

CHAPTER 16-000 PHARMACY SERVICES

16-001 Standards for Participation: A provider of pharmacy services ~~shall~~ must be a licensed pharmacy, licensed pharmacist, or dispensing physician. To participate in the Nebraska Medical Assistance Program (NMAP), the provider ~~shall~~ must 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~~ must meet all the Department's pharmacy regulations contained in this chapter.

The pharmacy provider ~~shall~~ must 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 Approval may be denied or withdrawn at the discretion of the Director.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~~ must 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. ~~Make a reasonable effort to obtain, record, and~~ Maintain adequate patient profiles which, ~~in the provider's professional judgment, are deemed significant. This may include:~~
 - a. Name, address, phone number, age, date of birth, and gender;
 - b. Individual history (i.e., diseases, allergies, drug reactions)
 - c. Comprehensive listing of medications; and
 - d. Relevant comments.

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 ~~LISTED~~ on the Department's website.

~~See 471 NAC 16-003, Non-Covered Services; 471 NAC 16-004.01A, Products Requiring Prior Approval; coverage as indicated on NE-POP System and the Department's website for exceptions to the above~~

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.)

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.

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. ~~(See the NE-POP System user's manual for billing instructions.)~~

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

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 ~~must~~ meet the conditions of items 1 through 6 listed in the definition of "Treatment Services" in 471 NAC 33-001.0403-. These services shall ~~must~~ 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.

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

1. Be a licensed pharmacist;
2. Complete a Department-approved tobacco cessation counselor training;
3. Maintain current training as a Tobacco Cessation counselor as required by the Department;
4. 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;

5. Provide Tobacco Cessation counseling which is separate and distinct from the prospective drug utilization review that is required in 471 NAC 16-001.~~012~~ and is not related to the dispensing of any drug product; and
6. Provide feedback to the physician/midlevel practitioner who ordered the services.

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.

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

1. ~~Requests for quantities not in compliance with 16-004.079. More than a three-month supply of birth control tablets. More than a three-month supply of oral medication. More than 100 tablets or capsules of medication taken once daily. More than a three-month supply of any other medication, except injectable medications. 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 (e.g., Lupron Depot 4 month, Depo-Provera Contraceptive 150 mg.).~~
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 (~~see 471 NAC 16-004.06~~);
5. Liquors (any alcoholic beverage);
6. ~~D.E.S.I. drugs (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.; and all identical, related, or similar drugs;~~
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 16-004.057);
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.
165. Drugs, items or products of manufacturers/labelers that are identifiable as non-covered on the ~~Ne-POP~~ NE-POP sSystem or on the Department's website;
176. 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); ~~and~~
187. 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).

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 ~~must~~ obtain prior authorization by submitting the request by standard electronic transaction or by phone, fax or mail, from either:

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) 471-9092
E-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.

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.

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.

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.

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 eSystem. 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.

The following prescribed products require prior approval:

- ~~1. Sunscreens (Example: Presun 29, Solbar 50);~~
- ~~2. Certain modified versions, double strength entities, or products considered by the Department to be equivalent to drug products contained on the state or federal upper limit listings (Example: Libritabs, Keftabs);~~
- ~~3. Human Growth Hormone;~~
- ~~4. Erythropoietin (Example: Epogen, Procrit);~~
- ~~5. Drugs or supplies intended for convenience use (Example: Refresh Ophthalmic 0.3 ml. and Novalin penfil insulin);~~
- ~~6. Drugs used for prevention of infection with respiratory syncytial virus (e.g., respiratory syncytial virus immune globulin, palivizumab); and~~
- ~~7. Certain drugs or classes of drugs used for gastrointestinal disorders, including but not limited to hyperacidity, gastroesophageal reflux disease, ulcers or dyspepsia (examples: omeprazole, famotidine);~~
- ~~8. Certain drugs or classes of drugs used for relief of pain, discomfort associated with musculoskeletal conditions, inflammation or fever (examples: butorphanol, carisoprodol, tramadol);~~
- ~~9. Certain drugs or classes of drugs used for relief of cough and/or symptoms of the common cold, influenza or allergic conditions (examples: loratadine, zanimivir, eseltamivir);~~
- ~~10. Certain drugs or classes of drugs that are used for non-covered services or indications (see 471 NAC 16-003 Non-Covered Services) and for covered services or indications (examples: orlistat, sildenafil);~~
- ~~11. Certain drugs or classes of drugs on the state maximum allowable cost or federal upper limit listings;~~
- ~~12. Certain drugs or classes of drugs upon initial availability or marketing or when Nebraska Medicaid coverage begins;~~
- ~~13. Certain drugs or classes of drugs that are used for tobacco cessation; and~~
- ~~14. Certain drugs or classes of drugs that are determined by the Pharmaceutical and Therapeutics Committee to not be placed onto the Preferred Drug List.~~

There are three reasons for the use of prior authorization; product based controls, utilization controls and scope controls.

- (1) 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.
- (2) Utilization Controls. Prior authorizations that fall under this category generally apply to the quantity of medication or duration of therapy approved.
- (3) 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.
 - A. 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 to a therapeutic category or treatment class for which a prior authorization is required; or

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

~~Identifiable products requiring approval prior to payment are designated as such on the NE-POP System or on the Department's website.~~

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 ~~prescription~~ 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 classifieds as Preferred Drugs will be eligible for Supplemental Rebates as described under the provision of 471 NAC 1-002.02M7.

The Department will include on the Preferred Drug List ~~prescription~~ 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.

Medications designated as non-preferred ~~Non-Preferred~~ in 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 ~~prescription~~ drug designated as non-preferred on ~~Non-Preferred~~ in the Preferred Drug List to a Medicaid client without prior authorization by the Department if the provider certifies that:

1. The client is achieving therapeutic success with a course of medication for human immunodeficiency virus, multiple sclerosis, cancer, or immunosuppressant therapy; or
2. The client has experienced a prior therapeutic failure with a medication designated as a Preferred Drug.

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 ~~Internet web site~~. Drugs and classes of drugs included on the PDL will be reviewed annually, ~~at least once every 12 months~~. Notice of 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 or the Department's contracted Drug Use Review Contractor operates a Drug Use Review (DUR) program. The Department is authorized by federal statute to conduct a DUR program. The DUR program shall must 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. All DUR Board meetings will be open to all interested parties who wish to provide comments concerning any issue under review by the DUR Board. The DUR Director will develop an agenda for each meeting and make it available to all interested parties at least 30 days before the meeting. The DUR contractor may charge a reasonable fee for providing copies and mailing information to interested parties.~~

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 must, 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 that will require prior authorization, the DUR Board shall must 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 Department's website. The DUR Board will review existing prior authorization criteria annually.

~~The Department may also determine that drugs or classes of drugs will require prior authorization. The Department must require the DUR Board to develop and recommend prior authorization criteria for these drugs. The Department may accept, reject, or modify the recommended criteria. The Department will communicate information related to prior authorization criteria on the Department's website. The Department will notify providers of prior authorization criteria through provider bulletins prior to implementation. Comments or concerns regarding prior authorization criteria may be communicated to the pharmacy consultant. The DUR Board will review existing prior authorization criteria annually every 12 months.~~

~~The Department may add a drug to the list of drugs that require prior authorization before consulting the DUR board. In this situation, the issue of prior authorizing that drug must be added to the next regularly scheduled DUR board meeting. This may necessitate that the DUR director waive the 30-day notification rule with the concurrence of the drug's manufacturer, or its being placed on the agenda may be delayed until a 30-day notice can be given.~~

~~The manufacturer or any interested party may request that a drug or class of drugs on the prior authorization list 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.~~

~~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.~~

~~The manufacturer, or any interested party, may request DUR Board review of any new drug, or soon to be released drug pending FDA approval. The manufacturer of any new drug, or soon to be released drug pending FDA approval, may request that the DUR director waive the 30-day notification rule for its product.~~

~~16-004.05 Milk Substitutes: See 471 NAC 7-000.~~

~~16-004.06 Anti-Obesity Agents: NMAP does not cover any drug or item prescribed or recommended for weight control and/or appetite suppression.~~

~~16-004.057 Pharmacy Services for clients residing in certain care facilities: Nursing Facility (NF) and Intermediate Care Facility for the Mentally Retarded (ICF/MR) Clients~~

~~16-004.057A 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.~~

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 ff.

16-004.057B Replacement Cost: Providers shall not duplicate medication, at the Department's expense, for clients residing in facilities. ~~for nursing facility or ICF/MR clients at the Department's expense.~~ 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.

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:~~

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. During the 15-day bedhold period – this is the time during which the NF or ICF/MR is paid the usual rate to hold the client's bed even though the client is not in the facility;~~
 - c. Following a change of directions; or
 - d. At any time that the medication is ordered for the client, unless the medication has expired.

16-004.057C Dispensing Fees: Pharmacies providing medications to NF and ICF/MR patients are allowed one dispensing fee per recipient and drug per month.

16-004.057D Unit Dose:

16-004.057D1 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.

Unit dose is a system of drug packaging, dispensing, returning, billing and crediting by a unit dose provider.

Unit dose packaging is drug packaging approved by the Nebraska Board of Pharmacy.

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

Unit dose returning is the process of returning unit dose packaged drugs to the dispensing pharmacy.

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 16-004.079E for exceptions). The quantity used is the difference between the quantity dispensed and the quantity returned. (Note: See 471 NAC 16-004.057B, 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: ~~(a) consistent from month to month, and (b) the date during the month that the last dispensing occurred, or the final day of the calendar month.~~

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.

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.

16-004.057D2 Reimbursement: The Department shall only reimburse ~~reimburse only~~ Unit Dose Providers for prescribed drugs dispensed to Medicaid clients residing in facilities. ~~Nursing Facilities or ICF/MRs.~~ A nursing 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.

~~16-004.07D2a Exception: Pharmacy providers that dispensed prescribed drugs to all Medicaid clients residing in a Nursing Facility or ICF/MR via a traditional bottle method as of August 28, 1999, shall be allowed to continue to provide services to those clients in that Nursing Facility or ICF/MR. This exception shall be granted for one year following the effective date of this regulation.~~

16-004.057E 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.

16-004.068 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.

16-004.079 Quantity Limitations: The Department imposes the following quantity limitations on certain drugs.

~~16-004.09A Minimum Quantity for Package Size: Federal regulation requires certain medications to be dispensed in their original unopened containers. NMAP does not cover these drugs unless they are dispensed in an original unopened container (Example: Nitroglycerin sublingual). The Department notifies all pharmacies of these products on the Department's web site. This information is also available through the NE-POP system.~~

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.

16-004.079B Maximum Quantities: See 16-003 Non-Covered Services. 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

16-004.079C 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 ~~physician provider~~ or hospital are not reimbursable through the pharmacy services ~~outpatient drug program~~ (see 471 NAC 10-003.02 ff. and 18-004.28 ff.);
2. Whenever available and the necessity warrants, multi-dose vials of medication ~~shall~~ must be dispensed rather than single-dose vials or unit-dose syringes;
3. ~~The Department allows one dispensing fee for each vial of influenza or other vaccines intended for mass injections of clients. The provider shall submit a single drug claim for these vaccines. The drug claim must include—~~
 - a. ~~A complete list of the names of all clients who received injections from each vial, either on the back of the claim or as a separate list attached to the claim; and~~
 - b. ~~The case number and ID number of one of the clients who received an injection listed on the drug claim;~~
4. Single-dose syringes ~~are~~ may be reimbursed at the proportionate cost of a multi-dose vial. ~~plus the same proportion of the dispensing fee;~~
5. Maintenance injectable medications which are not reconstituted or admixed by the pharmacy prior to administration to the patient ~~shall~~ must be dispensed and billed for the full month's supply;
6. 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, ~~hydration~~ 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
7. 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. may be billed by the pharmacy when the device is filled. Note: The Department may require you to bill Medicare before billing Medicaid, when appropriate.~~
8. Total parenteral nutrition (TPN) ~~shall~~ must be billed through the ~~supplier~~ Durable Medical Equipment and Medical Supplies program. This includes the amino acids, carbohydrates, lipids and all additives. All TPN-compatible additives ~~must~~ shall be billed through the supplier program regardless of who completes the addition of the ingredient or the method of administration.

16-004.079D 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.

Note: Providers ~~shall~~ ~~must~~ 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.

~~16-004.09E 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 must 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 must 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. The coverage period is limited to 90 consecutive calendar days, 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 drug products.~~
- ~~4. Nebraska Tobacco Free Quitline: For coverage of tobacco cessation products, clients must 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.~~

16-004.07E9F 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 ~~prescribing physician~~ first introduces a maintenance drug to a patient's course of therapy, the ~~physician prescriber~~ may prescribe a smaller quantity as his/her judgment dictates. Pharmacists ~~shall~~ must indicate that this is the initial filling of the medication when filing the drug claim. Any subsequent dispensing of this maintenance drug ~~shall~~ must be prescribed and dispensed in at least a month's supply.
2. When the ~~prescriber's~~ prescriber's ~~physician's~~ professional judgment indicates that these quantities of medication are not in the patient's best medical interest, the ~~physician prescriber~~ may prescribe as his/her judgment directs. This includes limitations for lock-in clients. The pharmacist ~~shall~~ must 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 100 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 100 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~~ must 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.

16-004.0840-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. ~~The Department recommends that~~ 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.

16-004.09E—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~~ ~~must~~ 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~~ ~~must~~ 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. ~~The coverage period is limited to 90 consecutive calendar days.~~ 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~~ ~~must~~ 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.

16-005 Payment for Pharmacy Services

16-005.01 Dispensing Fees

16-005.01A Pharmacies: The Department assigns a dispensing fee to each individual retail pharmacy, and hospital pharmacy. ~~The fee is calculated from the information obtained through the Department's prescription survey.~~ The Department notifies each pharmacy of its dispensing fee.

Note: If a pharmacy accepts a lesser fee from any other third party program, the Department may adjust its assigned dispensing fee to reflect this variance in total charge.

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

16-005.02 Drug or Ingredient Cost

16-005.02A Federal Upper Limit (FUL): Certain multiple source drug products will have an upper limit of reimbursement assigned by the Federal Government. The Federal Upper Limit is established by the Centers for Medicare & Medicaid Services (CMS) in accordance with applicable federal laws and regulations. ~~This limit is equal to 150 percent of the product's lowest price that is published in current national compendia of drug cost information. Additionally, at least three suppliers must list the product which has been classified by the FDA as Category A in its most recent publication of Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book).~~

~~The Department notifies all pharmacies of products which have been designated as FUL products and the respective FUL values via the NE-POP system and on the Department's website.~~

16-005.02B State Maximum Allowable Cost (SMAC): Certain multiple source drug products will have a state maximum allowable cost assigned by the Division of Medicaid and Long-Term Care, Medicaid Division of the Nebraska Department of Health and Human Services Finance and Support. The SMAC limit is the cost at which the drug is widely and consistently available to pharmacy providers in Nebraska. The determination of which products are assigned SMAC limits is the direct responsibility of the Medicaid Division of Medicaid and Long-Term Care in conjunction with the Nebraska Pharmacists Association Medicaid Advisory Committee. Any individual or organization may request a revision in a SMAC limit directly from the Department.

The Department notifies all pharmacies of products which have been designated as SMAC products and the respective SMAC values via the NE-POP system and on the Department's website.

16-005.02C Estimated Acquisition Cost (EAC): All drug products, including the FUL products and SMAC products, will be assigned an ~~an~~ as estimated acquisition cost. The EAC is defined as the average wholesale price (AWP) as published by the drug reference file utilized by the NE-POP system First Data Bank less eleven percent, or Wholesale Acquisition Cost (WAC) as published by the drug reference file utilized by the NE-POP system plus 6.8 percent. The Department will be responsible for assigning the EAC limits for all drug products. ~~Any individual or organization may at any time request a revision in any EAC value directly from the Department.~~

~~16-005.02D Cost Limitations: See 471 NAC 16-005.04A.~~

Note: Payment levels for all drugs will not exceed, in the aggregate, upper levels of reimbursement established by federal code or regulation.

~~16-005.02DE Brand Necessary Certification of FUL/SMAC Drugs~~ Physician Certification of FUL/SMAC Drugs: If the prescribing physician requires that a brand name product of a federal upper limit (FUL) or a state maximum allowable cost (SMAC) designated drug (see 471 NAC 16-005.02A and 16-005.02B) is medically necessary, the Department requires the physician to sign and date Form MC-6, "Physician Certification," (see 471-000-84). The FUL/SMAC limitation does not apply when the prescribing physician certifies on Form MC-6 that a brand name product is medically necessary and the Department shall reimburse the pharmacy provider at the EAC value for the trade name drug product. If Form MC-6 is not completed, the Department shall reimburse the pharmacy at the FUL/SMAC limit for the drug product. -In order to override the FUL/SMAC on an innovator multisource drug the prescriber shall certify the product is medically necessary for the well being of the patient.

~~16-005.02DE1 Completion of Form MC-6:~~ The Department requires completion of the physician prescriber certification form to meet federal requirements. ~~Form MC-6 must:~~

1. Form MC-6 shall ~~contain~~ the handwritten signature of the prescribing physician. Rubber stamp signatures, initials, etc., are not acceptable.
2. A separate Form MC-6 ~~MC-6 Form~~ is required for each drug product.
3. ~~The original (top) copy of Form MC-6 shall~~ must be submitted to the Department designated contractor. ~~Department or the Department's designated contractor.~~
4. ~~The duplicate e~~ Notice of approval or denial will be returned to the dispensing pharmacy via fax. Copies are to be retained by the dispensing pharmacy provider and prescriber ing physician and serve as their proof of certification. The Department does not provide additional authorization.
5. The original and subsequent prescriptions shall contain designation consistent with Nebraska pharmacy practice statutes noting drug product selection is not permitted. ~~drug claims shall~~ must be checked "dispense as written"; and
6. The prescriber shall certify the effective period (From and To) dates on Form MC-6. The duration shall not exceed one year. A new Form MC-6 is required when the effective dates of the certification expire. ~~or prescribing physician has changed.~~

16-005.03 Pricing Instructions: Pharmacists shall not, under any circumstances, submit charges to the Department which exceed the pharmacy's usual and customary charge.

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 shall ~~must~~ be considered the pharmacy's usual and customary charge to the general public.

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 shall ~~must~~ also be billed at the lowered price.

16-005.04 Payment Methodology

16-005.04A Legend Drugs and Compounded Prescriptions: The Department reimburses legend drugs and compounded prescriptions (~~except birth control products~~) at the lower of -

1. Product cost (~~FUL, SMAC, or EAC~~) (EAC or FUL or SMAC) plus the assigned dispensing fee(s); or
2. The pharmacy's usual and customary charge to the general public (see 471 NAC 16-005.03).

16-005.04B Unit Dose Prescriptions: The Department defines unit dose at 471 NAC 16-004.05D~~04D~~. Unit dose providers are allowed one dispensing fee per recipient and drug per month. For exceptions to the one dispensing fee per recipient and drug per month see 16-004.06E-07E.

The Department reimburses unit dose prescriptions at the lowest of -

1. Product cost (~~FUL, SMAC, or EAC~~) (EAC or FUL or SMAC) plus assigned dispensing fee(s); or
2. The pharmacy's usual and customary charge to the general public (see 471 NAC 16-005.03).

Note: The Department does allow the pharmacy provider to maintain a different usual and customary charge for those drug products dispensed through a recognized unit dose distribution system than the same drug products dispensed through a bottle. This applies only to legend drugs dispensed through a unit dose distribution system (capsules, tablets, etc., and not creams, or liquids). This usual and customary variance is not allowable for OTC drug products.

16-005.04C OTC Drugs: The Department reimburses listed ~~LISTED~~ OTC drugs at the lowest of -

1. Product cost (~~FUL, SMAC, or EAC~~) (EAC or FUL or SMAC) plus the appropriate dispensing fee(s); or
2. The pharmacy's usual and customary shelf price to the general public (maximum of FUL, SMAC, or EAC cost, plus a 50% mark-up).

~~16-005.04D Birth Control Products: Birth control products are reimbursed at the lowest of~~

~~-~~

- ~~1. Product cost (FUL, SMAC, or EAC) plus the appropriate dispensing fee(s); or~~
- ~~2. The pharmacy's usual and customary charge to the general public (maximum of FUL, SMAC, or EAC cost, plus a 50% mark-up).~~

~~Family planning agencies must bill for birth control products dispensed by a family planning agency and are reimbursed at actual acquisition cost, plus a 50% markup.~~

~~Note: The Department will not approve payment for more than a three months' supply of birth control tablets.~~

~~16-005.04DE Sales Tax: The State of Nebraska is tax exempt; therefore, providers do not charge sales tax on claims to the Department.~~

16-005.05 Third Party Liability: The pharmacy provider shall bill any third party resource for claims before billing Medicaid. All third party resources available to Medicaid clients ~~shall~~ must 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 party of the cost of any medical services furnished to a client. See 471 NAC 3-004 for further policy on third party liability.

16-006 Billing Requirements

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

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.

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 ~~electronic media claim~~ 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.