat. §§ 38-101 to 38-1,140 and the following:

002.01 COMPLETE APPLICATION. An application that contains all of the information requested on the application, with attestation to its truth and completeness, and submitted with all required fees and documentation.

002.02 COMPLETE PETITION. A complete petition contains all of the requested information on a form provided by the Department, with attestation to it truth and completeness, signatures of the applicant(s), submitted with all required fees and documentation.

~~Administer means to directly apply a drug or device by injection, inhalation, ingestion, or other means to the body of a patient or research subject.~~

~~Administration means the act of:~~

~~1. administering;~~
~~2. keeping a record of the activity; and~~
~~3. observing, monitoring, reporting, and otherwise taking appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device.~~

~~Agent means an authorized person who acts on behalf of or at the direction of another person but does not include a common or contract carrier, public warehouse keeper, or employee of a carrier or warehouse keeper.~~

~~Applicant means the individual, government, corporation, partnership, limited liability company or other form of business organization who applies for a license.~~

~~Biological or biological product means any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of disease or injuries of humans.~~

~~Board means the Board of Pharmacy.~~

~~Caregiver means any person acting as an agent on behalf of a patient or any person aiding and assisting a patient.~~

~~Central fill means the preparation, other than by compounding, of a drug, device or biological pursuant to a medical order where the preparation occurs in a pharmacy other than the pharmacy dispensing to the patient or caregiver.~~

~~Chart order means an order for a drug or device issued by a practitioner for a patient who is in the hospital where the chart is stored or for a patient receiving detoxification treatment or maintenance treatment pursuant to Neb. Rev. Stat. § 28-412. Chart order does not include a prescription.~~

~~Complaint means an expression of a concern or dissatisfaction.~~

~~Completed application means the application that contains all the information specified in 175 NAC 8-003 and includes all required attachments and documentation and the licensure fee.~~

~~Compounding means the preparation of components into a drug product.~~

- ~~(a) As the result of a practitioner's medical order or initiative occurring in the course of practice based upon the relationship between the practitioner, patient, and pharmacist; or~~
- ~~(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding includes the preparation of drugs or devices in anticipation of receiving medical orders based upon routine, regularly observed prescribing patterns.~~

~~D.E.A. means the Drug Enforcement Administration of the United States Department of Justice.~~

~~Department means the Department of Health and Human Services Regulation and Licensure.~~

~~Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a practitioner and dispensed by a pharmacist or other person authorized by law to do so.~~

~~Director means the Director of Regulation and Licensure.~~

~~Dispense or dispensing means interpreting, evaluating, and implementing a medical order, including preparing and delivering a drug or device to a patient or caregiver in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. Dispensing includes:~~

1. Dispensing incident to practice;
2. Dispensing pursuant to a delegated dispensing permit;
3. Dispensing pursuant to a medical order; and
4. Any transfer of a prescription drug or device to a patient or caregiver other than by administering.

Distribute means to deliver a drug or device, other than by administering or dispensing.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Grievance means a written expression of dissatisfaction, which may or may not be the result of an unresolved complaint.

Healing arts means a health profession in which a licensed practitioner offers or undertakes to diagnose, treat, operate on, or prescribe for any human pain, injury, disease, deformity, or physical or mental condition.

Health care practitioner means any individual credentialed under the Uniform Licensing Law or other laws of the State of Nebraska.

Labeling means the process of preparing and affixing a label to any drug container or device container, exclusive of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label must include all information required by federal and state law or regulation.

Licensee means the individual, government, corporation, partnership, limited liability company or other form of business organization legally responsible for the operation of the facility and to whom the Department has issued a license.

Long-term care facility means a nursing facility, skilled nursing facility, intermediate care facility, intermediate care facility for persons with mental retardation, or long-term care hospital, but not an assisted-living facility.

Medical order means a prescription, or chart order, or an order for pharmaceutical care issued by a practitioner.

NAC means Nebraska Administrative Code.

Patient counseling means the verbal communication by a pharmacist, pharmacist intern, or practitioner, in a manner reflecting dignity and the right of the patient to a reasonable degree of privacy, of information to the patient or caregiver in order to improve therapeutic outcomes by maximizing proper use of prescription drugs and devices and also includes the duties set out in Neb. Rev. Stat. § 71-1,147.35.

Person means an individual, corporation, partnership, limited liability company, association, or other legal entity.

~~Pharmaceutical care means the provision of drug therapy for the purpose of achieving therapeutic outcomes that improve a patient's quality of life. Such outcomes include:~~

1. ~~the cure of disease,~~
2. ~~the elimination or reduction of a patient's symptomatology,~~
3. ~~the arrest or slowing of a disease process, or~~
4. ~~the prevention of a disease or symptomatology.~~

~~Pharmaceutical care includes the process through which the pharmacist works in concert with the patient and his/her caregiver, physician, or other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient.~~

~~Pharmacist means any person who is licensed by the State of Nebraska to practice pharmacy.~~

~~Pharmacist-in-charge means a pharmacist who is designated on a pharmacy license or designated by a hospital as being responsible for the practice of pharmacy in the pharmacy for which a pharmacy license is issued and who works within the physical confines of the pharmacy for a majority of the hours per week that the pharmacy is open for business averaged over a 12-month period or 30 hours per week, whichever is less.~~

~~Pharmacy means a facility where drugs or devices are dispensed.~~

~~Pharmacist intern means~~

1. ~~A student currently enrolled in an accredited pharmacy program or~~
2. ~~A graduate of an accredited pharmacy program serving his/her internship, the internship to expire not later than 15 months after the date of graduation or at the time of professional licensure, whichever comes first.~~

~~Such pharmacist intern may compound and dispense drugs or devices and fill prescriptions only in the presence of and under the immediate personal supervision of a licensed pharmacist. Such licensed pharmacist must either be:~~

a. ~~The person to whom the pharmacy license is issued or a person in the actual employ of the pharmacy licensee or~~
b. ~~The delegating pharmacist designated in a delegated dispensing agreement by a hospital with a delegated dispensing permit.~~

~~Pharmacy technician means an individual at least 18 years of age who is a high school graduate or officially recognized by the State Department of Education as possessing the equivalent degree of education, who has never been convicted of any drug-related misdemeanor or felony, and who, under the written control procedures and guidelines of an employing pharmacy, may perform those functions which do not require professional judgment and which are subject to verification to assist a pharmacist in the practice of pharmacy.~~

~~Practice of Pharmacy means the~~

1. Interpretation, evaluation, and implementation of a medical order;
2. The dispensing of drugs and devices;
3. Drug product selection;
4. The administration of drugs or devices;
5. Drug utilization review;
6. Patient counseling;
7. Provision of pharmaceutical care, and
8. Responsibility for compounding and labeling of dispensed or repackaged drugs and devices, proper and safe storage of drugs and devices, and maintenance of proper records.

Practitioner means an advanced practice registered nurse, certified registered nurse anesthetist, certified nurse midwife, dentist, optometrist, physician assistant, physician, podiatrist, or veterinarian.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

Prescription drug or device or legend drug or device means:

1. A drug or device which is required under federal law, to be labeled with one of the following statements prior to being dispensed or delivered:

   a. Caution: Federal law prohibits dispensing without prescription; or
   b. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian; or
   c. Rx Only.

2. A drug or device which is required by any applicable federal or state law to be dispensed pursuant only to a prescription or which is restricted to use by practitioners only.

Prescription means an order for a drug or device issued by a practitioner for a specific patient, for emergency use, or for use in immunizations. Prescription does not include a chart order.

Signature means the name, word, or mark of a person written in his/her own hand with the intent to authenticate a writing or other form of communication or a digital signature which complies with Neb. Rev. Stat. § 86-611 or an electronic signature.

Supervision means the immediate personal guidance and direction by the licensed pharmacist on duty in the facility of the performance by a pharmacy technician of authorized activities or functions subject to verification by the pharmacist, except that when a pharmacy technician performs authorized activities or functions to assist a pharmacist on duty in the facility when the prescribed drugs or devices will be administered by a licensed staff member or consultant or by a licensed physician assistant to persons who are patients or residents of a facility, the activities or functions of the pharmacy technician are only subject to verification by a pharmacist on duty in the facility.

~~Verification means the confirmation by a supervising pharmacist of the accuracy and completeness of the acts, tasks, or functions undertaken by a pharmacy technician to assist the pharmacist in the practice of pharmacy.~~

~~Written control procedures and guidelines means the document prepared and signed by the pharmacist-in-charge and approved by the Board which specifies the manner in which basic levels of competency of pharmacy technicians employed by the pharmacy are determined, the manner in which supervision is provided, the manner in which the functions of pharmacy technicians are verified, the maximum ratio of pharmacy technicians to one pharmacist used in the pharmacy, and guidelines governing the use of pharmacy technicians and the functions which they may perform.~~

~~8-003.~~ LICENSING REQUIREMENTS~~. AND PROCEDURES: Any person, including a practitioner, intending to establish, operate, or maintain a pharmacy must first obtain a license from the Department. A pharmacy must not hold itself out as a pharmacy or as providing health care services unless licensed under the Health Care Facility Licensure Act.~~ An applicant for an initial ~~or renewal~~ license must submit a completed application provided by the Department and documentation that the applicant meets the requirements set in statute and this chapter. ~~demonstrate that the pharmacy meets the operational and physical plant standards contained in 175 NAC 8.~~

~~8-003.01 INITIAL LICENSURE. Application Process for Initial LicensureAn applicant must submit documentation demonstrating that the applicant that meets the requirements of Neb. Rev. Stat. §§ 71-432 to 71-438, and this chapter. The application must contain the following.~~

~~8-003.01A Applicant Responsibilities: No person may operate a pharmacy until the Department has issued either a provisional pharmacy license or a pharmacy license for that pharmacy. An applicant for an initial pharmacy license must:~~

~~1. Intend to provide pharmacy services as stated in the application;~~
~~2. Comply with the applicable standards specified in 175 NAC 8-006 and 8-007;~~
~~3. Submit a signed application verifying that all information in the application is correct. The application must contain the following:~~
~~a. Pharmacy or practitioner name,~~
~~b. Pharmacy or practitioner street address,~~
~~c. Pharmacy or practitioner telephone number,~~
~~d. Name of owner(s), partners, or corporation,~~
~~e. If a corporation, name of corporate officers,~~
~~f. Mailing address(es) of owner(s), partners, or corporation,~~
~~g. Anticipated opening date,~~
~~h. Anticipated days and hours pharmacy will be open for business,~~
~~i. Name of pharmacist-in-charge or name of practitioner,~~
~~j. Nebraska license number of pharmacist-in-charge or Nebraska license number of practitioner,~~
~~k. Expiration date of the license of the pharmacist-in-charge or expiration date of practitioner's license,~~

l. If controlled substances are to be dispensed, the D.E.A. registration number or proof that an application is in process,

m. A description of how the pharmacy meets the following requirements:

(1) The prescription inventory and prescription records of the pharmacy must be maintained in a secure location when there is no pharmacist on the premises.

(2) The pharmacy must store drugs, devices, and biologicals at the proper temperature.

(3) The pharmacy must not have in its saleable inventory any drug, device, or biological which is misbranded or adulterated.

(4) The pharmacy must provide the pharmacist access to all equipment appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy. List all services intended to be provided by the pharmacy.

(5) The pharmacy must provide the pharmacist access to all facilities appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy.

(a) Examples of services which may be provided by a pharmacy include, but are not limited to: ambulatory dispensing, unit-dose dispensing, sterile compounding, non-sterile compounding, and administration of vaccinations or injections.

(6) The pharmacy must provide the pharmacist access to all utilities appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy.

(7) The pharmacy must provide the pharmacist access to all reference material appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy. These references must be current, in either printed or electronic form, and available at all times while the pharmacist is practicing for that pharmacy. List the references to be used in the pharmacy; and

4. Submit the required fee as specified in 175 NAC 8-004.11.

8-003.01B Department Process for Initial Licensure: The initial license process occurs in two stages. The application is not complete until the Department receives the documents specified in 175 NAC 8-003.01A3.

8-003.01B1 PROVISIONAL PHARMACY LICENSE.: To obtain a provisional pharmacy license, an applicant must substantially meet the requirements in the Health Care Facility Licensure Act and sections 175 NAC 8-006 through 175 NAC 8-008 of this chapter. A license will be issued after a satisfactory initial inspection is completed. The first stage consists of the Department conducting an opening inspection according to 175 NAC 8-005.01 to determine the applicant's ability to comply with the operational and physical plant standards contained in 175 NAC 8-006 and 8-007. The Department will:

1. Review the application for completeness as part of the opening inspection in accordance with 175 NAC 8-005.01;
2. Provide notification to the applicant of any information needed to complete the application;
3. Issue a provisional pharmacy license if the Department determines that the pharmacy has substantially complied but fails to fully comply with the requirements for licensure under the Act and that the failure does not pose an imminent danger of death or physical harm to the persons served by the pharmacy. The provisional license:

    a. Is valid for up to one year;
    b. Is not renewable; and
    c. May be converted to a regular license upon a showing that the pharmacy has fully complied with the requirements for licensure; or

4. Deny the provisional pharmacy license if the Department determines that the pharmacy fails to fully comply with the requirements for licensure under the Act and that the failure poses an imminent danger of death or physical harm to the persons served by the pharmacy.

8-003.01B2 Pharmacy License: The second stage consists of the Department's initial on-site inspection of the pharmacy in accordance with 175 NAC 8-005.02. The Department determines whether or not the applicant for a pharmacy license fully meets the standards contained in 175 NAC 8 and the Health Care Facility Licensure Act. The Department will:

1. Conduct an initial on-site inspection in accordance with 175 NAC 8-005.02 within 60 days after the issuance of the provisional pharmacy license;
2. Provide notification to the applicant of the results of the initial on-site inspection within 10 days after the completion of the inspection, in accordance with 175 NAC 8-005.02;
3. Issue a pharmacy license based on the results of the initial on-site inspection if the Department determines that the pharmacy has fully complied with the requirements for licensure under the Act;
4. Issue a pharmacy license based on the results of the initial on-site inspection if the Department determines that the pharmacy has substantially complied but fails to fully comply with the requirements for licensure under the Act and that the failure does not pose an imminent danger of death or physical harm to the persons served by the pharmacy; and/or
5. Deny the pharmacy license if the Department determines that the pharmacy fails to fully comply with the requirements for licensure

~~under the Act and that the failure poses an imminent danger of death or physical harm to the persons served by the pharmacy.~~

~~8-003.01C Denial of License: The Department may deny a pharmacy license when an applicant fails to meet the requirements for licensure, including:~~

1. ~~Failing an inspection;~~
2. ~~Failing to meet a compliance assessment standard;~~
3. ~~Having had a license revoked within the two-year period preceding application; or~~
4. ~~Any of the grounds listed in 175 NAC 8-008.01B.~~

~~8-~~003.02 RENEWAL.~~Renewal Licenses~~ All pharmacy licenses expire annually on July 1. To renew a license an applicant for a renewal license must submit a complete application provided by the Department and documentation that the applicant meets the requirements in statute and in this chapter.

~~8-003.02A Department Responsibilities: The Department will:~~

1. ~~Send a notice of expiration and an application for renewal to the applicant's preferred mailing address no later than 30 days prior to the expiration date. The license renewal notice specifies:~~

   a. ~~Date of expiration;~~
   b. ~~Fee for renewal;~~
   c. ~~License number; and~~
   d. ~~Name and address of the pharmacy.~~

2. ~~Issue a renewal when it determines that the applicant has submitted a completed application;~~

3. ~~Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:~~

   a. ~~The licensee failed to pay the renewal fee or submit an application or both;~~
   b. ~~The license has expired;~~
   c. ~~The Department will suspend action for 30 days following the date of expiration;~~
   d. ~~Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and~~
   e. ~~That upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.~~

4. ~~Place the pharmacy license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the pharmacy~~

may not operate. The license remains in lapsed status until it is reinstated.

8-003.02B Licensee Responsibilities: The licensee must submit:

1. The application for renewal;
2. Confirmation as requested by the Department of the pharmacy's or practitioner's current D.E.A. Registration, if any;
3. The name of the pharmacist-in-charge or the practitioner; and
4. The required renewal fee as specified in 175 NAC 8-004.11.

8-003.02C Refusal to Renew: The Department may refuse renewal of a pharmacy license that fails to meet the requirements for renewal, including:

1. Failing an inspection;
2. Failing to meet a compliance assessment standard;
3. Having had a license revoked within the two-year period preceding application; or
4. Any of the grounds listed in 175 NAC 8-008.01B.

8-003.03 Reinstatement from Lapsed Status: A pharmacy requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required license fee specified in 175 NAC 8-004.11. The application must conform to the requirements specified in 175 NAC 8-003.02.

8-003.03A The Department will review the application for completeness and will decide if an on-site inspection is needed to determine compliance with the operational and physical plant standards of 175 NAC 8-006 and 8-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the pharmacy has provided pharmacy services from the site under a license that is different from the lapsed license.

8-003.03B When the Department decides that an on-site reinstatement inspection is warranted, it will conduct the inspection in accordance with 175 NAC 8-005.02.

8-003.03C When the Department decides that an on-site reinstatement inspection is not warranted, it will reinstate the license.

8-003.03D Refusal to Reinstate: The Department may refuse reinstatement of a pharmacy license that fails to meet the requirements for reinstatement, including:

1. Failing an on-site inspection;
2. Failing to meet a compliance assessment standard;

~~3. Having had a license revoked within the two-year period preceding application; or~~
~~4. Any of the grounds listed in 175 NAC 8-008.01B.~~

~~8-~~003.03~~04 Permanently Closing a Pharmacy~~ PERMANENTLY CLOSING A PHARMACY. When a licensee discontinues providing pharmacy services, the Department must be notified in writing within 15 days of the services being discontinued in the pharmacy. The notice must include the following information:

~~8-003.04A When a pharmacy ceases legal existence, discontinues business or has a change of ownership, the pharmacist-in-charge or practitioner of that pharmacy must notify the Department within 15 days of closing.~~

~~8-003.04B The notice must include the following information:~~

(1)~~1.~~The sale or other disposition of legend drug, device, or biological inventory,
(2)~~2.~~The sale or other disposition of controlled substances and controlled substances invoices and inventory records, and
(3)~~3.~~The location of all patient records including prescription files.

003.03(A) RETURN OF DOCUMENTS AND FORMS. Upon permanent closure of the pharmacy, the licensee must return the pharmacy license to the Department and may return the following to the Department to be forwarded to the Drug Enforcement Administration (DEA):
(i) The pharmacy's Drug Enforcement Administration (DEA) Registration, if any; and
(ii) All unused Drug Enforcement Administration (DEA) Forms for the pharmacy, if any.

~~8-003.04C The pharmacist-in-charge or practitioner must return the following to the Department:~~

~~1. The pharmacy license,~~
~~2. The pharmacy's D.E.A. Registration, if any,~~
~~3. All unused D.E.A. Forms 222 for the pharmacy, if any, and~~
~~4. All unused D.E.A. Forms 222a or 222d for the pharmacy, if any.~~

~~8-~~003.03(B)~~.04D~~ PATIENT NOTIFICATION. When the permanent closing of a pharmacy is anticipated, the licensee~~pharmacist-in-charge or practitioner~~ is responsible for notifying patients of that pharmacy at least 15 days prior to the permanent closing that they will need to seek service elsewhere. The notification can be accomplished through:
(i)~~1.~~Advertisement in a newspaper appropriate to the location of the pharmacy;~~,~~
(ii)~~2.~~Written notice to patients of the pharmacy;~~,~~ or
(iii)~~3.~~Other such notice as is appropriate.

003.04 REINSTATEMENT. Unless otherwise stated, a request for reinstatement must submit complete application provided by the Department and meet the requirements of Neb. Rev. Stat. § 71-433, 71-456, and 175 NAC 8.

003.04(A) REINSTATEMENT PRIOR TO THE COMPLETION OF PROBATION. A licensee may petition for reinstatement prior to the completion of probation or suspension and must submit a complete petition form provided by the Department:

004. INSPECTIONS. For the purpose of assuring compliance, each licensee must prepare an annual Pharmacy Quality Assurance Report (PQAR).

004.01 PHARMACY QUALITY ASSURANCE REPORT (PQAR). The Pharmacy Quality Assurance Report (PQAR) is due 1 year from the date of the initial on-site inspection and annually thereafter. All licensees must ensure that the pharmacist in charge or the practitioner annually submits a completed Pharmacy Quality Assurance Report (PQAR) on a form provided by the Department, electronically or upon request. A Pharmacy Quality Assurance Report (PQAR) self-inspection may be completed no more than 30 days before the due date of the report.

004.01(A) REPORTED INFORMATION. At a minimum, the Pharmacy Quality Assurance Report (PQAR) must provide information on the following:

(i) Standards for the Operations of a Pharmacy
  (1) Staffing requirements;
  (2) Storage requirements;
  (3) Record keeping requirements;
  (4) Dispensing requirements;
  (5) Controlled substance dispensing requirement for emergency situations; and
  (6) Disaster preparedness management;

(ii) Physical Plant Standards
  (1) Equipment, facilities, and utilities;
  (2) Shelving, counters, floor, inventory, fixtures, equipment, and utensils; and
  (3) Reference material;

(iii) Sterile Compounding Requirements, if applicable for the facility

(iv) Non-sterile compounding requirements, if applicable for the facility

004.01(B) VERIFICATION OF THE REPORT. The Pharmacy Quality Assurance Report (PQAR) must be accompanied by a signed statement from the pharmacist in charge or the practitioner verifying that all information in the Pharmacy Quality Assurance Report (PQAR) is accurate, complete, and correct.

004.02 ANNUAL INSPECTION. All licensees are required to complete and submit the Department Pharmacy Quality Assurance Report (PQAR) form for an annual self-inspection, and may be subject to an on-site inspection to verify the pharmacy fully complies with all requirements.

004.02(A) SELF-INSPECTION. The Pharmacy Quality Assurance Report (PQAR) will fulfill the annual inspection requirement when the Department determines that the report indicates that the licensee is in full compliance with the Health Care Facility Licensure Act, the Controlled Substances Act, the Prescription Drug Safety Act, and this chapter. However, the report will not fulfill the annual inspection requirement when:

(i) The Department has determined, based on the review of the Pharmacy Quality Assurance Report (PQAR), that the pharmacy is not in compliance with the Health Care Facility Licensure Act, or this chapter;
(ii) The pharmacy failed to be in full compliance with the Health Care Facility Licensure Act, or this chapter at the time of its last inspection;
(iii) The licensee failed to submit a Pharmacy Quality Assurance Report (PQAR);
(iv) The pharmacy is randomly selected as part of the 25% of licensed pharmacies chosen annually for inspection;
(v) Any other event that raises concerns about the maintenance, operation, or management of the pharmacy.

004.02(B) COMPLIANCE INSPECTION. An unannounced inspection may be conducted of the facility or service anytime the Department deems necessary, including, the passage of five years without an inspection.

~~8-004~~005. GENERAL REQUIREMENTS. The following requirements are applicable to all pharmacy licenses.

~~8-004.01 License Usage: The licensee must not provide pharmacy services except those set out in their initial application for a pharmacy license or any amendment thereto.~~

~~8-004.02 Effective Date and Term of License: A pharmacy license expires on July 1 of each year.~~

~~8-004.03~~005.01 LICENSE NOT TRANSFERABLE. ~~License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable.~~ Change of ownership (~~sale, whether of stock, title, or assets, lease, discontinuance of operations)~~ or change of premises terminates the license. ~~If there is a change of ownership and the pharmacy remains on the same premises, the inspection in 175 NAC 8-005 is not required.~~ The new owner~~(s)~~ or owners must apply for a new pharmacy license. ~~If there is a change of premises, the owner(s) must apply for a new pharmacy license and the pharmacy must pass the inspection specified in 175 NAC 8-005.~~

~~8-004.04 Notification~~005.02 NOTIFICATION.~~:~~ An applicant or licensee must notify the Department of any change as set forth in 175 NAC 8-005.03~~4.05~~ through 8-005.08~~4.10~~. The following information is required for all notifications:

(A)~~1.~~Current name and license number of the pharmacy or practitioner;
(B)~~2.~~Street address of pharmacy or practitioner;
(C)~~3.~~Name of owner(s), partners, or corporation;
(D)~~4.~~If a corporation the name of corporate officers;
(E)~~5.~~Mailing address(es) of owner(s), partners, or corporation;
(F)~~6.~~Reason for notifying the Department about a change in the existing license;
(G)~~7.~~A signed statement from the applicant or licensee verifying that all information is correct; and
(H)~~8.~~The required fee as specified in this chapter, ~~175 NAC 8-004.11,~~ if any.

~~8-004.05~~005.03 CHANGE OF PHARMACIST IN CHARGE. ~~Change of Pharmacist-in-Charge:~~ The licensee must notify the Department within 1 business day~~immediately~~ when there is a change in the pharmacist-in-charge.

~~8-004.06~~005.04 CHANGE OF OWNERSHIP OR PREMISES. ~~Change of Ownership or Premises:~~ The licensee must notify the Department in writing 15~~30~~ days of when the~~before a~~ pharmacy is sold, leased, discontinued, or moved to a new premises.

~~8-004.07~~005.05 CHANGE OF NAME OF THE PHARMACY. ~~Change of Name of the Pharmacy:~~ The licensee must notify the Department in writing within 5 working days when there is a change in the name of the pharmacy.

~~8-004.08~~005.06 CONTINUATION OF A PHARMACY BY THE HEIRS OR ESTATE OF A DECESASED LICENSEE. ~~Continuation of a Pharmacy by the Heirs or Estate of a Deceased Licensee:~~ The heirs or executor of the estate must notify the Department within 30 days of the death of a~~the~~ licensee.

~~8-004.09 Change of Services: The licensee must notify the Department of any change in the type or scope of services provided as listed on the application or amendments thereto.~~

~~8-004.10~~005.07 AN ACCIDENT, NATURAL DISASTER, OR INTERUPTION IN UTILITY SERVICES. ~~An Accident, Natural Disaster, or Interruption in Utility Services:~~ The licensee must notify the Department in writing by electronic mail, facsimile, or postal service within 24 hours of any change in environment which will adversely affect the potency, efficacy, safety or security of the drugs, devices, or biologicals in the pharmacy. The notification may be made by telephone if the event has affected the licensee's capacity to communicate in writing.

~~8-004.11~~005.08 FEES. ~~Fees: The licensee must pay fees for licensure as follows~~The following fees apply to this chapter:

~~8-004.11A The required fees are:~~

(A)~~1.~~Initial pharmacy license fee is $625

(B)~~2.~~Annual pharmacy license renewal fee is $625.

(C)~~3.~~Duplicate license fee is $10.

~~8-004.11B Refunds for denied applications~~

~~1. If the Department did not perform an initial on-site inspection, the license fee is refunded except for an administration fee of $25; or~~

~~2. If the Department performed an initial on-site inspection, the fee is not refunded.~~

~~8-005 INSPECTIONS: Each pharmacy has the responsibility to be in compliance, and to remain in compliance, with the regulations set out in this chapter. The Department has the responsibility to determine that the pharmacies are in compliance at all times. For the purpose of assuring initial and continued compliance, each pharmacy must prepare Pharmacy Quality Assurance Reports and the Department will conduct inspections as set out below:~~

8-005.01 Opening Inspection: The Department will conduct an opening inspection by a review of the application for a pharmacy license. The answers on this application will be reviewed for accuracy, completeness, and correctness by a pharmacy inspector. Because a pharmacy cannot be in full compliance with the operational and physical plant standards for a pharmacy as specified in 175 NAC 8-006 and 8-007 prior to the time the pharmacy has been in operation, the pharmacy inspector must provide a recommendation to the Department as to whether the application indicates substantial compliance with 175 NAC 8-003.01A item 3.m. in preparation for its opening, and whether the probability of full compliance exists when the pharmacy begins to operate.

8-005.01A Department Determination: The Department will make its determination based on the recommendation to issue or deny a pharmacy license.

8-005.01B Results of Opening Inspection

8-005.01B1 When the Department finds that the applicant substantially complies with 175 NAC 8-003.01A item 3.m. and that any failure does not pose an imminent danger of death or physical harm to the persons served by the pharmacy, the Department will issue a provisional pharmacy license.

8-005.01B2 When the Department finds that the applicant fails to substantially comply with 175 NAC 8-003.01A item 3.m., the Department will deny a pharmacy license.

8-005.02 Initial On-site Inspection: After April 1, 2002, the Department will conduct an announced initial on-site inspection within 60 days of the issuance of a provisional pharmacy license. The inspection will determine whether the pharmacy fully complies with the requirements for a pharmacy license. The pharmacist-in-charge must be present for the initial on-site inspection.

8-005.02A Department Determination: Such determination will be made when the pharmacy inspector:

1. Verifies the operational and physical plant standards as described on the application for a pharmacy license are in place;
2. Verifies whether the written control procedures and guidelines for using pharmacy technicians have been submitted to the Department, when the pharmacy intends to use pharmacy technicians;
3. Verifies that an initial controlled substances inventory was taken, if the pharmacy intends to dispense controlled substances, and that the inventory is on file in the pharmacy on the date the pharmacy first engages in the distribution or dispensing of prescription drugs; and
4. Ensures that the Pharmacy Quality Assurance Report as described in 175 NAC 8-005.03 is understood by the pharmacist-in-charge and clarifies and discusses any areas that warrant attention.

~~8-005.02B Results of Initial On-site Inspection: The Department will review the findings of an initial on-site inspection within 20 working days after the inspection.~~

~~8-005.02B1 When the Department finds that the provisional licensee fully complies with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007, the Department will issue a pharmacy license.~~

~~8-005.02B2 When the Department finds that the provisional licensee does not fully comply with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007 but the nature of the violations do not create an imminent danger of death or serious physical harm to the patients of the pharmacy and no direct or immediate adverse effect to the safety or security of the drugs, devices, and biologicals, the Department may send to the pharmacy a letter requesting that a statement of compliance be submitted. The letter will include:~~

~~1. A description of each violation;~~
~~2. A request that the pharmacy submit a statement of compliance within 10 working days; and~~
~~3. A notice that the Department may take further steps if the statement of compliance is not submitted.~~

~~8-005.02B3 The statement of compliance submitted by a pharmacy must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:~~

~~1. If the pharmacy submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department may:~~

~~a. Allow the pharmacy to continue practice under the provisional pharmacy license; or~~
~~b. Issue a pharmacy license.~~

~~2. If the pharmacy fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may:~~

~~a. Deny a pharmacy license; and~~
~~b. Initiate disciplinary action against the provisional pharmacy license.~~

~~8-005.02B4 When the Department finds the applicant fails to meet the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny a pharmacy license and revoke the provisional pharmacy license.~~

~~8-005.03 Pharmacy Quality Assurance Report: All pharmacies must ensure that the pharmacist-in-charge annually submits a completed Pharmacy Quality Assurance Report on a form made available by the Department, electronically or upon request, within 30 days of the due date of the report, as specified in 175 NAC 8-005.03C.~~

~~8-005.03A This report must provide information on the following:~~

1. ~~Adequate security;~~
2. ~~Proper environmental controls;~~
3. ~~Appropriate cleanliness and sanitation;~~
4. ~~Reference requirements are met;~~
5. ~~Poison control phone number is posted;~~
6. ~~Required equipment is available;~~
7. ~~A verbal offer to counsel the patient or the patient's caregiver is being made;~~
8. ~~Documentation of refusal of patient counseling exists;~~
9. ~~Only pharmacists or pharmacist interns are providing patient counseling;~~
10. ~~Prospective drug utilization review is being conducted;~~
11. ~~Record keeping requirements have been met;~~
12. ~~Computer back up, if applicable, has been completed;~~
13. ~~Outdated inventory is segregated from stock that is intended to be sold or dispensed and is stored in such a manner as to prevent it from being sold or dispensed;~~
14. ~~Misbranded or adulterated inventory is segregated from stock that is intended to be sold or dispensed and is stored in such a manner as to prevent it from being sold or dispensed;~~
15. ~~Unit-dose labels meet requirements, if applicable;~~
16. ~~Controlled substances inventory records are complete and accurate;~~
17. ~~A copy of the biennial inventory and other required inventories was sent to the Department, when applicable;~~
18. ~~All D.E.A. Forms 222 are properly completed;~~
19. ~~All controlled substance Schedule II invoices are properly maintained;~~
20. ~~All controlled substance Schedule III-V invoices are properly maintained;~~
21. ~~All controlled substances are properly stored;~~
22. ~~All controlled substance transfers between registrants have been properly recorded;~~
23. ~~Date of issuance is recorded on all prescriptions;~~
24. ~~Date of initial filling on all prescriptions;~~
25. ~~All prescriptions bear the name of the patient;~~
26. ~~All controlled substance prescriptions contain the patient's address;~~
27. ~~All prescriptions contain the name of the prescriber and if written, the prescriber's signature in indelible ink or indelible pencil and contain the name of the prescriber either stamped, typed or clearly handwritten;~~
28. ~~All controlled substance prescriptions contain the prescriber's address,~~
29. ~~All controlled substance prescriptions contain the D.E.A. number of the prescriber;~~

30. All prescriptions contain the name, strength and quantity of medication dispensed;
31. Compliance with refill requirements;
32. All prescriptions contain directions for use by the patient or caregiver;
33. Partial fillings are properly recorded and dispensed appropriately;
34. All dispensed prescriptions for a controlled substance Schedule II are signed and dated on the face of the written prescription by the pharmacist or pharmacist intern;
35. All emergency controlled substance Schedule II authorizations are properly recorded;
36. Facsimile or electronic transmission requirements are followed;
37. All prescriptions are checked for correct interpretation and filling;
38. All prescription containers are properly labeled;
39. All inventory labels meet the requirements;
40. An original hard copy is on file for all controlled substance Schedule II prescriptions, except when otherwise allowed by the Uniform Controlled Substances Act;
41. Compliance with the Drug Product Selection Act;
42. All initial prescription fillings and refills are dated, initialed, and documented;
43. Proper prescription filing system is used and maintained;
44. Proper records for emergency drug boxes are maintained, if applicable,
45. Approved written control procedures and guidelines for the use of pharmacy technicians are followed;
46. Controlled substance Power-of-Attorney forms are complete and appropriately filed, if applicable; and
47. All information supplied on the application for a pharmacy license pursuant to 175 NAC 8-003.01A item 3.m. is complied with.

8-005.03B This report must be accompanied by a signed statement from the pharmacist-in-charge verifying that all information in the Pharmacy Quality Assurance Report is accurate, complete, correct, and in compliance with 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007.

8-005.03C The Pharmacy Quality Assurance Report is due one year from the date of the initial on-site inspection, and annually thereafter.

8-005.03D Department Responsibilities: The Department will review the Pharmacy Quality Assurance Report within 20 working days after the report is submitted to determine whether the pharmacy:

1. Is providing the services and is operating in a manner that is consistent with the information provided in the application for a pharmacy license and any amendments thereto.
2. Is being operated in compliance with the Health Care Facilities Licensure Act and these regulations.

8-005.04 Annual Inspection: After April 1, 2002, all pharmacies are subject to an annual inspection to determine whether a pharmacy fully complies with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007. The inspection may occur by a self-inspection or by an on-site inspection.

8-005.04A Self-Inspection: The Pharmacy Quality Assurance Report will fulfill the annual inspection requirement when the Department determines that the report indicates that the pharmacy is in full compliance with the Health Care Facilities Licensure Act and these regulations. However, the report will not fulfill the annual inspection requirement when:

1. The Department has determined, based on the review of the Pharmacy Quality Assurance Report, that the pharmacy is not in compliance with the Health Care Facilities Licensure Act or these regulations;
2. The pharmacy failed to be in full compliance with the regulations at the time of its last inspection;
3. The pharmacy failed to submit a Pharmacy Quality Assurance Report;
4. The pharmacy is randomly selected as part of the 25% of licensed pharmacies chosen for inspection; or
5. Five years have elapsed since the pharmacy was subjected to an on-site inspection.

8-005.04B On-site Inspection: When the Department determines, based upon the criteria specified in 175 NAC 8-005.04A, that the Pharmacy Quality Assurance Report does not fulfill the annual inspection requirement, a pharmacy inspector will conduct an on on-site inspection to determine compliance with the Health Care Facilities Licensure Act and these regulations.

8-005.04C Results of Annual Inspections

8-005.04C1 When the Department finds that the pharmacy fully complies with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007, the Department will notify the pharmacy of its compliance within 30 days after the inspection.

8-005.04C2 When the Department finds that the licensee does not fully comply with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007, but the nature of the violations do not create an imminent danger of death or serious physical harm to the clients of the pharmacy and no direct or immediate adverse effect to the safety or security of the drugs, devices, and biologicals, the Department may send to the pharmacy a letter requesting that a statement of compliance be submitted. The letter will include:

1. A description of each violation;
2. A request that the pharmacy submit a statement of compliance within 10 working days; and

3. A notice that the Department may take further steps if the statement of compliance is not submitted.

8-005.04C3 The statement of compliance submitted by a pharmacy must indicate any steps that have been or will be taken to correct each violation and the estimated time when each correction will be completed. Based on the statement of compliance, the Department will take one of the following actions:

1. If the pharmacy submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will notify the licensee of the acceptance of the statement of compliance; or
2. If the pharmacy fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may initiate disciplinary action against the pharmacy license.

8-005.04C4 When the Department finds that the pharmacy fails to meet the requirements of 175 NAC 8-006 and 8-007, and the failure(s) would create an imminent danger of death or serious physical harm, the Department will revoke the pharmacy license.

8-005.05 Re-inspections

8-005.05A The Department may conduct re-inspections to determine if a pharmacy fully complies with the requirements of 175 NAC 8-006 and 8-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance for cited violations.

8-005.05B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 8-008.02; or
4. Grant full reinstatement of the license.

8-005.06 Compliance Inspections: The Department may, following the initial licensure of a pharmacy, conduct an unannounced on-site inspection at any time it deems necessary to determine compliance with 174 NAC 8-006 and 8-007. The inspection may occur based on random selection or focused selection.

~~8-005.06A Random Selection: Each year the Department may inspect up to 25% of the pharmacies based on a random selection of pharmacies.~~

~~8-005.06B Focused Selection: The Department may inspect a pharmacy when the Department is informed of one or more of the following:~~

~~1. An accident or natural disaster resulting in damage to the physical plant; or interruption of utility services which could result in adverse effects to the potency, efficacy, safety or security of the drugs, devices and biologicals;~~
~~2. A complaint alleging violation of the Health Care Facility Licensure Act or these regulations;~~
~~3. A complaint that raises concern about the maintenance, operation, or management of the pharmacy;~~
~~4. Financial instability of the licensee or of the licensee's parent company;~~
~~5. Change of: scope or type of services offered, management or location;~~
~~6. Failure to submit a Pharmacy Quality Assurance Report within 30 days of the due date;~~
~~7. Submitting incomplete or questionable answers on the Pharmacy Quality Assurance Report;~~
~~8. Any other event that raises concerns about the maintenance, operation, or management of the pharmacy.~~

~~8-006.~~ STANDARDS FOR THE OPERATION OF A PHARMACY.~~:~~ ~~The pharmacy must operate in accordance with the services as specified on the application for a pharmacy license or amendments thereto.~~ The licensee must comply with the Prescription Drug Safety Act, the Pharmacy Practice Act, the Controlled Substances Act, and the following:

~~8-~~006.01 STAFFING.~~ Staffing Requirements:~~ Each licensee must have a pharmacist in charge or practitioner with the qualifications, training, and skills necessary to meet the requirements according to this chapter.~~Each pharmacy must maintain a sufficient number of staff with the qualifications, training, and skills necessary to meet patient needs. The pharmacy must ensure that the staff hired meets the following requirements:~~

~~8-~~006.01(A) LICENSED PHARMACIST. Each licensee must employ a sufficient number of licensed pharmacists to meet the needs of the individuals seeking services at the pharmacy.~~Pharmacists hired by the pharmacy must have a pharmacist license on active status in accordance with 172 NAC 128.~~

~~8-006.01A1 A pharmacy must not coerce or attempt to coerce a pharmacist:~~

~~1. To dispense a prescription drug or device against the professional judgment of the pharmacist or as ordered by the prescribing practitioner;~~
~~2. To enter into a delegating dispensing agreement; or~~
~~3. To supervise any pharmacy technician for any purpose or in any manner contrary to the professional judgment of the pharmacist.~~

~~8-006.01B The pharmacy must have a pharmacist-in-charge and must ensure that the pharmacist-in-charge has the qualifications, training, and skills necessary to meet the requirements according to these regulations.~~

~~8-006.01C The pharmacy may employ pharmacist interns who must practice in accordance with 172 NAC 128-011.~~

~~8-006.01D The pharmacy may employ pharmacy technicians. Prior to the use of pharmacy technicians in a pharmacy, a copy of the pharmacy's written control procedures and guidelines must be submitted to the Department and these guidelines must be approved by the Board. The original, approved, written control procedures and guidelines and any approved amendments must be retained at the pharmacy. The written control procedures and guidelines, for the use of pharmacy technicians must contain the following information:~~

~~1. Name, street address, and telephone number of the pharmacy;~~
~~2. Name and Nebraska license number of the pharmacist-in-charge;~~
~~3. Means used by the pharmacy to determine that pharmacy technicians are at least 18 years of age;~~
~~4. Means used by the pharmacy to determine that pharmacy technicians have met the educational requirements of a high school diploma or G.E.D.;~~
~~5. Means used by the pharmacy to determine that pharmacy technicians have never been convicted of any drug-related misdemeanor or felony;~~
~~6. Means used by the pharmacy to provide training, on-site in the pharmacy, by a pharmacist, within the first month of employment of a pharmacy technician, on all components required by law;~~
~~7. Means used to document training of pharmacy technicians;~~
~~8. Means used by the pharmacy to confirm that pharmacy technicians have achieved a basic level of competency following training;~~
~~9. Maximum ratio of pharmacy technicians to one pharmacist working in the pharmacy at any time;~~
~~10. Method used by the pharmacy to supervise pharmacy technicians;~~
~~11. Tasks and functions which pharmacy technicians are allowed to perform in the pharmacy;~~
~~12. Method used by the pharmacy to assure that pharmacy technicians do NOT perform any task or function, which requires professional judgment;~~
~~13. Method of documentation used by the pharmacy to show that all drugs, devices, or biologicals dispensed with the assistance of a pharmacy technician conform to the order that authorized the drug, device, or biological to be dispensed;~~
~~14. Method of documentation used by the pharmacy to show that all acts, tasks and functions performed by pharmacy technicians are verified by a pharmacist as being accurate and complete;~~
~~15. Method used to identify pharmacy technicians while on duty; and~~
~~16. A notarized, signed statement from the pharmacist-in-charge verifying that all information in the application is correct.~~

~~8-~~006.02 STORAGE REQUIREMENTS. All drugs, medical devices, and biologicals must be stored in a manner that meets the manufacturer's labeled requirements or those listed in this chapter.

~~8-~~006.02(A) TEMPERATURE AND LABEL REQUIREMENTS. The licensee~~pharmacy~~ must provide equipment for the storage of drugs, devices, and biologicals at the proper temperature:

(i)~~1.~~Drugs, devices, or biologicals requiring refrigeration must be stored between 36 and 46 degrees Fahrenheit~~.~~;

(ii)~~2.~~Drugs, devices, or biologicals requiring a freezer must be stored between -13~~-4~~ and 14 degrees Fahrenheit~~.~~;

(1) For drugs, devices, or biologicals requiring a storage temp under -4 degrees Fahrenheit the temperature of the storage location must be within plus or minus 10 degrees;

(iii)~~3.~~Drugs, devices, or biologicals requiring storage in a cool place must be stored between 46 and 59 degrees Fahrenheit, or under refrigeration, between 36 and 46 degrees Fahrenheit, unless otherwise specified~~.~~;

(iv)~~4.~~Drugs, devices, or biologicals requiring storage at controlled room temperature must be stored between 68~~59~~ and 77~~86~~ degrees Fahrenheit~~.~~; and

(v)~~5.~~Other labeled storage instruction for drugs, devices, or biologicals must be followed.

~~8-~~006.02(B) SEPARATE STORAGE. Drugs, devices, and biologicals, dietary supplements or substances used in compounding cannot be stored in the same refrigerator as food. ~~stored in a refrigerator must be kept in a separate compartment from food.~~

006.02(C) MISBRANDED OR ADULTERATED DRUG STORAGE. All drugs which are misbranded or adulterated shall not be stored with saleable inventory.

~~8-006.02C The prescription inventory and prescription records of the pharmacy must be maintained in a secure location when there is no pharmacist on the premises. Loss of prescription inventory or prescription records due to theft or any other cause resulting from failure to secure the inventory or records are grounds for disciplinary action.~~

~~8-006.02D The pharmacy must not have in its dispensable inventory any drug, device, or biological which is misbranded or adulterated.~~

~~8-006.03 Record Keeping Requirements~~007. RECORD KEEPING REQUIREMENTS. Complete and accurate records must be maintained as set out in Title 21 of the Code of Federal Regulations, Part 1304 and Part 1306, and this chapter.

~~8-006.03A All pharmacies must maintain the following records:~~

~~1. All pharmacies which use electronic record keeping systems must comply with the non-inventory record keeping requirements set out in Title 21 of~~

the Code of Federal Regulations, Part 1304 and Part 1306, which are attached to these regulations and incorporated by this reference.

2. All pharmacies, which use a central record keeping system, must comply with all record keeping requirements set out in Title 21 of the Code of Federal Regulations, Part 1304, which are attached to these regulations and incorporated by this reference.
3. All pharmacies, which handle controlled substances, must keep complete and accurate records of receipt and disposition of all controlled substances accepted into inventory.
4. All pharmacies must keep accurate and complete records of dispensed drugs, devices, and biologicals returned to the dispensing pharmacy for immediate destruction by a pharmacist.
5. Both pharmacies involved in central filling must keep complete and accurate records of the receipt and disposition of drugs, devices, or biologicals, including but not limited to:

   a. Name of the pharmacist filling or refilling the prescription;
   b. Name of the pharmacy filling or refilling the prescription; and
   c. Name of the pharmacy that dispensed the prescription.

6. Any record, which contains privileged and confidential patient information, must be stored, secured, and disposed of in a manner that ensures confidentiality.
7. A copy of the documents used to determine the qualifications of a pharmacy technician as required in 175 NAC 8-006.01D items 3-5.

8-006.03A1 Prescription Files

1. Original hard copies of all dispensed prescriptions must be filed, in numeric order, in a three-file system as follows:

   a One file for controlled substance prescriptions in Schedule II;
   b. One file for controlled substance prescriptions in Schedules III, IV, and V; and
   c. One file for all other dispensed prescriptions.

2. Original hard copies of all dispensed prescriptions must include the following information:

   a. All information required for prescriptions as set forth in 175 NAC 8-006.04B;
   b. Prescription serial number;
   c. Date of initial filling;
   d. Quantity dispensed;
   e. If an emergency verbal Schedule II controlled substance prescription, “authorization for emergency dispensing” must appear on the face of the prescription; and

f. If a Schedule II controlled substance prescription, the pharmacist or practitioner filling the prescription must write the date of filling and his/her own signature on the face of the prescription.

3. Original hard copies of all prescriptions dispensed must be maintained by the pharmacy for five years from the date of dispensing.

8-006.04 Dispensing Requirements

8-006.04A An automatic or vending machine, as found in Neb. Rev. Stat. § 71-1,147.15, is a mechanical device or process which does not have a pharmacist verifying the final product prior to presentation to the patient or caregiver. These regulations do not prohibit the use of mechanized counting machines, robotics, or other mechanical devices in the process of filling prescriptions. These regulations prohibit the use of these machines when there is no verification by a pharmacist.

8-006.04A1 When a pharmacy utilizes an automatic counting machine to assist a pharmacist in dispensing drugs documentation as to type of equipment, serial numbers, and policies and procedures for system operation must be maintained on-site in the Pharmacy for review by the Board of Pharmacy. Systematic documentation must be established to assure:

1. All controlled substances dispensed using this system are accounted for;
2. Drugs are maintained in a clean and sanitary environment and stored in accordance with current USP standards and in accordance with manufacturer labeling;
3. Drug dispensed are tracked by lot number and expiration date; and
4. Cassettes used in the counting machine, if any, are labeled with the following:

a. Name of drug;
b. Strength of the drug, if applicable;
c. Dosage form of the drug; and
d. The lesser of manufacturer's expiration date or expiration date of one year from transfer of drug to cassette

8-006.04A2 Pharmacies must maintain records with complete and accurate information of the following:

1. Date of transfer of the drug from the original container to the cassette;
2. Drug name, strength, dosage form, and quantity;
3. Manufacturer, distributor, or packager name;
4. Manufacturer, distributor, or packager lot number;

5. Manufacturer, distributor, or packager expiration date; and
6. Name and signature of person performing the transfer.

a. If the person loading the cassette is not a pharmacist, the responsible pharmacist must co-sign the records, verifying all drug transfer information is complete and accurate; and
b. If the drug being transferred is a controlled substance, two signatures must appear in the records verifying the transfer.

7. Verification that the central delivery chute and drug cassettes are kept in a clean manner according to manufacturer's recommendations and the method and substances used to clean these items; and
8. Quarterly documentation, which verifies actual count, by a pharmacist, against the machine for controlled substances dispensed from the cassettes in the quantity most commonly dispensed.

8-006.04A3 The expiration date for drugs transferred to cassettes must be the expiration date as determined by the manufacturer/distributor or a maximum of one year from the date of transfer, whichever is shorter. In the event that a cassette holds products containing drugs reflecting different lot numbers and expiration dates, the shortest expiration date will apply.

8-006.04A4 In the event of a FDA or State ordered Class I or Class II recall, all affected drugs must be recalled and removed from commerce. In the event that a cassette holds products from multiple lot numbers, all dosage units remaining in the container must be removed from commerce.

8-006.04A5 When specially calibrated cassettes are used, any changes occurring in the drug strength, or the drug manufacturer, distributor, or packager will require the acquisition of a new calibrated cassette or die from the manufacturer or distributor of the automatic counting machine.

8-006.04A6 Schedule II controlled substances cannot be transferred into or dispensed from automatic counting machines.

8-006.04B A prescription must contain the following information prior to being filled at a pharmacy:

1. Patient's name or if the patient is non-human, the name of the owner and species of the animal;
2. Name of the drug, device, or biological;
3. Strength of the drug or biological, if applicable;
4. Dosage form of the drug or biological, if applicable;
5. Quantity of drug, device, or biological prescribed;
6. Directions for use;

7. Date of issuance;
8. Prescriber's name and the name of the supervising or collaborating physician, when applicable;
9. Number of authorized refills; and

a. When the refill designation on the prescription is prn or Pro re nata, such designation, unless otherwise limited, means:

(1) If a prescription for a controlled substance in Schedules III-V, refill five times in the six months from the date of issuance, or
(2) If a prescription for a non-controlled drug, device or biological, refill for 12 months from the date of issuance.
(3) Controlled Substances in Schedule II cannot be refilled and a refill designation on a prescription for a controlled substance in Schedule II has no meaning.

10. If the prescription is for a controlled substance, the following additional information is required to be on the prescription:

a. Patient's address,
b. Prescriber's address, and
c. Prescriber's D.E.A. registration number.

8-006.04C Unit-Dose is a Packaging System

1. That contains individual sealed doses of a drug;
2. That may or may not attach the sealed doses to each other by placement in a card or other container;
3. Where the container may not contain doses for a period of greater than 14 days; and
4. That is non-reusable.

8-006.04D Unit-Dose Containers: Unit-dose containers returned to the dispensing pharmacy, from a long term care facility, for credit, must have a lot number and expiration date/calculated expiration date.

1. The calculated expiration date is used when the drug has been repackaged by the pharmacist into a unit-dose packaging system and is 25% of the remaining time between the date of repackaging and the manufacturer's or distributor's expiration date or six months from the date of packaging, whichever is less.
2. Lot number is the lot number assigned by the manufacturer, distributor, or packager.

8-006.04E In order for a pharmacy to accept the return of tablets or capsules from a long term care facility, these tablets and capsules must be packaged in a unit-dose container meeting the following requirements:

1. Unit-dose containers must meet the Class A or Class B guidelines for single-unit containers and unit-dose containers for capsules and tablets as set forth by the United States Pharmacopoeia.

2. Manufacturers, distributors or pharmacists wishing to use a unit-dose packaging system must present certified, scientific data demonstrating compliance with the Class A or Class B guidelines for moisture permeability as required by the United States Pharmacopoeia.

3. A new certificate of moisture impermeability is required when changes are made in the product. These changes may include, but are not limited to changes in:

   a. Adhesives;
   b. Plastics; or
   c. Cardboard formulation.

4. Only containers, which meet the following tamper-evident requirements and are approved by the Board, are considered to be returnable unit-dose containers:

   a. The package has an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to the health care practitioner that tampering has occurred.
   b. To reduce the likelihood of substitution of a tamper-evident feature after tampering, the indicator or barrier to entry is required to be distinctive by design or by the use of an identifying characteristic. "Distinctive by design" means that the packaging cannot be duplicated or replaced with readily available materials or through commonly available processes.
   c. A tamper-evident package may involve an immediate-container and closure system or a secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity.
   d. The tamper-evident feature must be designed to be and must remain intact when handled in a reasonable manner during dispensing to and storage at a long-term care facility.
   e. The tamper-evident feature is destroyed or rendered useless after the container is opened.

5. The return to the pharmacy of controlled substances, halved tablets, other broken dosage forms, and extemporaneously compounded tablets and capsules is prohibited.

8-006.04F Prescription Label: The pharmacy must provide equipment that allows for a legible prescription label to be affixed to the container prior to dispensing a drug, device or biological. The prescription label must contain the following information:

1. Name, address, and telephone number of the dispensing pharmacy and the central filling pharmacy, if central fill is used;
2. Serial number of the prescription;
3. Name of the drug, device, or biological, unless instructed to omit by the prescriber;
4. Strength of the drug or biological, if applicable;
5. Directions for use;
6. Quantity of drug, device, or biological in the container; except for unit-dose containers;
7. Any cautionary statements contained in the prescription;
8. Name of the patient or if the patient is non-human, the name of the owner and species of the animal;
9. Name of the prescriber,

    a. If prescribed by a physician assistant, both the name of the physician assistant and the name of the supervising physician must appear on the label. (Neb. Rev. Stat. § 71-1,107.30);

10. Dosage form of the drug or biological if applicable; and
11. Date of filling.

8-006.04G Prescription Labels for Multi-Drug Containers: The pharmacy may allow for the dispensing of more than one drug, device or biological in the same container only when:

1. Such container is prepackaged by the manufacturer, packager, or distributor and shipped directly to the pharmacy in this manner; or
2. Each drug or biological product is individually wrapped or hermetically sealed by either the pharmacist, dispensing medical practitioner, manufacturer, packager, or distributor; or
3. The container does not accommodate greater than a 31-day supply of compatible dosage units and is labeled so as to identify each drug or biological in the container in addition to all information required in 175 NAC 8-006.04F.

8-006.04H Patient Counseling: The pharmacy must provide the necessary resources for patient counseling to occur, including but not limited to, sufficient time and space. The pharmacy must only allow a pharmacist or a pharmacist intern to provide patient counseling, except as provided in Neb. Rev. Stat. § 71-1,147.35.

8-006.04H1 A verbal offer to counsel must be provided to the:

1. Patient, or
2. Patient's caregiver.

8-006.04H2 Patient counseling must occur, unless one of the following is documented:

1. Drug, device, or biological is being administered by a health care professional credentialed by the Department to a resident of a hospital or a long term care facility;
2. Patient or caregiver refuses to be counseled;
3. Pharmacist, in his/her professional judgment, determines that counseling could harm or injure the patient; or
4. Prescriber designates "contact before counseling" or words of similar import on the prescription. In this instance, the pharmacist must contact the prescriber prior to counseling and may use his/her professional judgment regarding counseling following consultation with the prescriber.

8-006.04I Drug Product Selection: The employer or such employer's agent may not restrict a pharmacist from choosing to dispense, without the duly licensed prescriber's express authorization, a chemically equivalent and bioequivalent drug product in place of the drug product ordered or prescribed.

8-006.05 Controlled Substance Requirements: A pharmacy that dispenses controlled substances must meet the following storage and inventory requirements.

8-006.05A Controlled Substance Storage

8-006.05A1 The pharmacy must store Schedule II, III, IV, and V controlled substances:

1. In a locked cabinet; or
2. Distributed throughout the inventory of non-controlled substances in a manner, which will obstruct theft or diversion of the controlled substances.

8-006.05A2 The pharmacy must store all Schedule I controlled substances in a locked cabinet.

8-006.05B Controlled Substance Record Keeping

8-006.05B1 Each pharmacy registered with the D.E.A. to handle controlled substances must complete an initial inventory on the date that s/he first engages in controlled substances activities. The information to be included on this inventory includes:

1. Name, address, and D.E.A. registration number of the registrant;
2. Date and time the inventory was taken, or last prescription number filled prior to taking the inventory to use as a reference point;
3. Whether the inventory was conducted at the opening or closing of business, when applicable; and
4. Signature of the person or persons responsible for taking the inventory.

~~The original copy of the initial inventory must be maintained in the pharmacy, for five years.~~

~~8-006.05C Controlled Substance Inventory~~

~~8-006.05C1 Each pharmacy registered with the D.E.A. to handle controlled substances must complete a biennial inventory in odd numbered years within 24 months of the previous biennial inventory date. The information to be included on this inventory includes:~~

1. ~~Name, address, and D.E.A. registration number of the registrant;~~
2. ~~Date and time or last prescription number filled prior to the inventory being taken, for a reference point;~~
3. ~~Whether the inventory was conducted at the opening or closing of business, when applicable; and~~
4. ~~Signature of the person or persons responsible for taking the inventory.~~

~~The original copy of the biennial inventory must be maintained in the pharmacy for five years.~~

~~8-006.05C2 Each pharmacy registered with the D.E.A. to handle controlled substances must complete a controlled substances inventory whenever there is a change in the pharmacist-in-charge. Such inventory must contain all information required in the biennial inventory and the original copy of this inventory must be maintained in the pharmacy for five years.~~

~~8-006.05C3 Each inventory of controlled substances must contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.~~

~~8-006.05C4 A copy of the initial controlled substances inventory, biennial controlled substances inventory, or a controlled substances inventory taken pursuant to a change in the pharmacist-in-charge must be forwarded to the Department, within 30 days after completion.~~

~~8-006.05C5 When taking an inventory of controlled substances:~~

1. ~~An exact count or measurement of all controlled substances listed~~ in Schedule I or II must be made;
2. ~~An estimated count or measurement of all controlled substances listed in Schedules III, IV, or V may be made if the container holds 1,000 or fewer tablets or capsules;~~
3. ~~An exact count of all controlled substances listed in Schedules III, IV, or V must be made if the container holds greater than 1,000 tablets or capsules;~~
4. ~~All controlled substances, which are damaged, defective, or impure,~~

must be included in the inventory;

5. All controlled substances awaiting return or destruction must be included in the inventory;
6. All controlled substances used in compounding must be included in the inventory;
7. Schedule II controlled substances must be listed separately from controlled substances in Schedules III, IV, and V; and
8. The inventory must include the name and strength of each controlled substance, the finished form of the substance, and the number of units or volume of each controlled substance.
9. If a drug or device, that has not been previously controlled is placed into one of the controlled substance schedules, the drug or device must be inventoried as of the effective date of scheduling and this inventory should be stored with the biennial inventory records.
10. If a drug or device changes schedules or is de-scheduled, the drug or device must be inventoried as of the effective date of the change and this inventory should be stored with the biennial inventory records.

8-006.05C6 The owner of any stock of controlled substances listed in Neb. Rev. Stat. § 28-405, when the need for these substances ceases, may:

1. When the owner is a registrant:

   a. Transfer controlled substances listed in Schedule I or II to another registrant, but only on a D.E.A. Form-222 as required by Neb. Rev. Stat. § 28-413;
   b. Transfer controlled substances listed in Schedule III, IV, or V to another registrant, but only in accordance with subsection (4) of Neb. Rev. Stat. § 28-411;
   c. Maintain the controlled substances separate from inventory for destruction by a pharmacy inspector, by a reverse distributor, or by the federal D.E.A. to be documented on a D.E.A. Form-41 or on an equivalent form supplied by the Department; and
   d. Comply with the requirements for disposal of controlled substances set out in Title 21 of the Code of Federal Regulations, Part 1307.21 and Part 1307.22, which are attached to these regulations and incorporated by this reference.

2. When the owner is a patient:

   a. Present the controlled substance to a pharmacy for immediate destruction by two responsible parties acting on behalf of the patient, one of whom must be licensed to practice an healing art;

~~b. Who is a resident of a long term care facility or hospital, the long term care facility or hospital must assure that these controlled substances are destroyed as follows:~~

~~(1) If the controlled substance is listed in Schedule II or III of Neb. Rev. Stat. § 28-405, the destruction must be witnessed by an employee pharmacist or a consultant pharmacist and a member of the healing arts; or~~
~~(2) If the controlled substance is listed in Schedule IV or V of Neb. Rev. Stat. § 28-405, the destruction must be witnessed by an employee pharmacist or a consultant pharmacist and another responsible adult.~~

~~3. Complete records of controlled substances destruction must be maintained by the pharmacy, hospital, or long term care facility for five years from the date of destruction.~~

~~8-006.05D Controlled Substance Dispensing Requirement for Emergency Situations: For the purpose of authorizing an emergency prescription of a controlled substance listed in Schedule II of Neb. Rev. Stat. § 28-405, the term emergency situation means those situations in which the prescriber determines:~~

~~1. That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and~~
~~2. That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance listed in Schedule II, and~~
~~3. That it is not reasonably possible for the prescriber to provide a signed, written prescription to be presented to the person dispensing the substance, prior to dispensing.~~

~~8-006.06 Radiopharmaceutical Requirements~~

~~8-006.06A In addition to the preceding requirements, any pharmacy providing radiopharmaceutical services must comply with the regulations set forth in Neb. Rev. Stat. §§ 71-3515.01 to 71-3515.02 and the regulations promulgated thereunder.~~

007.01 SECURE RECORDS. The prescription inventory and prescription records of the pharmacy must be maintained in a secure location when there is no pharmacist or practitioner on the premises.

~~8-006.07 Disaster Preparedness and Management:~~007.02 DISASTER PREPAREDNESS AND MANAGEMENT. The ~~pharmacy~~ licensee must have~~establish~~ and implement disaster preparedness plans and procedures to protect the potency, efficacy, safety, and security of the drugs, devices, or biologicals in the pharmacy in instances of natural ~~(tornado, flood, etc.)~~ or other disasters, disease outbreaks, interruption of utility services, or other similar situations. Such plans and procedures must address how the licensee will~~and delineate~~:

(A)~~1.How the pharmacy will~~ P~~p~~rovide for the storage of drugs, devices, and biologicals at the proper temperature;

(B)~~2.How the pharmacy will~~ P~~p~~rovide for the disposal of drugs, devices, and biologicals if the pharmacy determines their potency, efficacy, or safety has been adversely affected;

(C)~~3.How the pharmacy will~~ S~~s~~ecure the drugs, devices, and biologicals from the public; and

(D)~~4.How the pharmacy will~~ M~~m~~aintain patient records and inventory records.

~~8-007~~8. PHYSICAL PLANT STANDARDS. A licensee must meet the requirements set out in this chapter.

~~8-008~~7.01 ACCESS BY PHARMACIST. The licensee~~pharmacy~~ must provide the pharmacist access to all equipment, facilities, and utilities appropriate for the accurate, efficient, and safe provision of the clinical services available in that pharmacy.

~~8-008~~7.02 CONDITIONS. The licensee~~pharmacy~~ must assure~~maintain~~ the prescription department, including shelving, counters, floor, inventory, fixtures, equipment, and utensils are maintained in a clean, orderly, and sanitary manner that supports the scope of pharmacy services provided at the site.

~~8-008~~7.03 REFERENCE MATERIAL. The licensee~~pharmacy~~ must provide the pharmacist access to all reference material appropriate for the accurate, efficient, and safe practice of pharmacy~~ or any specialty practice of pharmacy in the facility~~. These reference~~s~~ materials must be up-to date, in either printed or electronic form, and available at all times while the pharmacist is practicing for that pharmacy.

~~8-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION~~

~~8-008.01 Grounds for Denial, Refusal to Renew or Disciplinary Action~~

~~8-008.01A The Department may deny or refuse to renew a pharmacy license for failure to meet the requirements for licensure, including:~~

~~1. Failing an inspection specified in 175 NAC 8-005;~~
~~2. Failing to meet a compliance assessment standard adopted under Neb. Rev. Stat. § 71-442 as specified in 175 NAC 8-005.04A;~~
~~3. Having had a license revoked within the two-year period preceding an application; or~~
~~4. Any of the grounds specified in 175 NAC 8-008.01B.~~

~~8-008.01B The Department may take disciplinary action against a provisional pharmacy license or a pharmacy license for any of the following grounds:~~

~~1. Violation of any of the provisions of the Health Care Facility Licensure Act, or these regulations;~~

2. Committing or permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a pharmacy patient or employee;
4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the health care facility or health care service;
5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the pharmacy for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of these departments;
6. Discrimination or retaliation against a pharmacy patient or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;
7. Discrimination or retaliation against a pharmacy patient or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the hospital for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
9. Violation of the Emergency Box Drug Act;
10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;
11. Violation of the Medication Aide Act;
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711; or
13. Failure to account for significant, substantial shortages or overages of controlled substances.

8-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

8-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee, by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

8-008.02B The denial, refusal to renew, or disciplinary action will become final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

8-008.02C Informal Conference

1. At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference will be held in person or by other means, at the request of the applicant or licensee. If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.
2. Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.
3. If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.
4. If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing within five working days after receipt of the statement.

8-008.02D Administrative Hearing

1. When an applicant or a licensee contests the notice and request a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.
2. On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

    a. Be in writing;
    b. Be sent by registered or certified mail to the applicant or licensee; and
    c. Become final 30 days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

3. An applicant or a licensee's appeal of the Director's decision will be in accordance with the APA.

8-008.03 Types of Disciplinary Action

8-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license of a pharmacy:

1. A fine not to exceed $10,000 per violation;

2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the facility or service may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the facility or service may not operate; and
5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

8-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the pharmacy in identifying or correcting the violation;
5. Any previous violations committed by the pharmacy; and
6. The financial benefit to the facility of committing or continuing the violation.

8-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 8-008.03A.

8-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that patients of the pharmacy are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the pharmacy license, effective when the order is served upon the pharmacy. If the licensee is not involved in the daily operation of the pharmacy, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent; or
2. Order the temporary closure of the pharmacy pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

1. The Department will conduct the hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and

regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

2. If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

3. On the basis of evidence presented at the hearing, the Director will:

a. Order the revocation, suspension, or limitation of the license; or
b. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

4. Any appeal of the Department's decision after hearing must be in accordance with the APA.

8-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

8-008.04A Reinstatement at the End of Probation or Suspension

8-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

8-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 8-003.02;
2. Payment of the renewal fee as specified in 175 NAC 8-004.11; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 8-005, that the pharmacy is in compliance with the operational and physical plant standards of 175 NAC 8-006 and 8-007.

8-008.04B Reinstatement Prior to Completion of Probation or Suspension

8-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:

a. The reasons why the license should be reinstated prior to the probation completion date; and
b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and

2. Successfully complete any inspection that the Department determines necessary.

8-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
a. The reasons why the license should be reinstated prior to the suspension completion date; and
b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;

2. Submit a written renewal application to the Department as specified in 175 NAC 8-003.02;
3. Pay the renewal fee as specified in 175 NAC 8-004.11; and
4. Successfully complete an inspection.

8-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

a. Grant full reinstatement of the license;
b. Modify the probation or suspension; or
c. Deny the petition for reinstatement.

8-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

8-008.04C Re-Licensure after Revocation: A pharmacy license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

8-008.04C1 A pharmacy seeking re-licensure must apply for an initial pharmacy license and meet the requirements for licensure in 175 NAC 8-003.01.

8-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 8-003.01.

Approved by the Attorney General: April 18, 2007
Approved by the Governor: April 24, 2007

~~Filed by the Secretary of State: April 24, 2007~~
~~Effective Date: April 29, 2007~~

~~ATTACHMENT~~

~~CODE OF FEDERAL REGULATIONS (CFR)~~

~~PARTS 1304 to 1307~~

~~4/1/06 EDITION~~

~~ATTACHMENT~~

~~CODE OF FEDERAL REGULATIONS (CFR)~~

~~PARTS 1304 to 1307~~

~~4/1/06 EDITION~~

(d) If any person entitled to a hearing or to participate in a hearing pursuant to paragraph (b) of this section, fails to file a request for a hearing or notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1303.37 without a hearing.

[36 FR 7786, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1303.35 Burden of proof.

(a) At any hearing regarding the determination or adjustment of an aggregate production quota, each interested person participating in the hearing shall have the burden of proving any propositions of fact or law asserted by him in the hearing.

(b) At any hearing regarding the issuance, adjustment, suspension or denial of a procurement or individual manufacturing quota, the Administration shall have the burden of proving that the requirements of this part for such issuance, adjustment, suspension, or denial are satisfied.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13958, Mar. 24, 1997]

§ 1303.36 Time and place of hearing.

(a) If any applicant or registrant requests a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota pursuant to § 1303.34, the Administrator shall hold such hearing. Notice of the hearing shall be given to the applicant or registrant of the time and place at least 30 days prior to the hearing, unless the applicant or registrant waives such notice and requests the hearing be held at an earlier time, in which case the Administrator shall fix a date for such hearing as early as reasonably possible.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section or in the notice of hearing published in the FEDERAL REGISTER pursuant to § 1303.11(c) or § 1303.13 (c), but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1303.37 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order on the determination or adjustment of the aggregate production quota or on the issuance, adjustment, suspension, or denial of the procurement quota or individual manufacturing quota, as case may be. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his order upon each party in the hearing.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

GENERAL INFORMATION

Sec.

INVENTORY REQUIREMENTS

CONTINUING RECORDS

REPORTS

AUTHORITY: 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

GENERAL INFORMATION

§ 1304.01 Scope of part 1304.

Inventory and other records and reports required under section 307 or section 1008(d) of the Act (21 U.S.C. 827 and 958(d)) shall be in accordance with, and contain the information required by, those sections and by the sections of this part.

[36 FR 7789, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1304.03 Persons required to keep records and file reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities, either pursuant to §1301.22(b) of this chapter or pursuant to §§1307.11–1307.15 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately, nor that separate records are required for each activity. The intent of the Administration is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled substances used in any activity. Also, the Administration does not wish to acquire separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled item, he must keep a record of the quantity manufactured; when he distributes a quantity of the item, he must use and keep invoices or order forms to document the transfer; when he imports a substance, he keeps as part of his records the documentation required of an importer; and when substances are used in chemical analysis, he need not keep a record of this because such a record would not be required of him under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his controlled items in one place and every two years take inventory of all items on hand, regardless of whether the substances were manufactured by him, imported by him, or purchased domestically by him, of whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.

(b) A registered individual practitioner is required to keep records, as described in §1304.04, of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by prescribing or administering in the lawful course of professional practice.

(c) A registered individual practitioner is not required to keep records of controlled substances in Schedules II, III, IV, and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.

(d) A registered individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered. Records are required to be kept for controlled substances administered in the course of maintenance or detoxification treatment of an individual.

(e) Each registered mid-level practitioner shall maintain in a readily retrievable manner those documents required by the state in which he/she practices which describe the conditions and extent of his/her authorization to dispense controlled substances and shall make such documents available for inspection and copying by authorized employees of the Administration. Examples of such documentation include protocols, practice guidelines or practice agreements.

(f) Registered persons using any controlled substances while conducting preclinical research, in teaching at a registered establishment which maintains records with respect to such substances or conducting research in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections, are not required to keep records if he/she notifies the Administration of the name, address and registration number of the establishment maintaining such records. This notification shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

(g) A distributing registrant who utilizes a freight forwarding facility shall maintain records to reflect transfer of controlled substances through the facility. These records must contain the date, time of transfer, number of cartons, crates, drums or other packages in which commercial containers of controlled substances are shipped and authorized signatures for each transfer. A distributing registrant may, as part of the initial request to operate a freight forwarding facility, request permission to store records at a central location. Approval of the request to maintain central records would be implicit in the approval of the request to operate the facility. Otherwise, a request to maintain records at a central location must be submitted in accordance with §1304.04 of this part. These records must be maintained for a period of two years.

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 50 FR 40523, Oct. 4, 1985; 51 FR 5316, Feb. 13, 1986; 51 FR 26154, July 21, 1986; 58 FR 31175, June 1, 1993; 62 FR 13958, Mar. 24, 1997; 65 FR 44679, July 19, 2000]

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§ 1305.17 and 1305.27 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

(i) The nature of the records to be kept centrally.

(ii) The exact location where the records will be kept.

(iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

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

(2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this part for those additional registered sites at the retail pharmacy or other approved central location.

(b) All registrants that are authorized to maintain a central recordkeeping system shall be subject to the following conditions:

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

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

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

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

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to: ARCOS Unit, P.O. Box 28298, Central Station, Washington, DC 20005.

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

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

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

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

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

(2) Inventories and records of controlled substances listed in Schedules

III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances. However, if a pharmacy employs an ADP system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

(Authority: 21 U.S.C. 821 and 871(b), 28 CFR 0.100)

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37985, Oct. 25, 1974; 45 FR 47556, July 1, 1980; 47 FR 41735, Sept. 22, 1982; 51 FR 5330, Feb. 13, 1986; 62 FR 13959, Mar. 24, 1997; 70 FR 25466, May 13, 2005]

§ 1304.05 Records of authorized central fill pharmacies and retail pharmacies.

(a) Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central fill pharmacies, including name, address and DEA number, that are authorized to fill prescriptions on its behalf. The retail pharmacy must also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf. These records must be made available upon request for inspection by DEA.

(b) Every central fill pharmacy must keep a record of all retail pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy must also verify the registration for all retail pharmacies for which it is authorized to fill prescriptions. These records must be made available upon request for inspection by DEA.

[68 FR 37410, June 24, 2003]

INVENTORY REQUIREMENTS

§ 1304.11 Inventory requirements.

(a) *General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or by which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) *Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable.

In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d) *Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) *Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts.* Each person registered or authorized (by § 1301.13 or §§ 1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to § 1304.03 shall include in the inventory the information listed below.

(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

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

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

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

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

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

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

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

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

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

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

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

(2) *Inventories of distributors.* Except for reverse distributors covered by paragraph (e)(3) of this section, each

person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of dispensers, researchers, and reverse distributors.* Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:

(i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents, or

(ii) If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(4) *Inventories of importers and exporters.* Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5) *Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

[62 FR 13939, Mar. 24, 1997, as amended at 68 FR 41228, July 11, 2003]

Continuing Records

§ 1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to §1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in §1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he/she is registered, except as provided in §1304.22(d).

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

any documents of transfer (e.g., invoices or packing slips).

[36 FR 7792, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13960, Mar. 24, 1997]

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

Each person registered or authorized (by §1301.13(e) or §§1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export or conduct research with controlled substances shall maintain records with the information listed below.

(a) *Records for manufacturers.* Each person registered or authorized to manufacture controlled substances shall maintain records with the following information:

(1) For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

(i) The name of the substance;

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

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

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

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

(A) The date and batch or other identifying number of each manufacture;

(B) The quantity used in the manufacture;

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

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

(E) The quantity used in quality control;

(F) The quantity lost during manufacturing and the causes therefore, if known;

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

(H) The theoretical and actual yields; and

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

(vi) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (a)(1)(v) of this section;

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

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

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

(x) The originals of all written certifications of available procurement quotas submitted by other persons (as required by §1303.12(f) of this chapter) relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

(2) For each controlled substance in finished form,

(i) The name of the substance;

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

(iii) The number of containers of each such commercial finished form

manufactured from bulk form by the registrant, including the information required pursuant to paragraph (a)(1)(ii) of this section;

(iv) The number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;

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

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

(A) The date and batch or other identifying number of each manufacture;

(B) The operation performed (e.g., repackaging or relabeling);

(C) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and

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

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

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

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

(b) *Records for distributors.* Except as provided in paragraph (c) of this section, each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

(c) *Records for dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with § 1304.26.

(d) *Records for importers and exporters.* Each person registered or authorized to import or export controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2) (i), (iv), (v) and (vii) of this section. In addition, the quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer), which quantities are to be recorded pursuant to paragraphs (a)(1)(iv) and (v) of this section; and the quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and number of units and volumes) manufactured by an exporter under a

registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to paragraphs (a)(1)(xiii) or (a)(2)(xiii) of this section.

(e) *Records for reverse distributors.* Each person registered to distribute controlled substances as a reverse distributor shall maintain records with the following information for each controlled substance:

(1) For each controlled substance in bulk form the following:

(i) The name of the controlled substance.

(ii) The total quantity of the controlled substance to the nearest metric unit weight consistent with unit size.

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

(iv) The quantity returned to the original manufacturer of the controlled substance or the manufacturer's agent, including the date of and quantity of each distribution and the name, address and registration number of the manufacturer or manufacturer's agent to whom the controlled substance was distributed.

(v) The quantity disposed of including the date and manner of disposal and the signatures of two responsible employees of the registrant who witnessed the disposal.

(2) For each controlled substance in finished form the following:

(i) The name of the substance.

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

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

(iv) The number of commercial containers of each such finished form distributed back to the original manufacturer of the substance or the manufacturer's agent, including the date of and number of containers in each distribution and the name, address, and registration number of the manufacturer or manufacturer's agent to whom the containers were distributed.

(v) The number of units or volume of finished forms and/or commercial containers disposed of including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

[62 FR 13960, Mar. 24, 1997, as amended at 68 FR 41229, July 11, 2003; 70 FR 293, Jan. 4, 2005]

§ 1304.23 Records for chemical analysis.

(a) Each person registered or authorized (by § 1301.22(b) of this chapter) to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him) for each controlled substance:

(1) The name of the substance;

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

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

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

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

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

[36 FR 7793, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated at 62 FR 13961, Mar. 24, 1997]

§ 1304.24 Records for maintenance treatment programs and detoxification treatment programs.

(a) Each person registered or authorized (by § 1301.22 of this chapter) to maintain and/or detoxify controlled substance users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

(1) Name of substance;

(2) Strength of substance;

(3) Dosage form;

(4) Date dispensed;

(5) Adequate identification of patient (consumer);

(6) Amount consumed;

(7) Amount and dosage form taken home by patient; and

(8) Dispenser's initials.

(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with § 1304.22 without reference to § 1304.03.

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

(d) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by part 310 and 42 CFR part 2.

[39 FR 37985, Oct. 25, 1974. Redesignated and amended at 62 FR 13961, Mar. 24, 1997]

§ 1304.25 Records for treatment programs which compound narcotics for treatment programs and other locations.

Each person registered or authorized by § 1301.22 of this chapter to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information for each narcotic drug:

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

(1) The name of the substance;

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

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

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

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

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

(ii) The quantity used in the compound;

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

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

(v) The quantity used in quality control;

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

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

(viii) The theoretical and actual yields; and

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

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

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

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

(9) The quantity disposed of by destruction, including the reason, date and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1307.22.

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

(1) The name of the substance;

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

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

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

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

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

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

(ii) The operation performed (e.g., repackaging or relabeling);

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

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

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

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

(9) The number of units of finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1307.22.

[39 FR 37985, Oct. 25, 1974. Redesignated at 62 FR 13961, Mar. 24, 1997]

§ 1304.26 Additional recordkeeping requirements applicable to drug products containing gamma-hydroxybutyric acid.

In addition to the recordkeeping requirements for dispensers and researchers provided in § 1304.22, practitioners dispensing gamma-hydroxybutyric acid that is manufactured or distributed in accordance with an application under section 505 of the Federal Food, Drug, and Cosmetic Act must maintain and make available for inspection and copying by the Attorney General, all of the following information for each prescription:

(a) Name of the prescribing practitioner.

(b) Prescribing practitioner's Federal and State registration numbers, with

the expiration dates of these registrations.

(c) Verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance.

(d) Patient's name and address.

(e) Patient's insurance provider, if available.

[70 FR 293, Jan. 4, 2005]

Reports

§ 1304.31 Reports from manufacturers importing narcotic raw material.

(a) Every manufacturer which imports or manufactures from narcotic raw material (opium, poppy straw, and concentrate of poppy straw) shall submit information which accounts for the importation and for all manufacturing operations performed between importation and the production in bulk or finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary or other recognized medical standards. Reports shall be signed by the authorized official and submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for each type of narcotic raw material (quantities are expressed as grams of anhydrous morphine alkaloid):

(1) Beginning inventory;
(2) Gains on reweighing;
(3) Imports;
(4) Other receipts;
(5) Quantity put into process;
(6) Losses on reweighing;
(7) Other dispositions and
(8) Ending inventory.

(c) The following information shall be submitted for each narcotic raw material derivative including morphine, codeine, thebaine, oxycodone, hydrocodone, medicinal opium, manufacturing opium, crude alkaloids and other derivatives (quantities are expressed as grams of anhydrous base or anhydrous morphine alkaloid for manufacturing opium and medicinal opium):

(1) Beginning inventory;
(2) Gains on reweighing;
(3) Quantity extracted from narcotic raw material;
(4) Quantity produced/manufactured/synthesized;
(5) Quantity sold;
(6) Quantity returned to conversion processes for reworking;
(7) Quantity used for conversion;
(8) Quantity placed in process;
(9) Other dispositions;
(10) Losses on reweighing and
(11) Ending inventory.

(d) The following information shall be submitted for importation of each narcotic raw material:

(1) Import permit number;
(2) Date shipment arrived at the United States port of entry;
(3) Actual quantity shipped;
(4) Assay (percent) of morphine, codeine and thebaine and
(5) Quantity shipped, expressed as anhydrous morphine alkaloid.

(e) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopeia. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(f) Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(g) All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

[62 FR 13961, Mar. 24, 1997]

§ 1304.32 Reports of manufacturers importing coca leaves.

(a) Every manufacturer importing or manufacturing from raw coca leaves shall submit information accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. The reports shall be submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, DC 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for raw coca leaf, ecgonine, ecgonine for conversion or further manufacture, benzoylecgonine, manufacturing coca extracts (list for tinctures and extracts; and others separately), other crude alkaloids and other derivatives (quantities should be reported as grams of actual quantity involved and the cocaine alkaloid content or equivalency):

(1) Beginning inventory;
(2) Imports;
(3) Gains on reweighing;
(4) Quantity purchased;
(5) Quantity produced;
(6) Other receipts;
(7) Quantity returned to processes for reworking;
(8) Material used in purification for sale;
(9) Material used for manufacture or production;
(10) Losses on reweighing;
(11) Material used for conversion;
(12) Other dispositions and
(13) Ending inventory.

(c) The following information shall be submitted for importation of coca leaves:

(1) Import permit number;
(2) Date the shipment arrived at the United States port of entry;
(3) Actual quantity shipped;
(4) Assay (percent) of cocaine alkaloid and
(5) Total cocaine alkaloid content.

(d) Upon importation of coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submission, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(e) Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.

(f) All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

[62 FR 13963, Mar. 24, 1997]

§ 1304.33 Reports to ARCOS.

(a) *Reports generally.* All reports required by this section shall be filed with the ARCOS Unit, PO 28293, Central Station, Washington, DC 20005 on DEA Form 333, or on media which contains the data required by DEA Form 333 and which is acceptable to the ARCOS Unit.

(b) *Frequency of reports.* Acquisition/Distribution transaction reports shall be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted; except that a registrant may be given permission to file more frequently (but not more frequently than monthly), depending on the number of transactions being reported each time by that registrant. Inventories shall provide data on the stocks of each reported controlled substance on hand as of the close of business on December 31 of each year, indicating whether the substance is in storage or in process of manufacturing. These reports shall be

filed not later than January 15 of the following year. Manufacturing transaction reports shall be filed annually for each calendar year not later than January 15 of the following year, except that a registrant may be given permission to file more frequently (but not more frequently than quarterly).

(c) *Persons reporting.* For controlled substances in Schedules I, II, narcotic controlled substances in Schedule III, and gamma-hydroxybutyric acid drug product controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute, including each person who is registered to reverse distribute, shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, gamma-hydroxybutyric acid drug product controlled substances in Schedule III, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

(d) *Substances covered.* (1) Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II, on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V), and on gamma-hydroxybutyric acid drug products listed in Schedule III. Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:

(i) Schedule III
(A) Benzphetamine;
(B) Cyclobarbital;
(C) Methyprylon; and
(D) Phendimetrazine.
(ii) Schedule IV
(A) Barbital;
(B) Diethylpropion (Amfepramone);
(C) Ethchlorvynol;
(D) Ethinamate;
(E) Lefetamine (SPA);
(F) Mazindol;
(G) Meprobamate;
(H) Methylphenobarbital;
(I) Phenobarbital;
(J) Phentermine; and
(K) Pipradrol.

(2) Data shall be presented in such a manner as to identify the particular form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.

(e) *Transactions reported.* Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies). Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use in producing dosage forms.

(f) *Exceptions.* A registered institutional practitioner who repackages or relabels exclusively for distribution or who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the ARCOS Unit of the Administration.

(Approved by the Office of Management and Budget under control number 1117–0003)

[62 FR 13962, Mar. 24, 1997, as amended at 68 FR 41229, July 11, 2003; 70 FR 294, Jan. 4, 2005]

(c) The required data fields have not been completed.

(2) The order is not signed using a digital certificate issued by DEA.

(3) The digital certificate used had expired or had been revoked prior to signature.

(4) The purchaser's public key will not validate the digital signature.

(5) The validation of the order shows that the order is invalid for any reason.

(b) If an order cannot be filled for any reason under this section, the supplier must notify the purchaser and provide a statement as to the reason (*e.g.*, improperly prepared or altered). A supplier may, for any reason, refuse to accept any order, and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(c) When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original order and the statement must be retained in accordance with § 1305.27.

(d) Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

§ 1305.26 Lost electronic orders.

(a) If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement containing the unique tracking number and date of the lost order and stating that the goods covered by the first order were not received through loss of that order.

(b) If the purchaser executes an order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them.

(c) If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is "Not Accepted" and return it to the purchaser. The purchaser must link the returned order to the record of that order and the statement.

§ 1305.27 Preservation of electronic orders.

(a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement.

(b) A supplier must retain each original order filled and the linked records for two years.

(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location.

§ 1305.28 Canceling and voiding electronic orders.

(a) A supplier may void all or part of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order, indicate on the copy "Void," and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled.

(b) The purchaser must retain an electronic copy of the voided order.

(c) To partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided.

§ 1305.29 Reporting to DEA.

A supplier must, for each electronic order filled, forward either a copy of the electronic order or an electronic report of the order in a format that DEA specifies to DEA within two business days.

PART 1306—PRESCRIPTIONS

GENERAL INFORMATION

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

AUTHORITY: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

SOURCE: 36 FR 7799, Apr. 24, 1971; 36 FR 13386, July 21, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1306.01 Scope of part 1306.

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

§ 1306.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13964, Mar. 24, 1997]

§ 1306.03 Persons entitled to issue prescriptions.

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

(1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) Either registered or exempted from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13966, Mar. 24, 1997]

§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

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

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36343, June 23, 2005]

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. In addition, a prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the Administrator under § 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of § 1301.28(e). Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (*e.g.*, J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

(b) An individual practitioner exempted from registration under § 1301.22(c) of this chapter shall include on all prescriptions issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in § 1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

(c) An official exempted from registration under § 1301.22(c) shall include on all prescriptions issued by him his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 60 FR 36644, July 18, 1995; 62 FR 13966, Mar. 24, 1997; 70 FR 36343, June, 23, 2005]

§ 1306.06 Persons entitled to fill prescriptions.

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

[68 FR 37410, June 24, 2003, as amended at 70 FR 36343, June 23, 2005]

§ 1306.07 Administering or dispensing of narcotic drugs.

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependant person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

(1) The practitioner is separately registered with DEA as a narcotic treatment program.

(2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving

acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

(d) A practitioner may administer or dispense (including prescribe) any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of §1301.28 of this chapter.

[39 FR 37986, Oct. 25, 1974, as amended at 70 FR 36344, June 23, 2005]

Controlled Substances Listed in Schedule II

§ 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with §1304.04(h) of this chapter.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to §1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in §290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

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

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §1306.05, except for the signature of the prescribing individual practitioner;

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

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of §1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered

to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

(e) A prescription prepared in accordance with § 1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with § 1304.04(h) of this chapter.

(f) A prescription prepared in accordance with § 1306.05 written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with § 1304.04(h).

(g) A prescription prepared in accordance with § 1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h).

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 53 FR 4964, Feb. 19, 1988; 59 FR 26111, May 19, 1994; 59 FR 30632, June 15, 1994; 62 FR 13964, Mar. 24, 1997; 65 FR 45713, July 25, 2000; 68 FR 37410, June 24, 2003]

§ 1306.12 Refilling prescriptions.

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

§ 1306.13 Partial filling of prescriptions.

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

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill"

or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in § 1306.13(b).

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

(3) Retrieval of partially filled Schedule II prescription information is the same as required by § 1306.22(b) (4) and (5) for Schedule III and IV prescription refill information.

(Authority: 21 U.S.C. 801, *et seq.*)

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 54330, July 15, 1980; 56 FR 25027, June 3, 1991; 62 FR 13965, Mar. 24, 1997]

§ 1306.14 Labeling of substances and filling of prescriptions.

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

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (*i.e.* the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

(c) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized: *Provided*, That:

(1) Not more than 7-day supply of the controlled substance listed in Schedule II is dispensed at one time;

(2) The controlled substance listed in Schedule II is not in the possession of the ultimate user prior to the administration;

(3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule II; and

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

(d) All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of § 1304.04(h) of this chapter.

[36 FR 13368, July 21, 1971, as amended at 37 FR 15921, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13965, Mar. 24, 1997; 68 FR 37410, June 24, 2003]

§ 1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(1) Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(2) Ensure that all information required to be on a prescription pursuant to Section 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(3) Maintain the original prescription for a period of two years from the date the prescription was filled;

(4) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist filling the prescription, and the date of filling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (*i.e.* private, common or contract carrier).

[68 FR 37410, June 24, 2003]

Controlled Substances Listed in Schedules III, IV, and V

§ 1306.21 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the practitioner.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription, subject to § 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a written prescription signed by an individual practitioner, or pursuant to a facsimile of a written prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional practitioner-pharmacist, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in Section 1306.05 except for the signature of the individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to § 1306.07.

[62 FR 13955, Mar. 24, 1997]

§ 1306.22 Refilling of prescriptions.

(a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six

months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as a medication record, the document must be uniformly maintained and readily retrievable. The following information must be retrievable by the prescription number consisting of the name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription it shall be deemed that the full face amount of the prescription has been dispensed. The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the date, quantity of refill, number of additional refills authorized, and initials the prescription showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five refill, six-month limitation.

(b) As an alternative to the procedures provided by subsection (a), an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

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

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

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J. H. Smith, or John H. Smith). This document shall be maintained in a

separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

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

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

(c) When filing refill information for original prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in paragraphs (a) or (b) of this section.

[36 FR 7799, Apr. 24, 1971; 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 42 FR 28878, June 6, 1977; 45 FR 44266, July 1, 1980; 52 FR 3605, Feb. 5, 1987; 62 FR 13966, Mar. 24, 1997]

§ 1306.23 Partial filling of prescriptions.

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

(a) Each partial filling is recorded in the same manner as a refilling,

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and

(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[36 FR 18734, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5320, Feb. 13, 1986; 62 FR 13965, Mar. 24, 1997]

§ 1306.24 Labeling of substances and filing of prescriptions.

(a) The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy

name and address and a unique identifier, (*i.e.* the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

(c) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized: Provided, That:

(1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III, IV, or V is dispensed at one time;

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

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

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

(d) All prescriptions for controlled substances listed in Schedules III, IV, and V shall be kept in accordance with §1304.04(h) of this chapter.

[62 FR 13965, Mar. 24, 1997, as amended at 68 FR 37411, June 24, 2003]

§ 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

(a) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(i) Write the word ''VOID'' on the face of the invalidated prescription.

(ii) Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(1) Write the word ''transfer'' on the face of the transferred prescription.

(2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:

(i) Date of issuance of original prescription;

(ii) Original number of refills authorized on original prescription;

(iii) Date of original dispensing;

(iv) Number of valid refills remaining and date(s) and locations of previous refill(s);

(v) Pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;

(vi) Name of pharmacist who transferred the prescription.

(vii) Pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled;

(3) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

(c) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.

(d) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing state or other applicable law.

[46 FR 48919, Oct. 5, 1981. Redesignated and amended at 62 FR 13966, Mar. 24, 1997]

§ 1306.26 Dispensing without prescription.

A controlled substance listed in Schedules II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such dispensing is made only by a pharmacist (as defined in part 1300 of this chapter), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;

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

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of § 1304.04 of this chapter); and

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

(g) Central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this section.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesigated and amended at 62 FR 13966, Mar. 24, 1997; 68 FR 37411, June 24, 2003]

§ 1306.27 Provision of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule III, IV or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(1) Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(2) Ensure that all information required to be on a prescription pursuant to § 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(3) Indicate if the information transmitted the number of refills already dispensed and the number of refills remaining;

(4) Maintain the original prescription for a period of two years from the date the prescription was last refilled;

(5) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic

record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (*i.e.* private, common or contract carrier).

[68 FR 37411, June 24, 2003]

PART 1307—MISCELLANEOUS

GENERAL INFORMATION

AUTHORITY: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

SOURCE: 36 FR 7801, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1307.01 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13966, Mar. 24, 1997]

§ 1307.02 Application of State law and other Federal law.

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

[62 FR 13966, Mar. 24, 1997]

§ 1307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator may grant an exception in his discretion, but in no case shall he/she be required to grant an exception to any person which is otherwise required by law or the regulations cited in this section.

[62 FR 13966, Mar. 24, 1997]

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

§ 1307.11 Distribution by dispenser to another practitioner or reverse distributor.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to—

(1) Another practitioner for the purpose of general dispensing by the practitioner to patients, provided that—

(i) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(ii) The distribution is recorded by the distributing practitioner in accordance with § 1304.22(c) of this chapter

and by the receiving practitioner in accordance with § 1304.22(c) of this chapter;

(iii) If the substance is listed in Schedule I or II, an order form is used as required in part 1305 of this chapter; and

(iv) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and § 1301.25 of this chapter during each calendar year in which the practitioner is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(2) A reverse distributor who is registered to receive such controlled substances.

(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to paragraph (a)(1) of this section and § 1301.25 of this chapter will exceed 5 percent of this total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.

(c) The distributions that a registered retail pharmacy makes to automated dispensing systems or long term care facilities for which the retail pharmacy also holds registrations do not count toward the 5 percent limit in paragraphs (a)(1)(iv) and (b) of this section.

[68 FR 41229, July 11, 2003, as amended at 70 FR 25466, May 13, 2005]

§ 1307.12 Distribution to supplier or manufacturer.

(a) Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he/she obtained it or to the manufacturer of the substance, or, if designated, to the manufacturer's registered agent for accepting returns, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance in Schedule I or II, an order form shall be used in the manner prescribed in part 1305 of this chapter and be maintained as the written record of the transaction. Any person not required to register pursuant to sections 302(c) or 1007(b)(1) of the Act (21 U.S.C. 822(c) or 957(b)(1)) shall be exempt from maintaining the records required by this section.

(b) Distributions referred to in paragraph (a) may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

[65 FR 44679, July 19, 2000; 65 FR 45829, July 25, 2000, as amended at 68 FR 41229, July 11, 2003]

§ 1307.13 Incidental manufacture of controlled substances.

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to part 1303 of this chapter (if such substance or class is listed in Schedule I or II) shall be exempt from the requirement of registration pursuant to part 1301 of this chapter and, if such incidentally manufactured substance is listed in Schedule I or II, shall be exempt from the requirement of an individual manufacturing quota pursuant to part 1303 of this chapter, if such substances are disposed of in accordance with § 1307.21.

[36 FR 7801, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated at 62 FR 13967, Mar. 24, 1997]

DISPOSAL OF CONTROLLED SUBSTANCES

§ 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

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

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in charge may determine to assure that the substance does not become available to unauthorized persons.

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

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

[36 FR 7801, Apr. 24, 1971, as amended at 37 FR 15622, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982; 62 FR 13967, Mar. 24, 1997]

§ 1307.22 Disposal of controlled substances by the Administration.

Any controlled substance delivered to the Administration under § 1307.21 or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537 The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended. The delivery of such controlled drugs shall be ordered by the Administrator, if, in his opinion, there exists a medical or scientific need therefor.

[38 FR 7801, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13967, Mar. 24, 1997]

SPECIAL EXEMPT PERSONS

§ 1307.31 Native American Church.

The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration. Any person who manufactures peyote for or