NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

September 2, 2021
1:00 p.m. Central Time
Nebraska State Office Building – Lower Level B
301 Centennial Mall South, Lincoln, Nebraska
Phone call information: 888-820-1398; Participant code: 3213662#

The purpose of this hearing is to receive comments on proposed changes to Title 471, Chapter 16 of the Nebraska Administrative Code (NAC) – *Pharmacy Services.* The proposed changes specify the regulations' scope; update definitions; remove all duplicate statutory and inconsistent language in the regulations; restructure the regulatory chapter; set out coverage criteria of a physician/mid-level practitioner and licensed pharmacist; remove examples of personal care items; remove Pharmaceutical and Therapeutic Committee requirements; remove language on duplicate medication billing examples and submitting a written request to waive the unit dose packaging requirements; remove limitation of counseling sessions; remove requirements that Medicaid members be actively participating in the Nebraska Tobacco Free Quitline; align smoking cessation regulations in compliance with federal regulation; and update formatting. Additional proposed changes include performing a compliance review to ensure uniformity with the State Plan, other NAC chapters, federal law, and best practices.

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

In order to encourage participation in this public hearing, a phone conference line will be set up for any member of the public to call in and provide oral comments. Interested persons may provide verbal comments in person or by participating via phone conference line by calling 888-820-1398; Participant code: 3213662#.

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

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

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

NEBRASKA

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DEPT. OF HEALTH AND HUMAN SERVICES

Pete Ricketts, Governor

TO: Executive Board
Room 2108 State Capitol
Legislative Council

FROM: Marge Respeliers, Paralegal I
Legal Services
Department of Health and Human Services (DHHS)

DATE: July 26, 2021

RE: Notice of Rulemaking under Neb. Rev. Stat. § 84-907.06

The Department of Health and Human Services (DHHS) will be holding a public hearing on amending the following regulations:

TITLE:	471	Nebraska Medical Assistance Program
CHAPTER:	16	Pharmacy Services

These regulations are scheduled for public hearing on September 2, 2021.

The purpose of this hearing is to receive comments on proposed changes to Title 471, Chapter 16 of the Nebraska Administrative Code (NAC) – *Pharmacy Services.* The proposed changes specify the regulations' scope; update definitions; remove all duplicate statutory and inconsistent language in the regulations; restructure the regulatory chapter; set out coverage criteria of a physician/mid-level practitioner and licensed pharmacist; remove examples of personal care items; remove Pharmaceutical and Therapeutic Committee requirements; remove language on duplicate medication billing examples and submitting a written request to waive the unit dose packaging requirements; remove limitation of counseling sessions; remove requirements that Medicaid members be actively participating in the Nebraska Tobacco Free Quitline; align smoking cessation regulations in compliance with federal regulation; and update formatting. Additional proposed changes include performing a compliance review to ensure uniformity with the State Plan, other NAC chapters, federal law, and best practices.

The following items are enclosed for your referral to the chair of the relevant standing committee of the Legislature:

1. A copy of the notice of public hearing;
2. A copy of the proposed regulations;
3. A copy of the Policy Pre-Review Checklist; and

4. The estimated fiscal impact of this rulemaking action on state agencies, political subdivisions or persons being regulated.

FISCAL IMPACT STATEMENT

Agency: **Department of Health and Human Services**	
Title: 471	Prepared by: Erin Noble
Chapter: 16	Date prepared: 7-20-21
Subject: Pharmacy Services	Telephone: 531-530-7154

Type of Fiscal Impact:

Please check all that apply

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

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

TITLE 471 NEBRASKA MEDICAL ASSISTANCE PROGRAM SERVICES

CHAPTER 16 PHARMACY SERVICES

001. SCOPE AND AUTHORITY. The regulations govern the services provided under Nebraska's Medicaid program as defined by the Medical Assistance Act (Nebraska Revised Statute §§ 68-901 et seq).

002. DRUG UTILIZATION REVIEW. As a condition of participation, the provider is required to:

(A) Provide prospective drug utilization review before dispensing each prescription. This includes screening for:
  (i) Therapeutic duplication;
  (ii) Drug disease contraindications;
  (iii) Drug interactions;
  (iv) Incorrect dosage or duration;
  (v) Drug allergies; and
  (vi) Clinical abuse and misuse;

(B) Provide patient counseling on all matters which, in the provider's professional judgment, are deemed significant, including:
  (i) Name and description of the medication;
  (ii) Route, dosage form, duration of therapy;
  (iii) Directions for use;
  (iv) Adverse reactions, contraindications;
  (v) Storage; and
  (vi) Refill information; and

(C) Maintain adequate patient profiles which may include:
  (i) Name, address, phone number, date of birth, and gender;
  (ii) Individual history;
  (iii) Comprehensive listing of medications; and
  (iv) Relevant comments.

003. COVERED SERVICES. Nebraska Medicaid covers outpatient drugs in accordance with the Omnibus Budget Reconciliation Act of 1990 including:

(A) Legend drugs;
(B) Compounded prescriptions; and
(C) Over-the-counter drugs indicated as covered on the Nebraska Point of Purchase System or listed on the Nebraska Medicaid Pharmacy Program website.

004. COMPOUNDED PRESCRIPTIONS. A compounded prescription is a mixture of ingredients which the provider prepares in the pharmacy.

004.01 REIMBURSEMENT FOR COMPOUNDED PRESCRIPTIONS. Reimbursement for compounded prescriptions will be limited to those ingredients which are indicated as covered on the Nebraska Point of Purchase System or listed on the Nebraska Medicaid Pharmacy Program website. Any mixture of drugs which results in a commercially available over-the-counter preparation is not considered a compounded prescription.

005. OVER-THE-COUNTER DRUGS. Covered drugs include only over-the-counter drugs indicated as covered on the Nebraska Point of Purchase System or those listed on the Nebraska Medicaid Pharmacy Program website. Over-the-counter drugs must be prescribed by a licensed practitioner.

006. TOBACCO CESSATION COUNSELING. In addition to a physician or mid-level practitioner, only a licensed pharmacist, meeting Department conditions of participation listed above as a Tobacco Cessation Counselor, may provide tobacco cessation counseling.

006.01 TOBACCO CESSATION COUNSELING CONDITIONS OF PARTICIPATION. As a condition of participation as a Tobacco Cessation Counselor, the provider must:

(A) Be a licensed pharmacist;
(B) Complete a Department-approved tobacco cessation counselor training;
(C) Maintain current training as a Tobacco Cessation counselor as required by the Department;
(D) Complete and sign a new provider agreement, indicating the employing pharmacy as the "pay to" provider, and submit proof of completing the Department-required training as part of the provider agreement completion process, or upon request by the Department;
(E) Provide Tobacco Cessation counseling which is separate and distinct from the prospective drug utilization review required in this chapter and is not related to the dispensing of any drug product; and
(F) Provide feedback to the physician or mid-level practitioner who ordered the services.

007. PRESCRIPTION REFILLS. Prescription refills must be performed and recorded in a manner consistent with existing State and Federal laws, rules, and regulations. Automatic refills are not allowed. All prescription refills must be initiated by a request from the prescriber, client, or an authorized representative. If the client is residing in a facility, a nurse or other authorized agent of the facility pursuant to a valid prescriber's order may initiate the request for refill.

008. NON-COVERED DRUGS. Payment by Nebraska Medicaid will not be approved for:

(A) Requests for quantities not in compliance with the requirements of this chapter;
(B) Experimental drugs or drugs not approved by the Food and Drug Administration;
(C) Drugs or other items not prescribed for a medically accepted indication;
(D) Drugs or other items prescribed or recommended for weight control or appetite suppression;
(E) Any alcoholic beverage;
(F) Drug Efficacy Study Implementation Program drugs identified as Less Than Effective or Identical, Related, or Similar with an indicator value assigned by the Food and Drug Administration of either 5 or 6;
(G) Personal care items;

(H) Medical supplies and certain drugs for nursing facility and intermediate care facility patients;
(I) Over-the-counter drugs not listed on the Nebraska Medicaid Pharmacy Program website;
(J) Drugs or other items used for cosmetic purposes or hair growth;
(K) Baby foods, milk substitutes, or metabolic agents normally supplied by the Department;
(L) Drugs distributed or manufactured by certain drug manufacturers or labelers which have not agreed to participate in the drug rebate program;
(M) Products used to promote fertility;
(N) Medications dispensed as partial month fills for nursing facility or group home residents when dispensed by more than one pharmacy;
(O) Medications dispensed to replace products which have been recalled by the drug manufacturer;
(P) Drugs, or other products of manufacturers or labelers identifiable as non-covered on the Nebraska Point of Purchase System or on the Nebraska Medicaid Pharmacy Program website;
(Q) Drugs, classes of drugs, or therapeutic categories of drugs which are Medicare Part D Drugs and Medicare Part D Covered supplies or equipment, for all individuals eligible for benefits under Medicare Part D, whether or not the individual is enrolled in a Medicare Part D Plan;
(R) Drugs or classes of drugs approved by the Federal Food and Drug Administration for treatment of sexual or erectile dysfunction, or drugs or classes of drugs which are being used for the treatment of sexual or erectile dysfunction. Drugs or classes of drugs which are approved by the Federal Food and Drug Administration for treatment of sexual or erectile dysfunction and for conditions other than treatment of sexual or erectile dysfunction, and are prescribed for those other conditions may be covered, but Nebraska Medicaid may require prior authorization; and
(S) Automatic refills.

009. LIMITATIONS AND REQUIREMENTS FOR CERTAIN DRUGS.

009.01 PRIOR AUTHORIZATION. The Department requires authorization be granted prior to payment for certain drugs. Should a practitioner dispense a prescription prior to the actual authorization, he or she takes a business risk payment for the prescription can be denied.

009.01(A) PRIOR AUTHORIZATION RESPONSE. The Nebraska Point of Purchase contractor or the Department will respond to any request for prior authorization within 24 hours of receipt of the request.

009.01(B) APPROVAL DECISION. The Nebraska Point of Purchase contractor or the Department will notify the provider prescribing the drug or the pharmacy dispensing the drug if the authorization has been granted, the eligible dates of the authorization, and the identification of the provider who requested the authorization. The prior authorization is given for the drug, the client, and the prior authorization dates.

009.01(C) DENIAL DECISION. The Nebraska Point of Purchase contractor or the Department will notify the provider prescribing the drug or the pharmacy dispensing the drug if coverage is denied.

009.01(D) EMERGENCY DECISION. The Nebraska Point of Purchase contractor or the Department will authorize dispensing up to a 72-hour supply of a covered outpatient prescribed medication for cases meeting the definition of a medical emergency as outlined in chapter two of this title.

009.01(E) UNKNOWN DECISION. If the provider prescribing the drug or the pharmacy dispensing the drug has not received an authorization from the Nebraska Point of Purchase contractor or the Department, payment may be denied.

009.01(F) VERIFYING STATUS OF REQUESTS. The pharmacy can verify the status of prior authorization requests for prescriptions by submitting a claim via the Nebraska Point of Purchase System. If the prior authorization request has not been approved, the pharmacy may contact the Nebraska Point of Purchase contractor or the Department for prior authorization.

009.02 PRODUCTS REQUIRING PRIOR APPROVAL. Identifiable products requiring approval prior to payment are designated as such on the Nebraska Point of Purchase System or on the Nebraska Medicaid Pharmacy Program website. Reasons for prior authorization include:

(A) Product Based Controls. Prior authorizations falling under this category are products where there are medically appropriate alternative treatments which are more cost-effective for the Department;

(B) Utilization Controls. Prior authorizations falling under this category generally apply to the quantity of medication or duration of therapy approved; and

(C) Scope Controls. Scope controls ensure a drug is used for an approved or medically accepted indication, is clinically appropriate, medically necessary, and cost-effective;

(i) Medications which have been approved by the Federal Food and Drug Administration for multiple indications may be subject to a scope-based prior authorization when at least one of the approved indications places the drug in a therapeutic category or treatment class for which a prior authorization is required;

(ii) Prior authorization may be required to assure compliance with Federal Food and Drug Administration approved and medically accepted indications, dosage, duration of therapy, quantity, or other appropriate use criteria including pharmacoeconomic consideration; or

(iii) Prior authorization may be required for certain non-standard dosage forms of medications when the drug is available in standard dosage forms.

009.03 PREFERRED DRUG LIST.

009.03(A) PREFERRED DRUG LIST. The Medicaid Prescription Drug Act of 2008 requires the Department to establish and maintain a Preferred Drug List for the Medicaid program with the aid of the Pharmaceutical and Therapeutics Committee. Individual drugs will be designated as preferred or non-preferred within therapeutic classes of prescribed drugs reviewed by the Pharmaceutical and Therapeutics Committee. Drugs designated as preferred drugs can be prescribed for Medicaid clients without prior authorization from the Department; however some Preferred Drugs may have clinical claim limits to ensure appropriate use. The Preferred Drug List and other related activities are not construed to

replace, prohibit, or limit other lawful activities of the Department not specifically permitted or required by the Act. Drugs classified as Preferred Drugs will be eligible for supplemental rebates as described under the provisions of this title. The Department will maintain an updated Preferred Drug List in electronic format and will make the list available to the public from the Nebraska Medicaid Pharmacy Program website. Drugs and classes of drugs included on the Preferred Drug List will be reviewed annually. Changes will be communicated to providers at least 30 days prior to implementation.

009.03(B) DRUGS INCLUDED ON THE PREFERRED DRUG LIST. The Department will include on the Preferred Drug List prescribed drugs which are found to be therapeutically equivalent to or superior to other drugs within a therapeutic class, and the net cost of the drugs are equal to or less than other drugs within a therapeutic class after consideration of applicable rebates or discounts negotiated by the Department or its designated contractor. All classes of medications are considered for inclusion on the preferred drug list (PDL) except the antidepressants, antipsychotics or anticonvulsant medications.

009.03(C) NON-PREFERRED DRUGS. Medications designated as non-preferred on the Preferred Drug List will be subject to prior authorization. The Pharmaceutical and Therapeutics Committee will develop criteria for use of medications with non-preferred status. A health care provider may prescribe a drug designated as non-preferred on the Preferred Drug List to a Medicaid client without prior authorization by the Department if the provider certifies:

(i) The client is achieving therapeutic success with a course of medication for Human Immunodeficiency Virus, Multiple Sclerosis, cancer, or immunosuppressant therapy; or

(ii) The client has experienced a prior therapeutic failure with a medication designated as a Preferred Drug.

010. DRUG UTILIZATION REVIEW. The Department is authorized by federal statute to conduct a Drug Utilization Review program. The Drug Utilization Review program consists of prospective drug review, retrospective drug review, the application of explicit predetermined standards, and an educational program. The purpose of the Drug Utilization Review program is to improve the quality of pharmaceutical care by ensuring prescriptions are appropriate and medically necessary and not likely to result in adverse medical results.

010.01 DRUG UTILIZATION REVIEW BOARD. The Department or the Department's contractor utilizes a Drug Utilization Review Board to review and analyze available clinical and economic data. The Drug Utilization Review Board reviews and makes recommendations based on predetermined standards submitted to them by the Department or the Department's contractor and, in concert with retrospective review of claims data, makes recommendations for educational interventions, prospective Drug Utilization Review, and the prior authorization process.

010.02 REVIEW FOR PRIOR AUTHORIZATION RECOMMENDATION. The Drug Use Review Board will, upon the Department's request, review drugs or classes of drugs and make recommendations to the Department regarding drugs or classes of drugs for prior authorization. The Department makes the final decision on which drugs or classes of drugs will require prior authorization. For those drugs which will require prior authorization, the Drug

Utilization Review Board will develop and recommend prior authorization criteria to the Department. The Department may accept, reject, or modify the recommended criteria. The Department will communicate information related to prior authorization criteria on the Nebraska Medicaid Pharmacy Program website. The Drug Utilization Review Board will review existing prior authorization criteria annually.

010.03 MANUFACTURER REQUESTS FOR DRUG REVIEW. The manufacturer or any interested party may request a drug or class of drugs on prior authorization be placed on the agenda of a Drug Utilization Review board meeting, but no drug or class of drugs will be placed on the Drug Utilization Review agenda more than once every 12 months without the consent of the Drug Utilization Review director, in consultation with the Department's Pharmacy Consultant. The manufacturer of the drug may request the Drug Utilization Review director waive the 30-day notification rule when asking to have its product placed on the agenda.

011. PHARMACY SERVICES FOR CLIENTS RESIDING IN CERTAIN CARE FACILITIES.

011.01 NON-COVERED ITEMS. Nebraska Medicaid does not cover hydrogen peroxide, rubbing alcohol, and over-the-counter enemas as pharmacy services for clients residing in a nursing facility or intermediate care facility. The nursing facility or intermediate care facility may be reimbursed for these items under the Department's payment plan for nursing facility and intermediate care facility services. For clients residing in nursing facilities and intermediate care facilities, the Department does not cover medical supplies or durable medical equipment as pharmacy services.

011.02 REPLACEMENT COST. Providers cannot duplicate medication, at the Department's expense, for clients residing in facilities. The pharmacy or the facility is responsible for providing a replacement. Providers cannot bill the Department for medication which was destroyed upon a client's discharge.

011.03 PROFESSIONAL DISPENSING FEES. Pharmacies providing medications to nursing facility and intermediate care facility patients are allowed one professional dispensing fee per recipient and drug per month.

011.04 UNIT DOSE DEFINITIONS.

011.04(A) TRADITIONAL BOTTLE METHOD. Dispensing multiple tablets and capsules in one vial or bottle. This excludes systems such as cassettes, individually packaged doses on cards containing multiple doses, and all similar systems.

011.04(B) UNIT DOSE. A system of drug packaging, dispensing, returning, billing, and crediting by a unit dose provider.

011.04(C) UNIT DOSE PACKAGING. Drug packaging approved by the Nebraska Board of Pharmacy.

011.04(D) UNIT DOSE DISPENSING. The provision to the patient of a 14-day or less supply of a drug in unit dose packaging.

011.04(E) UNIT DOSE RETURNING. The process of returning unit dose packaged drugs to the dispensing pharmacy.

011.04(F) UNIT DOSE BILLING. Billing the Department one time per calendar month for the quantity of drug used by the patient during the month, with the exceptions described in this chapter. The quantity used is the difference between the quantity dispensed and the quantity returned. The date of service for each unit dose billing must be consistent from month to month.

011.04(G) UNIT DOSE CREDITING. A process of issuing credits by the pharmacy to the Department for drugs accepted for return into inventory which were previously billed to and covered by the Department.

011.04(H) UNIT DOSE PROVIDER. A pharmacy approved by the Department as a unit dose provider. Initial approval is contingent upon written agreement by the provider and demonstration by the provider, to the satisfaction of the Department, of the provider's ability to use unit dose packaging, unit dose dispensing, unit dose returning, unit dose billing, and unit dose crediting. Continuing approval is contingent upon the provider's actual performance as specified in the written agreement.

011.05. REIMBURSEMENT. The Department will only reimburse unit dose providers for prescribed drugs dispensed to Medicaid clients residing in facilities.

011.06 DRUGS RETURNED FOR CREDIT. Providers which accept returns of dispensed drugs from long term care facilities must credit the Department for those drugs. A drug cost level, below which credits will not be mandatory, may be established by the Department.

012. MEDICAL SUPPLIES AND DURABLE MEDICAL EQUIPEMENT. Any medical supply or durable medical equipment indicated as covered on the Nebraska Point of Purchase System or on the Nebraska Medicaid Pharmacy Program website is covered as a pharmacy service under this chapter.

013. QUANTITY LIMITATIONS. The Department imposes the following quantity limitations on certain drugs.

013.01 QUANTITIES NOT ALLOWED. Payment from Nebraska Medicaid will not be approved for:

(A) More than a three month supply of any maintenance medication;
(B) More than a one month supply of any controlled substance; and
(C) More than a one month supply of any injectable medication except insulin and those injectable drugs with a duration of greater than one month from one dose.

013.02 QUANTITIES. The following types of limits may be utilized to ensure appropriate utilization and billing:

(A) Maximum quantity over time;
(B) Maximum daily dose;
(C) Maximum days' supply per fill;
(D) Maximum quantity per fill;

(E) Minimum quantity per fill;
(F) Maximum cost per fill;
(G) Tablet splitting; and
(H) Number of units to require medication be submitted in multiples of the package size.

013.03 INJECTIONS. The Department applies the following limitations to injectable drug products:

(A) Only those injections which are either self-administered by the client or are administered for the client at the client's place of residence are reimbursable. Injections administered by the provider or hospital are not reimbursable through the pharmacy services program;
(B) Whenever available and necessity warrants, multi-dose vials of medication are dispensed rather than single-dose vials or unit-dose syringes;
(C) Single-dose syringes may be reimbursed at the proportionate cost of a multi-dose vial;
(D) Maintenance injectable medications which are not reconstituted or admixed by the pharmacy prior to administration to the patient are dispensed and billed for the full month's supply;
(E) Non-maintenance injectable medications and those injectable medications which must be reconstituted or admixed by the pharmacy prior to administration to the patient including subcutaneous, intramuscular, and intravenous medication delivery by large volume parenteral, piggyback, syringe pump, or other methods may be provided at the pharmacist's discretion. Courses of therapy of ten days or less duration are billed at the end of the course of therapy. Courses of therapy of greater than ten days duration are billed at the end of the course of therapy or after each ten days of therapy;
(F) Injectable medications administered by implanted or similar devices may not be billed to the pharmacy services program when the device is filled in the clinic or hospital; and
(G) Total parenteral nutrition is billed through the Durable Medical Equipment and Medical Supplies program. This includes the amino acids, carbohydrates, lipids and all additives. All total parenteral nutrition-compatible additives are billed through the supplier program regardless of who completes the addition of the ingredient or the method of administration.

013.04 MAINTENANCE DRUGS. The Department requires any other maintenance drug or any drug used in a chronic manner be prescribed and dispensed in a minimum of a one-month supply. Providers will not reduce prescriptions which are written for quantities larger than a month's supply to a month's supply. The Department considers prescription splitting to be fraudulent except when such reduction is done to comply with State or Federal regulations or statute.

013.05 EXCEPTIONS TO QUANTITY LIMITATIONS. The Department allows the following exceptions to the quantity limitations of this subsection only for those clients receiving medications through a non-unit-dose system, except where noted otherwise:

(A) When the prescriber first introduces a maintenance drug to a patient's course of therapy, the prescriber may prescribe a smaller quantity as his or her judgment dictates. Pharmacists must indicate this is the initial filling of the medication when

filing the drug claim. Any subsequent dispensing of this maintenance drug must be prescribed and dispensed in at least a month's supply;

(B) When the prescriber's professional judgment indicates these quantities of medication are not in the patient's best medical interest, the prescriber may prescribe as his or her judgment directs. This includes limitations for lock-in clients. The pharmacist must maintain documentation when an exception is being made to the Department's requirements;

(C) The Department will consider replacement of any lost, misplaced, or stolen drug products for clients only when the pharmacy provider or prescriber documents the conditions requiring replacement. The Department will require additional information prior to replacing controlled substances;

(D) Schedule II drugs are an exception to the quantity limitations. This also applies to unit dose systems, unless the Schedule II drug is used in a chronic or maintenance manner; and

(E) The Department will accept certain original shelf package sizes of medication, under the following conditions:

(i) An original shelf package of 480 ml or less when not packaged in the pint size, is sufficient for the quantity limitations requirement for liquids. This also applies to unit dose systems;

(ii) An original shelf package of l00 tablets or capsules, or less when not available in the 100 tablet or capsule size, for seldom-prescribed solid dosage drugs is sufficient for the quantity limitations requirement;

(iii) Original shelf packages of l00 tablets or capsules of routinely prescribed drugs are not acceptable as sufficient for fulfillment of the quantity limitations requirement. The full month's supply must be prescribed and dispensed; and

(iv) Ready-made ointments and creams, when used in a chronic or maintenance manner, may be dispensed in an original shelf package size provided the original size is closest to the needed amount of medication. This also applies to unit dose systems.

014. UTILIZATION. Since it is the pharmacist's professional responsibility to ascertain drugs are being utilized according to the prescriber's directions and no abuse or overuse exists, the Department will not reimburse pharmacists for prescriptions which demonstrate a lack of this professional obligation. Providers are required to maintain patient record systems or other adequate records to prevent these errors in dispensing. The Department's professional staff is responsible for determining whether a claim violates the Department's regulations. The Nebraska Point of Purchase system will identify drug claims when potential overuse exists, and these claims will be denied.

014.01 TOBACCO CESSATION. Medicaid covers tobacco cessation services as practitioner and pharmacy services under the following conditions:

(A) Tobacco cessation counseling visits with an enrolled medical provider or pharmacist tobacco cessation counselor may be a combination of intermediate or intensive tobacco cessation counseling visits;

(B) Tobacco cessation products are covered by Medicaid as a pharmacy service for those clients meeting Federal Food and Drug Administration approved dosing and age guidelines who require this particular assistance. Tobacco cessation counseling

provided by a Tobacco Cessation counselor must be ordered by the physician or mid-level practitioner; and

(C) Nebraska Tobacco Free Quitline: In conjunction with tobacco cessation products, recipients are encouraged to be enrolled in and active with the Nebraska Tobacco Free Quitline. Referral to the Quitline may be made by a medical professional or a self-referral. Recipient access to the Nebraska Tobacco Free Quitline is unlimited.

015. PAYMENT FOR PHARMACY SERVICES.

015.01 PROFESSIONAL DISPENSING FEES.

015.01(A) DISPENSING FEE. The fee-for-service professional dispensing fee will be assigned to each claim payment based on the lesser of methodology described below.

015.01(B) DISPENSING PHYSICIANS. The Department assigns a professional dispensing fee to a dispensing physician only when there is no pharmacy within a 25-mile radius of the physician's place of practice.

015.02 REIMBURSEMENT METHODOLOGY. Payment levels for all drugs will not exceed, in the aggregate, upper levels of reimbursement established by federal law.

015.02(A) BRAND NECESSARY CERTIFICATION OF DRUGS. The Federal Upper Limit or State Maximum Allowable Cost limitations will not apply in any case where the prescribing physician certifies a specific brand is medically necessary. In these cases, the usual and customary charge or National Average Drug Acquisition Cost will be the maximum allowable cost. The prescriber must certify that a brand name is medically necessary.

015.03 PRICING INSTRUCTIONS. Pharmacists will not, under any circumstances, submit charges to the Department which exceed the pharmacy's usual and customary charge.

015.03(A) PRICING. Any loss leader, shelf, sale, cash only, coupon certificate, or newspaper and brochure ad prices which are in effect on the date the prescription is dispensed will be considered the pharmacy's usual and customary charge to the general public.

015.03(B) PRICE MATCHING. When a pharmacy lowers its usual and customary price for a prescription, all claims submitted to Nebraska Medicaid for the same drug and quantity dispensed during that business day will also be billed at the lowered price.

015.04 PAYMENT METHODOLOGY.

015.04(A) LEGEND DRUGS, NON-LEGEND DRUGS, AND COMPOUNDED PRESCRIPTIONS. The Nebraska Medicaid Drug Program is required to reimburse ingredient cost for covered outpatient legend and non-legend drugs at the lowest of:

(i) The usual and customary charge to the public;

(ii) The National Average Drug Acquisition Cost, plus the established professional dispensing fee;

(iii) The Affordable Care Act Federal Upper Limit plus the established professional dispensing fee; or
(iv) The calculated State Maximum Allowable Cost, plus the established professional dispensing fee.

015.04(B) BACKUP INGREDIENT COST BENCHMARK. If the National Average Drug Acquisition Cost is not available, the allowed ingredient cost will be the lesser of Wholesale Acquisition Cost + 0%, State Maximum Allowable Cost, or the Affordable Care Act Federal Upper Limit plus the established professional dispensing fee.

015.04(C) SPECIALTY DRUGS. Specialty drugs will be reimbursed at National Average Drug Acquisition Cost. If National Average Drug Acquisition Cost is not available, then the Backup Ingredient Cost Benchmark will apply.

015.04(D) DRUG PRICING PROGRAM. Covered legend and non-legend drugs, including specialty drugs, purchased through the Federal Public Health Service's 340B Drug Pricing Program by covered entities which carve Medicaid into the 340B Drug Pricing Program will be reimbursed at the 340B actual acquisition cost, but no more than the 340B ceiling price plus the established professional dispensing fee. A 340B contract pharmacy under contract with a 340B covered entity described in section 1927 (a)(5)(B) of the Act is not covered.

015.04(E) FEDERAL SUPPLY SCHEDULE. Facilities purchasing drugs through the Federal Supply Schedule will be reimbursed at no more than their actual acquisition cost plus the established professional dispensing fee.

015.04(F) CLOTTING FACTOR.
(i) Pharmacies dispensing Antihemophilic Factor products will be reimbursed at the lesser of methodology plus the established professional dispensing fee. If National Average Drug Acquisition Cost is not available, the lesser of methodology for the allowed ingredient cost will be the Wholesale Acquisition Cost + 0%, the Average Sales Price + 6%, or the Affordable Care Act Federal Upper Limit; and
(ii) Pharmacies dispensing Antihemophilic Factor products purchased through the Federal Public Health Service's 340B Drug Pricing Program by pharmacies which carve Medicaid into the 340B Drug Pricing Program will be reimbursed at the 340B actual acquisition cost, but no more than the 340B ceiling price plus the established professional dispensing fee.

015.04(G) DRUGS PURCHASED AT NOMINAL PRICE. Facilities purchasing drugs at Nominal Price, outside of Federal Public Health Service's 340B Drug Pricing Program or Federal Supply Schedule, will be reimbursed by their actual acquisition cost plus the established professional dispensing fees.

015.04(H) INVESTIGATIONAL DRUGS. Excluded from coverage.

015.04(I) TRIBAL RATES. Tribal pharmacies will be paid the federal encounter rate.

015.04(J) CERTIFIED LONG-TERM CARE. Pharmacies providing covered outpatient prescription services for Certified Long-Term Care beneficiaries will be reimbursed for ingredient cost using the lesser of methodology plus the established professional dispensing fee.

015.04(K) UNIT DOSE PRESCRIPTIONS. The Department defines unit dose in this chapter. Unit dose providers are allowed one professional dispensing fee per recipient and drug per month.

015.04(L) SALES TAX. The State of Nebraska is tax exempt; therefore, providers do not charge sales tax on claims to the Department.

015.04(M) THIRD PARTY LIABILITY. The pharmacy provider will bill any third party resource for claims before billing Medicaid. All third party resources available to Medicaid clients must be utilized for all or part of their medical costs before Medicaid. Third party resources are any individual, entity, or program which is, or may be, liable to pay all or part of the cost of any medical services furnished to a client.

016. BILLING REQUIREMENTS.

016.01 DRUG CLAIMS. Claims for pharmacy services must meet the requirements listed in the Nebraska Point of Purchase System user's manual. The same standards apply to non-Point of Purchase system claims.

016.02 MEDICAL SUPPLIES AND DURABLE MEDICAL EQUIPMENT CLAIMS. Providers must bill electronically using the standard Health Care Claim: Professional transaction or the Health Insurance Claim Form to submit claims for medical supplies and durable medical equipment unless otherwise stipulated.

016.03 ELECTRONIC MEDIA CLAIM REQUIREMENTS. While the Department utilizes the Nebraska Point of Purchase System, providers are responsible for any errors, omissions, or inappropriate billings submitted by themselves or on their behalf by billing agents. The submission of any electronic media claim for reimbursement by the provider or by an approved company or organization on behalf of an approved provider constitutes certification of:

(A) The services or items for which payment is claimed were provided in compliance with the provisions of Title VI of the Civil Rights Act of 1964 and section 504 of the Rehabilitation Act of 1973;
(B) The amounts claimed are in accordance with the Department's regulations, and no additional charge, other than Medicaid copayment, has been or will be claimed;
(C) Each service is documented and the documentation is open to audit by the Department or its agents; and
(D) The charge does not exceed the pharmacy's usual and customary charge to the general public.

CHAPTER 16-000 PHARMACY SERVICES

16-001 Standards for Participation: A provider of pharmacy services shall be a licensed pharmacy, licensed pharmacist, or dispensing physician. To participate in the Nebraska Medical Assistance Program (NMAP), the provider shall fully meet the standards established by the Department of Health and Human Services and any applicable state and federal laws or regulations governing the provision of the service. Providers shall meet all the Department's pharmacy regulations contained in this chapter.

The pharmacy provider shall complete and sign Form MC-19, "Medical Assistance Provider Agreement," (see 471-000-90) and submit it to the Department to be approved for provider enrollment. Approval may be denied or withdrawn at the discretion of the Director.

16-001.01 Drug Utilization Review: As a condition of participation, the provider is required to:

1. Provide prospective drug utilization review before dispensing each prescription. This shall include screening for:
   a. Therapeutic duplication;
   b. Drug disease contraindications;
   c. Drug interactions;
   d. Incorrect dosage or duration;
   e. Drug allergies; and
   f. Clinical abuse/misuse; and
2. Provide patient counseling on all matters which, in the provider's professional judgment, are deemed significant, including:
   a. Name/description of the medication;
   b. Route, dosage form, duration of therapy;
   c. Directions for use;
   d. Adverse reactions, contraindications;
   e. Storage; and
   f. Refill information; and
3. Maintain adequate patient profiles which may include:
   a. Name, address, phone number, date of birth, and gender;
   b. Individual history (i.e., diseases, allergies, drug reactions)
   c. Comprehensive listing of medications; and
   d. Relevant comments.

Remain in section 2as modified

16-002 Covered Services: NMAP covers outpatient drugs in accordance with the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Public Law 101-508) including:

1. Legend drugs;
2. Compounded prescriptions; and
3. Over-the-counter (OTC) drugs indicated as covered on the Nebraska Point of Purchase (NE-POP) System or listed on the Department's website.

Remains in section 3 as modified

16-002.01 Compounded Prescriptions: A compounded prescription is a mixture of ingredients which the provider prepares in the pharmacy. (See the NE-POP System User's manual for billing instructions.) Remains in section 4 as modified

Reimbursement for compounded prescriptions will be limited to those ingredients which are indicated as covered on the NE-POP System or listed on the Department's website. Remains in section 4 as modified

Any mixture of drugs which results in a commercially available OTC preparation is not considered a compounded prescription, for example, dilute HCL, MOM with cascara, OTC hydrocortisone preparations. Remains in section 4 as modified

16-002.02 Over-the-Counter (OTC) Drugs: NMAP covers only OTC drugs indicated as covered on the NE-POP System or listed on the Department's website. OTC drugs shall be prescribed by a licensed practitioner. Remains in section 5 as modified

16-002.03 HEALTH CHECK (EPSDT) Treatment Services: Services not covered under the Nebraska Medical Assistance Program (NMAP) but defined in Section 1905(a) of the Social Security Act shall meet the conditions of items 1 through 6 listed in the definition of "Treatment Services" in 471 NAC 33-001.04. These services shall be prior authorized by the Division of Medicaid and Long-Term Care of the Department of Health and Human Services.

16-002.04 Tobacco Cessation Counseling: In addition to a physician/mid-level practitioner, only a licensed pharmacist, meeting Department conditions of participation in 471 NAC 16-002.04A as a Tobacco Cessation Counselor, may provide tobacco cessation counseling. Remains in section 6 as modified

16-002.04A Tobacco Cessation Counseling — Conditions of Participation: As a condition of participation as a Tobacco Cessation Counselor, the provider shall:

(G) Be a licensed pharmacist;
(H) Complete a Department-approved tobacco cessation counselor training;
(I) Maintain current training as a Tobacco Cessation counselor as required by the Department;
(J) Complete and sign a new provider agreement (Form MC-19), indicating the employing pharmacy as the "pay to" provider, and submit proof of completing the Department-required training as part of the provider agreement completion process, or upon request by the Department;

(K) Provide Tobacco Cessation counseling which is separate and distinct from the prospective drug utilization review that is required in 471 NAC 16-001.01 and is not related to the dispensing of any drug product; and

(L) Provide feedback to the physician/mid-level practitioner who ordered the services.

Remains in section 6 as modified

16-002.05 Prescription Refills: Prescription refills shall be performed and recorded in a manner consistent with existent State and Federal laws, rules and regulations. Automatic refills are not allowed. All prescription refills shall be initiated by a request from the prescriber, client, or other person acting as an agent of the client, i.e., family member. In the event the client is residing in a facility, a nurse or other authorized agent of the facility pursuant to a valid prescriber's order may initiate the request for refill. Remains in section 7 as modified

16-003 Non-Covered Services: Payment by NMAP will not be approved for:

1. Requests for quantities not in compliance with 16-004.07.
2. Experimental drugs or non-FDA approved drugs;
3. Drugs or items when the prescribed use is not for a medically accepted indication;
4. Drugs or items prescribed or recommended for weight control and/or appetite suppression;
5. Liquors (any alcoholic beverage);
6. Drug Efficacy Study Implementation Program (DESI) drugs identified as Less Than Effective or Identical, Related or Similar (LTE/IRS) with an indicator value assigned by the FDA of either 5 or 6;
7. Personal care items (examples: non-medical mouthwashes, deodorants, talcum powders, bath powders, soaps, dentifrices, eye washes, and contact solutions);
8. Medical supplies and certain drugs for nursing facility and intermediate care facility for the mentally retarded (ICF/MR) patients (see 471 NAC 7-000 and 16-004.05);
9. Over-the-counter (OTC) drugs not listed on the Department's website;
10. Drugs or items used for cosmetic purposes or hair growth;
11. Baby foods, milk substitutes or metabolic agents (Lofenalac, etc.,) normally supplied by Nebraska Department of Health and Human Services (see 471 NAC 16-002.03 for exceptions);
12. Drugs distributed or manufactured by certain drug manufacturers or labelers that have not agreed to participate in the drug rebate program;
13. Products used to promote fertility;
14. Medications dispensed as partial month fills for nursing facility or group home residents when dispensed by more than one pharmacy;
15. Medications dispensed to replace products which have been recalled by the drug manufacturer;

16. Drugs, items or products of manufacturers/labelers that are identifiable as non-covered on the NE-POP System or on the Department's website;
17. Drugs, classes of drugs or therapeutic categories of drugs that are Medicare Part D Drugs and Medicare Part D Covered supplies or equipment, for all persons eligible for benefits under Medicare Part D, whether or not such persons are enrolled into a Medicare Part D Plan (see 471 NAC 3-004 for definitions of Medicare Part D Drugs, Medicare Part D Covered supplies and equipment, Medicare Part D and Medicare Part D plan);
18. Drugs or classes of drugs approved by the Federal Food and Drug Administration for treatment of sexual or erectile dysfunction, or drugs or classes of drugs that are being used for the treatment of sexual or erectile dysfunction. Drugs or classes of drugs that are approved by the Federal Food and Drug Administration for treatment of sexual or erectile dysfunction and for conditions other than treatment of sexual or erectile dysfunction, and are prescribed for those other conditions may be covered, but NMAP may require prior authorization. (See 471 NAC 16-004); and
19. Automatic refills. (See 471 NAC 16-002.05).

Remains in section 8 as modified

16-004 Limitations and Requirements for Certain Services

16-004.01 Prior Authorization: The Department requires that authorization be granted prior to payment for certain drugs. Should a practitioner dispense a prescription prior to the actual authorization he/she takes a business risk that payment for the prescription may be denied. Providers that are prescribing these drugs or pharmacists that are dispensing these drugs shall obtain prior authorization by submitting the request by standard electronic transaction or by phone, fax or mail, from either: Remains in section 9 as modified

1. The Department's NE-POP contractor; or
2. The Pharmacy Consultant (or designee)
   Nebraska Department of Health and Human Services
   Division of Medicaid and Long-Term Care
   P O Box 95026
   301 Centennial Mall South, 5th Floor
   Lincoln, NE 68509-5026
   Phone: (877) 255-3092
   Fax (402) 742-2348

The NE-POP contractor or the Department will respond to any request for prior authorization within 24 hours of receipt of the request. In cases of medical emergency, provisions are made for dispensing a seventy-two (72) hour supply of a covered outpatient prescribed medication. Remains in section 9 as modified

16-004.01A Approval Decision: The NE-POP contractor or the Department will notify the provider prescribing the drug or the pharmacy dispensing the drug if the authorization has been granted, the eligible dates of the authorization, and the identification of the provider who requested the authorization. The prior authorization

is given for the drug, the client, and the prior authorization dates. Remains in section 9 as modified

16-004.01B Denial Decision: The NE-POP contractor or the Department will notify the provider prescribing the drug or the pharmacy dispensing the drug if coverage is denied. Remains in section 9 as modified

16-004.01C Emergency Decision: The NE-POP contractor or the Department will authorize dispensing up to a seventy-two (72) hour supply of a covered outpatient prescribed medication for cases meeting the definition of a medical emergency as outlined in 471 NAC 2-004.04A.

16-004.01D Unknown Decision: If the provider that is prescribing the drug or the pharmacy that is dispensing the drug has not received an authorization from the NE-POP contractor or the Department, payment may be denied. Remains in section 9 as modified

16-004.01E Verifying Status of Requests: The status of prior authorization requests for drugs may be verified by the pharmacy by submitting a claim via the NE-POP System. If the prior authorization request has not been approved, the pharmacy may contact the NE-POP contractor or the Department for prior authorization.

16-004.02 Products Requiring Prior Approval: Identifiable products requiring approval prior to payment are designated as such on the NE-POP System or on the Department's website. There are three reasons for the use of prior authorization; product based controls, utilization controls and scope controls.

(D) Product Based Controls. Prior authorizations that fall under this category are products where there are medically appropriate alternative treatments which are more cost-effective for the Department.

(E) Utilization Controls. Prior authorizations that fall under this category generally apply to the quantity of medication or duration of therapy approved.

(F) Scope Controls. Scope controls are used to ensure a drug is used for an approved or medically accepted indication, is clinically appropriate, medically necessary and cost-effective.

(iv) Medications which have been approved by the FDA for multiple indications may be subject to a scope-based prior authorization when at least one of the approved indications places that drug in a therapeutic category or treatment class for which a prior authorization is required; or

(v) Prior authorization may be required to assure compliance with FDA approved and/or medically accepted indications, dosage, duration of therapy, quantity, or other appropriate use criteria including pharmacoeconomic consideration; or

(vi) Prior authorization may be required for certain non-standard dosage forms of medications when the drug is available in standard dosage forms.

16-004.03 Preferred Drug List and Pharmaceutical and Therapeutics Committee

16-004.03A Preferred Drug List (PDL): The Medicaid Prescription Drug Act of 2008 requires the Department to establish and maintain a Preferred Drug List for the Medicaid program with the aid of the Pharmaceutical and Therapeutics Committee. Individual drugs will be designated as Preferred or Non-Preferred within therapeutic classes of prescribed drugs reviewed by the Pharmaceutical and Therapeutics Committee. Drugs designated as Preferred Drugs may be prescribed for Medicaid clients without prior authorization from the Department; however some Preferred Drugs may have clinical claim limits to ensure appropriate use. The Preferred Drug List and other related activities shall not be construed to replace, prohibit, or limit other lawful activities of the Department not specifically permitted or required by the Act. Drugs classified as Preferred Drugs will be eligible for Supplemental Rebates as described under the provision of 471 NAC 1-002.02M7. Remains in section 9 as modified

The Department will include on the Preferred Drug List prescribed drugs that are found to be therapeutically equivalent to or superior to other drugs within a therapeutic class, and the net cost of the drugs are equal to or less than other drugs within a therapeutic class after consideration of applicable rebates or discounts negotiated by the Department or its designated contractor. All classes of medications shall be considered for inclusion on the PDL except the antidepressants, antipsychotics or anticonvulsant medications. Remain in section 9 as modified

Medications designated as non-preferred on the Preferred Drug List will be subject to Prior Authorization. The Pharmaceutical and Therapeutics Committee will develop criteria for use of medications with non-preferred status. Remains in section 9 as modified

A health care provider may prescribe a drug designated as non-preferred on the Preferred Drug List to a Medicaid client without prior authorization by the Department if the provider certifies that:

(iii) The client is achieving therapeutic success with a course of medication for human immunodeficiency virus, multiple sclerosis, cancer, or immunosuppressant therapy; or

(iv) The client has experienced a prior therapeutic failure with a medication designated as a Preferred Drug.

Remains in section 9 as modified

The Department will maintain an updated Preferred Drug List in electronic format and will make the list available to the public from the Department's website. Drugs and classes of drugs included on the PDL will be reviewed annually. Changes will be communicated to providers at least 30 days prior to implementation.

16-004.03B Pharmaceutical and Therapeutics Committee (P & T Committee): The Department will establish a Pharmaceutical and Therapeutics Committee to review certain classes of drugs for efficacy, safety and cost, for inclusion on or exclusion from the Department's Preferred Drug List. The Pharmaceutical and Therapeutics

~~Committee will advise the Department on all matters related to the Preferred Drug List.~~

~~The members of the Pharmaceutical and Therapeutics Committee will be appointed by the Director of the Division of Medicaid and Long Term Care. The members will meet the requirements as set forth in the Medicaid Prescription Drug Act of 2008. Members of the Committee will be reimbursed for their actual and necessary expenses.~~

~~The Pharmaceutical and Therapeutics Committee will receive and review data as reviewed and approved by the Department's Pharmacy Consultant. The data shall include information about each drug's efficacy relative to other drugs in the class being reviewed and the relative safety of each drug. After drugs or drug classes have been reviewed and their efficacy and safety determined, the net cost of each may be provided by the Department's Pharmacy Consultant to the Committee, if needed, in order to determine a Preferred Drug. The drug net cost may be provided to allow comparability, such as on the net cost per day of therapy. Drug rebates and supplemental drug rebates will be included in the drug net cost determination.~~

~~All Pharmaceutical and Therapeutics Committee meetings will be open to all interested parties. Public comments will be allowed, but may be constrained by necessity by time or other resources. The Preferred Drug List Program Coordinator shall develop an agenda for each meeting and make it available to all interested parties at least 30 days before the meeting. Pharmaceutical and Therapeutics Committee meetings or portions thereof may not be open to all interested parties if confidential material is being covered, such as Unit Rebate Amounts or Supplemental Unit Rebate Amounts.~~

~~The proceedings of each Pharmaceutical and Therapeutics Committee meeting or portion thereof that is open to the general public will be published.~~

~~16-004.04 Drug Utilization Review (DUR): The Department is authorized by federal statute to conduct a DUR program. The DUR program shall be in compliance with U.S.C., Title 42, Chapter 7, Subchapter XIX, Section 1396r – 8. The DUR program consists of prospective drug review, retrospective drug review, the application of explicit predetermined standards and an educational program. The purpose of the DUR program is to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate and medically necessary and that they are not likely to result in adverse medical results.~~ Remains in section 10 as modified

~~The Department or the Department's contractor utilizes a DUR Board to review and analyze clinical and economic data available. The DUR Board reviews and makes recommendations based on predetermined standards submitted to them by the Department or the Department's contractor(s) and, in concert with retrospective review of claims data, makes recommendations for educational interventions, prospective DUR and the prior authorization process. The DUR Director shall develop an agenda for each meeting and make it available to all interested parties at least 30 days before the meeting. The Department or the~~

Department's contractor may charge a reasonable fee for providing copies and mailing information to interested parties.

The Drug Use Review Board shall, upon the Department's request, review drugs or classes of drugs and make recommendations to the Department regarding drugs or classes of drugs for prior authorization. The Department makes the final decision on which drugs or classes of drugs will require prior authorization. Remains in section 10 as modified

For those drugs that will require prior authorization, the DUR Board shall develop and recommend prior authorization criteria to the Department. The Department may accept, reject, or modify the recommended criteria. Remains in section 10 as modified

The Department will communicate information related to prior authorization criteria on the Department's website. The DUR Board will review existing prior authorization criteria annually. Remains in section 10 as modified

The manufacturer or any interested party may request that a drug or class of drugs on prior authorization be placed on the agenda of a DUR board meeting, but no drug or class of drugs will be placed on the DUR agenda more than once every 12 months without the consent of the DUR director, in consultation with the Department's Pharmacy Consultant. The manufacturer of the drug may request that the DUR director waive the 30-day notification rule when asking to have its product placed on the agenda. Remains in section 10 as modified

All DUR Committee meetings will be open to all interested parties. Public comments will be allowed, but may be constrained by necessity of time or other resources. The minutes of the proceedings of each DUR Committee meeting or portion thereof that is open to the general public will be published.

16-004.05 Pharmacy Services for clients residing in certain care facilities:

16-004.05A Non-Covered Items: NMAP does not cover the following items as pharmacy services for clients residing in a Nursing Facility (NF) or Intermediate Care Facility for the Mentally Retarded (ICF/MR):

1. Hydrogen peroxide;
2. Rubbing alcohol; and
3. OTC enemas.

Remains in section 11 as modified

The NF or ICF/MR may be reimbursed for these items under the Department's payment plan for NF and ICF/MR services.

For clients residing in NFs and ICF/MRs, the Department does not cover medical supplies or durable medical equipment as pharmacy services. See 471 NAC 7-000.

16-004.05B Replacement Cost: Providers shall not duplicate medication, at the Department's expense, for clients residing in facilities. The pharmacy or the facility is

responsible for providing a replacement. Providers shall not bill the Department for medication that was destroyed upon a client's discharge. Remains in section 11 as modified

Examples of situations which are NOT to be billed to the Department include, but are not limited to, the following:

If the client's medication is:

1. Lost;
2. Broken;
3. Misplaced;
4. Not received by the facility;
5. Destroyed:
   a. During a client's temporary absence from the facility (e.g., during therapeutic leave days, bedhold period, medical/surgical days);
   b. Following a change of directions; or
   c. At any time that the medication is ordered for the client, unless the medication has expired.

16-004.05C Professional Dispensing Fees: Pharmacies providing medications to NF and ICF/MR patients are allowed one professional dispensing fee per recipient and drug per month. Remains in section 11 as modified

16-004.05D Unit Dose:

16-004.05D1 Definitions:

Traditional bottle method: Dispensing multiple tablets and capsules in one vial or bottle. This excludes systems such as cassettes, individually packaged doses on cards containing multiple doses and all similar systems. Remains in section 11 as modified

Unit dose is a system of drug packaging, dispensing, returning, billing and crediting by a unit dose provider. Remains in section 11 as modified

Unit dose packaging is drug packaging approved by the Nebraska Board of Pharmacy. Remains in section 11 as modified

Unit dose dispensing is the provision to the patient of a 14-day or less supply of a drug in unit dose packaging. Remains in section 11 as modified

Unit dose returning is the process of returning unit dose packaged drugs to the dispensing pharmacy. Remains in section 11 as modified

Unit dose billing is billing the Department one time per calendar month for the quantity of drug used by the patient during the month (see 471 NAC 16-004.07E for exceptions). The quantity used is the difference between the quantity

dispensed and the quantity returned. (Note: See 471 NAC 16-004.05B, Replacement Cost, for examples of drugs which are NOT considered to have been used by the patient and are NOT billable to the Department). The date of service for each unit dose billing shall be consistent from month to month. Remains in section 11 as modified

Unit dose crediting is a process of issuing credits by the pharmacy to the Department for drugs accepted for return into inventory that were previously billed to and covered by the Department. Remains in section 11 as modified

Unit dose provider is a pharmacy approved by the Department as a unit dose provider. Initial approval is contingent upon written agreement by the provider and demonstration by the provider, to the satisfaction of the Department, of the provider's ability to use unit dose packaging, unit dose dispensing, unit dose returning, unit dose billing and unit dose crediting. Continuing approval is contingent upon the provider's actual performance as specified in the written agreement. Remains in section 11 as modified

16-004.05D2 Reimbursement: The Department shall only reimburse unit dose providers for prescribed drugs dispensed to Medicaid clients residing in facilities. A facility may submit a written request to the Department to waive the unit dose packaging requirements for clients participating in a rehabilitation program that includes training in medication management under the traditional bottle method. If a waiver is granted, the Department will notify the facility and the pharmacy of approval of the request. Remains in section 11 as modified

16-004.05E Drugs Returned for Credit: Providers that accept returns of dispensed drugs from long term care facilities shall credit the Department for those drugs. A drug cost level, below which credits shall not be mandatory, may be established by the Department. Remains in section 12 as modified

16-004.06 Medical Supplies and Durable Medical Equipment: Any medical supply or durable medical equipment indicated as covered on the NE-POP System or on the Department's web site is covered as a pharmacy service under this chapter. Remains in section 12 as modified

16-004.07 Quantity Limitations: The Department imposes the following quantity limitations on certain drugs. Remains in section 13 as modified

16-004.07A Payment from NMAP will not be approved for:

1) More than a 3 month supply of any maintenance medication.
2) More than a one month supply of any controlled substance.
3) More than a one month supply of any injectable medication except insulin and those injectable drugs with a duration of greater than one month from one dose.

Remains in section 13 as modified

16-004.07B Quantities: The following types of limits may be utilized to ensure appropriate utilization and billing.

a. Maximum quantity over time
b. Maximum daily dose
c. Maximum days supply per fill
d. Maximum quantity per fill
e. Minimum quantity per fill
f. Maximum cost per fill
g. Tablet splitting
h. Number of units to require medication be submitted in multiples of the package size

Remains in section 13 as modified

16-004.07C Injections: The Department applies the following limitations to injectable drug products:

1. Only those injections that are either self-administered by the client or are administered for the client at the client's place of residence are reimbursable. Injections that are administered by the provider or hospital are not reimbursable through the pharmacy services program (see 471 NAC 10-003.02 and 18-004.28);
2. Whenever available and the necessity warrants, multi-dose vials of medication shall be dispensed rather than single-dose vials or unit-dose syringes;
3. Single-dose syringes may be reimbursed at the proportionate cost of a multi-dose vial;
4. Maintenance injectable medications which are not reconstituted or admixed by the pharmacy prior to administration to the patient shall be dispensed and billed for the full month's supply;
5. Non-maintenance injectable medications and those injectable medications which must be reconstituted or admixed by the pharmacy prior to administration to the patient including subcutaneous, intramuscular, and intravenous medication delivery by large volume parenteral, piggyback, syringe pump or other methods may be provided at the pharmacist's discretion. Courses of therapy of ten days or less duration shall be billed at the end of the course of therapy. Courses of therapy of greater than ten days duration shall be billed at the end of the course of therapy or after each ten days of therapy; and
6. Injectable medications administered by implanted or similar devices may not be billed to the pharmacy services program when the device is filled in the clinic or hospital.
7. Total parenteral nutrition (TPN) shall be billed through the Durable Medical Equipment and Medical Supplies program. This includes the amino acids, carbohydrates, lipids and all additives. All TPN-compatible additives shall be billed through the supplier program regardless of who completes the addition of the ingredient or the method of administration.

Remains in section 13 as modified

16-004.07D Maintenance Drugs: The Department requires that any other maintenance drug or any drug used in a chronic manner be prescribed and dispensed in a minimum of a one-month supply. Remains in section 13 as modified

Note: Providers shall not reduce prescriptions which are written for quantities larger than a month's supply to a month's supply. The Department considers prescription splitting to be fraudulent except when such reduction is done to comply with State or Federal regulations or statute.

16-004.07E Exceptions to Quantity Limitations: The Department allows the following exceptions to the quantity limitations of this subsection only for those clients that are receiving their medications by/through a non-unit dose system, except where noted otherwise.

1. When the prescriber first introduces a maintenance drug to a patient's course of therapy, the prescriber may prescribe a smaller quantity as his/her judgment dictates. Pharmacists shall indicate that this is the initial filling of the medication when filing the drug claim. Any subsequent dispensing of this maintenance drug shall be prescribed and dispensed in at least a month's supply.
2. When the prescriber's professional judgment indicates that these quantities of medication are not in the patient's best medical interest, the prescriber may prescribe as his/her judgment directs. This includes limitations for lock-in clients. The pharmacist shall maintain documentation that an exception is being made to the Department's requirements.
3. The Department will consider replacement of any lost, misplaced, or stolen drug products for clients, only when the pharmacy provider or prescriber documents the conditions that require replacement. The Department will require additional information (police reports, etc.) prior to replacing controlled substances.
4. Schedule II drugs are exceptions to the quantity limitations. This also applies to unit dose systems, unless the Schedule II drug is used in a chronic or maintenance manner (e.g., methylphenidate for certain chronic conditions).
5. The Department will accept certain original shelf package sizes of medication, under the following conditions:
    a. An original shelf package of 480 ml, or less when not packaged in the pint size, is sufficient for the quantity limitations requirement for liquids. This also applies to unit dose systems;
    b. An original shelf package of l00 tablets or capsules, or less when not available in the 100 tablet or capsule size, for seldom prescribed solid dosage drugs is sufficient for the quantity limitations requirement;
    c. Original shelf packages of l00 tablets or capsules of routinely prescribed drugs are not acceptable as sufficient for fulfillment of the quantity limitations requirement. The full month's supply shall be prescribed and dispensed; and

d. Ready-made ointments, creams, etc., when used in a chronic or maintenance manner, may be dispensed in an original shelf package size provided the original size is closest to the needed amount of medication. This also applies to unit dose systems.

Remains in section 13 as modified

16-004.08 Utilization: Since it is the pharmacist's professional responsibility to ascertain that drugs are being utilized according to the prescriber's directions and that no abuse or overuse exists, the Department will not reimburse pharmacists for prescriptions which demonstrate a lack of this professional obligation. Providers are required to maintain patient record systems or other adequate records to prevent these errors in dispensing.

The Department's professional staff is responsible for determining whether a claim violates the Department's regulations.

The NE-POP system will identify drug claims when potential overuse exists; these claims will be denied.

Remains in section 14 as modified

16-004.09 Tobacco Cessation: Medicaid covers tobacco cessation services as practitioner and pharmacy services under the following conditions:

1. Up to two tobacco cessation sessions may be covered in a 12-month period. A session is defined as medical encounters and drug products as listed in items 2 and 3 below. Client access to the Nebraska Tobacco Free Quitline will be unlimited.
2. Practitioner Office Visits:
   a. Clients shall see their medical care provider (physician/mid-level practitioner) for evaluation particularly for any contraindications for drug products and to obtain prescription(s) if tobacco cessation products are needed.
   b. (1) In addition to the evaluation under item 2a, a total of four tobacco cessation counseling visits with a medical care provider or tobacco cessation counselor (see 471 NAC 16-002.04) are covered for each tobacco cessation session. This may be a combination of intermediate or intensive tobacco cessation counseling visits.
   (2) Tobacco cessation counseling provided by a Tobacco Cessation counselor shall be ordered by the physician/mid-level practitioner.
3. Tobacco cessation products are covered by Medicaid as a pharmacy service (see 471 NAC 16-000) for those clients 18 years of age or older who require that particular assistance.
   a. Coverage of products used for tobacco cessation is limited to a maximum 90 days supply in one tobacco cessation session. Up to two 90 day supplies may be covered in a 12 month period, beginning with the date the first prescription for the products is dispensed.
   b. Tobacco cessation products will only be covered when clients are currently enrolled with and actively participating in the Nebraska Tobacco Free Quitline. Disenrollment or lack of active participation in the Nebraska Tobacco Free

Quitline will result in discontinuation of Medicaid coverage of tobacco cessation drug products.

4. Nebraska Tobacco Free Quitline: For coverage of tobacco cessation products, clients shall be enrolled in and active with the Nebraska Tobacco Free Quitline. Referral to the Quitline may be made by a medical professional (physician/mid-level practitioner) or a self referral.

Remains in section 14 as modified

16-005 Payment for Pharmacy Services

16-005.01 Professional Dispensing Fees

16-005.01A: A professional dispensing fee of $10.02 will be assigned to each claim payment based on the lesser of methodology described below. Remains in section 15 as modified

16-005.01B Dispensing Physicians: The Department assigns a professional dispensing fee to a dispensing physician only when there is no pharmacy within a 25-mile radius of the physician's place of practice. Remains in section 15 as modified

16-005.02 Reimbursement Methodology

Note: Payment levels for all drugs will not exceed, in the aggregate, upper levels of reimbursement established by federal law. Remains in section 15 as modified

16-005.02A Brand Necessary Certification of Drugs: The Federal Upper Limit (FUL) or State Maximum Allowable Cost (SMAC) limitations will not apply in any case where the prescribing physician certifies that a specific brand is medically necessary. In these cases, the usual and customary charge or National Average Drug Acquisition Cost (NADAC) will be the maximum allowable cost. The prescriber must certify on Form MC-6 that a brand name is medically necessary. Remains in section 15 as modified

16-005.02A1 Completion of Form MC-6: The Department requires completion of the prescriber certification form to meet federal requirements:

1. Form MC-6 will contain the handwritten signature of the prescriber. Rubber stamp signatures and initials are not acceptable;
2. A separate Form MC-6 is required for each drug product;
3. Form MC-6 will be submitted to the Department or the Department's designated contractor;
4. Notice of approval or denial will be returned to the dispensing pharmacy via fax. Copies are to be retained by the dispensing pharmacy and serve as proof of certification;
5. The original and subsequent prescriptions will contain designation consistent with Nebraska pharmacy practice law noting drug product selection is not permitted; and

6. The prescriber will certify the effective period (From and To) dates on Form MC-6. The duration will not exceed one year. A new Form MC-6 is required when the effective dates of the certification expire.

16-005.03 Pricing Instructions: Pharmacists will not, under any circumstances, submit charges to the Department which exceed the pharmacy's usual and customary charge. Remains in section 15 as modified

16-005.03A Pricing: Any loss leader prices, shelf prices, sale prices, cash only prices, coupon certificates, newspaper or brochure ad prices that are in effect on the date the prescription is dispensed will be considered the pharmacy's usual and customary charge to the general public. Remains in section 15 as modified

16-005.03B Price Matching: When a pharmacy lowers its usual and customary price for a prescription (for example: to match a competitor's price), all claims submitted to Medicaid for the same drug and quantity dispensed during that business day will also be billed at the lowered price. Remains in section 15 as modified

16-005.04 Payment Methodology

16-005.04A Legend, Non-legend Drugs and Compounded Prescriptions: The Nebraska Medicaid Drug Program is required to reimburse ingredient cost for covered outpatient legend and non-legend drugs at the lowest of:

a. The usual and customary charge to the public;
b. The National Average Drug Acquisition Cost (NADAC), plus the established professional dispensing fee;
c. The Affordable Care Act (ACA) Federal Upper Limit (FUL), plus the established professional dispensing fee; or
d. The calculated State Maximum Allowable Cost (SMAC), plus the established professional dispensing fee.

Remains in section 15 as modified

Backup Ingredient Cost Benchmark

If National Average Drug Acquisition Cost (NADAC) is not available, the allowed ingredient cost will be the lesser of Wholesale Acquisition Cost (WAC) + 0%, State Maximum Allowable Cost (SMAC) or the Affordable Care Act (ACA) Federal Upper Limit (FUL), plus the established professional dispensing fee.

Remains in section 15 as modified

Specialty Drugs

Specialty drugs will be reimbursed at National Average Drug Acquisition Cost (NADAC). If National Average Drug Acquisition Cost (NADAC) is not available, then the Backup Ingredient Cost Benchmark will apply. Remains in section 15 as modified

340B Drug Pricing Program

Covered legend and non-legend drugs, including specialty drugs, purchased through the Federal Public Health Service's 340B Drug Pricing Program

(340B) by covered entities that carve Medicaid into the 340B Drug Pricing Program, will be reimbursed at the 340B actual acquisition cost, but no more than the 340B ceiling price, plus the established professional dispensing fee. A 340B contract pharmacy under contract with a 340B covered entity described in section 1927 (a)(5)(B) of the Act is not covered. Remains in section 15 as modified

Federal Supply Schedule (FSS)

Facilities purchasing drugs through the Federal Supply Schedule (FSS) will be reimbursed at no more than their actual acquisition cost, plus the established professional dispensing fee. Remains in section 15 as modified

Clotting Factor

a. Pharmacies dispensing Antihemophilic Factor products will be reimbursed at the lesser of methodology, plus the established professional dispensing fee. If National Average Drug Acquisition Cost (NADAC) is not available, the lesser of methodology for the allowed ingredient cost will be the Wholesale Acquisition Cost (WAC) + 0%, the Average Sales Prices (ASP) + 6%, or the Affordable Care Act (ACA) Federal Upper Limit (FUL); and

b. Pharmacies dispensing Antihemophilic Factor products purchased through the Federal Public Health Service's 340B Drug Pricing Program (340B) by pharmacies that carve Medicaid into the 340B Drug Pricing Program will be reimbursed at the 340B actual acquisition cost, but no more than the 340B ceiling price, plus the established professional dispensing fee.

Remains in section 15 as modified

Drugs Purchased at Nominal Price

Facilities purchasing drugs at Nominal Price (outside of Federal Public Health Service's 340B Drug Pricing Program [340B] or Federal Supply Schedule [FSS]) will be reimbursed by their actual acquisition cost, plus the established professional dispensing fees. Remains in section 15 as modified

Investigational Drugs

Excluded from coverage. Remains in section 15 as modified

Tribal Rates

Tribal pharmacies will be paid the federal encounter rate. Remains in section 15 as modified

Certified Long-Term Care

Pharmacies providing covered outpatient prescription services for Certified Long-Term Care beneficiaries will be reimbursed for ingredient cost using the lesser of methodology, plus the established professional dispensing fee. Remains in section 15 as modified

16-005.04B Unit Dose Prescriptions: The Department defines unit dose at 471 NAC 16-004.05D. Unit dose providers are allowed one professional dispensing fee per recipient and drug per month. For exceptions to the one professional dispensing fee per recipient and drug per month, see 471 NAC 16-004.07E. Remains in section 15 as modified

16-005.04C Sales Tax: The State of Nebraska is tax exempt; therefore, providers do not charge sales tax on claims to the Department. Remains in section 15 as modified

16-005.05 Third Party Liability: The pharmacy provider will bill any third party resource for claims before billing Medicaid. All third party resources available to Medicaid clients shall be utilized for all or part of their medical costs before Medicaid. Third party resources are any individual, entity, or program that is, or may be, liable to pay all or part of the cost of any medical services furnished to a client. See 471 NAC 3-004. Remains in section 15 as modified

16-006 Billing Requirements

16-006.01 Drug Claims: Claims for pharmacy services shall meet the requirements listed in the NE POP System user's manual. The same standards apply to non-NE POP system claims. Remains in section 16 as modified

16-006.02 Medical Supplies and Durable Medical Equipment Claims: Providers shall bill electronically using the standard Health Care Claim: Professional transaction (ASC X12N 837) or Form CMS-1500, "Health Insurance Claim Form," (see 471-000-55) to submit claims for medical supplies and durable medical equipment unless otherwise stipulated. See 471 NAC 7-000 on durable medical equipment and medical supplies. Remains in section 16 as modified

16-006.03 Electronic Media Claim (EMC) Requirements: While the Department utilizes the NE POP System, providers are responsible for any errors, omissions, or inappropriate billings submitted by themselves or on their behalf by billing agents. The submission of any EMC for reimbursement by the provider or by an approved company or organization on behalf of an approved provider constitutes certification that -

1. The services or items for which payment is claimed were provided in compliance with the provisions of Title VI of the Civil Rights Act of 1964 and section 504 of the Rehabilitation Act of 1973;
2. The amounts claimed are in accordance with the Department's regulations, and no additional charge (other than Medicaid copayment) has been or will be claimed;
3. Each service is documented and the documentation is open to audit by the Department or its agents; and
4. The charge does not exceed the pharmacy's usual and customary charge to the general public.

Remains in section 16 as modified