TITLE 172 PROFESSIONAL AND OCCUPATIONAL LICENSURE

CHAPTER 128 PRACTICE OF PHARMACY

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TITLE 172 PROFESSIONAL AND OCCUPATIONAL LICENSURE

CHAPTER 128 PRACTICE OF PHARMACY BY CREDENTIALED PHARMACY PERSONNEL

128-001 SCOPE AND AUTHORITY: These regulations govern the credentialing of pharmacists, pharmacist interns, pharmacy technicians, and the practice of pharmacy under the Uniform Controlled Substances Act, Neb. Rev. Stat. §§ 28-401 et seq.; the Pharmacy Practice Act, Neb. Rev. Stat. §§ 38-2801 et seq.; the Prescription Drug Safety Act, Neb. Rev. Stat. §§ 71-2477 et seq.; and the Uniform Credentialing Act (UCA), Neb. Rev. Stat. §§ 38-101 et seq.

128-002 DEFINITIONS: For purposes of these regulations, definitions in the Uniform Credentialing Act, the Uniform Controlled Substances Act, the Pharmacy Practice Act, the Prescription Drug Safety Act, and the following definitions are hereby adopted.

Attest/Attestation means that the individual declares that all statements on the application are true and complete.

Complete application means an application that contains all of the information requested on the application with attestation to its truth and completeness, and that is submitted with the required fees fees and all required documentation.

Confidential information means information protected as privileged under applicable law. Social security numbers obtained under these regulations are not public information but may be shared by the Department for administrative purposes if necessary and only under appropriate circumstances to ensure against any unauthorized access to this information.

Conviction means a plea or verdict of guilty or a conviction following a plea of nolo contendere or non vult contendere made to a formal criminal charge, or a judicial finding of guilt irrespective of the pronouncement of judgment or the suspension thereof, and includes instances in which the imposition or the execution of sentence is suspended following a judicial finding of guilt and the defendant is placed on probation.

Credential means a license, certificate, or registration

Department means the Nebraska Department of Health and Human Services, Division of Public Health Licensure.

Licensure in another jurisdiction means holding a credential that authorizes the individual to engage in the profession of Pharmacist, Pharmacist Intern, or Pharmacy Technician which would otherwise be unlawful, from the District of Columbia or any state, territory, or possession of the United States of America, or any province of Canada.

Military service means full-time duty in the active military service of the United States, a National Guard call to active service for more than 30 consecutive days or active service as a Commissioned Officer of the Public Health Service or the National Oceanic and Atmospheric Administration. Military service may also include any period during which a service member is absent from duty on

account of sickness, wounds, leave, or other lawful cause. (From the Servicemembers Civil Relief Act, 50 U.S.C. App. 501 et seq., as it existed in 2016)

NABP means the National Association of Boards of Pharmacy.

NAC means the Nebraska Administrative Code.

Practice agreement means a document signed by a pharmacist and a practitioner with independent prescribing authority, wherein the pharmacist agrees to design, implement and monitor a therapeutic plan based on a written protocol.

Written protocol means a written template, agreed to by a pharmacist and a practitioner with independent prescribing authority, working in concert, which directs how the pharmacist will implement and monitor a specified therapeutic plan.

128-003 INITIAL CREDENTIAL: An applicant for a credential must submit an application and documentation to the Department that she/he meets the licensure or registration requirements. To receive a license to practice as a Pharmacist or Pharmacist Intern or register as a Pharmacy Technician, an individual must submit a complete application, pay the appropriate fee, and meet the following:

128-003.01 Requirements:

128-003.01A Age and Good Character: Be at least 19 years old and of good character.

128-003.01B Citizenship/Lawful Presence: Meet the requirements set out in Neb. Rev. Stat. §38-129 and §§ 4-108 through 4-111.

128-003.01C Education and/or Examination requirements: Applicants for licensure as a Pharmacist, Pharmacist Intern, or Pharmacy Technician must meet additional requirements as specified:

128-003.01C1 Pharmacist Licensure:

A. Education:
   1. Have graduated from an accredited pharmacy program; or
   2. Have graduated from a pharmacy program located outside the United States which is not accredited and have obtained the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification given by the National Association of Boards of Pharmacy(NABP);
   3. Have satisfactorily completed not less than 1500 hours of pharmacy internship experience;

B. Examination:
   1. Pass the North American Pharmacist Licensure Examination (NAPLEX) or its predecessor exam given by the National Association

of Boards of Pharmacy (NABP) with a score of 75 or above; and

2. Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) that relates to federal law and the Nebraska statutes and regulations that govern the practice of pharmacy given by the National Association of Boards of Pharmacy(NABP) with a score of 75 or above; and
3. Have scores and results from the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) examination(s) sent directly to the Department from the National Association of Boards of Pharmacy (NABP).

C. Current Competency: Present proof of having met one of the following requirements to demonstrate his/her current competency:

1. Has passed the North American Pharmacist Licensure Examination (NAPLEX) given by the National Association of Boards of Pharmacy (NABP within the last three years;
2. Has been in the active practice of the profession of pharmacy in another state, territory, or the District of Columbia for at least one year within the three years immediately preceding the application for licensure;
3. Has become board certified in a specialty recognized by the Board of Pharmacy Specialties or its successor within the seven years immediately preceding the application for licensure;
4. Is licensed as a pharmacist in some other state, territory, or the District of Columbia in which, under like conditions, licensure as a pharmacist is granted in this state; or
5. Has completed continuing competency in pharmacy that is approved by the Board of Pharmacy.

128-003.01C2 Pharmacist Intern License:

A. Education:

1. Be a student currently enrolled in an accredited pharmacy program; or
2. Be a graduate of an accredited pharmacy program serving his/her internship; or
3. Be a graduate of a pharmacy program located outside the United States which is not accredited and have obtained the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification given by National Association of Boards of Pharmacy (NABP).

128-003.01C3 Pharmacy Technician Registration:

A. Have attained at least the age of 18.

B. Education:

1. Have graduated from high school; or

2. Possess an equivalent degree of education as recognized by the State Department of Education;

128-003.01D Military Service: Effective December 15, 2015, upon presentation of satisfactory evidence that the education, training, or service completed by an applicant for a credential while a member of the armed forces of the United States, active or reserve, the National Guard of any state, the military reserves of any state, or the naval militia of any state is substantially similar to the education required for the credential, the department, with the recommendation of the appropriate board, will accept such education, training, or service toward the minimum standards for the credential.

128-003.02 Application: The application must contain all of the information and documentation required by Neb. Rev. Stat. §38-129, §38-130, §38-131 and §4-111 and these regulations, including;

128-003.02A Information:

1. The legal name of the applicant, maiden name (if applicable), and any other names by which the applicant is known;
2. Mailing address (street, rural route, or post office address; and city, state,
3. and zip code or country information);
4. The applicant's:
   a. Social Security Number (SSN); or
   b. Alien Registration Number (A#);

   Disclosing a social security number is mandatory. Certain applicants may have both a social security number (SSN) and an alien registration number (A#), and if so, must report both.

128-003.02B Education: An official transcript from an accredited school showing the graduation date must be sent directly to the department by the originating program or institution;

1. Applicants for the practice of a Pharmacist or Pharmacy Intern must demonstrate graduation by submitting an official transcript from an accredited pharmacy program, or be a graduate of a pharmacy program located outside the United States which is not accredited and have obtained the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification given by National Association of Boards of Pharmacy (NABP).
2. Applicants for the practice of a Pharmacy Technician must demonstrate graduation from an accredited high school or equivalent.

128-003.02C Credentialed in Another Jurisdiction Information: Any credential held or previously held by the applicant to provide health services, health related services,

or environmental services in Nebraska or in any other jurisdiction. Such information must include:

1. The jurisdiction where each credential was issued;
2. The credential number;
3. The type of credential;
4. The date of issuance and the expiration date of each credential, if any. The applicant must have a certification of each credential submitted to the Department by the issuing agency or through an acceptable primary source verification.

128-003.02D Adverse Actions: History of disciplinary actions, adverse actions, denials, denial of the right to take a credentialing examination, or other actions against a credential in any state or jurisdiction, including, but not limited to:

1. Voluntary surrenders or voluntary limitations;
2. Prior refusals to issue or to renew a credential;
3. Any disciplinary actions or denials of a credential; and
4. An explanation for an adverse action and or denial.

128-003.02E: Convictions: Any misdemeanor or felony conviction(s). If the applicant has been convicted, the following information and documentation must be submitted to the Department:

1. A list of any misdemeanor or felony convictions;
2. A copy of the court records, if the convictions occurred in a state other than Nebraska, which includes charges and disposition;
3. Explanation from the applicant of the events leading to the conviction (what, when, where, why) and a summary of actions the applicant has taken to address the behaviors/actions related to the convictions;
4. A current addiction/mental health evaluation, if the conviction involved a drug and/or alcohol related offense and if the conviction(s) occurred within the last 10 years;
5. A letter from the probation officer addressing probationary conditions and current status, if the applicant is currently on probation; and
6. The applicant may be requested to submit additional documentation such as police reports.

128-003.02E Documentation that the applicant meets the requirements set out in Neb. Rev. Stat. §38-129 and §§ 4-108 through 4-111.

128-003.02F Practice Statement: A statement that the applicant has not practiced as a Pharmacist, Pharmacist Intern, or Pharmacy Technician in Nebraska before submitting the application; or if the applicant has practiced as a Pharmacist, Pharmacist Intern, or Pharmacy Technician in Nebraska before submitting the application a statement of the number of days practiced and the name and location of practice;

128-003.03 Non-English Documents: Any documents written in a language other than English must be accompanied by a complete translation into the English language. The translation must be an original document and contain the notarized or equivalent signature of the translator. An individual may not translate his/her own documents.

128-004 Denied or Withdrawn Applications:

128-004.01 An applicant for a Pharmacist, Pharmacist Intern, or Pharmacy Technician credential whose application is denied by the Department will be allowed the return of his/her fee, except for a $25 administrative fee to be retained by the Department.

128-004.02 A request to withdraw an application will be granted:

A. When the application is incomplete; or
B. When the request for withdrawal is received within five business days of the receipt of a complete application.

If a request to withdraw an application is granted, the applicant will be allowed the return of his/her fee, except for a $25 administrative fee to be retained by the Department.

128-005 RENEWAL: An individual who wants to renew his/her credential must, prior to the expiration date, file an application for renewal, pay the fee, and, demonstrate compliance with applicable continuing competency requirements and Neb. Rev. Stat. §38-129 and §§ 4-108 through 4-111.

128-005.01 Credential Expiration Dates:

a. All pharmacist licenses issued by the Department will expire on January 1 of each even-numbered year.
b. All pharmacy technician registrations issued by the Department will expire on January 1 of each odd-numbered year.
c. All pharmacist intern registrations issued by the Department cannot be renewed after their respective expiration date.

128-005.02 Renewal Application: The applicant must provide the following information:

a. The legal name of the applicant, maiden name (if applicable), and any other names by which the applicant is known;
b Mailing address (street, rural route, or post office address; and city, state, and zip code, or country information);
c. The applicant's:
1. Social Security Number (SSN);
2. Alien Registration Number (A#);
Disclosing a social security number is mandatory. Certain applicants may have both

a social security number (SSN) and an alien registration number (A#) or I-94 number, and if so, must report both.

128-005.03 Documentation: Must submit the following documentation and information with the application:

a. Alien or Non-Immigrant: Documentation that the applicant meets the requirements set out in Neb. Rev. Stat. §38-129 and §§ 4-108 through 4-111.
b. Other Credential Information: If the applicant holds a credential to provide health services, health-related services, or environmental services in Nebraska or in another jurisdiction, the applicant must submit the name of the state, credential number, type of credential, date issued, and expiration date of each credential where the applicant has been or is currently credentialed;
c. Disciplinary Action: A list of any disciplinary actions taken against the applicant's credential and a copy of the disciplinary action(s), including charges and disposition;
d. Denial: If the applicant was denied a credential or denied the right to take a credentialing examination, an explanation of the basis for the denial and a copy of the denial documentation;
e. Conviction Information: If the applicant has been convicted of a felony or misdemeanor since his/her last renewal or during the time period since initial credentialing if such occurred within the previous two years, the applicant must submit to the Department:
    1. A list of any misdemeanor or felony convictions;
    2. A copy of the court records, if the convictions occurred in a state other than Nebraska, which includes charges and disposition;
    3. Explanation from the applicant of the events leading to the conviction (what, when, where, why) and a summary of actions the applicant has taken to address the behaviors/actions related to the convictions;
    3. A current addiction/mental health evaluation, if the conviction involved a drug and/or alcohol related offense and if the conviction(s) occurred within the last 10 years;
    4. A letter from the probation officer addressing probationary conditions and current status, if the applicant is currently on probation; and
    5. The applicant may be requested to submit additional documentation such as police reports.

128-006 Acceptable Continuing Competency for Pharmacists:

128-006.01 On or before the license expiration date, the pharmacist must complete 30 hours of continuing education during the preceding 24 month period, The following are approved continuing education providers:

a. The Accreditation Council for Pharmacy Education (ACPE);
b. The Nebraska Council ~~on~~ for Continuing Pharmacy Education (NCCPE);

c. The Accreditation Council for Continuing Medical Education (ACCME) Category 1 continuing education; or

d. Other providers demonstrating the same quality continuing education standards as those established in the Criteria for Quality of Accreditation Council for Pharmacy Education (ACPE) and approved by the Board.

128-006.01A Have achieved or maintained certification through the Board of Pharmacy Specialties (BPS).

128-006-01B Have achieved or maintained certification through the National Certification Board of Diabetes Education.

128-006.02 Waivers of Continuing Education:

128-006.02A Military Service

1. Licensees actively engaged in military service are not required to pay the renewal fee.
2. The Department waives continuing competency requirements if a licensee has served in the regular armed forces of the U.S. during part of the credentialing period immediately preceding the renewal date.

128-006.02B First Licensed: The Department waives continuing education requirements for individuals who were first credentialed within the 24-month period immediately preceding the renewal date.

128-006.03 Audit of Continuing Competency Requirements: The Department or the Board may biennially select, in a random manner, a sample of the renewal applications for audit of continuing competency requirements. Each credential holder selected for audit must produce documentation of the continuing competency activities Within 30 days.

128-006.04 Inactive Status: When an individual wants to have his/her license to practice Pharmacy placed on inactive status, s/he must submit a request in writing to the Department. There is no fee to have a credential placed on inactive status and continuing competency is not required. The Department will notify the credential holder in writing of the acceptance or denial of the request. To reinstate a license from inactive status, see section 128-011 of the regulations.

128-007 IDENTIFICATION REQUIREMENTS FOR PHARMACIST, PHARMACIST INTERN AND PHARMACY TECHNICIAN

128-007.01 Each pharmacist must be identified as a pharmacist while performing the duties of a pharmacist within a facility licensed under the Health Care Facility Licensure Act.

128-007.02 Nothing in these regulations will be construed to prohibit one pharmacist intern or one pharmacy technician from being supervised by more than one pharmacist at any time.

128-007.03 Each pharmacist intern must be identified as a pharmacist intern while performing the duties of a pharmacist intern.

128-007.04 A pharmacist intern must be supervised at all times while performing the functions of a pharmacist intern, which may include all aspects of the practice of pharmacy, unless otherwise restricted. This supervision must be provided by a pharmacist who possesses a Nebraska pharmacist's license which is free from disciplinary measures at the time of supervision. This requirement for pharmacist supervision does not apply to pharmacist interns who are receiving experiential training directed by the accredited program in which s/he is enrolled.

128-007.05 In the case of a pharmacist intern, the result of failure to comply with any of these standards may be loss of accumulated pharmacy internship hours and revocation of any license issued on the basis of such pharmacy internship.

128-007.06 Each pharmacy technician must be identified as a pharmacy technician while performing the duties of a pharmacy technician.

128-007.07 A pharmacist intern must not supervise another pharmacist intern nor a pharmacy technician.

128-008 REQUIREMENTS FOR PRACTICE AGREEMENTS

128-008.01 A pharmacist may enter into a practice agreement with a practitioner with independent prescribing authority to provide pharmaceutical care according to written protocols.

128-008.02 The pharmacist must notify the Board of any practice agreement. Such notice must be given to both the Board of Pharmacy and the medical practitioner's professional Board. Such notice must contain the names of the pharmacist(s) and the practitioner(s) with independent prescribing authority and a description of the therapy being monitored or initiated.

A. A copy of the practice agreement and written protocols must be available for review by any representative of the Department, and
B. A copy of the practice agreement or written protocols must be sent to the Board upon request from the Board.
C. Written notice must be given to the Board at initiation and at any time there is a change in parties or protocols.

128-009 DISCIPLINARY ACTIONS

128-009.01A Grounds for Discipline: A pharmacist license or a pharmacist intern registration may be denied, refused renewal, or have other disciplinary measures taken against it for grounds specified in Neb. Rev. Stat. §§ 38-178, or for unprofessional conduct.

128-009.01B Unprofessional Conduct: Unprofessional conduct means any departure from

or failure to conform to the standards of acceptable and prevailing practice of pharmacy or the ethics of the profession, regardless of whether a person, patient, or entity is injured, but does not include a single act of ordinary negligence. Unprofessional conduct also means conduct that is likely to deceive or defraud the public or is detrimental to the public interest. Unprofessional conduct includes but is not limited to the acts set out in Neb. Rev. Stat. § 38-179 and the following:

1. Refusal to cooperate or failure to furnish requested information during a licensing or discipline investigation by the Department.
2. Any departure from or failure to conform to the ethics of the pharmacy profession, which ethics were adopted by the membership of the American Pharmacists
3. Association on October 27, 1994;
4. Misrepresenting one's credentials in an application submitted to a healthcare
5. facility, insurance company, or prospective employer;
6. Refusal to provide professional service to a person because of such person's
7. race, color, or national origin;
8. Refusal to undergo an examination defining competency as required by the
9. Board;
10. Failure to ensure a verbal offer to counsel is made, unless specifically exempt as provided in Neb. Rev. Stat. § 38-2869;
11. Willfully or negligently violating the confidentiality between a pharmacist and a patient, except as allowed by law;
12. Except as otherwise permitted by law, dispensing, selling, administering, distributing, ordering, or giving to a person, known by the pharmacist to be an addict or any person previously drug dependent, any drug legally classified as a controlled substance;
13. Exercising influence on the patient in such a manner as to exploit the patient for the financial gain of the pharmacist or of a third party, which includes, but is not limited to, the promotion or sale of services, goods, drugs, devices, or biologicals;
14. Refusal to allow access to the records appropriate to practice pharmacy in a facility and required to be kept pursuant to 175 NAC 8.
15. Return of dispensed drugs or devices to saleable stock, unless specifically allowed by law;
16. Dispensing, selling, or administering anabolic steroids to a person for other than therapeutic purposes;
17. Practicing pharmacy under a false or assumed name;
18. Allowing a pharmacy technician, knowingly or unknowingly, to perform functions requiring professional judgment and licensure as a pharmacist;
19. Lack of inappropriate direction, collaboration or direct supervision of any person employed by, supervised by or assigned to the pharmacist;
20. Claiming credit for any continuing competency activities not actually participated in and earned;
21. Any false or misleading statement on a pharmacy self-inspection form;
22. Advertisement for health care services that does not provide accurate information on the type of credential(s) held nor include deceptive or misleading information pursuant to Neb. Rev. Stat. § 38-124.

128-009.02 Pharmacy Technicians: A pharmacy technician registration may be denied refused renewal, or suspended or have other disciplinary measures taken against it pursuant to Neb. Rev. Stat. § 38-2894, or for unprofessional conduct.

128-009.02A Unprofessional conduct means any departure from or failure to conform to the standards of acceptable and prevailing practice of pharmacy or the ethics of the profession, regardless of whether a person, patient, or entity is injured, but does not include a single act of ordinary negligence. Unprofessional conduct also means conduct that is likely to deceive or defraud the public or is detrimental to the public interest. Unprofessional conduct includes but is not limited to the acts set out in Neb. Rev. Stat. § 38-179 and the following:

1. Refusal to cooperate or failure to furnish requested information during a licensing or discipline investigation by the Department;

128-010 VOLUNTARY SURRENDER OR LIMITATION: A credential holder may offer to voluntarily surrender or limit a credential issued by the Department. The credential holder must make the offer in writing on a form provided by the Department or constructed by the credential holder, which must include the following information:

A. Personal Information:
   1. First, middle and last name;
   2. Mailing address (street, rural route, or post office address), city, state, and zip code;
   3. Telephone number; and
   4. Fax number.

B. Information Regarding the Credential Being Offered for Surrender or Limitation:
   1. List credential(s) and credential number(s) that would be surrendered or limited;
   2. Indicate the desired time frame for offered surrender or limitation:
      (1) Permanently;
      (2) Indefinitely; or
      (3) Definite period of time (specify);
   3. Specify reason for offered surrender or limit of credential; and
   4. Specify any terms and conditions that the credential holder wishes to have the Department consider and apply to the offer.

C. Attestation: The credential holder must:
   1. Attest that all the information on the offer is true and complete; and
   2. Provide the credential holder's signature and date.

128-011 REINSTATEMENT: This section applies to individuals previously licensed in Nebraska who seek the authority to return to practice in Nebraska with a valid Nebraska license.

128-011.01 Individuals may apply for reinstatement as follows:

A. An individual whose license has expired, been placed on inactive status, voluntarily surrendered for an indefinite period of time, or suspended or limited for disciplinary

reasons, may apply for reinstatement at any time.

B. An individual whose license has been voluntarily surrendered for a definite period of time may apply for reinstatement after that period of time has elapsed.

C. An individual whose license has been revoked may apply for reinstatement only after a period of two years has elapsed from the date of revocation.

128-011.02 Individuals not eligible for reinstatement: An individual whose license has been permanently voluntarily surrendered is not eligible for reinstatement and may not reapply for a new credential of the same license type.

128-011.03 To reinstate a license, an individual must submit a complete application, have met the continuing competency requirements, pay the renewal fee and reinstatement fee (if applicable), meet the requirements set out in Neb. Rev. Stat.§38-129 and §§ 4-108 through 4-111 and provide the following on his or her application:

128-011.03A Information:

1. The legal name of the applicant, maiden name (if applicable), and any other names by which the applicant is known;
2. Mailing address (street, rural route, or post office address; and city, state, and zip code or country information);
3. The applicant's:
   a. Social Security Number (SSN); or
   b. Alien Registration Number (A#);
   Disclosing a social security number is mandatory. Certain applicants may have both a social security number (SSN) and an alien registration number (A#), and if so, must report both.
4. If the applicant holds a professional credential in another jurisdiction; and
5. If making application following voluntary surrender or disciplinary action, information relating to what actions s/he has taken to address the reasons that caused the action.

128-011.03C Must attest that s/he:

1. Is of good character;
2. Has met the continuing competency requirements specified in 172 NAC 128-006 within the 24 months immediately preceding submission of the application (or other requirements as specified by the practice act);
3. Has not practiced in Nebraska since s/he last held an active credential, or if the applicant has practiced in Nebraska since s/he last held an active credential, the actual number of days practiced;
4. Has not committed any act which would be grounds for action against a credential as specified in 172 NAC 128-009 since the last renewal or issuance of the credential (whichever is later), or if an act(s) was committed, provide an explanation of all such acts; and

128-011.04 Documentation: Must submit the following documentation with the application:

a. Alien or Non-Immigrant: Documentation that the applicant meets the requirements set out in Neb. Rev. Stat. §38-129 and §§ 4-108 through 4-111.

b. Other Credential Information: If the applicant holds a credential to provide health services, health-related services, or environmental services in Nebraska or in another jurisdiction, the applicant must submit the name of the state, credential number, type of credential, date issued, and expiration date of each credential where the applicant has been or is currently credentialed.

c. Disciplinary Action: A list of any disciplinary actions taken against the applicant's credential and a copy of the disciplinary action(s), including charges and disposition;

d. Denial: If the applicant was denied a credential or denied the right to take a credentialing examination, an explanation of the basis for the denial and a copy of the denial documentation

e. Conviction Information: If the applicant has been convicted of a felony or misdemeanor since his/her last renewal or during the time period since initial credentialing if such occurred within the previous two years, the applicant must submit to the Department:

1. A list of any misdemeanor or felony convictions;
2. A copy of the court records, if the convictions occurred in a state other than Nebraska, which includes charges and disposition;
3. Explanation from the applicant of the events leading to the conviction (what, when, where, why) and a summary of actions the applicant has taken to address the behaviors/actions related to the convictions;
4. A current addiction/mental health evaluation, if the conviction involved a drug and/or alcohol related offense and if the conviction(s) occurred within the last 10 years;
5. A letter from the probation officer addressing probationary conditions and current status, if the applicant is currently on probation; and
6. The applicant may be requested to submit additional documentation such as police reports.

128-012 Denied or Withdrawn Applications for Reinstatement

128-012.01 Denied Applications: An applicant for reinstatement whose application is denied by the Department will be allowed the return of his/her fee, except for a $25 administrative fee to be retained by the Department.

128-012.02 Withdrawn Applications: An applicant for reinstatement may request to withdraw the application. A request to withdraw an application will be granted:

A. When the application is incomplete; or
B. When the request for withdrawal is received within five business days of the receipt of a completed application.

If a request to withdraw an application is granted, the applicant will be allowed the return of his/her fee, except for a $25 administrative fee to be retained by the Department.

128-013 ADMINISTRATIVE PENALTY: The Department may assess an administrative penalty when evidence exists of practice without a credential to practice a profession or operate a business. Practice without a credential for the purpose of this regulation means practice:

a. Prior to the issuance of a credential;
b. Following the expiration of a credential; or
c. Prior to the reinstatement of a credential.

128-014 FEES: Fees referred to in these regulations are set out in 172 NAC 2, unless otherwise specified.

TITLE 172 PROFESSIONAL AND OCCUPATIONAL LICENSURE

CHAPTER 128 PRACTICE OF PHARMACY

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Copies of the attached Code of Ethics for Pharmacists are available at http://www.aphanet.org/pharmcare/ethics.html **NOTE:** This is same information that was copied from the website on 07/27/2005, which was filed with the Secretary of State on October 27, 2005.

~~TITLE 172 PROFESSIONAL AND OCCUPATIONAL LICENSURE~~

~~CHAPTER 128 PRACTICE OF PHARMACY~~

~~128-001 SCOPE AND AUTHORITY: These regulations govern the practice of pharmacy pursuant to the Uniform Controlled Substances Act, Neb. Rev. Stat. §§ 28-1437 to 28-1439.01; 71-1,142 to 71-1,151; 71-2401 to 71-2405; the Mail Service Pharmacy Licensure Act; the Nebraska Drug Product Selection Act; and the Uniform Licensing Law.~~

~~Any application required by 172 NAC 128 may be submitted on a form provided by the Department or in an alternate format.~~

~~128-002 DEFINITIONS: In addition to the definitions found in Neb. Rev. Stat. §§ 28-401 and 71-1,142, the following definitions apply to 172 NAC 128:~~

~~Accredited or approved program means a pharmacy program which maintains accreditation approved by the Accreditation Council for Pharmacy Education (ACPE) or other accrediting agencies and is approved by the Department upon recommendation of the Board.~~

~~Attest/Attestation means that the individual declares that all statements on the application/petition are true and complete.~~

~~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.~~

~~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.~~

~~Director means the Director of Regulation and Licensure or the Chief Medical Officer if one has been appointed pursuant to Neb. Rev. Stat. § 81-3201, for performance of the duties set out in that statute.~~

NAC means the Nebraska Administrative Code, the system for classifying State agency rules and regulations. These regulations are 172 NAC 128.

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

Pharmacist Intern means a person who meets the requirements of Neb. Rev. Stat. § 71-1,144 and these regulations.

Pharmacy internship means a period of training, in the practice of pharmacy, of the pharmacist intern under the direction of a pharmacist or experiential training in an accredited pharmacy program approved by the Board of Pharmacy as a requirement for licensure to practice pharmacy in the State of Nebraska.

Practice agreement means a document signed by a pharmacist and a medical practitioner, wherein the pharmacist agrees to implement and monitor a therapeutic plan based on a written protocol.

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.

Reciprocity means an applicant for pharmacist licensure who has requested to transfer the pharmacists license through National Association of Boards of Pharmacy (NABP) Transfer of Pharmaceutic Licensure Program.

Score Transfer means an applicant for pharmacist licensure who has requested to participate in the score transfer program offered by the National Association of Boards of Pharmacy (NABP).

Supervision of a pharmacist intern means the presence of and the responsible and immediate personal guidance and direction by a pharmacist.

Written protocol means a written template, agreed to by a pharmacist and a medical practitioner, working in concert, which directs how the pharmacist will implement and monitor a therapeutic plan.

128-003 PHARMACIST LICENSURE REQUIREMENTS

128-003.01 An applicant for licensure as a pharmacist on the basis of examination or score transfer must:

1. Have graduated from an accredited pharmacy program;
1. Have satisfactorily completed not less the 1500 hours of pharmacy internship experience;
2. Pass the North American Pharmacist Licensure Examination (NAPLEX) given by NABP with a score of 75 or above;
3. Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) that relates to federal law and the Nebraska statutes and regulations that govern the practice of pharmacy given by NABP with a score of 75 or above;
4. Be of good moral character and have attained at least the age of 21; and

6. Submit to the Department:

a. An application for licensure as a pharmacist, that must include the following information:

(1) Legal name;
(2) Place and date of birth;
(3) Social Security Number;
(4) Mailing address;
(5) Telephone number (optional)
(6) E-mail address/fax number (optional)
(7) Permanent address;
(8) Name and location of accredited pharmacy program attended by the applicant;
(9) Date of graduation from accredited pharmacy program;
(10) Whether the applicant is applying by examination, by score transfer or by reciprocity;
(11) Answer the following questions either yes or no; if answered yes, explain the circumstances and the outcome:

(a) Has any state or territory of the U.S. ever taken any of the following actions against your license?
Denied Limited Restricted Revoked Suspended
(b) Has any licensing or disciplinary authority ever taken any of the following actions against your license?
Denied Limited Restricted Revoked Suspended
(c) Has any licensing or disciplinary authority placed your license on probation?
(d) Have you ever voluntarily surrendered a license issued to you by a licensing or disciplinary authority?
(e) Have you ever voluntarily limited in any way a license issued to you by a licensing or disciplinary authority?
(f) Have you ever been requested to appear before any licensing agency?
(g) Have you ever been notified of any charges or complaints filed against you by any licensing or disciplinary authority or criminal prosecution authority?
(h) Have you ever been addicted to, dependent upon or chronically impaired by alcohol, narcotics, barbiturates, or other drugs which may cause physical and/or psychological dependence?
(i) Have you ever been treated for alcohol or substance abuse?
(j) During the past ten years, have you voluntarily entered or been involuntarily admitted to an institution or health care facility for treatment of a mental or emotional disorder/condition?
(k) Have you been diagnosed with or treated for bipolar disorder, schizophrenia, or any psychotic disorder?

(l) Have you ever been convicted of a felony?
(m) Have you ever been convicted of a misdemeanor?
(n) Have you ever been called before any licensing agency or lawful authority concerned with DEA controlled substances?
(o) Have you ever been notified of any malpractice claim against you?

(12) Have you ever been licensed as a pharmacist in another state/jurisdiction?

(a) If yes, list all the states/jurisdiction where you have been or are currently licensed, including license number, issuance date and expiration date;

(13) A statement from the applicant that s/he is of good moral character and that the statements on the application are true and complete.

b. Official documentation of successful completion of a pharmacy degree program of an accredited pharmacy program;
c. Official documentation of passing the NAPLEX with a score of 75 or above, sent directly to the Department by NABP;
d. Official documentation of passing the MPJE for Nebraska with a score of 75 or above, sent directly to the Department by NABP;
e. Official documentation of satisfactory completion of not less than 1500 hours of pharmacy internship experience, sent directly to the Department from the accredited pharmacy program or another state Board of Pharmacy;
f. Certification of licensure (if applicable) which reflects the status of licensure, how license was obtained, date of issuance, expiration date; and any disciplinary information (if applicable), sent directly to the Department, from the state Board of Pharmacy;
g. The required licensure fee pursuant to 172 NAC 128-017; and
h. A copy of the applicant's birth certificate, marriage license, driver's license, or other valid verification of age.

128-003.02 An applicant for licensure as a pharmacist on the basis of reciprocity from another state/jurisdiction must:

1. Be duly licensed/registered by examination in another state in which, under like conditions, reciprocal licensure/registration as a pharmacist, without examination, is granted to pharmacists duly licensed by examination in Nebraska;
2. Have graduated from an accredited pharmacy program;
3. Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) that relates to federal law and the Nebraska statutes and regulations that govern the practice of pharmacy given by NABP with a score of 75 or above;
4. Be of good moral character and have attained at least the age of 21; and

5. Submit to the Department;

(a) An application pursuant to 172 NAC 128-003.01 item 6.a.(1) through (13);
(b) Official documentation of successful completion of a pharmacy degree program of an accredited pharmacy program;
(c) Official documentation of passing the MPJE for Nebraska with a score of 75 or above, sent directly to the Department by NABP;
(d) Official Application for Transfer of Pharmaceutic Licensure issued by NABP;
(e) The required licensure fee pursuant to 172 NAC 128-017; and
(f) A copy of the applicant's birth certificate, marriage license, driver's license, or other valid verification of age.

128-003.03 A foreign trained applicant for licensure as a pharmacist on the basis of examination or score transfer must:

1. Have graduated from a foreign pharmacy program;
2. Have obtained the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification given by NABP;
3. Have satisfactorily completed not less the 1500 hours of pharmacy internship experience;
4. Pass the North American Pharmacist Licensure Examination (NAPLEX) given by NABP with a score of 75 or above;
5. Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) that relates to federal law and the Nebraska statutes and regulations that govern the practice of pharmacy given by NABP with a score of 75 or above;
6. Have good moral character and have attained at least the age of 21; and
7. Submit to the Department:

(a) An application pursuant to 172 NAC 128-003.01 item 6.a.(1) through (13);
(b) Official translated documentation of successful completion of a pharmacy degree from a foreign pharmacy program;
(c) A copy of his/her certificate from the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification Program of NABP;
(d) Official documentation of passing the NAPLEX with a score of 75 or above, sent directly to the Department by NABP;
(e) Official documentation of passing the MPJE for Nebraska with a score of 75 or above, sent directly to the Department by NABP;
(f) Official documentation of satisfactory completion of not less than 1500 hours of pharmacy internship experience, sent directly to the Department from another state Board of Pharmacy;
(g) Certification of licensure (if applicable) which reflects the status of licensure, how license was obtained, date of issuance, expiration date; and any disciplinary information (if applicable), sent directly to the Department, from the state Board of Pharmacy;
(h) The required licensure fee pursuant to 172 NAC 128-017; and

(i) A copy of the applicant's birth certificate, marriage license, driver's license, or other valid verification of age.

128-003.04 A foreign trained applicant for licensure as a pharmacist on the basis of reciprocity from another state/jurisdiction must:

1. Be duly licensed/registered by examination in another state/jurisdiction in which, under like conditions, reciprocal licensure/registration as a pharmacist, without examination, is granted to pharmacists duly licensed by examination in Nebraska;
2. Have graduated from a foreign pharmacy program;
3. Have obtained the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification given by NABP;
4. Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) that relates to federal law and the Nebraska statutes and regulations that govern the practice of pharmacy given by NABP with a score of 75 or above;
5. Be of good moral character and have attained at least the age of 21; and
6. Submit to the Department;

(a) An application pursuant to 172 NAC 128-003.01 item 6.a.(1) through (13);
(b) Official documentation of successful completion of a pharmacy degree from a foreign pharmacy program;
(c) A copy of his/her certificate from the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification Program of NABP;
(d) Official documentation of passing the MPJE for Nebraska with a score of 75 or above, sent directly to the Department by NABP;
(e) Official Application for Transfer of Pharmaceutic Licensure issued by NABP;
(f) The required licensure fee pursuant to 172 NAC 128-017; and
(g) A copy of the applicant's birth certificate, marriage license, driver's license, or other valid verification of age.

128-003.05 The Department will act within 150 days upon all completed applications for licensure.

128-003.06 A pharmacist may use the identifying terms or designations such as: pharmacist, registered pharmacist, R.P., R.Ph., pharmacist-in-charge, or licensed pharmacist that indicates a pharmacist with an active license to practice pharmacy in Nebraska.

128-003.07 No one, other than a duly licensed pharmacist, is allowed to use the following terms or designations or any other terms, designations, or letters implying licensure as a pharmacist in this state or in any other jurisdiction:

1. pharmacist,
2. registered pharmacist, R.P., or R.Ph.,
3. pharmacist-in-charge,

4. licensed pharmacist, or
5. natural pharmacist, herbal pharmacist.

128-004 PROCEDURES FOR RENEWAL OF A LICENSE: All licenses issued by the Department under the Act and 172 NAC 128 expire on January 1 of each even-numbered year.

128-004.01 Renewal process: Any licensee who wishes to renew his/her license must:

1. Meet the continuing competency requirements pursuant to 172 NAC 128-006;
2. Pay the renewal fee pursuant to 172 NAC 128-017;
3. Respond to the following questions:

a. Has your license in any profession in another state been revoked, suspended, limited or disciplined in any manner?
b. Have you been convicted of a misdemeanor or felony?

These questions relate to the time period since the last renewal of the license or during the time period since initial licensure in Nebraska if such occurred within the two years prior to the license expiration date.

4. Cause to be submitted to the Department:

a. The renewal notice;
b. The renewal fee;
c. Attestation of completing 30 hours of continuing education earned within 24 months of the date of expiration or an application for waiver of continuing competency. Attestation to meeting continuing competency requirements satisfies the submission of documentation requirement of Neb. Rev. Stat. § 71-110;
d. If any disciplinary action was taken against the applicant's license by another state, an official copy of the disciplinary action, including charges and disposition;
e. If the licensee has been convicted of a felony or misdemeanor:

(1) Official Court Record, which includes charges and disposition;
(2) Copies of arrest records;
(3) A letter from the licensee explaining the nature of the conviction;
(4) All addiction/mental health evaluations and proof of treatment, if the conviction involved a drug and/or alcohol related offense and if treatment was obtained and/or required; and
(5) A letter from the probation officer addressing probationary conditions and current status, if the applicant is currently on probation.

128-004.02 First Notice: At least 30 days before January 1 of each even-numbered year, the Department will send a renewal notice by means of regular mail to each licensee at the licensee's last place of residence as noted in the records of the Department. It is the

~~responsibility of the licensee prior to the renewal period to notify the Department of any name and/or address changes.~~

~~128-004.02A The renewal notice must specify:~~

~~1. The name of the licensee;~~
~~2. The licensee's last known address of record;~~
~~3. The license number;~~
~~4. The expiration date of the license;~~
~~5. The renewal fee pursuant to 172 NAC 128-017;~~
~~6. The number of continuing education hours or type of continued competency required for renewal; and~~
~~7. The option to place the license on either inactive or lapsed status.~~

~~128-004.02B The licensee must apply for renewal by submitting to the Department:~~

~~1. The renewal notice;~~
~~2. The renewal fee;~~
~~3. The licensee's social security number;~~
~~4. Attestation of completing 30 hours of continuing education earned within 24 months of the date of expiration or an application for waiver of continuing competency; and~~
~~5. Documentation relating to misdemeanor or felony conviction(s) or licensure revocation, suspension, limitation or disciplinary action since the last renewal (if applicable).~~

~~128-004.02C If the licensee wishes to place his/her license on either inactive or lapsed status s/he must:~~

~~1. Request that his/her license be placed on inactive status by submitting to the Department:~~

~~a. The renewal notice with a check in the box marked inactive; and~~
~~b. The fee of $25; or~~

~~2. Request that his/her licensed be placed on lapsed status by submitting to the Department:~~

~~a. The renewal notice with a check in the box marked lapsed.~~

~~128-004.02D The Department will notify the licensee in writing of the acceptance or denial of the request to allow the license to be placed on lapsed or inactive status.~~

~~128-004.03 Second Notice: The Department will send to each licensee who fails to renew his/her license or place the license on inactive or lapsed status in response to the first notice, a second notice of renewal pursuant to 172 NAC 128-004.01 that specify:~~

1. That the licensee failed to pay the renewal fee;
2. That the license has expired;
3. That the licensee is subject to an administrative penalty pursuant to 172 NAC 128-018 if s/he practices after the expiration date;
4. That upon receipt of the renewal fee, together with an additional late fee of $25, and documentation of continuing competency hours within that time, no order of revocation will be entered; and
5. That upon failure to receive $25 in addition to the regular renewal fee, and documentation of continuing competency hours, the license will be revoked pursuant to 172 NAC 128-005.

128-004.03A The licensee must apply for renewal by submitting to the Department:

1. The renewal notice;
2. The renewal fee and the additional late fee of $25;
3. The licensee's social security number;
4. Attestation by the licensee:

   a. That s/he has not practiced in Nebraska since the expiration of his/her license; or
   b. To the actual number of days practiced in Nebraska since the expiration of his/her license;

5. Attestation of completing 30 hours of continuing education earned within 24 months of the date of expiration or an application for waiver of continuing competency; and
6. Documentation relating to misdemeanor or felony conviction(s) or licensure revocation, suspension, limitation or disciplinary action since the last renewal (if applicable).

128-004.03B If the licensee wishes to place his/her license on either inactive or lapsed status s/he must:

1. Request that his/her license be placed on inactive status by submitting to the Department:

   a. The renewal notice with a check in the box marked inactive; and
   b. The fee of $25; or

2. Request that his/her license be placed on lapsed status by submitting to the Department:

   a. The renewal notice with a check in the box marked lapsed.

128-004.03C The Department will notify the licensee in writing of the acceptance or

denial of the request to allow the license to be placed on lapsed or inactive status.

128-004.04 When any licensee fails, within 30 days of expiration of a license, to pay the renewal fee, to submit documentation of continuing competency, and/or to pay an additional late fee of $25, the Department will automatically revoke the license without further notice of hearing and makes proper record of the revocation.

128-004.05 Failure to meet the continuing competency requirement for renewal within 30 days of expiration of his/her license will constitute non-renewal of a license, unless a waiver of continuing competency is granted or the license is placed on inactive or lapsed status. When any licensee fails, within 30 days of expiration of a license, to meet the continuing competency requirements for renewal, and pay an additional late fee of $25, the Department revokes the license after notice and opportunity for hearing. Hearings held before the Department will be conducted pursuant to Neb. Rev. Stat. §§ 84-901 to 84-920, Administrative Procedure Act and 184 NAC 1, Rules of Practice and Procedure of the Department.

128-004.06 When the licensee has given notification to the Department that s/he desires to have the license lapse or be placed on inactive status upon expiration, 172 NAC 004.04 and 004.05 will not apply.

128-004.07 The Department may refuse to renew a license for falsification of any information submitted for renewal of a license. The refusal must be made pursuant to Neb. Rev. Stat. §§ 71-149 to 71-155 and 184 NAC 1, Rules of Practice and Procedure of the Department.

128-004.08 An individual who practices after the expiration of his/her credential, is subject to assessment of an Administrative Penalty pursuant to 172 NAC 128-018, or such other action as provided in the statutes and regulations governing the credential.

128-005 CREDENTIAL REVOCATION FOR FAILURE TO MEET RENEWAL REQUIREMENTS: The Department will revoke a credential when the credential holder fails to meet the renewal requirements.

128-005.01 Revocation for Nonpayment of Renewal Fee or Late fee, or Failure to Submit Documentation of Continuing Competency within 30 Days of Expiration of the Credential.

128-005.01A When a credential holder fails to pay the required renewal fee, to submit documentation of continuing competency, and/or to pay a late fee of $25 and fails to request that his/her credential be placed on either inactive or lapsed status within 30 days of its expiration, the Department automatically revokes the credential without further notice or hearing.

128-005.01A1 A post revocation notice will be sent which will specify that:

1. The credential holder was given a first and final notice of renewal requirements and the respective dates for these notices;
2. The credential failed to renew the credential or to request that his/her credential be placed on inactive or lapsed status;

3. Department has revoked the credential; and
4. The credential holder has a right to request reinstatement of the credential.

128-005.02 Revocation for Failure to Meet Continuing Competency Requirements.

128-005.02A When a credential holder fails within 30 days of the expiration of his/her credential to meet the continuing competency requirement, the Department revokes his/her credential after notice and opportunity for a hearing.

128-005.02A1 The revocation notice for failure to meet continuing competency requirements specifies that:

1. The credential holder was given a first and second notice of failure to meet the continuing competency requirement and the respective dates of each notice;
2. The credential holder failed to meet continuing competency renewal requirements or to have his/her credential timely placed on inactive or lapsed status;
3. The credential has been revoked for failure to meet continuing competency requirements within 30 days after expiration of the credential and that the revocation will become final unless a request for hearing is filed by the credential holder with the Department within 30 days of date of receipt of the notice; and
4. The credential holder has a right to request reinstatement of the credential after revocation.

128-006 CONTINUING COMPETENCY

128-006.01 General Requirements for Licensee: On or before January 1 of each even-numbered year, every Pharmacist who is licensed in the State of Nebraska must as a condition for renewal of his/her license:

128-006.01A Complete 30 hours of acceptable continued education during the preceding 24 month period, no more hours than the total number of acceptable hours offered in Nebraska will be required during this period.

128-006.01A1 The Board of Pharmacy has approved the following providers of continuing education:

1. The Accreditation Council for Pharmacy Education (ACPE);
2. The Nebraska Council on Continuing Pharmaceutical Education; or
3. Other providers demonstrating the same quality standards as those established in the Criteria for Quality of ACPE.

128-006.01B Be responsible for maintaining in his/her personal files certificates or records of credit from acceptable continuing education activities attended.

128-006.02 Wavier of Continuing Competency: The Department, on recommendation of the Board, may waive the continuing competency requirements, in whole or in part, for any two year license or for the period of time when a licensee submits documentation that circumstances beyond his/her control prevented the completion of such requirements.

128-006.02A Such circumstances will include situations in which the licensee:

1. Holds a Nebraska pharmacist license but has not practiced in Nebraska during the 24 months immediately preceding the license renewal date; or
2. Has been in the service of regular armed forces of the United States during any part of the 24 months immediately preceding the license renewal date; or
3. Has been suffering from a serious or disabling illness or physical disability which prevented completion of the required number of continuing education hours during the 24 months immediately preceding the license renewal date; or
4. Has been first licensed in Nebraska within 24 months immediately preceding the renewal date.

128-006.02B Application for Wavier of Continuing Competency: Any licensee who seeks wavier of continuing competency requirements, in part or in total, for any two year licensing period must apply to the Department. The Department, on the recommendation of the Board, may waive continuing competency requirements in part or in total for any two year period.

128-006.03 Audit of Continuing Competency: The Board may biennially select, in a random manner, a sample of the licensee renewal applications for audit of continuing competency. Licensees selected for audit are required to produce documentation of his/her continuing education activities listed on his/her renewal application.

128-006.03A The Department will send to each licensee selected for audit a notice of audit.

128-006.03B When selected for audit the licensee must provide satisfactory documentation of attendance at or participation in the acceptable continuing education activities listed on the licensees attestation of continuing competency of his/her renewal application.

128-006.03C Failure to comply with the audit may be grounds for non-renewal of the license.

128-007 GROUNDS ON WHICH THE DEPARTMENT MAY DENY, REFUSE RENEWAL OF, OR DISCIPLINE A LICENSE

128-007.01 The Department will deny an application for a license when the applicant fails to

meet the requirements for licensure pursuant to 172 NAC 128-003 or is found to be in violation of any of the provisions of 172 NAC 128.

128-007.02 The Department will refuse renewal of a license if the licensee fails to meet the requirements pursuant to 172 NAC 128-004, 128-006.03C, or 128-007.03.

128-007.03 The Department may deny, refuse renewal of, limit, suspend, or revoke licenses for any of the following grounds:

1. Fraud, forgery, or misrepresentation of material facts, in procuring or attempting to procure a license or certificate;
2. Grossly immoral or dishonorable conduct evidencing unfitness or lack of proficiency sufficient to meet the standards required for practice of the profession in this state;
3. Habitual intoxication or dependence or failure to comply with a treatment program or an aftercare program entered into under the Licensee Assistance Program (LAP) established pursuant to Neb. Rev. Stat. § 71-172.01;
4. Conviction of a misdemeanor or felony under state law, federal law, or the law of another jurisdiction and which, if committed within this state, would have constituted a misdemeanor or felony under state law and which has a rational connection with the applicant's, or licensee's fitness or capacity to practice the profession;
5. Practice of the profession (a) fraudulently, (b) beyond its authorized scope, (c) with manifest incapacity, (d) with gross incompetence or gross negligence, or (e) in a pattern of negligent conduct. Pattern of negligent conduct means continued course of negligent conduct in performing the duties of the profession;
6. Practice of the profession while the ability to practice is impaired by alcohol, controlled substances, narcotic drugs, physical disability, mental disability, or emotional disability;
7. Physical or mental incapacity to practice the profession as evidenced by a legal adjudication or a determination thereof by other lawful means;
8. Permitting, aiding, or abetting the practice of a profession or the performance of activities requiring a license/certificate/registration/permit by a person not licensed/certified/registered/permitted to do so;
9. Having had his/her license, certificate, registration, or permit denied, refused renewal, limited, suspended, or revoked or having had such license, certificate, or registration disciplined in any other manner in accordance with Neb. Rev. Stat. § 71-155 by another state or jurisdiction to practice the particular profession involved, based upon acts by the applicant, licensee, certificate holder, registrant, or permit holder similar to acts described in this section. A certified copy of the record of denial, refusal of renewal, limitation, suspension, or revocation of a license, certificate, registration, or permit or the taking of other disciplinary measures against it by another state or jurisdiction will be conclusive evidence;
10. Unprofessional conduct, which term includes all acts pursuant to Neb. Rev. Stat. § 71-148 and such other acts as may be defined in rules and regulations adopted and promulgated by the Board with the approval of the Department;
11. Use of untruthful or improbable statements, or flamboyant, exaggerated, or extravagant claims concerning such licensee's/certificate

holder's/registrant's/permit holder's professional excellence or abilities, in advertisements;

12. Conviction of fraudulent or misleading advertising or conviction of a violation of the Uniform Deceptive Trade Practices Act;
13. Distribution of intoxicating liquors, controlled substances or drugs for any other than lawful purposes;
14. Willful or repeated violations of the Uniform Licensing Law or these rules and regulations;
15. Unlawful invasion of the field of practice of any profession mentioned in the Uniform Licensing Law which the licensee is not licensed or certified to practice;
16. Practicing the profession of Pharmacy while his/her license is suspended or in contravention of any limitation placed upon his/her license;
17. Physical or mental illness or physical or mental deterioration or disability which would render the applicant or licensee unqualified to practice Pharmacy;
18. Refusal of an applicant for a license or of a licensee to submit to a physical or mental examination request by the Board, pursuant to Neb. Rev. Stat. §§ 71-161.12 thru 71-161.16 to determine his/her qualifications to practice or to continue in the practice of Pharmacy;
19. Violation of the Uniform Controlled Substances Act or any rules and regulations adopted pursuant to the Act; and
20. Failure to file a report pursuant to Neb. Rev. Stat. § 71-168.

128-008 RE-CREDENTIALING: This section applies to individuals previously issued a Nebraska credential who have lost the legal authority to practice in total or in part and who seek the authority to return to practice in Nebraska with a valid Nebraska credential.

128-008.01 Eligibility

128-008.01A An individual whose credential has been previously:

1. Placed on lapsed status;
2. Placed on inactive status;
3. Revoked for failure to meet the renewal requirements;
4. Suspended or limited for disciplinary reasons; or
5. Voluntarily surrendered or voluntarily limited for an indefinite period of time;

may request, at any time, to be re-credentialed and re-authorized to practice under the credential, in accord with these regulations.

128-008.01B An individual whose credential has been revoked for disciplinary reasons may apply for reinstatement only after a period of two years has elapsed from the date of revocation.

128-008.01C An individual who practices prior to re-credentialing, is subject to:

1. Assessment of an Administrative Penalty pursuant to 172 NAC 128-018 , and
2. Limitation or other sanction on the credential, or denial of the request to be re-credentialed and re-authorized to practice under the credential, and referral for prosecution for uncredentialed practice, as provided in the statutes and regulations governing the credential.

128-008.02 Requirements for Restoration from Lapsed Status: A person whose credential has been placed on lapsed status may have their credential restored from lapsed to active status by the Department upon proof to the Department that they meet the requirements pursuant to 172 NAC 128-003.

128-008.02A If the Department has evidence that an applicant has practiced while his/her credential was lapsed, the Department may:

1. Assess an Administrative Penalty pursuant to 172 NAC 128-018;
2. Initiate disciplinary action against the lapsed credential;
3. Deny the request to restore the credential from lapsed to active status; or
4. Restore the credential to active status and impose limitation(s) or other sanctions on the credential.

128-008.02B If the Department has evidence that an applicant has committed any other violation of the statutes and regulations governing the credential, the Department may:

1. Initiate disciplinary action against the lapsed credential;
2. Deny the request to restore the credential from lapsed to active status; or
3. Restore the credential to active status and impose limitation(s) or other sanctions on the credential.

128-008.02C The Department will act within 150 days on all completed applications.

128-008.02D The applicant will be provided with notice and the opportunity for hearing in accord with the Department's Rules of Practice and Procedure and Neb. Rev. Stat. §§ 84-901 to 84-920 before any of the actions pursuant to 172 NAC 128-008.02A and 128-008.02B are final.

128-008.03 Requirements to Move a Credential from Inactive to Active Status: A person whose credential has been placed on inactive status may have his/her credential moved from inactive to active status upon proof to the Department that they meet the following requirements:

1. Meet renewal requirements, including:

(a) The continuing competency requirements;
(b) Paying the renewal fee and any other applicable fees;

2. Attest:

(a) That s/he has not practiced in Nebraska since s/he last held an active credential; or
(b) To the actual number of days practiced if the applicant has practiced in Nebraska since s/he last held an active credential.

128-008.04 Procedures for Moving from Inactive to Active Status: To move a credential from inactive status to active status, the applicant must submit the following to the Department:

1. A written application which contains the following information about the applicant:

a. Name;
b. Address;
c. Social security number;
d. If the applicant holds a professional credential in another state, a list of the state(s) and type of credential; and
e. A statement describing all:

(1) Felony or misdemeanor convictions during the time period since the credential was active;

(a) If the applicant has been convicted of a felony or misdemeanor, provide copies of:

[1] Official Court Record, which includes charges and disposition;
[2] Arrest records;
[3] A letter from the applicant explaining the nature of the conviction;

[4] All addiction/mental health evaluations and proof of treatment, if the conviction involved a drug and/or alcohol related offense and if treatment was obtained and/or required; and
[5] A letter from the probation officer addressing probationary conditions and current status, if the applicant is currently on probation.

(2) Revocations, suspensions, or other disciplinary actions against any professional credential held by the applicant during the time period since the credential was active;

(a) If any disciplinary action was taken against the applicant's credential by another state, submit an official copy of the disciplinary action, including charges and disposition; and

(3) Disciplinary charges pending against any professional credential held by the applicant.

f. Attestation that the continuing competency requirements for renewal have been met;

2. The renewal fee and any other applicable fees.

3. Attestation by applicant:

a. That s/he has not practiced in Nebraska since s/he last held an active credential; or

b. To the actual number of days practiced if the applicant has practiced in Nebraska since s/he last held an active credential.

128-008.04A If an applicant has practiced while his/her credential was inactive, the Department may:

1. Assess an Administrative Penalty pursuant to 172 NAC 128-018;
2. Initiate disciplinary action against the credential;
3. Deny the request to move the credential from inactive to active status; or
4. Move the credential to active status and impose limitation(s) or other sanctions on the credential.

128-008.04B If an applicant has committed any other violation of the statutes and regulations governing the credential, the Department may:

1. Initiate disciplinary action against the credential;
2. Deny the request to move the credential from inactive to active status; or
3. Move the credential to active status and impose limitation(s) or other sanctions on the credential.

128-008.04C In either event pursuant to 172 NAC 128-008.04A or 128-008.04B, a notice and the opportunity for hearing will be given to the applicant.

128-008.04D The Department will act within 150 days on all completed applications.

128-008.05 Requirements for Reinstatement Within One Year Following Revocation for Failure to Meet the Renewal Requirements: An applicant for reinstatement who applies not more than one year following revocation for failure to meet renewal requirements must:

1. Meet the renewal requirements, including:

a. The continuing competency requirements;

b. Paying the renewal fee, the late fee of $35 and any other applicable fees;

2. Attest:

a. That s/he has not practiced in Nebraska since s/he last held an active credential, or
b. To the actual number of days practiced if the applicant has practiced in Nebraska since s/he last held an active credential.

128-008.06 Procedures for Reinstatement Within One Year Following Revocation for Failure to Meet the Renewal Requirements: To reinstate a credential not more than one year following revocation for failure to meet renewal requirements, the applicant must submit the following to the Department:

1. A written application which contains the following information about the applicant:

a. Name;
b. Address;
c. Social security number;
d. If the applicant holds a professional credential in another state, a list of the state(s) and type of credential; and
e. A statement describing all:

(1) Felony or misdemeanor convictions during the time period since the credential was active;

(a) If the applicant has been convicted of a felony or misdemeanor, provide copies of:

[1] Official Court Record, which includes charges and disposition;
[2] Arrest records;
[3] A letter from the applicant explaining the nature of the conviction;

[4] All addiction/mental health evaluations and proof of treatment, if the conviction involved a drug and/or alcohol related offense and if treatment was obtained and/or required; and

[5] A letter from the probation officer addressing probationary conditions and current status, if the applicant is currently on probation.

(2) Revocations, suspensions, or other disciplinary actions against any professional credential held by the applicant during the time period

since the credential was revoked;

(a) If any disciplinary action was taken against the applicant's credential by another state, submit an official copy of the disciplinary action, including charges and disposition; and

(3) Disciplinary charges pending against any professional credential held by the applicant.

f. Attestation that the continuing competency requirements for renewal have been met;

2. The renewal fee, the late fee of $35 and any other applicable fees.
3. Attestation by the applicant:

a. That s/he has not practiced in Nebraska since s/he last held an active credential; or
b. To the actual number of days practiced if the applicant has practiced in Nebraska since s/he last held an active credential.

(1) If an applicant has practiced after his/her credential was revoked the Department may assess an Administrative Penalty pursuant to 172 NAC 128-018 in which case a notice and opportunity for hearing will be sent to the applicant.
(2) If an applicant has practiced after his/her credential was revoked, or has committed any other violation of the statutes and regulations governing the credential, other action may be taken pursuant to 172 NAC 128-008.06B below.

The Department will forward the application to the Board for its recommendation pursuant to Neb. Rev. Stat. § 71-110 (5).

128-008.06A The Board's recommendation to the Department may be to:

1. Reinstate the credential;
2. Reinstate the credential with terms, conditions or restrictions; or
3. Deny reinstatement.

128-008.06B Upon receipt of the Board's recommendation, the Department will, within 150 days, send to the applicant a written notice of the Department's response. The Department may:

1. Reinstate the credential. An Administrative Penalty may be assessed pursuant to 172 NAC 128-018 if warranted;
2. If the Department determines that the applicant has committed acts or offenses prohibited by Neb. Rev. Stat. §§ 71-147 or 71-148, the

Department may:

a. Reinstate the credential with terms, conditions or restrictions. In such case the applicant will be provided notice and the opportunity for hearing before the Department pursuant to the Department's Rules of Practice and Procedure and Neb. Rev. Stat. §§ 84-901 to 84-920. An Administrative Penalty may be assessed pursuant to to172 NAC 128-018 if warranted; or

b. Deny reinstatement. In such case the applicant will be provided notice and the opportunity for hearing before the Department pursuant to the Department's Rules of Practice and Procedure and Neb. Rev. Stat. §§ 84-901 to 84-920.

128-008.07 Requirements for Reinstatement More Than One Year Following Revocation for Failure to Meet the Renewal Requirements: An applicant for reinstatement who applies more than one year after revocation for failure to meet the renewal requirements must:

1. Petition the Board for reinstatement as prescribed in Neb. Rev. Stat. § 71-161.05. The petition for reinstatement must be accompanied by:

a. Verified recommendations from at least two credentialed practitioners of the same profession as the petitioner each having personal knowledge of the activities of the petitioner since the credential was revoked; and

b. Verified recommendations from at least two citizens each having personal knowledge of the activities of the petitioner since the credential was revoked.

2. Meet the renewal requirements, including:

a. The continuing competency requirements; and

b. Paying the renewal fee, the late fee of $75 and any other applicable fees.

3. Attest:

a. That s/he has not practiced in Nebraska since s/he last held an active credential; or

b. To the actual number of days practiced if the petitioner has practiced in Nebraska since s/he last held an active credential.

128-008.08 Procedures for Reinstatement More Than One Year Following Revocation for Failure to Meet Renewal Requirements: An applicant for reinstatement more than one year following revocation for failure to meet renewal requirements must submit to the Board:

1. A petition for reinstatement:

a. Stating the reason the petitioner believes his/her credential should be

reinstated;

b. Accompanied by verified recommendations from at least two credentialed practitioners of the same profession as the petitioner each having personal knowledge of the activities of the petitioner since the credential was revoked; and verified recommendations from at least two citizens each having personal knowledge of the activities of the petitioner since the credential was revoked.

c. Containing the following information about the petitioner:

(1) Name;

(2) Address;

(3) Social security number; and

(4) If the petitioner holds a professional credential in another state, a list of the state(s) and type of credential;

(5) A statement describing all:

(a) Felony or misdemeanor convictions during the time period since the credential was active;

[1] If the petitioner has been convicted of a felony or misdemeanor, provide copies of:

[a] Official Court Record, which includes charges and disposition;

[b] Arrest records;

[c] A letter from the petitioner explaining the nature of the conviction;

[d] All addiction/mental health evaluations and proof of treatment, if the conviction involved a drug and/or alcohol related offense and if treatment was obtained and/or required; and

[e] A letter from the probation officer addressing probationary conditions and current status, if the petitioner is currently on probation.

(b) Revocations, suspensions, or other disciplinary actions against any professional credential held by the petitioner during the time period since the credential was revoked;

[1] If any disciplinary action was taken against the petitioner's credential by another state, submit an official copy of the disciplinary action, including charges and disposition; and

(c) Disciplinary charges pending against any professional credential held by the petitioner.

(6) Attestation that the continuing competency requirements for renewal have been met.

2. The renewal fee, the late fee of $75 and any other applicable fees.

3. Attestation by the petitioner:

a. That s/he has not practiced in Nebraska since s/he last held an active credential; or

b. To the actual number of days practiced if the petitioner has practiced in Nebraska since s/he last held an active credential.

(1) If a petitioner has practiced after his/her credential was revoked the Department may assess an Administrative Penalty pursuant to 172 NAC 128-018 in which case a notice and opportunity for hearing will be sent to the petitioner.

(2) If a petitioner has practiced after his/her credential was revoked, or has committed any other violation of the statutes and regulations governing the credential, other action may be taken pursuant to 172 NAC 128-008.08F below.

128-008.08A The petition to recommend reinstatement will be considered at the next meeting of the Board that is held, but not earlier than 30 days after the petition is filed.

128-008.08B Any petition to recommend reinstatement of a credential will be conclusively acted upon by the Board within 180 days after the filing of a properly prepared petition and the necessary accompanying documents with the Board.

128-008.08C If the Board recommends reinstatement of the credential, no public hearing need be held on the petition.

128-008.08D Prior to any recommendation by the Board against reinstatement of the credential, an opportunity for a formal public hearing on the petition will be granted by the Board, if formally requested by the petitioner.

128-008.08D1 The petitioner's request for a formal hearing must be submitted within 30 days of the Board's notification of an opportunity for a formal public hearing.

128-008.08E If the petitioner formally requests a formal public hearing or if the Board otherwise holds such a hearing, the petitioner will be given at least 30 days prior notice by sending to the petitioner a copy of the notice of hearing by certified or registered mail at his/her last known residence or business post office address as shown by the files or records of the Department or as otherwise known. Notice may be given to the petitioner by personal service. The hearing will be conducted pursuant to 172 NAC 1.

128-008.08F The Board will review the petition to recommend reinstatement and the record of any hearing held, and submits its recommendation regarding reinstatement

and the record on which such recommendation is made to the Department within 180 days of receipt of the petition to recommend reinstatement.

128-008.08F1 If the Board recommends reinstatement of the credential, the Department may:

1. Accept the Board's recommendation and grant reinstatement of the credential.
2. If the Department determines that the Board's recommendation is: in excess of statutory authority; made upon unlawful procedure; unsupported by competent, material, and substantial evidence; or arbitrary or capricious, the department may not accept the Board's recommendation and either:

a. Deny reinstatement of the credential, or
b. Grant reinstatement with terms, conditions, or restrictions.

128-008.08F2 If the Board recommends denial of reinstatement, the Board will send to the petitioner a written notice of the Board's recommendation. The petitioner may appeal the Board's decision to the District Court of Lancaster County pursuant to Neb. Rev. Stat. §§ 84-901 to 84-920.

128-008.08F3 If the Board recommends reinstatement with terms, conditions, or restrictions, the Department may:

1. Accept the Board's recommendation and grant reinstatement with terms, conditions, or restrictions; or

2. Not accept the Board's recommendation and either:

a. Deny reinstatement of the credential; or
b. Grant reinstatement of the credential.

128-008.08F4 The Department will, within 150 days of receipt of the Board's recommendation, send to the petitioner a written notice of the Department's reinstatement with or without terms, conditions, or restrictions or denial of reinstatement of the credential.

128-008.08F5 The petitioner may appeal the Department's decision to the District Court of Lancaster County pursuant to Neb. Rev. Stat. §§ 84-901 to 84-920.

128-008.09 Requirements to Reinstate a Credential Following Suspension, Limitation, or Revocation for Disciplinary Reasons: An applicant for reinstatement following suspension, limitation, or revocation for disciplinary reasons must meet the following requirements:

1. Petition the Board for reinstatement;

a. The petition for reinstatement must be accompanied by verified recommendations from at least two credentialed practitioners of the same profession as the petitioner each having personal knowledge of the activities of the petitioner since the credential was suspended, limited, or revoked; and

b. Verified recommendations from at least two citizens each having personal knowledge of the activities of the petitioner since the credential was suspended, limited, or revoked.

2. Pay the reinstatement fee of $75, and other profession-specific requirements if expressly set by law;

3. If the credential was revoked or suspended, attest:

a. That s/he has not practiced in Nebraska since s/he last held an active credential; or
b. To the actual number of days practiced if the petitioner has practiced in Nebraska since s/he last held an active credential.

128-008.10 Procedures for Reinstatement Following Suspension, Limitation, or Revocation for Disciplinary Reasons: An applicant for reinstatement following suspension, limitation, or revocation for disciplinary reasons must submit to the Board:

1. A petition for reinstatement:

a. Stating the reason the petitioner believes his/her credential should be reinstated;
b. Accompanied by verified recommendations from at least two credentialed practitioners of the same profession as the petitioner each having personal knowledge of the activities of the petitioner since the credential was suspended, limited, or revoked; and verified recommendations from at least two citizens each having personal knowledge of the activities of the petitioner since the credential was suspended, limited, or revoked.

a. Containing the following information about the petitioner:

(1) Name;
(2) Address;
(3) Social security number;
(4) If the petitioner holds a professional credential in another state, a list of the state(s) and type of credential; and
(5) A statement describing all:

(a) Felony or misdemeanor convictions during the time period since the credential was suspended, limited, or revoked;

[1] If the petitioner has been convicted of a felony or misdemeanor, provide copies of:

[a] Official Court Record, which includes charges and disposition;
[b] Arrest records;
[c] A letter from the petitioner explaining the nature of the conviction;
[d] All addiction/mental health evaluations and proof of treatment, if the conviction involved a drug and/or alcohol related offense and if treatment was obtained and/or required; and
[e] A letter from the probation officer addressing probationary conditions and current status, if the petitioner is currently on probation.

(b) Revocations, suspensions, or other disciplinary actions against any professional credential held by the petitioner during the time period since the credential was suspended, limited, or revoked;

[1] If any disciplinary action was taken against the petitioner's credential by another state, submit an official copy of the disciplinary action, including charges and disposition; and

(c) Disciplinary charges pending against any professional credential held by the petitioner;

(6) Any continuing competency activities.

2. The reinstatement fee of $75.
3. Attestation by the petitioner, if the credential was revoked or suspended:

a. That s/he has not practiced in Nebraska since s/he last held an active credential; or
b. To the actual number of days practiced if the petitioner has practiced in Nebraska since s/he last held an active credential.

(1) If a petitioner has practiced after his/her credential was revoked the Department may assess an Administrative Penalty pursuant to 172 NAC 128-018 in which case a separate notice and opportunity for hearing will be sent to the petitioner.

(2) If a petitioner has practiced after his/her credential was revoked, or has committed any other violation of the statutes and regulations

governing the credential, other action may be taken pursuant to 172 NAC 128-008.10G below.

128-008.10A The Board will make a recommendation to the Director regarding reinstatement following disciplinary action. In determining whether reinstatement should be recommended, the Board may:

1. Request the Department investigate all activities of the petitioner since the disciplinary action was taken against him/her, including activities prohibited by Neb. Rev. Stat. §§ 71-147 and 71-148.
2. Require the petitioner to submit to a complete diagnostic examination by one or more physicians appointed by the Board, the petitioner being free also to consult a physician or physicians of his/her own choice for a complete diagnostic examination and make available a report or reports thereof to the Board;
3. Require the petitioner to pass a written, oral, or practical examination or any combination of such examinations; or
4. Require the petitioner to complete additional education.

128-008.10B The petition to recommend reinstatement will be considered at the next meeting of the Board that is held, but not earlier than 30 days after the petition is filed.

128-008.10C Any petition to recommend reinstatement of a credential will be conclusively acted upon by the Board within 180 days after the filing of a properly prepared petition and the necessary accompanying documents with the Board.

128-008.10D If the Board recommends reinstatement of the credential, no public hearing need be held on the petition.

128-008.10E Prior to any recommendation by the Board against reinstatement of the credential, an opportunity for a formal public hearing on the petition must be granted by the Board, if formally requested by the petitioner.

128-008.10E1 The petitioner's request for a formal hearing must be submitted within 30 days of the Board's notification of an opportunity for a formal public hearing.

128-008.10E2 If the petitioner had a hearing or an opportunity for a hearing on a prior petition to recommend reinstatement filed pursuant to Neb. Rev. Stat. § 71-161.04 within a period of two years immediately preceding the filing of the current petition, the Board may grant or deny, without a hearing, the current petition to recommend reinstatement filed pursuant to Neb. Rev. Stat. § 71-161.04.

128-008.10F If the petitioner formally requests a formal public hearing or if the Board otherwise holds such a hearing, the petitioner will be given at least 30 days prior notice by sending to the petitioner a copy of the notice of hearing by certified or registered mail

at his/her last known residence or business post office address as shown by the files or records of the Department or as otherwise known. Notice may be given to the petitioner by personal service. The hearing will be conducted pursuant to 172 NAC 1.

128-008.10G The Board reviews the petition to recommend reinstatement, any examination or investigatory information and the record of hearing, if one was held. The Board will submit its recommendation to the Director within 180 days of receipt of the petition to recommend reinstatement.

128-008.10G1 If the Board recommends reinstatement of the credential:

1. The Board will send its recommendation to the petitioner by certified mail along with notification that the petitioner must file an application for reinstatement with the Director.
2. The petitioner must submit, to the Department, an application for reinstatement by the Director within 30 days of receipt of the Board's recommendation.

   a. The application must include:

      (1) Name of the petitioner; and
      (2) Signed statement that the petitioner requests the Director to issue the credential in accordance with the Board's recommendation for reinstatement.

3. Upon receipt of the application for reinstatement from the petitioner, the Department will submit the following to the Director:

   a. The application;
   b. The written recommendation of the Board, including any finding of fact or order of the Board;

   c. The petition submitted to the Board;
   d. The record of hearing, if any;
   e. Any pleadings, motions, requests, preliminary or intermediate rulings and orders, and similar correspondence to or from the Board and the petitioner.

4. The Director will issue a decision regarding reinstatement within 150 days of receipt of the petitioner's application for reinstatement. The Director's decision will be based upon a review of the record of the proceedings before the Board. The Director will not hold a second hearing. The Director may affirm, reverse or modify the Board's recommendation. A decision by the Director to reverse or modify the Board's recommendation will be based on finding that the Board's recommendation is: in excess of statutory authority, made upon unlawful procedure, unsupported by competent, material, and substantial evidence in view of the entire record, or arbitrary or

capricious.

a. When the Director affirms, modifies or reverses the Board's recommendation for reinstatement, the Director will enter an Order setting forth the decision regarding reinstatement of the petitioner's credential. The order will be sent by certified mail to the petitioner;

b. If the petitioner does not accept the Director's decision, s/he may appeal such decision to the District Court of Lancaster County pursuant to Neb. Rev. Stat. §§ 84-901 to 84-920.

128-008.10G2 If the Board recommends reinstatement of the credential with terms, conditions, or restrictions:

1. The Board will send its recommendation to the petitioner by certified mail along with notification that the petitioner must file an application for reinstatement with the Director.

2. The petitioner must submit, to the Department, an application for reinstatement by the Director within 30 days of receipt of the Board's recommendation.

a. The application must include:

(1) Name of the petitioner; and
(2) Signed statement that the petitioner requests the Director to issue the credential in accordance with the Board's recommendation for reinstatement.

3. Upon receipt of the application for reinstatement from the petitioner, the Department will submit the following to the Director:

a. The application;
b. The written recommendation of the Board, including any finding of fact or order of the Board;
c. The petition submitted to the Board;
d. The record of hearing, if any;
e. Any pleadings, motions, requests, preliminary or intermediate rulings and orders, and similar correspondence to or from the Board and the petitioner.

4. The Director will issue a decision regarding reinstatement within 150 days of receipt of the petitioner's application for reinstatement. The Director's decision will be based upon a review of the record of the proceedings before the Board. The Director will not hold a second

hearing. The Director may affirm, reverse or modify the Board's recommendation. A decision by the Director to reverse or modify the Board's recommendation will be based on finding that the Board's recommendation is: in excess of statutory authority, made upon unlawful procedure, unsupported by competent, material, and substantial evidence in view of the entire record, or arbitrary or capricious.

a. When the Director affirms, modifies or reverses the Board's recommendation for reinstatement, the Director will enter an Order setting forth the decision regarding reinstatement of the petitioner's credential. The order will be sent by certified mail to the petitioner;

b. If the petitioner does not accept the Director's decision, s/he may appeal such decision to the District Court of Lancaster County pursuant to Neb. Rev. Stat. §§ 84-901 to 84-920.

128-008.10G3 If the Board denies reinstatement, the Board will send to the petitioner a written notice of the Board's recommendation to deny reinstatement. The petitioner may appeal the Board's decision to the District Court of Lancaster County pursuant to Neb. Rev. Stat. §§ 84-901 to 84-920.

128-008.11 Procedures for Restoration of Credentials Voluntarily Surrendered or Limited for an Indefinite Period of Time.

128-008.11A Credentials voluntarily surrendered or limited for an indefinite period of time pursuant to Neb. Rev. Stat. § 71-161.11 may be restored at the discretion of the Department.

128-008.11A1 An applicant for restoration of a credential that was voluntarily surrendered or limited for an indefinite period of time must submit to the Department:

1. A written application which contains the following information about the applicant:

a. Name;
b. Address;
c. Social security number;
d. If the applicant holds a professional credential in another state, a list of the state(s) and type of credential; and
e. A statement describing all:

(1) Felony or misdemeanor convictions during the time period since the credential was active;

(a) If the applicant has been convicted of a felony or

misdemeanor, provide copies of:

[1] Official Court Record, which includes charges and disposition;
[2] Arrest records;
[3] A letter from the applicant explaining the nature of the conviction;

[4] All addiction/mental health evaluations and proof of treatment, if the conviction involved a drug and/or alcohol related offense and if treatment was obtained and/or required; and
[5] A letter from the probation officer addressing probationary conditions and current status, if the applicant is currently on probation.

(2) Revocations, suspensions, or other disciplinary actions against any professional credential held by the applicant during the time period since the credential was active;

(a) If any disciplinary action was taken against the applicant's credential by another state, submit an official copy of the disciplinary action, including charges and disposition; and

(3) Disciplinary charges pending against any professional credential held by the applicant.

f. Any continuing competency activities.
g. Attest:

(1) That s/he has not practiced in Nebraska prior to the voluntary surrender of his/her credential; or
(2) To the actual number of days practiced if the applicant has practiced in Nebraska prior to the voluntary surrender of his/her credential.

128-008.11A2 If an applicant has practiced while his/her credential was voluntarily surrendered, the Department may:

1. Assess an Administrative Penalty pursuant to 172 NAC 128-018;
2. Initiate disciplinary action against the credential;
3. Deny the request to restore the credential; or
4. Restore the credential to active status and impose limitation(s) or other sanctions on the credential.

128-008.11A3 If an applicant has committed any other violation of the statutes and regulations governing the credential while his/her credential was voluntarily surrendered or limited, the Department may:

1. Initiate disciplinary action against the credential;
2. Deny the request for restoration of the credential; or
3. Restore the credential to active status and impose limitation(s) or other sanctions on the credential.

128-008.11A4 In either event pursuant to 172 NAC 128-008.11A2 or 128-008.11A3, a notice and the opportunity for hearing will be given to the applicant.

128-008.11A5 The Department will act within 150 days on all completed applications.

128-008.12 Procedures for Restoration of Credentials Voluntarily Surrendered or Limited for a Specific and Definite Period of Time.

128-008.12A Credentials voluntarily surrendered or limited for a specific and definite period of time as agreed to between the holder and Department pursuant to Neb. Rev. Stat. § 71-161.11, will be automatically restored at the expiration of that period of time.

128-008.12B If an individual has practiced while his/her credential was voluntarily surrendered for a specific and definite period of time, the Department may assess an Administrative Penalty pursuant to 172 NAC 128-018.

128-008.13 Credentials Voluntarily Surrendered or Limited Permanently.

128-008.13A Credentials that are voluntarily surrendered or limited permanently pursuant to Neb. Rev. Stat. § 71-161.11 will not be restored.

128-009 UNPROFESSIONAL CONDUCT: In addition to the unlawful or unprofessional acts listed in Neb. Rev. Stat. §§ 71-147 through 71-148, the following conduct will be considered unprofessional acts as defined by the Board per Neb. Rev. Stat. § 71-147(10):

1. Return of dispensed drugs or devices to saleable stock, unless specifically allowed by law;
2. Failure to conduct patient/client counseling, unless specifically exempt as provided in Neb. Rev. Stat. §71-1,147.35;
3. Claiming credit for any continuing education activities not actually participated in and earned;
4. Willfully or negligently violating the confidentiality between a pharmacist and a patient, except as allowed by law;
5. Any false or misleading statement on a pharmacy self inspection form;

6. Practicing pharmacy under a false or assumed name;
7. Except as otherwise permitted by law, dispensing, selling, administering, distributing, ordering, or giving to a person, known by the pharmacist to be an addict or any person previously drug dependent, any drug legally classified as a controlled substance;
8. Refusal to allow access to the records required to be kept pursuant to 175 NAC 8-006.03;
9. Refusal to cooperate or furnish evidentiary information, legally requested in writing, in an investigation by the Department or law enforcement of any alleged violation;
10. Violation of any provision(s) of the Pharmacy Practice Act, or the Uniform Controlled Substances Act, or the rules and regulations of the Department or of an action, stipulation, or agreement of the Board or Department;
11. Any violation of the federal Controlled Substances Act;
12. Exercising influence on the patient in such a manner as to exploit the patient for the financial gain of the pharmacist or of a third party, which includes, but is not limited to, the promotion or sale of services, goods, drugs, devices, or biologicals;
13. Refusal to provide professional service to a person because of such person's race, creed, color, or national origin;
14. Dispensing, selling, or administering anabolic steroids to a person for other than therapeutic purposes;
15. Lack of or inappropriate direction, collaboration or direct supervision of any person employed by, supervised by or assigned to the pharmacist;
16. Any violation of the Medicare / Medicaid anti-kickback statute, 42 United States Code Chapter 7 Section 1320a-7b(b), which prohibits illegal remuneration, including but not limited to any kick-back or bribe;
17. Any violation of the federal Resource Conservation and Recovery Act;
18. Any violation of the federal Prescription Drug Marketing Act of 1987;
19. Any violation of the federal Poison Prevention Packaging Act of 1970;
20. Any violation of the Cancer Drug Repository Program Act;
21. Any departure from or failure to conform to the ethics of the pharmacy profession, which ethics were adopted by the membership of the American Pharmacists Association on October 27, 1994, and are attached to these regulations and incorporated by this reference;
22. Misrepresentation of material facts in applying for or procuring a renewal of a license/certification/registration/permit;
23. Misrepresenting one's credentials in an application submitted to a healthcare facility, insurance company, or prospective employer; or
24. The use of false or deceptive statements in any advertisement.

128-010 TEMPORARY EDUCATIONAL PERMIT

128-010.01 Permit Requirements: An applicant for a temporary educational permit must:

1. Have graduated from an accredited pharmacy program;
2. Be of good moral character and attained the age of 21;
3. Have been requested by an accredited hospital or clinic or an accredited pharmacy program in the State of Nebraska to serve as a graduate student in its approved program; and

4. Submit to the Department:

a. An application pursuant to 172 NAC 128-003.01 item 6.a.(1) through (8) and (11) through (13);
b. Name and location of the accredited hospital or clinic or the accredited pharmacy program where the applicant will be serving in a supervised educational program or the approved graduate pharmacy education program, which should include dates of service;
c. A signed statement from the applicant requesting that a temporary educational permit be issued and verifying that all information in the application is true and correct.
d. Official documentation that an accredited hospital or clinic or an accredited pharmacy program in the State of Nebraska has requested that the applicant will be serving as a graduate student in its approved program for a set period of time;
e. The required temporary educational permit fee pursuant to 172 NAC 128-017; and
f. A copy of a birth certificate, marriage license, driver's license, or other valid verification of age.

128-010.02 The Department will act within 150 days upon all completed applications for licensure.

128-010.03 Procedures for Renewal of Temporary Educational Permit: A temporary educational permit issued by the Department under the Act and these Regulations will expire one year from the date of issuance. The permit may be renewed for no more than five one-year periods.

128-010.03A Renewal Process: A temporary educational permit holder who wishes to renew his/her temporary educational permit must:

1. Provide documentation that s/he is currently enrolled in an supervised educational program or the approved graduate pharmacy education program;
2. Respond to the following questions:

a. Has your license/permit in any profession in another state been revoked, suspended, limited or disciplined in any manner?
b. Have you been convicted of a misdemeanor or felony?

These questions relate to the time period since the last renewal of the permit or during the time period since the permit was issued.

3. Submit to the Department:

a. The renewal notice;

b. Documentation that s/he is currently enrolled in a supervised educational program or the approved graduate pharmacy education program;
c. If any disciplinary action was taken against the applicant's license by another state, an official copy of the disciplinary action including charges and disposition;
d. If the licensee has been convicted of a felony or misdemeanor:

(1) Official Court Record, which includes charges and disposition;
(2) Copies of arrest records;
(3) A letter from the licensee explaining the nature of the conviction;
(4) All addiction/mental health evaluations and proof of treatment, if the conviction involved a drug and/or alcohol related offense and if treatment was obtained and/or required; and

(5) A letter from the probation officer addressing probationary conditions and current status; if the applicant is currently on probation.

128-010.03B First Notice: At least 30 days before the temporary educational permit is due to expire, the Department will send a renewal notice by means of regular mail to each temporary educational permit holder at his/her last place of residence as noted in the records of the Department. It is the responsibility of the temporary educational permit holder, prior to the renewal period, to notify the Department of any name and/or address changes.

128-010.03B1 The renewal notice will specify:

1. The name of the temporary educational permit holder;
2. The temporary educational permit holder's last known address of record;
3. The temporary educational permit number;
4. The expiration date of the temporary educational permit;
5. Answer the following questions either yes or no; if you answer yes, explain the circumstances and the outcome:

a. Have you ever been convicted of a misdemeanor or a felony?
b. Have you ever been denied a license or the right to take an examination?
c. Have a current license in another state or jurisdiction?

(1) List all the other states/jurisdictions where you have been licensed or are currently licensed, including license number and expiration date.

d. Has your pharmacist license in any state or jurisdiction ever been suspended, revoked, or disciplined in any manner? (if applicable)

6. A signed statement from the applicant that he/she is renewing his/her temporary educational permit, is still in supervised educational program or the approved graduate pharmacy education program in the State of Nebraska, he/she is the person referred to in this renewal, and that the statements are true and complete.

128-010.02B2 The permit holder must apply for renewal by submitting to the Department:

1. The renewal notice;
2. The permit holder's social security number;
3. Documentation that s/he is currently enrolled in a supervised educational program or the approved graduate pharmacy education program;
4. Documentation relating to misdemeanor or felony conviction(s) or licensure revocation, suspension, limitation or disciplinary action (if applicable).

128-010.03C Second Notice: The Department must send to each temporary educational permit holder who fails to renew his/her temporary educational permit in response to the first notice, a second notice of renewal pursuant to 172 NAC 128-010.03B that specifies:

1. The temporary educational permit holder failed to renew his/her temporary educational permit;
2. The temporary educational permit has expired;
3. The Department will suspend action for 30 days following the date of expiration;
4. Upon receipt of the renewal notice and documentation of current enrollment, no order of revocation will be entered; and
5. Upon failure to receive the renewal notice and documentation of current enrollment the temporary educational permit will be revoked pursuant to 172 NAC 128-005.

128-010.03C1 The temporary educational permit holder must apply for renewal by submitting to the Department:

1. The renewal notice;
2. The permit holder's social security number;
3. Documentation that s/he is currently enrolled in a supervised educational program or the approved graduate pharmacy education program;

4. Attestation by the licensee:
   a. That s/he has not practiced in Nebraska since the expiration of his/her permit; or
   b. To the actual number of days practiced in Nebraska since the expiration of his/her license;

5. Documentation relating to misdemeanor or felony conviction(s) or licensure revocation, suspension, limitation or disciplinary action (if applicable).

128-010.03D When any permit holder fails, within 30 days of expiration of the permit, to submit documentation that s/he is currently enrolled in a supervised educational program or the approved graduate pharmacy education program, the Department will automatically revoke the permit without further notice of hearing and make proper record of the revocation.

128-010.03E The Department may refuse to renew a temporary educational permit for falsification of any information submitted for renewal of the permit. Such refusal will be made pursuant to Neb. Rev. Stat. §§ 71-149 to 71-155 and 184 NAC 1.

128-011 PHARMACIST INTERN REQUIREMENTS

128-011.01 An applicant for registration as a pharmacist intern may apply at any time following enrollment in an accredited pharmacy program, or having graduated from a foreign pharmacy program, or if a pharmacy graduate, not licensed in Nebraska, application may be made at any time prior to licensure as a pharmacist in Nebraska.

128-011.02 An applicant for registration as a pharmacist intern on the basis of current enrollment in an accredited pharmacy program must:

1. Be currently enrolled in an accredited pharmacy program; and
2. Submit to the Department:

   a. An application for registration as a pharmacist intern, that must include the following information:

      (1) An application pursuant to 172 NAC 128-003.01 item 6.a.(1) through (8) and (11) through (13);
      (2) Official documentation of the month and year the applicant enrolled in the pharmacy program and the expected month and year of graduation;
      (3) A statement that the applicant is aware that s/he must not practice as a pharmacist intern without the immediate personal supervision of a licensed pharmacist; and
      (4) A signed statement from the applicant verifying that all information in the application is true and correct;

b. The required licensure fee pursuant to 172 NAC 128-017; and
c. A copy of a birth certificate, marriage license, driver's license, or other valid verification of age.

128-011.03 An applicant for registration as a pharmacist intern on the basis of graduation from a foreign pharmacy program must:

1. Have graduated from a foreign pharmacy program;
2. Have obtained the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification given by NABP;
3. Submit to the Department:

a. An application for registration as a pharmacist intern, that must include the following information:

(1) An application pursuant to 172 NAC 128-003.01 item 6.a.(1) through (8) and (11) through (13);
(2) Official documentation of successful completion of a pharmacy degree from a foreign pharmacy program;
(3) A copy of his/her certificate from the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification Program of NABP;
(4) A statement that the applicant is aware that s/he must not practice as a pharmacist intern without the supervision of a licensed pharmacist; and
(5) A signed statement from the applicant verifying that all information in the application is true and correct;
(6) The required licensure fee pursuant to 172 NAC 128-017; and
(7) A copy of a birth certificate, marriage license, driver's license, or other valid verification of age.

128-011.04 An applicant for registration as a pharmacist intern on the basis of graduation from an accredited pharmacy program must:

1. Have graduated from an accredited pharmacy program;
2. Submit to the Department:

a. An application for registration as a pharmacist intern, that must include the following information:

(1) An application pursuant to 172 NAC 128-003.01 item 6.a.(1) through (8) and (11) through (13);
(2) Official documentation of the month and year the applicant graduated from the pharmacy program;
(3) A statement that the applicant is aware that s/he must not practice as a pharmacist intern without the supervision of a licensed pharmacist; and

(4) A signed statement from the applicant verifying that all information in the application is true and correct;

b. The required licensure fee pursuant to 172 NAC 128-017; and

c. A copy of a birth certificate, marriage license, driver's license, or other valid verification of age.

128-011.05 The Department will act within 150 days upon all completed applications for licensure.

128-011.06 A pharmacist intern must notify the Department of any change in enrollment, address, or name.

128-011.07 A pharmacist intern registration based on enrollment in or graduation from an accredited pharmacy program expires not later than 15 months after the date of graduation or at the time of professional licensure, whichever comes first.

128-011.08 A pharmacist Intern registration based on graduation from a pharmacy program located outside of the United States which is not accredited expires not later than 15 months after the date of issuance of the registration or at the time of professional licensure, whichever comes first.

128-011.09 No person may function as a pharmacist intern until s/he receives a registration card from the Department. A pharmacist intern must have his/her registration card available at all times when functioning as an intern.

128-011.10 When a pharmacist intern desires to obtain credit for experience received in a state other than Nebraska, s/he must abide by all the provisions of the internship rules in that state, and must provide evidence of the number of pharmacy internship hours actually participated in by the pharmacist intern from:

1. The state Board of Pharmacy were the pharmacy internship hours were earned; or
2. The Nebraska-licensed pharmacist who supervised the training.

All pharmacy internship hours submitted to the Department must contain a notarized signature of the supervising Nebraska-licensed pharmacist or be certified by the state Board of Pharmacy.

128-011.11 The maximum number of hours which may be accepted from experiential training directed by an accredited pharmacy program are:

1. 640 hours, if the applicant for licensure as a pharmacist was awarded a Bachelor's degree in Pharmacy; or
2. 1500 hours, if the applicant for licensure as a pharmacist was awarded a Doctor of Pharmacy degree.

128-011.12 A pharmacist intern must be supervised at all times while performing the functions of a pharmacist intern, which may include all aspects of the practice of pharmacy, unless otherwise restricted. This supervision must be provided by a pharmacist who possesses a Nebraska pharmacist's license which is free from disciplinary measures at the time of supervision. This requirement for pharmacist supervision does not apply to pharmacist interns who are receiving experiential training directed by the accredited pharmacy program in which s/he is enrolled.

128-011.13 Registration as a pharmacist intern will remain in effect until the pharmacist intern gains licensure as a pharmacist, 15 months following graduation from an accredited pharmacy program, or dismissal or disenrollment from an accredited pharmacy program, whichever occurs first.

128-011.14 Each pharmacist intern must be identified as a pharmacist intern while performing the duties of an intern.

128-011.15 In the case of a pharmacist intern, the result of failure to comply with any of these standards may be loss of accumulated pharmacy internship hours and revocation of any license issued on the basis of such pharmacy internship.

128-011.16 A pharmacist intern must not supervise another pharmacist intern nor a pharmacy technician.

128-012 PHARMACIST INTERN & PHARMACY TECHNICIAN SUPERVISION REQUIREMENTS

128-012.01 A pharmacist may supervise pharmacist interns and pharmacy technicians in the following ratios:

1. A pharmacist may supervise up to two pharmacy technicians at any time, unless prohibited by a disciplinary action. (1:2)
2. A pharmacist may supervise up to three pharmacist interns at any time, unless prohibited by a disciplinary action. (1:3)
3. A pharmacist may supervise any combination of pharmacy technicians and pharmacist interns at any time up to a total of three people, as long as no more than two are pharmacy technicians. (1:3)
4. The supervision ratios of these regulations do not apply to pharmacist interns who are receiving experiential training directed by the accredited pharmacy program in which he or she is enrolled.
5. A pharmacy may apply to use more than two pharmacy technicians per pharmacist and the Board may approve such an application under the following guidelines:

    a. The pharmacy is participating in a scientific study based upon improved patient care or enhanced pharmaceutical care,
    b. The pharmacy has provided the Board with the following information regarding the patient care study:

(1) Duration of the study, not to exceed 12 months.

(2) Duration may be extended twice in not greater than six month increments,

c. Goal of the study or the hypothesis being tested,
d. Names of the pharmacists participating in the study,
e. Expected date of completion of the study,
f. Expected date of study data to be forwarded to the Board, and
g. An affidavit that the pharmacy will provide all study data and results to the Board at the completion of the study report.

6. The Board may revoke permission to use more than two pharmacy technicians per pharmacist at any time when they have reason to believe that patient care is not being benefitted by the study.
7. The Board may grant permission to continue the practices used in the study for up to 24 months during the promulgation of rules and regulations.
8. Nothing in these regulations will be construed to require the Board to approve an increase in number of technicians per pharmacist for any study.

128-012.02 Nothing in these regulations will be construed to prohibit one pharmacist intern or one pharmacy technician from being supervised by more than one pharmacist at any time.

128-012.03 All persons functioning as pharmacy technicians must meet the requirements of Neb. Rev. Stat. § 71-1,147.33.

128-012.04 Each pharmacy technician must be identified as a pharmacy technician while performing the duties of a technician.

128-013 PHARMACEUTICAL CARE REQUIREMENTS

128-013.01 A pharmacist may enter into a practice agreement with a licensed medical practitioner to provide pharmaceutical care according to written protocols.

128-013.02 The pharmacist must assure that the Board is notified of any practice agreement. Such notice must be given to both the Board of Pharmacy and the medical practitioner's professional Board. Such notice must contain the names of the pharmacist(s) and the licensed medical practitioner(s) and a description of the therapy being monitored or initiated.

1. A copy of the practice agreement and written protocols must be available for review by any representative of the Department, and
2. A copy of the practice agreement or written protocols must be sent to the Board upon request from the Board.
3. Written notice must be given to the Board at initiation and at any time there is a change in parties or protocols.

128-013.03 Practice agreements and written protocols must be signed by the pharmacist and the medical practitioner and must be reviewed, signed, and dated every 12 months.

128-013.04 Practice agreements and written protocols will cease immediately upon:

1. The death of either the pharmacist or the licensed medical practitioner, or
2. Loss of license of either the pharmacist or the medical practitioner, or
3. Disciplinary action limiting the ability of either the pharmacist or the medical practitioner to enter into practice agreements, or
4. Individual decision or mutual agreement of the pharmacist(s) or medical practitioner(s) to end the agreement.

128-013.05 Nothing in these agreements will allow a pharmacist to practice beyond his/her scope of practice.

128-014 DISPENSING REQUIREMENTS

128-014.01 A prescription must contain the following information prior to being filled by the pharmacist:

1. Patient's name,
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,

   a. The quantity for residents of long term care facilities must be 60 days, unless otherwise limited by the prescriber.

6. Directions for use,
7. Date of issuance,
8. Prescriber's name and the name of the supervising or collaborating physician, when applicable,

   a. If the prescription is written, it must contain the prescriber's signature and the name of the prescriber stamped, typed, or clearly handwritten in addition to the signature.

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 5 times in the 6 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.

128-014.02 A Chart Order Must Contain the Following Information:

1. Patient's name,
2. Date of the order,
3. Name of the drug, device, or biological,
4. Strength of the drug or biological, if applicable,
5. Directions for administration to the patient, including the dose to be given, and
6. Prescriber's name.

128-014.03 Prescription Label: Prior to dispensing a drug, device or biological, the pharmacist assure that a legible prescription label is affixed to the container. Such 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.

128-014.04 Prescription Labels for Multi-Drug Containers: A pharmacist may dispense more than one drug 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, manufacturer, packager, or distributor; or
3. The container does not accommodate greater than a one month supply of compatible dosage units and is labeled so as to identify each drug or biological in the container in addition to all information pursuant to 172 NAC 128-014.03.

128-014.05 Prescriber's Employee or Agent: A prescription, chart order, or refill authorization issued by a prescriber may be communicated to a pharmacist or a pharmacist intern by an employee or agent of the prescriber.

128-015 PATIENT COUNSELING

128-015.01 Only a pharmacist or a pharmacist intern can provide patient counseling, except as provided in Neb. Rev. Stat. § 71-1,147.53.

128-015.02 A verbal offer to counsel must be provided to the:

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

128-015.03 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 judgement, 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 judgement regarding counseling following consultation with the prescriber.

128-015.04 Whenever a pharmacist receives a prescription for a brand name product and chooses to dispense a bioequivalent drug, device or biological, the pharmacist must advise the patient or the patient's caregiver that drug product selection has occurred. The patient or the patient's caregiver may instruct the pharmacist that s/he does not desire drug product selection.

128-016 MAIL SERVICE PHARMACY LICENSE REQUIREMENTS: Any person operating a mail service pharmacy outside of the State of Nebraska must obtain a mail service pharmacy license prior to shipping, mailing, or in any manner delivering dispensed prescription drugs as defined in Neb. Rev. Stat. § 71-1,142 into the State of Nebraska.

128-016.01 In order for the Board to determine that the requirements and qualifications are

substantially equivalent between Nebraska and the state, jurisdiction or territory where the pharmacy is located, and to assure that the Nebraska Secretary of State is designated the Agent of Service of Process in all matters regarding the Mail Service Pharmacy Licensure Act,

the applicant for a Mail Service Pharmacy License must submit the following information and the required fee pursuant to 172 NAC 128-017:

1. Pharmacy name,
2. Pharmacy street address,
3. Pharmacy telephone number,
4. Pharmacy permit or license number and state of issuance,
5. Expiration date of pharmacy permit or license number,
6. Name of a pharmacist, employed by and working in the pharmacy, who has an active Nebraska pharmacist's license,
7. License number of a pharmacist, employed by and working in the pharmacy, who has an active Nebraska pharmacist's license,
8. Expiration date of the Nebraska pharmacist's license,
9. Name of the pharmacist-in-charge,
10. Mailing address of the pharmacist-in-charge,
11. License number of the pharmacist-in-charge and state of issuance,
12. Expiration date of the license of the pharmacist-in-charge,
13. A copy of the most recent state pharmacy inspection from the state in which the pharmacy is located,
14. Acknowledgment whether or not the pharmacy is a Verified Internet Pharmacy Practice Site (V.I.P.P.S.) pharmacy as certified by N.A.B.P., if applicable,
15. A declaration that the Nebraska Secretary of State has been designated the Agent of Service of Process in all matters regarding the Mail Service Pharmacy Licensure Act, and
16. A statement concerning licensure of the pharmacist-in-charge and the permit of the pharmacy in another State, including any history of disciplinary action on a professional credential or pharmacy permit, sent directly to the Department from the State Board or agency that issued the license or permit,
17. An attestation from the applicant verifying that all information in the application is correct.

128-016.02 Renewal Licenses

128-016.02A 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;
d. Name and address of the pharmacy;

e. Name and license number of the designated Nebraska licensed pharmacist who is responsible for compliance with the Nebraska Mail Service Pharmacy Licensure Act;

f. A request for a current copy of the pharmacy credential issued by the State/Jurisdiction/Territory in which pharmacy is located; and

g. A request for documentation pertaining to past disciplinary actions against the pharmacy credential.

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 mail service pharmacy license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the mail service pharmacy may not ship, mail, or in any manner deliver dispensed prescription drugs into the State of Nebraska. The license remains in lapsed status until it is reinstated.

128-016.02B Licensee Responsibilities: The licensee must submit:

1. The application for renewal;

2. A current copy of the pharmacy credential issued by the State/Jurisdiction/Territory the pharmacy is located in

3. The name of the pharmacist-in-charge;

4. The name and license number of the Nebraska licensed pharmacist who is responsible for compliance with the Nebraska Mail Service Pharmacy Licensure Act;

5. Documentation pertaining past disciplinary action against pharmacy (if applicable); and

6. The required renewal fee pursuant to 172 NAC 128-017.17.

128-016.02C Refusal to Renew: The Department may refuse renewal of a mail service pharmacy license that fails to meet the requirements for renewal, including:

1. Violation of any of the provisions of the Mail Service Pharmacy Licensure Act, or 172 NAC 128-016.

128-016.03 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 pursuant to 172 NAC 128-017.17. The application must conform to the requirements pursuant to 172 NAC 128-016.01.

128-016.03A Refusal to Reinstate: The Department may refuse reinstatement of a pharmacy license that fails to meet the requirements for reinstatement, including:

1. Violations of any of the provisions of the Mail Service Pharmacy Licensure Act, 172 NAC 128-016.

128-017 SCHEDULE OF FEES: The following fees have been set by the Department:

128-017.01 Initial License by Examination or Score Transfer Fee: By an applicant for a license to practice pharmacy, the fee of $75 and the Licensee Assistance Program fee of $1 for each year remaining during the current biennial renewal period.

128-017.02 Proration of Initial License by Examination or Score Transfer Fee: For issuance of a license that will expire within 180 days after its initial issuance date, a fee of $25 and the Licensee Assistance Program fee of $1.

128-017.03 Initial License by Reciprocity Fee: By an applicant for a license to practice pharmacy, the fee of $75 and the Licensee Assistance Program fee of $1 for each year remaining during the current biennial renewal period.

128-017.04 Proration of Initial License by Reciprocity Fee: For issuance of a license that will expire within 180 days after its initial issuance date, a fee of $25 and the Licensee Assistance Program fee of $1.

128-017.05 Pharmacist License Renewal Fee: By an applicant for renewal on a biennial basis of a license to practice pharmacy, the fee of $75 and the Licensee Assistance Program fee of $2.

128-017.06 Inactive License Status Fee: By an applicant to have his/her credential placed on inactive status, the fee of $25.

128-017.07 Renewal Late Fee: By an applicant for renewal on a biennial basis of credential, who fails to pay the renewal fee on or before the expiration date of his/her credential, the fee of $25 in addition to the renewal fee.

128-017.08 Certification of License Fee: For issuance of a certification of a credential, the fee of $25. The certification includes information regarding:

1. The basis on which a credential was issued;
2. The date of issuance;
3. Whether disciplinary action has been taken against the credential; and
4. The current status of the credential.

128-017.09 Verification of License Fee: For issuance of a verification of a credential, the fee of $5. The verification includes written confirmation as to whether a credential was valid at the time the request was made.

128-017.10 Duplicate License Fee: For a duplicate of original license document or reissued license, the fee of $10.

128-017.11 Administrative Fee: For a denied credential or a withdrawn application, the administrative fee of $25 will be retained by the Department, except if the credentialing fee is less than $25, the fee will be forfeited and an examination fee will not be returned.

128-017.12 Reinstatement Late Fee: For reinstatement of a credential for failure to meet renewal requirements:

1. Within one year of revocation, the fee of $35 in addition to the renewal fee.
2. After one year of revocation, the fee of $75 in addition to the renewal fee.

128-017.13 Reinstatement Fee: For reinstatement of a pharmacist credential following suspension, limitation, or revocation for disciplinary reasons, the fee of $75.

128-017.14 Fee for Temporary Educational Permit: By a recipient of a temporary educational permit, the annual fee of $50.

128-017.15 Fee for Pharmacist Intern Registration: For each registration as a pharmacist intern, the fee of $50.

128-017.16 Initial License Fee for a Mail Service Pharmacy: For each license for a mail service pharmacy, the fee of $255.

128-017.17 Mail Service Pharmacy License Renewal Fee: By an applicant for a renewal on an annual basis of a mail service pharmacy license, the fee of $255.00.

128-017.18 Initial Registration Fee for Pharmacy Technician: By an applicant for a registration as a pharmacy technician, the fee of $25 and the Licensee Assistance Program fee of $1 for each year remaining during the current biennial renewal period.

128-017.19 Proration of Initial Registration Fee for Pharmacy Technician: For issuance of a registration that will expire within 180 days after its initial issuance date, a fee of $25 and the Licensee Assistance Program fee of $1.

128-017.20 Pharmacy Technician Registration Renewal Fee: By an applicant for renewal on a biennial basis of a registration as a pharmacy technician, the fee of $25 and the Licensee Assistance Program fee of $2.

128-018 ADMINISTRATIVE PENALTY: The Department may assess an administrative penalty when evidence exists that a person or entity practices without a credential. Practice without a credential for the purpose of this regulation means practice:

1. Prior to the issuance of a credential;
2. Following the expiration of a credential; or
3. Prior to the reinstatement of a credential.

128-018.01 Evidence of Practice: The Department will consider any of the following conditions as prima facie evidence of practice without a credential:

1. The person admits to engaging in practice;
2. Staffing records or other reports from the employer of the person indicate that the person was engaged in practice;
3. Billing or payment records document the provision of service, care, or treatment by the person;
4. Service, care, treatment records document the provision of service, care, or treatment by the person;
5. Appointment records indicate that the person was engaged in practice; and
6. The person or entity opens a business or practice site and announces or advertises that the business or site is open to provide service, care, or treatment.

For purposes of this regulation prima facie evidence means a fact presumed to be true unless disproved by some evidence to the contrary.

128-018.02 Penalty: The Department may assess an administrative penalty in the amount of $10 per day, not to exceed a total of $1,000 for practice without a credential. To assess such penalty, the Department will:

1. Provide written notice of the assessment to the person. The notice must specify:

   a. The total amount of the administrative penalty;
   b. The evidence on which the administrative penalty is based;

c. That the person may request, in writing, a hearing to contest the assessment of an administrative penalty;

d. That the Department will within 30 days following receipt of payment of the administrative penalty, transmit the penalty to the State Treasurer for credit to the Permanent School Fund; and

e. That an unpaid administrative penalty constitutes a debt to the State of Nebraska which may be collected in the manner of a lien foreclosure or sued for and recovered in a proper form of action in the name of the state in the District Court of the county in which the violator resides or owns property.

2. Send by certified mail, a written notice of the administrative penalty to the last known address of the person to whom the penalty is assessed.

128-018.03 Administrative Hearing: When a person contests the administrative penalty and requests a hearing, the Department will hold a hearing pursuant to Neb. Rev. Stat. §§ 84-901 to 84-920 and the Department's rules and regulations adopted pursuant to these statutes.

Code of Ethics for Pharmacists

PREAMBLE

Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists. These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

I. A pharmacist respects the covenantal relationship between the patient and pharmacist.

Considering the patient-pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.

II. A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.

A pharmacist places concern for the well-being of the patient at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.

III. A pharmacist respects the autonomy and dignity of each patient.

A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A pharmacist communicates with patients in terms that are understandable. In all cases, a pharmacist respects personal and cultural differences among patients.

IV. A pharmacist acts with honesty and integrity in professional relationships.

A pharmacist has a duty to tell the truth and to act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.

V. A pharmacist maintains professional competence.

A pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.

VI. A pharmacist respects the values and abilities of colleagues and other health professionals.

~~When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.~~

~~VII. A pharmacist serves individual, community, and societal needs.~~

~~The primary obligation of a pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly.~~

~~VIII. A pharmacist seeks justice in the distribution of health resources.~~

~~When health resources are allocated, a pharmacist is fair and equitable, balancing the needs of patients and society.~~

~~* adopted by the membership of the American Pharmacists Association October 27, 1994.~~

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 8 PHARMACIES

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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 by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-~~459~~470; the Pharmacy Practice Act, Neb. Rev. Stat. §§38-2801 to 38-28,116; and the Prescription Drug Safety Act, Neb. Rev. Stat. §§71-2457 to 72-2483.

8-002 DEFINITIONS: For purposes of these regulations, the definitions in the Health C~~c~~are Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-470; the Pharmacy Practice Act, Neb. Rev. Stat. §§38-2801 to 38-28,116; the Prescription Drug Safety Act, Neb. Rev. Stat. §§71-2457 to 72-2483; the Uniform Credentialing Act, Neb. Rev. Stat. §§38-101 to 38-1,140, and the following definitions apply:

~~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~~ an individual, government entity, or business entity ~~, corporation, partnership, limited liability company or other form of business organization who applies~~ that has submitted an application for a pharmacy 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 where dispensing to the patient or caregiver occurs.

~~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 for the purpose of these regulations~~ means substances as defined in the same as Neb. Rev. Stat. § 71-1,142~~38-2819~~.

~~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~~ or entity 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~~ the same as Neb. Rev. Stat. § 38-2838.

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~~ applicant individual or entity that intends , ~~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.~~ To receive a license, a~~A~~n applicant for an initial or renewal license must demonstrate that the pharmacy meets the operational and physical plant standards contained in 175 NAC 8-007 and 8-008.

8-003.01 ~~Application Process for~~ Initial Licensure

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~~ Demonstrate the ability to comply with the applicable standards specified in 175 NAC 8-00~~6~~7 and 8-00~~7~~8;
2 ~~3.~~ Submit a signed application verifying that all information in the application is correct:; and ~~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.~~

~~(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.~~

~~(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.~~

~~(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~~

3. ~~4.~~ Submit the required fee as specified in 175 NAC 8-~~004~~005.~~11~~09.

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: ~~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;~~

1~~3.~~ The Department will ~~Issue~~issue a provisional pharmacy license if the Department determines based upon review of the application that the applicant ~~pharmacy~~ has substantially complied ~~but fails to fully comply~~ with the requirements for licensure under the Health Care Facility Licensure Act ~~and~~or that the ~~failure~~ operation of the pharmacy 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

24. The Department will otherwise Ddeny the application. 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. After issuing a provisional license, tThe Department will conduct an announced initial on-site inspection with the pharmacist in charge or the practitioner present, after which the department will take one of the following actions:

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.
6.

1. Issue a pharmacy license, if it determines that the pharmacy has fully complied with the requirements for licensure under the Health Care Facility Licensure Act and that the operation of the pharmacy does not pose an imminent danger of death or physical harm to the persons served by the pharmacy;

2. Request the pharmacy provide a statement of compliance that indicates the pharmacy's effort(s) to correct violation(s) identified during the initial on-site inspection, if it determines that the pharmacy does not fully comply with the requirements of the Health Care Facility Licensure Act but the nature of the violations do not create an imminent danger of death or physical harm to the persons served by the pharmacy; and issue a pharmacy license after conducting a subsequent review to determine whether the provisional licensee has corrected the violations addressed in the statement of compliance; or

3. Revoke the provisional pharmacy license, if it determines that the pharmacy does not fully comply with the requirements for licensure under the Health Care Facility Licensure Act and that the nature of the violation(s) pose(s) 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 Licenses

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~~ at least 30 days prior to the expiration date~~.~~ and ~~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~~ Renew the license when it determines that the applicant has submitted a completed application; or

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,~~ No provision of services by the pharmacy may occur when the license is in lapsed status~~not operate~~. The license remains in lapsed status until it is reinstated.

8-003.02B Licensee Responsibilities: The licensee must submit~~:~~ the information and the fee required by the Department.

~~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~~005.~~11~~09. The application must conform to the requirements specified in 175 NAC 8-003.~~02~~01A.

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~~007 and 8-~~007~~008. 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 continued to provide~~d~~ pharmacy services from the site or 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.~~

8-003.04 Permanently Closing a Pharmacy

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

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

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

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.

8-003.04D When the closing of a pharmacy is anticipated, the pharmacist in charge or practitioner is responsible for notifying patients of that pharmacy at least 15 days prior to closing that they will need to seek service elsewhere. The notification can be accomplished through:

1. Advertisement in a newspaper appropriate to the location of the pharmacy,
2. Written notice to patients of the pharmacy, or
3. Other such notice as is appropriate.

8-004 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

8-004.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

8-004.01A 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 8-006;
2. Failing to meet a compliance assessment standard adopted under Neb. Rev. Stat. § 71-442 as specified in 175 NAC 8-006;
3. Having had a license revoked within the two-year period preceding an application; or
4. Any of the grounds specified in 175 NAC 8-004.01B.

8-004.01B The Department may take disciplinary action against a provisional pharmacy license or a pharmacy license for the grounds set out in Neb. Rev. Stat. § 71-448 or any of the following grounds:

1. Violation of the Prescription Drug Safety Act;
2. Failure to account for significant, substantial shortages or overages of controlled substances; and
3. Loss of prescription inventory or prescription records due to theft or any other cause resulting from failure to secure the inventory or records.

8-004.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

8-004.02A 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~~ the grounds that support the Department's determination, ~~and~~ identify the statute or regulation violated and, if applicable, describe the type of disciplinary action pending.

8-004.02B 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~~ Department for an informal conference under Neb. Rev. Stat. § 71-453 or an administrative hearing.

8-004.03 Reinstatement from Disciplinary Probation, Suspension, ~~and~~ or Following Revocation

8-004.03A 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 8-005.09; and
3. Successful completion of an inspection, if the Department determines an inspection is warranted.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 8-006, that the pharmacy is in compliance with the operational and physical plant standards of 175 NAC 8-007 and 8-008.

8-004.03B Reinstatement Prior to Completion of Probation or Suspension

8-004.03B1 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.

8-004.03B2 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 8-005.09; and
4. Successfully complete an inspection.

8-004.03C Reinstatement Following Revocation: A license may be reinstated following revocation upon:

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 8-005.09; and
3. Successful completion of an inspection, if the Department determines an inspection is warranted.

8-~~004~~005 GENERAL REQUIREMENTS

~~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.~~

8-00~~4~~5.0~~2~~1 Effective Date and Term of License: A pharmacy license expires on July 1 of each year.

8-00~~4~~5.0~~3~~2 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. The new owner(s) must apply for a new pharmacy license. If ~~there is~~ a change of ownership occurs and the pharmacy remains on the same premises, the inspection in 175 NAC 8-~~005~~006.02 is not required. ~~The new owner(s) must apply for a new pharmacy license.~~ If there is a change of premises, the new owner(s) ~~must apply for a new pharmacy license and~~ the pharmacy must pass the inspection specified in 175 NAC 8-~~005~~006.02.

8-00~~4~~5.0~~4~~3 Notification: An applicant or licensee must notify the Department of any change as set forth in 175 NAC 8-005.04 through 8-005.08. The following information is required for all notifications:

8-00~~4~~5.0~~5~~4 Change of Pharmacist in Charge: The licensee must notify the Department ~~immediately~~ at least one business day ~~when~~ before there is a change in the pharmacist in charge.

8-00~~4~~5.0~~6~~5 Change of Ownership or Premises: The licensee must notify the Department in writing at least 30 days before a pharmacy is sold, leased, discontinued, or moved to new premises.

8-00~~4~~5.0~~7~~6 Change of Name of the Pharmacy: The licensee must notify the Department in writing within at least 5 working days when there is a change in the name of the pharmacy.

8-00~~4~~5.0~~8~~7 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 at least 30 days of the after death of 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.~~

8-0045.~~10~~08 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~~ at least 24 hours ~~of~~ after 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.

8-0045.~~11~~09 Fees: The licensee must pay fees for licensure as follows:

8-0045.~~11~~09A The required fees are:

1. Initial pharmacy license fee is $625.
2. Annual pharmacy license renewal fee is $625.
3. Duplicate license fee is $10.

8-0045.~~11~~09B 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.

8-00~~5~~6 INSPECTIONS: Each ~~pharmacy~~ licensee has the responsibility to be in compliance, and to remain in compliance, with the regulations set out in this chapter. For the purpose of assuring compliance, each licensee must prepare a Pharmacy Quality Assurance Report (PQAR) and the Department will conduct inspections as set out below. 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~~may conduct an unannounced on-site inspection at any time it deems necessary to determine compliance with applicable statutes and regulations.~~:~~

~~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 t~~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 2. Verifies that an initial controlled substances inventory was taken, if the ~~pharmacy intends to dispense~~ controlled substances will be dispensed from the pharmacy, 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 3. ~~Ensures that~~ Reviews the ~~Pharmacy Quality Assurance Report~~ PQAR as described in 175 NAC 8-00~~5~~6.03 ~~is understood by~~ with the pharmacist-in-charge or practitioner 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.

8-0056.03 Pharmacy Quality Assurance Report (PQAR): The PQAR is due one year from the date of the initial on-site inspection and annually thereafter. All pharmacies licensees must ensure that the pharmacist in charge or the practitioner annually submits a completed Pharmacy Quality Assurance Report PQAR on a form made available by the Department, electronically or upon request, within at least 30 days of before the due date of the report, as specified in 175 NAC 8-005.03C. The Department must shall provide notice to all licensees of any significant changes made to the PQAR at least 30 days prior to such changes being implemented.

8-0056.03A This report At a minimum the PQAR 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.~~

1. Standards for the Operations of a Pharmacy
   a. Staffing Requirements;
   b. Storage Requirements;
   c. Record Keeping Requirements;
   d. Dispensing Requirements;
   e. Controlled Substance Dispensing Requirement for Emergency Situations; and
   f. Disaster Preparedness and Management
2. Physical Plant Standards
   a. Equipment, facilities, and utilities;
   b. Shelving, counters, floor, inventory, fixtures, equipment, and utensils; and
   c. Reference Material
3. Sterile Compounding Requirements (if applicable)
4. Non-Sterile Compounding Requirements (if applicable)

8-00~~5~~6.03B ~~This report~~ The 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~~, 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.~~

8-00~~5~~6.03~~D~~C Department Responsibilities: The Department will review the ~~Pharmacy Quality Assurance Report~~ PQAR to determine whether the pharmacy is being operated in compliance with the Health Care Facility Licensure Act, the Prescription Drug Safety Act, and these regulations. ~~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~~5~~6.04 Annual Inspection: ~~After April 1, 2002, a~~All ~~pharmacies~~ licensees 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 8-00~~6~~7 and 8-00~~7~~8. The inspection may occur by a self-inspection or by an on-site inspection.

8-005~~5~~6.04A Self-Inspection: The ~~Pharmacy Quality Assurance Report~~ PQAR 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~~Facility Licensure Act, the Prescription Drug Safety 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~~PQAR, that the pharmacy is not in compliance with the Health Care ~~Facilities~~ Facility Licensure Act, the Prescription Drug Safety Act, or these regulations;
2. The pharmacy failed to be in full compliance with the Health Care Facility Licensure Act, the Prescription Drug Safety Act, and these regulations at the time of its last inspection;
3. The pharmacy failed to submit a ~~Pharmacy Quality Assurance Report~~PQAR;
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~~5~~6.04B On-site Inspection: When the Department determines, based upon the criteria specified in 175 NAC 8-005~~5~~6.04A, that the ~~Pharmacy Quality Assurance Report~~PQAR 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~~ Facility Licensure Act, the Prescription Drug Safety Act, and these regulations.

8-005~~5~~6.04C Results of Annual Inspections

8-005~~5~~6.04C1 When the Department finds that the ~~pharmacy~~ licensee fully complies with the requirements of ~~175 NAC 8-003.01A item 3.m.,~~ 175 NAC 8-00~~6~~7 and 8-00~~7~~8, the Department will notify the ~~pharmacy~~ licensee of its compliance ~~within~~ at least 30 days after the inspection.

8-005~~5~~6.04C2 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 8-00~~6~~7 and 8-00~~7~~8, but the nature of the violation(s) does 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~~will request a statement of compliance that indicates the effort to correct the violation(s) has addressed the Department concerns. ~~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.~~

8-00~~5~~6.04C~~4~~3 When the Department finds that the ~~pharmacy~~ licensee fails to meet the requirements of 175 NAC 8-00~~6~~7 and 8-00~~7~~8, and the ~~failure(s)~~ nature of the violation(s) would create an imminent danger of death or ~~serious~~ physical harm, the Department will revoke the pharmacy license.

8-00~~5~~6.05 Re-inspections

8-00~~5~~6.05A The Department may conduct re-inspections to determine if ~~a pharmacy fully complies~~full compliance of the pharmacy operations have been met ~~with~~ and the requirements of 175 NAC 8-00~~6~~7 and 8-00~~7~~8 have been demonstrated by the licensee. ~~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.

8-0067 STANDARDS FOR THE OPERATION OF A PHARMACY: The pharmacy licensee must operate in accordance with the services as specified on the application for a pharmacy license or amendments theretocomply with the following requirements:.

8-0067.01 Staffing Requirements: 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: Each licensee must have a specific pharmacist in charge or practitioner with the qualifications, training, and skills necessary to meet the requirements according to these regulations.

8-007.01A Each licensee must employ a sufficient number of actively-licensed pharmacists to meet the needs of individuals seeking services at the pharmacy.

8-007.01B Each licensee must employ a sufficient number of actively-registered pharmacy technicians who have been certified by an approved state or national certification body by January 1, 2017, for those registered as a Pharmacy Technician as of January 1, 2016; or within one year of initial registration for those with initial registration dates after January 1, 2016.

8-006.01A 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.~~

8-00~~6~~7.02 Storage Requirements

8-00~~6~~7.02A The pharmacy must provide equipment for the storage of drugs~~, devices, and biologicals~~ at the proper temperature:

1. Drugs, devices, or biologicals requiring refrigeration must be stored between 36 and 46 degrees Fahrenheit.
2. Drugs~~, devices, or biologicals~~ requiring a freezer must be stored between ~~-4~~13 and 14 degrees Fahrenheit.
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.
4. Drugs~~, devices, or biologicals~~ requiring storage at controlled room temperature must be stored between ~~59~~68 and ~~86~~77 degrees Fahrenheit.
5. Other labeled storage instruction for drugs~~, devices, or biologicals~~ must be followed.

8-00~~6~~7.02B Drugs~~, devices, and biologicals~~ stored in a refrigerator must be kept in a separate ~~compartment~~ refrigerator from food.

8-00~~6~~7.02C 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. 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.

8-00~~6~~7.02D ~~The pharmacy must not have in its dispensable inventory any drug, device, or biological which is misbranded or adulterated.~~ All drugs which are misbranded or adulterated shall not be stored with saleable inventory.

8-007.02E Dispensed drugs that are returned to a pharmacy for disposal or in response to a recall, or if a device is defective or malfunctioning, must be stored separately from saleable inventory.

8-00~~6~~7.03 Record Keeping Requirements

8-00~~6~~.03A ~~All pharmacies must maintain the following records:~~All licensees must assure the establishment and maintenance of record keeping systems to account for the receipt and disposition of prescription drugs.

~~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.~~

8-00~~6~~7.04 Dispensing Requirements

8-007.04A The return to the pharmacy of controlled substances, halved tablets, other broken dosage forms, and extemporaneously compounded tablets and capsules is prohibited, except for the purpose of disposal.

8-007.04B The quantity of a drug indicated in a medical order for residents of a long-term care facility shall be 60 days, unless otherwise limited by the prescriber.

8-007.04C 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, 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.

8-007.04D Prescription Label for Central Fill: If central fill is used for controlled substances, the prescription label must contain the DEA registration number of the central fill pharmacy.

8-007.04E Prescription Labels for Multi-Drug Containers: The licensee 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. 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 by statutes and/or regulations.

~~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.~~

8-00~~6~~7.05~~D~~4F Controlled Substance Dispensing Requirement for Emergency Situations: For the purpose of authorizing an emergency oral 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.~~

8-00~~6~~7.0~~7~~5 Disaster Preparedness and Management: The ~~pharmacy~~ licensee must 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 and delineate:

1. How the pharmacy will provide for the storage of drugs~~, devices, and biologicals~~ at the proper temperature;
2. How the pharmacy will provide for the disposal of drugs~~, devices, and biologicals~~ if the pharmacy determines their potency, efficacy, or safety has been adversely affected;
3. How the pharmacy will secure the drugs~~, devices, and biologicals~~ from the public; and
4. How the pharmacy will maintain patient records and inventory records.

8-007~~8~~ PHYSICAL PLANT STANDARDS

8-007~~8~~.01 The ~~pharmacy~~ licensee must provide the pharmacist(s) access to all equipment, facilities, and utilities appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy.

8-007~~8~~.02 The ~~pharmacy~~ licensee must ~~maintain~~ assure the prescription department, including shelving, counters, floor, inventory, fixtures, equipment, and utensils are maintained in a clean, orderly, and sanitary manner.

8-007~~8~~.03 The ~~pharmacy~~ licensee must provide the pharmacist(s) 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 references 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:

5. Submit a petition to the Department stating:

a. The reasons why the license should be reinstated prior to the suspension completion date; and

c. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;

6. Submit a written renewal application to the Department as specified in 175 NAC 8-003.02;

7. Pay the renewal fee as specified in 175 NAC 8-004.11; and

8. 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.

8-009 HOSPITAL PHARMACY STANDARDS

8-009.01 Each pharmacist in charge must ensure that all pharmacy personnel holds an active credential issued pursuant to the Uniform Credentialing Act.

8-009.02 The Board of Pharmacy or its designated representative(s) may examine and inspect the practice of pharmacy within any hospital licensed by the department by either an on-site inspection or by having the pharmacist in charge submit a PQAR to the Department. The PQAR is due annually at the time of facility licensure renewal.

8-009.03 Hospital Drug Administration:

1. When drug administration occurs in a hospital on the basis of a chart order, hospital personnel may provide the unused portion of drugs to the patient upon discharge from the hospital for continued use in treatment of the patient if:

   a. the drug has been opened and used for treatment of the patient while at the hospital, is necessary for the continued treatment of that patient, and would be wasted if not used by that patient; and
   b. the drug is:
      i. in a multidose device; or
      ii. in the form of a liquid reconstituted from a dry stable state to a liquid resulting in a limited stability; or
      iii. in the form of a solution or ointment and is in tubes, bottles or other containers intended for multidose use.

2. Any drugs provided to a patient under section (1) shall be labeled with the name of the patient, the drug (including quantity) provided, the date the drug was provided, directions for use, and the prescriber's name and (if appropriate) DEA number.

3. A licensed healthcare professional with prescribing authority may provide to hospital patients being discharged a sufficient quantity of drugs adequate, in the judgment of the licensed health care professional with prescribing authority, to continue treatment begun in the hospital until the patient is reasonably able to access a pharmacy. Adequate records of the such drugs provided to discharged hospital patients shall be maintained by the pharmacist in charge and shall include the name of the patient, the drug (including quantity) provided, the date the drug was provided, directions for use, and the prescriber's name and (if appropriate) DEA number.

4. Procedures for providing drugs to patients under (1) or (3):

   a. The drugs shall be kept in a locked cabinet with access only by licensed healthcare professionals;
   b. Prior to dispensing the drug, a written order shall be in the patient's record;

c. The dispensing process at the hospital shall be under the direct supervision of the prescriber;

d. If the label is prepared by a nurse, the prescriber shall verify the drug and the directions;

e. When possible the directions for the patient shall be preprinted on the label by the pharmacist (e.g., Take tablet(s) times daily; Instill 2 drops in eye twice daily.);

f. Each container shall have an expiration date;

g. The label shall include the name of the patient, the drug (including quantity) provided, the date the drug was provided, directions for use, and the prescriber's name and (if appropriate) DEA number;

h. A written information sheet shall be provided to the patient for each drug dispensed;

i. Proper documentation shall be provided to the pharmacy in the form of a written prescription.

j. An inventory list of the drugs shall be available at the hospital pharmacy. The list shall include the number of packages of each medication and the number of doses in each package;

k. A log sheet shall be maintained to document each time a medication is dispensed from the hospital pharmacy's inventory. The log shall include the date of dispensing, patient, medication, and prescriber.

l. The pharmacist or the pharmacist's designee shall conduct a physical inventory of the drugs at least every 90 days to verify accountability, expiration dates, and proper storage conditions.

~~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 fa

(e) If a s entitled to a hearing or to par in a hearing waive or are deeme e their opportunity for the hear participate in the hearing, the trator may cancel the hearing, if ed, and issue his final order purs 1303.37 without a hearing.

[36 FR 7786, Apr. 24, mended at 36 FR 18731, Sept. 21, 197 5920, Aug. 8, 1972. Redesignated at 3 9, Sept. 24, 1973]

§ 1303.35 Burden of proo

(a) At any hearing rega e determination or adjustment regate production quota, each ed person participating in the g shall have the burden of prov propositions of fact or law asse him in the hearing.

(b) At any hearing regarding issuance, adjustment, suspensio denial of a procurement or indi manufacturing quota, the Adm tion shall have the burden of g that the requirements of thi or such issuance, adjustment, ion, or denial are satisfied.

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

§ 1303.36 Time an f hearing.

(a) If any appl registrant requests a heari e issuance, adjustment, sus or denial of his procurement individual manufacturing q rsuant to § 1303.34, the Admi r shall hold such hearing. f the hearing shall be given t plicant or registrant of the ti place at least 30 days prior 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 ma ontinued from day to day or r to a later day without notic than announcement there e presiding officer at the hear

[36 FR 7786, Apr. as amended at 37 FR 15920, Aug. 8, esignated at 38 FR 26609, Sept. 24, 1

§ 1303.37 Fi er.

As soon ticable after the presiding o s certified the record to the istrator, the Administrator sue his order on the determi or adjustment of the aggreg oduction quota or on the iss adjustment, suspension, or d the procurement quota or in- manufacturing quota, as case e. The order shall include the gs of fact and conclusions of law n which the order is based. The der shall specify the date on which it ll take effect. The Administrator serve one copy of his order upon party in the hearing.

786, Apr. 24, 1971, as amended at 37 Aug. 8, 1972. Redesignated at 38 FR 24, 1973]

304—RECORDS AND S OF REGISTRANTS

L INFORMATION

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1304.01 Scop 1304.
1304.02 Defini
1304.03 Person to keep records and file reports.
1304.04 Maintena cords and inventories.
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INVENTORY RE TS

1304.11 Inventory require

CONTINUING RECORDS

1304.21 General requirements for continuing records.

AUTHORITY: 21 U.S.C. [illegible]871(b), 958(e), 965, unless otherwise no[illegible]

GENERAL INFO[illegible]

§ 1304.01 Scope of part 13[illegible]

Inventory and other rec[illegible]l reports required under section [illegible]ection 1008(d) of the Act (21 U.S[illegible]nd 958(d)) shall be in accordance w[illegible]l contain the information requi[illegible] those sections and by the secti[illegible] this part.

[36 FR 7789, Apr. 24, 1971. Redesignated a[illegible] FR 26609, Sept. 24, 1973]

§ 1304.02 Definitions.

Any term contained in this pa[illegible] have the definition set forth in [illegible]n 102 of the Act (21 U.S.C. 802[illegible]rt 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1304.03 Persons req[illegible]s keep records and file rep[illegible]

(a) Each registran[illegible] maintain the records and inv[illegible]s and shall file the reports re[illegible]by this part, except as exem[illegible] this section. Any registrant [illegible] authorized to conduct other [illegible]es without being registered to [illegible] those activities, either purs[illegible] § 1301.22(b) of this chapter or [illegible]t to §§ 1307.11–1307.15 of this [illegible] shall maintain the records [illegible]ntories and shall file the re[illegible]quired 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 doe[illegible]ish to acquire separate stock[illegible]e same substance to be purc[illegible]d stored for separate activ[illegible] Otherwise, there is no advant[illegible]ned by permitting several [illegible]s under one registration. Thu[illegible]n a researcher manufactures [illegible]olled item, he must keep a [illegible] of the quantity manufactured[illegible] he distributes a quantity of [illegible]n, he must use and keep invoi[illegible]rder forms to document the [illegible]r; when he imports a substanc[illegible] keeps as part of his records [illegible]cumentation required of an im[illegible] and when substances are used [illegible]nical analysis, he need not kee[illegible]cord of this because such a re[illegible]ould not be required of him [illegible] registration to do chemical [illegible]s. All of these records may be [illegible]tained in one consolidated record [illegible]em. Similarly, the researcher may [illegible] all of his controlled items in one [illegible] and every two years take inven[illegible] all items on hand, regardless of [illegible] the substances were manufac[illegible]him, imported by him, or purcha[illegible]estically by him, of whether the [illegible]es will be administered to subje[illegible]ributed to other researchers, or [illegible]d during chemical analysis.

(b) A [illegible]d individual practitioner is [illegible] to keep records, as described in[illegible], of controlled substances in Sc[illegible] II, III, IV, and V which are disp[illegible]her than by prescribing or adm[illegible]g in the lawful course of professi[illegible]ctice.

(c) A registere[illegible]dual practitioner is not requi[illegible]eep records of controlled substa[illegible] Schedules II, III, IV, and V whi[illegible]rescribed in the lawful course [illegible]ssional practice, unless such s[illegible]es 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 to patients, charges patients, either separately or together with charges for other professional services, for substances so prescribed or administered. Records are required to be kept for controlled substances administered in the course of maintenance or detoxification treatment by the individual.

(e) Each registered practitioner shall maintain in a readily retrievable manner the 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 documents 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, 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 application to operate the facility. Other requests to maintain records at a central location must be submitted in accordance with §1304.04 of this chapter. These records must be maintained for a period of two years.

[36 FR 7790, [illegible] 1971, as amended at 36 FR 18731, S[illegible]971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 50 FR 40623, Oct. 4, 1985; 51 FR 5[illegible]13, 1986; 51 FR 26154, July 21, 1986; 5[illegible]75, June 1, 1993; 62 FR 13958, Mar. [illegible]5 FR 44679, July 19, 2000]

§ 1[illegible] Maintenance of records and inventories.

(a)(1) Except as provided in paragraphs (a)(2) 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.

(2) Financial and shipping records (such as invoices and packing slips but not including order forms subject to §§ 13[illegible] 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 readab

(2) A [illegible] retail pharmacy that possesses [illegible]nal registrations for automated [illegible]ing systems at long term care [illegible]es may keep all records requ[illegible]his part for those additional reg[illegible]ites at the retail pharmacy or ot[illegible]oved central location.

(b) All registra[illegible] are authorized to maintain [illegible]ral recordkeeping system shal[illegible]ject to the following conditions:

(1) The records to b[illegible]ained at the central record loca[illegible]ll not include executed order fo[illegible]scriptions and/or inventories w[illegible]ll be maintained at each register[illegible]on.

(2) If the records are kept [illegible]o-film, computer media or in a[illegible]n requiring special equipment to the records easily readable, th[illegible] istrant shall provide access to equipment with the records. If code system is used (other than p[illegible] information), a key to the code s[illegible] provided to make the records standable.

(3) The registrant agrees [illegible]ver all or any part of such re[illegible] the registered location within[illegible]siness days upon receipt of a w[illegible]equest from the Administra[illegible]r such records, and if the [illegible]istration chooses to do so in li[illegible]quiring delivery of such reco[illegible]e registered location, to allow[illegible]ized employees of the Adm[illegible]on to inspect such records a[illegible]entral location upon request [illegible] employees without a warrant[illegible]kind.

(4) In the [illegible]at a registrant fails to comply [illegible]nese conditions, the Special [illegible]n Charge may cancel such ce[illegible]cordkeeping authorization, [illegible] other central recordkeepi[illegible]orizations 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 a[illegible]se computer system.

(d) ARCOS partic[illegible] who desire authorization to [illegible] from other than their regist[illegible]cations must obtain a separ[illegible]tral reporting identifier. Req[illegible] central reporting identifier[illegible]be submitted to: ARCOS Unit[illegible]Box 28298, Central Station, Wa[illegible]n, DC 20005.

(e) All c[illegible]ecordkeeping permits previousl[illegible]d by the Administration exp[illegible]ptember 30, 1980.

(f) E[illegible]stered manufacturer, distribut[illegible]porter, exporter, narcotic trea[illegible] program and compounder for[illegible]ic treatment program shall m[illegible] inventories and records of [illegible]ed substances as follows:

[illegible]nventories and records of con[illegible]ed substances listed in Schedules I [illegible] II shall be maintained separately [illegible]m all of the records of the reg[illegible]ant; and

Inventories and records of con[illegible]d substances listed in Schedules [illegible] and V shall be maintained ei[illegible]arately from all other records o[illegible]ristrant or in such form that the[illegible]ation required is readily retrie[illegible]om the ordinary business recor[illegible] registrant.

(g) E[illegible]stered individual practitioner r[illegible]to keep records and institution[illegible]itioner shall maintain inventorie[illegible]ecords of controlled substances [illegible]anner prescribed in paragraph (f)[illegible]ection.

(h) Each re[illegible] pharmacy shall maintain the in[illegible]s and records of controlled substa[illegible] follows:

(1) Inventories a[illegible]ds of all controlled substances [illegible] Schedules I and II shall be mai[illegible] separately from all other records [illegible]harmacy, and prescriptions for [illegible]stances 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 a 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 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 4[illegible] July 1, 1980; 47 FR 41735, Sept. 22, 1982; [illegible]0, Feb. 13, 1986; 62 FR 13959, Mar. 2[illegible]0 FR 25466, May 13, 2005]

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

(a) Every retail pharmacy that utilizes the services of a central fill pharmacy must maintain 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, 2[illegible]

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 means 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 for 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 with which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of the opening of business or as of the close of business on the inventory date and it shall be indicated in the inventory.

(b) *Initial inventory.* 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.[illegible]8.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on such schedule, every registrant required to keep records who possesses such 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 (or capable of use in) the manufacture of the same or other controlled substances or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The quantity of the substance to the nearest metric unit weight or volume 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, 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), 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. 200 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance included in paragraphs (e)(1) (i), (ii) and (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compounding), the inventories shall include:

(A) The name of the substance;

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

(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 required 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 registe[illegible]uthorized to dispense, conduct [illegible], or act as a reverse distributo[illegible]ontrolled substances shall includ[illegible] inventory the same information [illegible] of manufacturers pursuant to p[illegible]hs (e)(1)(iii) and (iv) of this sect[illegible] determining the number of units [illegible] finished form of a controlled su[illegible] in a commercial container whi[illegible]een opened, the dispenser, rese[illegible] or reverse distributor shall do as [illegible].

(i) If the substance is [illegible]n Schedule I or II, make an [illegible]unt or measure of the contents, [illegible].

(ii) If the substance [illegible]d in Schedule III, IV or V, ma[illegible]stimated count or measure o[illegible]ntents, unless the container ho[illegible]e than 1,000 tablets or capsules i[illegible] case he/she must make an exact [illegible] of the contents.

(4) *Inventories of importers and exp[illegible]ers.* Each person registered or auth[illegible]ized to import or export controlled [illegible]stances shall include in the inve[illegible] the same information required o[illegible]ufacturers pursuant to pa[illegible] (e)(1) (iii) and (iv) of this sect[illegible]h such person who is also regi[illegible]s a manufacturer or as a distr[illegible]shall include in his/her invento[illegible]n importer or exporter only [illegible]ocks of controlled substances t[illegible] actually separated from his st[illegible] a manufacturer or as a di[illegible]r (e.g., in transit or in storag[illegible]pment).

(5) *Inventories [illegible]ical analysts.* Each person regi[illegible]f authorized to conduct chemi[illegible]lysis with controlled substa[illegible]all include in his inventory t[illegible]e information required of [illegible]turers pursuant to paragraph[illegible](iii) and (iv) of this section [illegible]ubstances which have been m[illegible]ured, imported, or received [illegible]n 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 wi[illegible]gard to a need for an invento[illegible]ose substances. No invento[illegible]equired of known or suspecte[illegible]rolled substances received a[illegible]ntiary materials for analysis.

[62 FR 13959, Mar[illegible], as amended at 68 FR 41228, July 11[illegible]

Co[illegible]G RECORDS

§ 1304.21 [illegible]l requirements for conti[illegible]ecords.

(a) E[illegible]gistrant required to keep record[illegible]ant to §1304.03 shall maintain[illegible]urrent basis a complete and ac[illegible]ecord of each such substance m[illegible]tured, imported, received, [illegible]livered, exported, or otherwise [illegible]ed of by him/her, except that no [illegible]trant shall be required to main[illegible] a perpetual inventory.

[illegible] Separate records shall be main[illegible]l by a registrant for each reg[illegible] location except as provided in [illegible](a). In the event controlled s[illegible]s are in the possession or un[illegible]control of a registrant at a loca[illegible] which he is not registered, the s[illegible]s shall be included in the record[illegible] registered location to which t[illegible]subject to control or to which th[illegible] possessing the substance is re[illegible]le.

(c) Separa[illegible]ds shall be maintained by a [illegible]t for each independent activi[illegible] which he/she is registered, exc[illegible] provided in §1304.22(d).

(d) In recording [illegible] receipt, importation, distribut[illegible]rtation, or other transfers, the [illegible] which the controlled substances [illegible]ually received, imported, distri[illegible]ported, or otherwise transferred [illegible] 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 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 resulting 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, 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 registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit declaration number for each importation;

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

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

(B) The quantity used in the manufacture;

(C) The finished form (e.g., 10-milligram tablet 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 the 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 commentary 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 for available procurement quotas submitted by other persons (as required by §1315.12(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)(v) of this section;

(iv) The number of units of finished forms and/or commercial containers acquired from other persons, including the d[redacted]nd number of units and/or comm[redacted]ntainers in each acquisition to[redacted]ory and the name, address, a[redacted]ration number of the person fr[redacted]n the units were acquired;

(v) The n[redacted]f units of finished forms and/o[redacted]ercial containers imported direc[redacted]he person (under a registration o[redacted]rization to import), including [redacted] of, the number of units and/[redacted]nercial containers in, and the[redacted] permit or declaration number [redacted] importation;

(vi) The number of un[redacted]or commercial containers ma[redacted]ed by the registrant from unit[redacted]ished form received from others [redacted]ted, including:

(A) The date and batch or o[redacted]tifying number of each manufac[redacted]

(B) The operation performed (e[redacted] packaging or relabeling);

(C) The number of units of fin[redacted] form used in the manufactur[redacted] number manufactured and the [redacted] lost during manufacture, w[redacted]e causes for such losses, if know[redacted]

(D) Such other informatio[redacted]necessary to account for a[redacted]rolled substances used in the [redacted]turing process;

(vii) The number of [redacted]rcial containers distributed to[redacted]ersons, including the date of [redacted]nber of containers in each re[redacted] from inventory, and the na[redacted]ress, and registration numb[redacted]the person to whom the cont[redacted]were distributed;

(viii) The nu[redacted] commercial containers exp[redacted]rectly by the registrant (u[redacted]egistration as an exporter), i[redacted] the date, number of containe[redacted] export permit or declaratio[redacted]r for each exportation; and

(ix[redacted]umber of units of finished for[redacted] 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 [redacted] this section, each person regi[redacted]r authorized to distribute con[redacted]substances shall maintain reco[redacted]n the same information requi[redacted]anufacturers pursuant to par[redacted] (a)(2)(i), (ii), (iv), (v), (vii), (v[redacted](ix) of this section.

(c) *Records f[redacted]nsers and researchers.* Each pe[redacted]gistered or authorized to dis[redacted]r conduct research with cont[redacted]ubstances shall maintain reco[redacted]n the same information require[redacted]nufacturers pursuant to parag[redacted](2)(i), (ii), (iv), (vii), and (ix) o[redacted]ection. In addition, records sha[redacted]aintained of the number of un[redacted]olume of such finished form d[redacted]l, including the name and ad-[redacted] the person to whom it was dis-[redacted], the date of dispensing, the [redacted]ber of units or volume dispensed, [redacted] the written or typewritten name or [redacted]tials of the individual who dispensed [redacted] administered the substance on be-[redacted]f of the dispenser. In addition to the [redacted]irements of this paragraph, practi-[redacted]rs dispensing gamma-hydroxy-[redacted] acid under a prescription must [redacted]ply with § 1304.26.

[redacted]*rds for importers and exporters.* Ea[redacted]n registered or authorized to imp[redacted]xport controlled substances shall[redacted]n records with the same inform[redacted]quired of manufacturers pursuan[redacted]agraphs (a)(2) (i), (iv), (v) and ([redacted]is section. In addition, the quant[redacted]osed of in any other manner by [redacted]trant (except quantities used i[redacted]cturing by an importer under [redacted]ation as a manufacturer), which[redacted]ties are to be recorded pursuant[redacted]agraphs (a)(1) (iv) and (v) of t[redacted]ion; and the quantity (or numbe[redacted]s or volume in finished form) e[redacted] including the date, quantity (o[redacted]r of units or volume), and the e[redacted]rmit 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 in the nearest metric unit weight consistent with unit size.

(iii) The quantity received from other persons, including the date and quantity of each receipt, 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 in 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, 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, quantity of the substance in each form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

[62 FR 13960, March 24, 1997, as amended at 68 FR 41329, July 11, 2003; 70 FR 293, Jan. 4, 2005]

§ 1304.23 Records for chemical analysts.

(a) Each person registered or authorized (pursuant to § 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 obtainable 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, 10 1-milliliter vials, or 10 grams 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 and manner by the registrant (except quantities used in chemical analysis or 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 s

[36 FR 7 24, 1971, as amended at 36 FR 13386, 971; 36 FR 18732, Sept. 21, 1971. Redes t 38 FR 26609, Sept. 24, 1973, and fur ignated at 62 FR 13961, Mar. 24, 1997]

§ 1304.24 Reco r maintenance treatment p and detoxification treatmen ms.

(a) Each person r d or authorized (by § 1301.22 o hapter) to maintain and/or de controlled substance users in a c treatment program shall ma records with the following inform r each narcotic controlled substa

(1) Name of substance;

(2) Strength of substance;

(3) Dosage form;

(4) Date dispensed;

(5) Adequate identification of p (consumer);

(6) Amount consumed;

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

(8) Dispenser's initials.

(b) The records required b aph (a) of this section will be m ed in a dispensing log at the p treatment program site and e maintained in compliance § 1304.22 without reference to

(c) All sites which ound a bulk narcotic solution ulk narcotic powder to liquid site use must keep a separat record of the compounding.

(d) Record entity, diagnosis, prognosis, c ment of any patients which ar ained in connection with th mance of a narcotic treatm ram shall be confidential, e at such records may be disc 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 progr l maintain records which the following information n narcotic drug:

(a) For each nar ntrolled substance in bulk f be used in, or capable of use i ng used in, the compounding c me or other noncontrolled su s in finished form:

(1) The na e substance;

(2) The q compounded in bulk form by t strant, including the date, qu nd batch or other identifying r of each batch compound

(3) antity received from other per cluding the date and quantit ch receipt and the name, ad d registration number of the erson from whom the substance eceived;

The quantity imported directly by registrant (under a registration as importer) for use in compounding by m, including the date, quantity and ort permit or declaration number ch importation;

The quantity used to compound e substance in finished form, date and batch or other identif ber of each compounding;

(ii) uantity used in the compound

(iii) hed form (e.g., 10-milligram t or 10-milligram concentratio d ounce or milliliter;

(iv) The of units of finished form compo

(v) The qua ed in quality control;

(vi) The q lost during compounding and ses therefore, if known;

(vii) The total q of the substance contained in t ed form;

(viii) The theoreti l 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 address and registration number of the program to whom a distribution was made;

(8) The quantity exported directly by the registrant (or 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 of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(3) The number of containers of each such commercial finished form 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 authorization to import), including the date of, the number of units and/or commercial containers in 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 causes for such losses, if known;

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

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

(8) The number of commercial containers received directly by the registrant (or 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 disposed of 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 13955, 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 shall 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 29[illegible]2005]

PORTS

§ 1304.31 Re[illegible]om manufacturers importing [illegible] raw material.

(a) Every m[illegible]rer which imports or manuf[illegible] from narcotic raw material (opi[illegible]y straw, and concentrate of pop[illegible]) shall submit information whi[illegible]nts for the importation and for a[illegible]facturing operations performed b[illegible]importation and the production[illegible] or finished marketable produc[illegible]ndardized in accordance with th[illegible]Pharmacopeia, National Formul[illegible]her recognized medical standard[illegible]ts shall be signed by the author[illegible]cial and submitted quarterly [illegible]pany letterhead to the Drug E[illegible]ment Administration, Drug and C[illegible]ical Evaluation Section, Washing[illegible] D.C. 20537, on or before the 15th da[illegible] the month immediately followin[illegible] period for which it is submitted.

(b) The following informatio[illegible] be submitted for each type of[illegible]c raw material (quantities are[illegible]sed as grams of anhydrous mo[illegible]lkaloid):

(1) Beginning inventory[illegible]

(2) Gains on reweighin[illegible]

(3) Imports;

(4) Other receipts;

(5) Quantity put i[illegible]ess;

(6) Losses on rew[illegible]

(7) Other dispos[illegible]nd

(8) Ending inv[illegible]

(c) The foll[illegible]nformation shall be submitted[illegible] narcotic raw material deriv[illegible]cluding morphine, codeine, [illegible]hine, oxycodone, hydrocod[illegible]dicinal opium, manufacturin[illegible], crude alkaloids and other [illegible]ves (quantities are expres[illegible]ams 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 [illegible]ion;

(8) Quantity placed [illegible]ss;

(9) Other dispositi[illegible]

(10) Losses on re[illegible]e and

(11) Ending inv[illegible]

(d) The follo[illegible]formation shall be submitted [illegible]portation of each narcotic raw [illegible]l:

(1) Import[illegible] number;

(2) Date [illegible]ent arrived at the United St[illegible]rt of entry;

(3) Ac[illegible]ntity shipped;

(4) A[illegible]ercent) of morphine, codeine[illegible]baine and

(5)[illegible]ity shipped, expressed as anhy[illegible]orphine alkaloid.

[illegible]n importation of crude opium, [illegible]s will be selected and assays [illegible] by the importing manufacturer [illegible]e manner and according to the [illegible]thod specified in the U.S. Pharmacopeia. Where final assay data is not [illegible]mined at the time of rendering re[illegible] the report shall be made on the [illegible] the best data available, subject [illegible]tment, and the necessary adju[illegible]tries shall be made on the nex[illegible]

(f) [illegible]factory procedure is such that p[illegible]ithdrawals of opium are made fr[illegible]vidual containers, there shall be [illegible]d to each container a stock rec[illegible]d on which shall be kept a co[illegible]record of all withdrawals ther[illegible]

(g) All in-pr[illegible]ventories should be expressed in [illegible]of end-products and not precurso[illegible] precursor material has been c[illegible]r placed into process for the ma[illegible]e of a specified end-product, it [illegible] longer be accounted for as p[illegible]r stocks available for conversi[illegible]se, but rather as end-product in[illegible]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 [illegible] or finished products standardi[illegible] ccordance with U.S. Pharmacop[illegible]ational Formulary, or other rec[illegible]standards. The reports shall be [illegible]tted quarterly on company lette[illegible]o the Drug Enforcement Admi[illegible]on, Drug and Chemical Evalua[illegible]ection, Washington, DC 20537, [illegible]fore the 15th day of the month[illegible]diately following the period fo[illegible] it is submitted.

(b) The following in[illegible]n shall be submitted for raw c[illegible]ecgonine, ecgonine for conve[illegible]further manufacture, benz[illegible]ine, manufacturing coca extract[illegible]for tinctures and extracts; and o[illegible]arately), other crude alkalo[illegible] other derivatives (quantities sh[illegible] reported as grams of actual qua[illegible] involved and the cocaine alkaloid [illegible]tent or equivalency):

(1) Beginning inventory;
(2) Imports;
(3) Gains on reweighing;
(4) Quantity purchased;
(5) Quantity produced;
(6) Other receipts;
(7) Quantity returned to pro[illegible]or reworking;
(8) Material used in pur[illegible]d for sale;
(9) Material used for m[illegible]ture or production;
(10) Losses on reweig[illegible]
(11) Material used f[illegible]ersion;
(12) Other disposi[illegible]d
(13) Ending inve[illegible]

(c) The follow[illegible]rmation shall be submitted f[illegible]rtation of coca leaves:

(1) Import [illegible]umber;
(2) Date t[illegible]ment arrived at the United St[illegible] of entry;
(3) Act[illegible]tity shipped;
(4) As[illegible]rcent) of cocaine alkaloid an[illegible]
(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 [illegible]leter-mined at the time of s[illegible]n, the report shall be made on [illegible]s of the best data available, s[illegible]o adjustment, and the neces[illegible]justing entries shall be made [illegible]next report.

(e) Where factor[illegible]dure is such that partial with[illegible]s of medicinal coca leaves are [illegible]rom individual containers, th[illegible]l be attached to the containe[illegible]k record card on which shall [illegible] a complete record of withdraw[illegible]refrom.

(f) All i[illegible]ss inventories should be expre[illegible] terms of end-products and not [illegible]ors. Once precursor material [illegible]n changed or placed into proce[illegible]he manufacture of a specified [illegible]oduct, it must no longer be ac[illegible] for as precursor stocks a[illegible]e for conversion or use, but [illegible]s end-product in-process inven-[illegible]

[illegible]& 13962, Mar. 24, 1997]

[illegible]33 Reports to ARCOS.

(a) *[illegible]eports generally.* All reports re[illegible]y this section shall be filed wi[illegible]ARCOS Unit, PO 28293, Central[illegible], Washington, DC 20005 on DEA [illegible]3, or on media which contains [illegible] required by DEA Form 333 an[illegible] is acceptable to the ARCOS [illegible]

(b) *Freq[illegible]f reports.* Acquisition/Distributio[illegible]action reports shall be filed eve[illegible]ter not later than the 15th day [illegible]month succeeding the quarter fo[illegible]it is submitted; except that a r[illegible]t may be given permission to file [illegible]equently (but not more frequentl[illegible]monthly), depending on the num[illegible]ransactions being reported each [illegible] that registrant. Inventories sh[illegible]ide data on the stocks of each[illegible]d controlled substance on ha[illegible]of the close of business on De[illegible]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 permiss[redacted]e more frequently (but not more [redacted]ly than quarterly).

(c) *Perso*[redacted]*ting.* For controlled substances [redacted]dules I, II, narcotic controlled su[redacted]s in Schedule III, and gamma-hy[redacted]utyric acid drug product contr[redacted]substances in Schedule III, eac[redacted]n who is registered to manufa[redacted] bulk or dosage form, or to p[redacted] repackage, label or relabel, and [redacted]son who is registered to distribu[redacted]ding each person who is registere[redacted]erse distribute, shall report [redacted]on/distribution transactions. In[redacted]on to reporting acquisition[redacted]tion transactions, each person w[redacted]egistered to manufacture contr[redacted]bstances in bulk or dosage form [redacted]port manufacturing transacti[redacted] controlled substances in Sched[redacted] and II, each narcotic controlled [redacted]stance listed in Schedules III, IV, [redacted] V, gamma-hydroxybutyric acid dr[redacted] product controlled substances [redacted] Schedule III, and on each psychotr[redacted] controlled substance listed in S[redacted]ules III and IV as identified in[redacted]graph (d) of this section.

(d) *Substances covered.* (1) [redacted]turing and acquisition/d[redacted]on transaction reports shall i[redacted]data on each controlled substa[redacted]ed in Schedules I and II, on [redacted]arcotic controlled substance li[redacted]chedule III (but not on any[redacted]al, compound, mixture or [redacted]ation containing a quantity [redacted]stance having a stimulant [redacted]n the central nervous system, [redacted]aterial, compound, mixture[redacted]aration is listed in Schedule II[redacted]any narcotic controlled subst[redacted]ed in Schedule V), and on g[redacted]ydroxybutyric acid drug prod[redacted]ted in Schedule III. Addition[redacted]orts on manufacturing transact[redacted]hall include the following [redacted]otropic 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) Methylphenoba[redacted]

(I) Phenobarbital;[redacted]

(J) Phentermine[redacted]

(K) Pipradrol.

(2) Data shall [redacted]ented in such a manner as to[redacted]y the particular form, strengt[redacted]rade name, if any, of the pro[redacted]ontaining the controlled su[redacted] for which the report is being [redacted]For this purpose, persons fil[redacted]rts shall utilize the National [redacted]ode Number assigned to the p[redacted] under the National Drug Cod[redacted]m of the Food and Drug Admi[redacted]on.

[redacted]*nsactions reported.* Acquisition/[redacted]tion transaction reports shall [redacted]e data on each acquisition to in[redacted]ory (identifying whether it is, e.g., [redacted]urchase or transfer, return from a [redacted]ner, or supply by the Federal [redacted]ment) and each reduction from i[redacted] (identifying whether it is, e.g[redacted]le or transfer, theft, destructio[redacted]zure by Government agencies)[redacted]cturing reports shall provide [redacted] material manufactured, manufa[redacted]om other material, use in manu[redacted]g other material and use in pro[redacted]osage forms.

(f) *Excep*[redacted] registered institutional practi[redacted]who repackages or relabels exclu[redacted]r distribution or who distributes[redacted]vely to (for dispensing by) age[redacted]ployees, or affiliated institutio[redacted]ctitioners of the registrant may[redacted]mpted from filing reports under [redacted]ion by applying to the ARCOS[redacted] the Administration.

(Approved by the Office of [redacted]nt and Budget under control number [redacted])

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

(1) 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 ...ion of the order shows that the o... invalid for any reason.

(b) If an o... not be filled for any reason unde... ction, the supplier must notify t... haser and provide a statement as... reason (*e.g.*, improperly prepar... ltered). A supplier may, for any... refuse to accept any order, and ... plier refuses to accept the order... ment that the order is not acce... sufficient for purposes of this par...

(c) When a purchase... ves an unaccepted electronic or... n the supplier, the purchaser mu... roni-cally link the statement of ... ptance to the original order. Th... al order and the statement mus... tained in accordance with §1305...

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

§ 1305.26 Lost electronic orders.

(a) If a purchaser determines ... unfilled electronic order has l... t before or after receipt, the ... er must provide, to the suppli... gned statement containing ... nique tracking number and da... e lost order and stating that ... ods covered by the first or... e not received through loss o... rder.

(b) If the purchas... tes an order to replace the lost ... the purchaser must electronic... an electronic record of the s... rder and a copy of the statem... the record of the first order a... h them.

(c) If the ... to whom the order was direc... equently receives the first ord... supplier must indicate that it ... Accepted'' and return it to th... haser. 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 re... original order filled and th... records for two years.

(c) If electronic ... ecords are maintained on a ... server, the records must be r... etrievable at the registered loc...

§ 1305.28 Canc... nd voiding electronic ord...

(a) A supp... void all or part of an electro... er by notifying the purchaser ... voiding. If the entire order is ... the supplier must make an elec... copy of the order, indicate o... opy ''Void,'' and return it to t... haser. The supplier is not req... retain a record of orders th... ot filled.

... purchaser must retain an ...ic copy of the voided order.

...To partially void an order, the ...ier must indicate in the linked ...rd that nothing was shipped for ... item voided.

...29 Reporting to DEA.

...lier must, for each electronic o... ed, forward either a copy of th... nic order or an electronic repo... e order in a format that DEA ... to DEA within two business da...

PAR... –PRESCRIPTIONS

GE... FORMATION

Sec.

1306.01 Scope of...
1306.02 Definition...
1306.03 Persons en... issue prescriptions.
1306.04 Purpose of iss... cription.
1306.05 Manner of issu... rescriptions.
1306.06 Persons entitled... escriptions.
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CONTROLLED SUBSTANCES LIS... EDULE II

1306.11 Requirement of prescription.

AUTHORITY: 21 U.S.C. 821, 829 unless otherwise noted.

SOURCE: 36 FR 7799, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 2

GENERAL INFORMATION

§ 1306.01 Scope of part 1306.

Rules governing the issuance, 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

§ 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. A prescription 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.

A prescription may not be issued unless for an individual practitioner to dispense 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, as 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 reg[illegible] number of the practitioner. In[illegible]n, a prescription for a Schedule [illegible]r V narcotic drug approved by [illegible]ecifically for ''detoxification [illegible]nt'' or ''maintenance treatm[illegible]ust include the identification [illegible] issued by the Administrator u[illegible]01.28(d) of this chapter or a wr[illegible]otice stating that the practitio[illegible]cting under the good faith exce[illegible] § 1301.28(e). Where a prescription [illegible]amma-hydroxybutyric acid, t[illegible]ctitioner shall note on the face [illegible]escription the medical need of t[illegible]nt for the prescription. A pract[illegible] may sign a prescription in the sa[illegible]ner as he would sign a check or l[illegible]ument (*e.g.*, J.H. Smith or [illegible] Smith). Where an oral order is [illegible]mitted, prescriptions shall be w[illegible] with ink or indelible pencil or [illegible] writer and shall be manually signe[illegible] the practitioner. The prescripti[illegible] may be prepared by the secretar[illegible] agent for the signature of a p[illegible]tioner, but the prescribing practi[illegible] is responsible in case the pres[illegible] does not conform in all esse[illegible]spects to the law and regu[illegible] A corresponding liability rest[illegible] the pharmacist, including a[illegible]acist employed by a central [illegible]rmacy, who fills a prescription [illegible]pared in the form prescribed [illegible] regulations.

(b) An individua[illegible]itioner exempted from [illegible]tion under § 1301.22(c) of this [illegible] shall include on all prescript[illegible]ued by him or her the registr[illegible]umber of the hospital or othe[illegible]tution and the special interna[illegible]number assigned to him or her [illegible]hospital or other institution [illegible]ided in § 1301.22(c) of this cha[illegible]lieu of the registration numbe[illegible] practitioner required by this [illegible]. 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 [illegible]ection. The service identificati[illegible]ber for a Public Health Service [illegible]ee is his Social Security iden[illegible]n number. Each prescription s[illegible]e the name of the officer s[illegible], typed, or handprinted on it[illegible] as the signature of the offic[illegible]

[36 FR 7799, Ap[illegible], as amended at 36 FR 18733, Sept[illegible]. Redesignated at 38 FR 26609, Sep[illegible]3, and amended at 60 FR 36641, Ju[illegible]5; 62 FR 13966, Mar. 24, 1997; 70 FR [illegible]ne, 23, 2005]

§ 1306.06 [illegible]ns entitled to fill prescr[illegible]

A [illegible]tion for a controlled substan[illegible] only be filled by a pharma[illegible]cting in the usual course of h[illegible]essional practice and either [illegible]ed individually or employed in [illegible]istered pharmacy, a registered [illegible]al fill pharmacy, or registered in[illegible]utional practitioner.

[illegible] 37410, June 24, 2003, as amended at 70 [illegible]43, June 23, 2005]

[illegible] Administering or dispensing [illegible]cotic drugs.

([illegible] [illegible]ctitioner may administer or disp[illegible]ectly (but not prescribe) a narco[illegible] listed in any schedule to a narc[illegible]pendant person for the purpose[illegible]ntenance or detoxification tre[illegible] if the practitioner meets both [illegible] following conditions:

(1) The pr[illegible]er is separately registered with [illegible] a narcotic treatment program.

(2) The practi[illegible]s in compliance with DEA regula[illegible]garding treatment qualificatio[illegible]rity, records, and unsupervised u[illegible]e drugs pursuant to the Act.

(b) Nothing in this [illegible]shall prohibit a physician who [illegible] specifically registered to con[illegible]arcotic treatment program from [illegible]istering (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 restrictions on a physician or authorized medical 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 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 of 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 seven 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 it ''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 [illegible] a written prescription to him; if the pharmacist to do so shall [illegible] authority conferred by this par[illegible]o dispense without a written pr[illegible]n of a prescribing individual pra[illegible].

(5) Central fi[illegible]macies shall not be authorized u[illegible]s paragraph to prepare prescripti[illegible] a controlled substance listed in [illegible]e II upon receiving an oral aut[illegible]on from a retail pharmacist [illegible]ndividual practitioner.

(e) A prescription prep[illegible] accordance with §1306.05 written [illegible] Schedule II narcotic substance [illegible] compounded for the direct adm[illegible]ion to a patient by parenter[illegible]a-venous, intramuscular, subc[illegible]s or intraspinal infusion may be [illegible] mitted by the practitioner or th[illegible] titioner's agent to the pharmac[illegible] facsimile. The facsimile serves as [illegible] original written prescription for p[illegible] poses of this paragraph (e) and it s[illegible] be maintained in accordance [illegible] §1304.04(h) of this chapter.

(f) A prescription prepared in [illegible] ance with §1306.05 written for [illegible]e II substance for a resident [illegible]ng Term Care Facility may [illegible]ans-mitted by the practitioner[illegible] practitioner's agent to the di[illegible]g pharmacy by facsimile. [illegible]csimile serves as the original [illegible] prescription for purposes of [illegible]ragraph (f) and it shall be ma[illegible] in accordance with §1304.04([illegible]

(g) A prescripti[illegible]ared in accordance with §1306[illegible]en for a Schedule II narcotic[illegible]ce for a patient enrolled in a [illegible] care program certified and/or[illegible] by Medicare under Title XVII[illegible]spice program which is license[illegible]e state may be transmitted [illegible]ractitioner or the practitione[illegible] 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 30832, June 15, 1994; 6[illegible]4, Mar. 24, 1997; 65 FR 45713, July 2[illegible] FR 37410, June 24, 2003]

§ 1306.12 Refilling p[illegible]ions.

The refilling of [illegible]ription for a controlled substa[illegible]ed in Schedule II is prohibited.

§ 1306.13 Par[illegible]ing of prescriptions.

(a) The p[illegible]filling of a prescription for a [illegible]led substance listed in Schedule [illegible]ermissible, if the pharmacist [illegible]ble to supply the full quanti[illegible]ed for in a written or emer[illegible]oral prescription and he ma[illegible]otation of the quantity supp[illegible] the face of the written pre[illegible] (or written record of the [illegible]ncy oral prescription). The re[illegible]ng portion of the prescription be filled within 72 hours of the t partial filling; however, if the re[illegible]ing portion is not or cannot be within the 72-hour period, the [illegible]cist shall so notify the pre[illegible] individual practitioner. No fu[illegible]uantity may be supplied be[illegible]yo[illegible]nrs without a new prescription.

(b) [illegible]ription for a Schedule II contro[illegible]stance written for a patient in[illegible]g Term Care Facility (LTCF) o[illegible]atient with a medical diagnosis [illegible]ting a terminal illness may be [illegible]n partial quantities to include i[illegible]l dosage units. If there is any q[illegible]whether a patient may be classifi[illegible]ving a terminal illness, the pha[illegible] must contact the practitioner p[illegible]partially filling the prescriptio[illegible] the pharmacist and the presc[illegible]ractitioner have a corresponding [illegible]sibility to assure that the contro[illegible]stance is for a terminally ill pati[illegible] 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 identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in 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 paragraph (b).

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

(3) Retrieval of only 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 7776, April 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 a patient 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 patient user prior to the administration;

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

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

(d) All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of § 1306.71(a) of this chapter.

[36 FR 13368, July 21, 1971, as amended and redesignated 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 by 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 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 when it is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by the 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 the 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 licensed for immediate administration to the ultimate user, subject to

[62 FR 13965, 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 medical record, the document must be readily maintained and readily retrievable. The following information must be retrievable by the prescription number, consisting of the name and dosage 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 refill authorization records on the back of the original prescription the date, quantity of refill, number of additional refills authorized, and initials of 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 or separate prescription for any additional quantities beyond the five-refill, six-month limitation.

(b) As an alternative to the procedures required 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 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 drug, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), 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, the total number of refills dispensed, 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. Such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, which printout shall be verified, dated, and signed by the individual pharmacist who supplied 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 involved with such dispensing. [illegible] of such a printout, the pharmacy [illegible] 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 [illegible] by him and is correct as shown. [illegible] book or file must be maintained by the pharmacy employing such a system for a period of two years after the date of dispensing the appropriate [illegible] orized refill.

(4) Any such computerized system shall have the capability of providing a printout of any refill data which the user pharmacy is responsible for obtaining 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 the name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refilling, date of dispensing for each refilling, and the initials or identification code of the dispensing pharmacist, and the number of the original prescription order. If any computerized system used by a user pharmacy has a central record-keeping location it must be capable of sending the printout to the pharmacy within 48 hours. If a DEA Special Agent or Diversion Investigator requests a copy of such a printout from the user pharmacy, the pharmacist, if requested to do so by the Agent or Investigator, must verify the system's transmittal capability by documentation (e.g., post

(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 [illegible] system is available for use [illegible]

(c) When filling refill [illegible]ation for original prescription [illegible]or Schedule III or IV contro[illegible]bstances, a pharmacy may use [illegible]e of the two systems described [illegible]agraphs (a) or (b) of this section

[36 FR 7799, Apr. [illegible]6 FR 13386, July 21, 1971. Redesigna[illegible] FR 26609, Sept. 24, 1973, and ame[illegible]42 FR 28878, June 6, 1977; 45 FR 44[illegible]1, 1980; 52 FR 3605, Feb. 5, 1987; 62 FR [illegible]ar. 24, 1997]

§ 1306.23 [illegible]l filling of prescription.

The [illegible] filling of a prescription for [illegible]rolled substance listed in Sch[illegible]II, IV, or V is permissible, pr[illegible]that:

[illegible]ch partial filling is recorded in [illegible]he manner as a refilling,

The total quantity dispensed in [illegible]artial fillings does not exceed the [illegible] quantity prescribed, and

No dispensing occurs after 6 [illegible] after the date on which the [illegible]tion was issued.

[36 [illegible]3, Sept. 21, 1971. Redesignated at 38 F[illegible]Sept. 24, 1973, and amended at 51 FR 5[illegible]13, 1986; 62 FR 13965, Mar. 24, 1997]

§ 1306.24 [illegible]ing of substances and filing [illegible]scriptions.

(a) The p[illegible]ist filling a prescription for a co[illegible] substance listed in Schedule III, [illegible] shall affix to the package a lab[illegible]ng the pharmacy name and addr[illegible] serial number and date of initi[illegible], the name of the patient, the [illegible]f the practitioner issuing the p[illegible]tion, and directions for use and [illegible]ary statements, if any, conta[illegible] such prescription as required by

(b) If the prescription [illegible]d at a central fill pharmacy, th[illegible]l 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 for 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, lot or 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 pharmacy 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) The date of issuance of original prescription;

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

(iii) The 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.

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

(3) The original and transferred prescription shall 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 multiple prescription transferral.

(d) The procedure governing 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 [illegible] provided that:

(a) Such [illegible]sing is made only by a pharmacist [illegible]fined in part 1300 of this chapter, not by a nonpharmacist employee [illegible]n if under the supervision of [illegible]macist (although after the pharmacist has fulfilled his professional and [illegible]responsibilities set forth in this [illegible]n, the actual cash, credit transaction or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 [illegible]unces) of any such controlled substance containing opium, nor more than [illegible]cc. (4 ounces) of any other such controlled substance nor more than [illegible]age units of any such controlled substance containing opium, nor more than [illegible]4 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 pharmacies and central [illegible]armacies for initial and refil[illegible]iptions of Schedule III, IV [illegible] controlled substances.

Prescription info[illegible]n may be provided to an autho[illegible]ntral fill pharmacy by a re[illegible]armacy for dispensing purpo[illegible]he following requirements s[illegible] apply:

(a) Prescr[illegible] for controlled substances lis[illegible]Schedule III, IV or V may be [illegible]mitted electronically from a r[illegible]harmacy to a central fill pharma[illegible]uding via facsimile. The retail [illegible]acy transmitting the prescri[illegible]formation must:

(1) [illegible] the word "CENTRAL FILL" o[illegible]e of the original prescription a[illegible]rd the name, address, and DEA [illegible]ation number of the central fill [illegible]nacy to which the prescription [illegible]been transmitted and the name of [illegible] retail pharmacy pharmacist transing the prescription, and the date [illegible]nsmittal;

[illegible]nsure that all information re[illegible] be on a prescription pursuant t[illegible]5 of this part is transmitted to [illegible]tral fill pharmacy (either on the [illegible] the prescription or in the electr[illegible]ansmission of information);

(3) Ind[illegible] the information transmitted t[illegible]ber of refills already dispensed [illegible] number of refills remaining;

(4) Maintai[illegible]iginal prescription for a period o[illegible]rs from the date the prescription[illegible]t refilled;

(5) Keep a rec[illegible]receipt of the filled prescription[illegible]ing the date of receipt, the meth[illegible]elivery (private, common or co[illegible]arrier) and the name of the reta[illegible]nacy employee accepting delive[illegible]

(b) The central fill ph[illegible]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 of the prescription;

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

[68 FR 37411, June

PART 1307—MISCELLANEOUS

GENERAL INFO

Sec.

1307.01 Definitions.

1307.02 Application of State law and other Federal law.

1307.03 Exceptions to regulations.

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

1307.11 Distribution by dispenser to another practitioner or reverse distributor.

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DISPOSAL OF CONTROLLED SUBSTANCES

1307.21 Procedure for disposing of controlled substances.

1307.22 Disposal of controlled substances by the Administration.

SPECIAL EXEMPT

1307.31 Native American

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

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

GE FORMATION

§ 1307.01 ons.

Any t tained in this part shall have t nition set forth in section 102 o ct (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 protocol der the law of the State in wh e desires to do such act nor ompliance with such parts be c d as compliance with other F r State laws unless expressly in such other laws.

[62 FR 13966, Ma]

§ 1307.03 E s to regulations.

Any per y apply for an exception to th cation of any provision of this by filing a written request the reasons for such exceptio uests shall be filed with the istrator, Drug Enforcement Ad ation, Department of Justi hington, DC 20537. The Admin may grant an exception in his tion, but in no case shall he/she quired to grant an exception to person which is otherwise required law or the regulations cited in this on.

13966, Mar. 24, 1997]

EXCEPTIONS FOR MANUFACTURE STRIBUTION OF CONTROLLED ES

§ 1307 tribution by dispenser to an actitioner or reverse distrib

(a) A p ner who is registered to dispense olled substance may distribute (being registered to distribute) a ty of such substance to—

(1) Another pr er for the purpose of general d by the practitioner to patient ed that—

(i) The practitione m the controlled substance is t ributed is registered under the dispense that controlled substanc

(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 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 with the written record of the transaction. Any person not required to register pursuant to sections 302(c) and 302(b)(1) of the Act (21 U.S.C. 822(c) and 822(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 from 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.

A registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to part 1303 of this chapter, 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 substance is 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. 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 the area; or

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

(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 substances in one of the following manners:

(1) By transfer to person 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 manner 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 not 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 governing in any way the disposal of controlled substances through programs provided in laws and regulations adopted by any State.

[36 FR 7801, Apr. 24, 1971, as amended at 37 FR 15922, Aug. 5, 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 to 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 controlled drugs shall be ordered by the Administrator, if, in his opinion, the applicant 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 EXEMPTIONS FOR 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