NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

September 23, 2019
10:00 a.m. Central Time
Nebraska State Office Building – Lower Level A
301 Centennial Mall South, Lincoln, Nebraska

The purpose of this hearing is to receive comments on proposed changes to Title 471, Chapter 1 of the Nebraska Administrative Code (NAC) – *Administration.* The regulations govern the administration of services provided under Nebraska's Medicaid Program. The proposed regulations incorporate restricted services to medical services in Medicaid fee for service and Managed Care. The proposed changes also remove duplicate statutory and inconsistent language from the regulations, restructure the regulatory chapter, and ensure compliance 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).

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 with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: **Department of Health and Human Services**	
Title: 471	Prepared by: Heather Leschinsky
Chapter: 1	Date prepared: 11.19.18
Subject: Administration	Telephone: 402.471.9185

	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: DHHS, Divisioon of Medicaid and Long Term Care

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

TITLE 471 NEBRASKA MEDICAL ASSISTANCE PROGRAM SERVICES

CHAPTER 1 ADMINISTRATION

001. SCOPE AND AUTHORITY. The regulations govern the services provided under Nebraska's Medicaid program as defined by Nebraska Revised Statute (Neb. Rev. Stat.) §§ 68-901 to 68-991.

002. NEBRASKA MEDICAID-COVERABLE SERVICES. Medicaid covers the services included and outlined in each service specific chapter in Nebraska Administrative Code (NAC) Titles 471, 473, 480, and 482. Each service must be medically necessary and appropriate, in accordance with this chapter, and any additional medical necessity requirements imposed by each service specific chapter in Title 471 NAC.

002.01 NEBRASKA MEDICAID MANAGED CARE PROGRAM. Each Managed Care Organization (MCO) provides behavioral health, physical health, and pharmacy services to eligible enrolled Medicaid clients. The Dental Benefits Manager is a Pre-Paid Ambulatory Health Plan (PAHP) that provides dental services to eligible enrolled Medicaid clients. Medicaid operates Managed Care in accordance with Title 482 NAC.

002.01(A) BENEFITS. The Heritage Health plan is required to provide the services in the core benefits package as defined in 482 NAC 4, in the amount, duration, and scope as described in this chapter. The Managed Care Organizations (MCOs) and Pre-Paid Ambulatory Health Plan (PAHP) can place appropriate limits on covered services consistent with medical necessity or based on utilization control.

002.01(B) PRIOR AUTHORIZATION, BILLING, AND PAYMENT. Services provided to clients enrolled in Managed Care are not billed to Medicaid. The provider will provide services only under an arrangement with the Managed Care Organization (MCO) or Pre-Paid Ambulatory Health Plan (PAHP), and the Managed Care Organization (MCO) or Pre-Paid Ambulatory Health Plan (PAHP) will make timely payment in accordance with 482 NAC 4. The prior authorization requirements, payment limitations, and billing instructions outlined in Title 471 NAC do not apply to services provided to clients enrolled in Managed Care unless otherwise stated in this chapter.

002.02 GENERAL REQUIREMENTS FOR ALL SERVICES. Providers must be enrolled in Medicaid for the service provided, ordered, referred, or rendered to be coverable.

002.02(A) MEDICAL NECESSITY. Services and supplies which do not meet the definition of medical necessity are not covered. For purposes of Medicaid fee-for-service and

Managed Care, medical necessity is health care services and supplies which are medically appropriate and:

(i) Necessary to meet the basic health needs of the client;
(ii) Rendered in the most cost-efficient manner;
(iii) Rendered in a type of setting appropriate for the delivery of the covered service;
(iv) Consistent in type, frequency, and duration of treatment with scientifically based guidelines of national medical, research, or health care coverage organizations or governmental agencies;
(v) Consistent with the diagnosis of the condition;
(vi) Required for means other than convenience of the client or the physician;
(vii) No more intrusive or restrictive than necessary to provide a proper balance of safety, effectiveness, and efficiency; and
(viii) Relative to the goal of improved patient health outcomes.

002.02(B) PLACE OF SERVICE. Covered services in fee-for-service and Managed Care must be provided at the least expensive appropriate place of service. As deemed appropriate by Medicaid, payment for services provided at alternate places of service may either be denied, or reduced to what would have been payable at the least expensive appropriate place of service.

002.02(C) EXPERIMENTAL OR INVESTIGATIONAL. Medicaid in fee-for-service and Managed Care does not cover medical services which are considered investigational or experimental or which are not generally employed by the medical profession. While the circumstances leading to participation in an experimental or investigational program may meet the definition of medical necessity, payment for these services are prohibited.

002.02(C)(i) RELATED SERVICES. Medicaid does not pay for associated or adjunctive services that are directly related to non-covered experimental or investigational services.

002.02(C)(ii) INVESTIGATIONAL OR EXPERIMENTAL CRITERIA. Services are deemed investigational or experimental by the Department. The Department may convene ad hoc advisory groups of experts to review requests for coverage. A service is deemed investigational or experimental if it meets any one of the following criteria:

(1) The Food and Drug Administration (FDA), or other regulatory authority, has not approved the service or treatment for general marketing to the public for the proposed use;
(2) Reliable evidence does not lead to the conclusion that there is a consensus within the medical community that the service is a generally accepted standard of care employed by the medical profession as a safe and effective service for treating or diagnosing the condition or illness for which its use is proposed. Reliable evidence includes peer reviewed literature with statistically significant data regarding the service for the specific disease and age group. Also, facility specific data, including short and long term outcomes, must be submitted to the Department;

(3) The service is available only through an Institutional Review Board (IRB) research protocol for the proposed use or subject to such an Institutional Review Board (IRB) process; or

(4) The service is the subject of an ongoing clinical trial that meets the definition of a Phase I, Phase II, or Phase III Clinical Trial, regardless of whether the trial is actually subject to Food and Drug Administration (FDA) oversight and regardless of whether an Institutional Review Board (IRB) process is required at any one particular institution.

002.02(C)(iii) DEFINITION OF CLINICAL TRIALS. For services not subject to Food and Drug Administration (FDA) approval, the following definitions apply:

(1) Phase I: Initial introduction of an investigational service into humans;

(2) Phase II: Controlled clinical studies conducted to evaluate the effectiveness and safety of the service being investigated; and

(3) Phase III: Clinical studies to further evaluate the effectiveness and safety of a service that is needed to determine the overall risk and benefit and to provide an adequate basis for determining patient selection criteria for the service as the recommended standard of care. These studies usually compare the new service to the current recommended standard of care.

002.02(D) FAMILY PLANNING SERVICES. Medicaid in fee-for-service and Managed Care covers family planning services, including consultation and procedures, when requested by the client. Family planning services and information must be provided to clients without regard to age, sex, or marital status, and must include medical, social, and educational services. The client must be allowed to exercise freedom of choice in choosing a method of family planning. Family planning services performed in family planning clinics must be prescribed by a physician, and furnished, directed, or supervised by a physician or registered nurse.

002.02(D)(i) COVERED SERVICES. Covered services for family planning include initial physical examination and health history, annual and follow-up visits, laboratory services, prescribing and supplying contraceptive supplies and devices, counseling services, and prescribing medication for specific treatment.

002.02(E) SERVICES PROVIDED OUTSIDE NEBRASKA. Payment in fee-for-service and Managed Care may be approved for services provided outside Nebraska in the following situations:

(1) When an emergency arises from accident or sudden illness while a client is visiting in another state and the client's health would be endangered if medical care is postponed until the client returns to Nebraska;

(2) When a client customarily obtains a medically necessary service in another state because the service is more accessible; and

(3) When the client requires a medically necessary service that is not available in Nebraska.

002.02(E)(i) PRIOR AUTHORIZATION REQUIREMENTS. Prior authorization in fee-for-service is required for services provided outside Nebraska when:

(1) The service is not available in Nebraska; or

(2) The service requires prior authorization under the applicable service specific chapter of Title 471 NAC.

002.02(E)(ii) PRIOR AUTHORIZATION PROCEDURES FOR OUT-OF-STATE SERVICES. In fee-for-service, the referring physician must submit request to the Department in written or electronic form. The request must include the following information or explanation as appropriate to the case:

(1) A summary evaluation by a licensed provider for the type of service rendered, and a statement indicating that the service is not available in Nebraska or is inadequate to meet the client's needs;
(2) The name, address, and telephone number of the out-of-state provider;
(3) An indication of whether the out-of-state provider is enrolled or is willing to enroll as a Nebraska Medicaid provider and accept the Medicaid allowable payment as payment in full for the services;
(4) A description of the client's condition. The physician must certify, based on a thorough evaluation, that the services being requested are medically necessary and not experimental or investigational;
(5) Identification of the physician who will be assuming follow-up care when the client returns to Nebraska;
(6) Any plan for follow-up and return visits, including a timeline for the visits and an explanation of the medical necessity for the return visits;
(7) If the client is requesting assistance with transportation, the type of transportation appropriate for the client's condition, and when ambulance, air ambulance, or commercial air transportation is being requested, the request must provide an explanation of medical necessity; and
(8) The client’s name, address, and Medicaid recipient identification number, or date of birth.

002.02(E)(iii) MANAGED CARE PROVIDERS. In Managed Care, the provider must provide services only under an arrangement with the Managed Care Organization (MCO).

002.02(F) SERVICES NOT DIRECTLY PROVIDED FOR TREATMENT OR DIAGNOSIS. Unless otherwise expressly allowed in Title 471, Medicaid in fee for service and Managed Care does not cover services provided to a client that are not directly related to diagnosis or treatment of the client’s condition.

002.02(G) SERVICES REQUIRED TO TREAT COMPLICATIONS OR CONDITIONS RESULTING FROM NON-COVERED SERVICES. Medicaid in fee-for-service and Managed Care may consider payment for medically necessary services that are required to treat complications or conditions resulting from non-covered services. Coverage of complication or conditions resulting from non-covered services will be determined at the discretion of the Department.

If the services in question are determined to be part of a previous non-covered service, that is, an extension or a periodic segment of a non-covered service or follow-up care associated with it, the subsequent services will be denied.

002.02(H) DRUG REBATES. Medicaid covers prescribed drugs only if the labeler has signed a Rebate Participation Agreement with the Secretary of Health and Human Services, Centers for Medicare and Medicaid Services (CMS).

002.02(H)(i) REBATE DISPUTE RESOLUTION. In any quarter, if a manufacturer discovers a discrepancy in Medicaid utilization information that the manufacturer and the Department are unable to resolve in good faith, the manufacturer must provide written notice of the discrepancy by National Drug Code (NDC) number to the Department within 30 days of receipt of the quarterly drug rebate invoice which contains the Medicaid utilization information.

002.02(H)(i)(1) MANUFACTURER DISPUTE. If the manufacturer, in good faith, believes that the Medicaid utilization information is erroneous, the manufacturer must pay the Department that portion of the rebate amount claimed that is not disputed within 30 days after receiving the Medicaid utilization information. Following resolution of the dispute, the balance due, if any, plus a reasonable rate of interest as set forth in Section 1903(d)(5) of the Social Security Act must be paid or credited by the manufacturer or by the Department by the due date of the next quarterly payment.

002.02(H)(i)(2) WRITTEN REQUEST. The Department and the manufacturer must use their best efforts to resolve the discrepancy within 60 days of receipt of notification. If the Department and the manufacturer are not able to resolve a discrepancy within 60 days, the manufacturer may file a written request for an administrative hearing under 465 NAC 6.

002.02(H)(i)(2)(a) HEARING DECISION. The hearing decision is not binding on the Secretary of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), for purposes of their authority to implement a civil money penalty provision in accordance with the statute or rebate agreement.

002.02(H)(i)(3) PAYMENT ADJUSTMENTS. Adjustments to rebate payments must be made if information indicates that either Medicaid utilization information, average manufacturer price (AMP), or best price is greater or less than the amount previously specified.

002.02(H)(ii) MANUFACTURER RIGHT TO APPEAL. Every manufacturer of a rebatable drug that has a signed rebate agreement has the limited right to appeal to the Medicaid Director for a hearing. This appeal right is limited to any discrepancies in the quarterly Medicaid utilization information only. No other matter relating to that manufacturer's drugs may be appealed to the Director.

002.02(H)(ii)(1) HEARING REQUEST. A manufacturer must request a hearing within 90 days of the date the Department gives notice to the manufacturer of the availability of the hearing process for the disputed drugs.

002.02(H)(ii)(2) HEARING PROCEDURES. Hearings are scheduled and conducted according to 465 NAC 6.

002.02(H)(iii) SUPPLEMENTAL DRUG REBATES. In addition to the requirements for drug rebates as described in this chapter. Medicaid may negotiate and contract for supplemental rebates with labelers of prescribed drugs. The negotiations and contracts may be between the labeler and the Department or an entity under contract with the Department to negotiate these supplemental rebates, including a single or multi-state drug purchasing pool. Any entity under contract with the Department will be fee based, and there will be no financial incentives or bonuses based on inclusion or exclusion of medications from the Preferred Drug List.

002.02(I) REQUIREMENTS FOR WRITTEN PRESCRIPTIONS. Medicaid in fee-for-service and Managed Care will not pay for written prescriptions for prescribed drugs unless executed on a tamper-resistant pad as required by federal law.

002.02(I)(i) EXCLUSIONS. The following prescriptions and other items are not required to be written on tamper-resistant prescription pads:

(1) Orders for drugs provided in Nursing Facilities, Intermediate Care Facility for clients with Developmental Disabilities (ICF/DD) facilities, and other specified institutional and clinical settings for which the drug is not separately reimbursed, but is reimbursed as part of a total service including:
  (a) Inpatient and outpatient hospital;
  (b) Hospice;
  (c) Dental;
  (d) Laboratory;
  (e) X-ray; and
  (f) Renal dialysis;
(2) Faxed prescriptions;
(3) Telephoned, or otherwise orally transmitted prescriptions; and
(4) E-prescribed, when the prescription is transmitted electronically.

002.02(I)(ii) REQUIREMENTS. A written Medicaid prescription must contain at least one of the three following characteristics:

(1) An industry-recognized feature designed to prevent unauthorized copying of a completed or blank prescription form, such as a high security watermark on the reverse side of the blank or thermochromic ink;
(2) An industry-recognized feature designed to prevent erasure or modification of information written on the prescription by the prescriber, such as tamper-resistant background ink that shows erasures or attempts to change written information; or
(3) An industry-recognized feature designed to prevent the use of counterfeit prescription forms, such as sequentially numbered blanks or duplicate or triplicate blanks.

002.02(I)(iii) EMERGENCY FILLS. Medicaid will pay for emergency fills for prescriptions written on non-tamper resistant pads only when the prescriber provides a verbal, faxed, electronic, or compliant written prescription within 72 hours after the date on which the prescription was filled. In an emergency situation, this allows a pharmacy to telephone a prescriber to obtain a verbal order for a prescription written

on a non-compliant paper. The pharmacy must document the call on the face of the written prescription.

002.02 (J) MANAGED CARE CLIENTS. Clients participating in the Managed Care plans and Dental Benefits Manager are required to access services through their primary care provider.

003. FEDERAL AND STATE REQUIRMENTS. The Department is required by federal and state law to meet certain provisions in the administration of Medicaid.

003.01 MEDICAL ASSISTANCE ADVISORY COMMITTEE. The Medicaid Director will appoint an advisory committee to advise the Director in the development of health and medical care services policies. Members of the committee include: physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care; members of consumers' groups, including Medicaid clients; and consumer organizations, such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; the of Director Public Health and the Chief Executive Officer of Health and Human Services. Members are appointed on a rotating basis to provide continuity of membership.

003.02 UTILIZATION REVIEW. Any individual or entity must provide the Department with any documentation or information requested as part of the Department's utilization review.

004. TELEHEALTH SERVICES FOR PHYSICAL AND BEHAVIORAL HEALTH SERVICES. This section applies to medical services in Medicaid fee-for-service and Managed Care.

004.01 DEFINITIONS. The following definitions apply to this section:

004.01(A) CHILD. An individual under 19 years of age.

004.01(B) COMPARABLE SERVICE. A service provided face-to-face.

004.01(C) DISTANT SITE. The location of the provider of the telehealth service.

004.01(D) ORIGINATING SITE. The location of the client at the time of the telehealth consultation.

004.01(E) TELEHEALTH CONSULATION. Any contact between a client and a health care practitioner relating to the health care diagnosis or treatment of such client through telehealth. For the purposes of telehealth services, a consultation includes any service delivered through telehealth.

004.01(F) TELEMONITORING. The remote monitoring of a client's vital signs, biometric data, or subjective data by a monitoring device which transmits such data electronically to a health care practitioner for analysis and storage.

004.02 APPLICABLE LAWS. Health care practitioners providing telehealth services must follow all applicable state and federal laws and regulations governing their practice and the services they provide.

004.03 ORIGINATING SITES. Health care practitioners must ensure that the originating sites meet the standards for telehealth services. Originating sites must provide a place where the client's right to receive confidential and private services is protected.

004.04 INFORMED CONSENT. Before an initial telehealth consultation, the health care practitioner must provide the client the following written information which must be acknowledged by the client in writing or via email:

(A) Alternative options are available, including in-person services. These alternatives are specifically listed on the client's informed consent statement;

(B) All existing laws and protections for services received in-person also apply to telehealth, including:

(i) Confidentiality of information;

(ii) Access to medical records; and

(iii) Dissemination of client identifiable information;

(C) Whether the telehealth consultation will be or will not be recorded;

(D) The identification of all the parties who will be present at each telehealth consultation, and a statement indicating that the client has the right to exclude anyone from either the originating or the distant site; and

(E) The written consent form becomes a part of the client's medical record and a copy must be provided to the client or the client's authorized representative.

004.05 BEHAVIORAL HEALTH SERVICES FOR CHILDREN. For each client who is a child who is receiving telehealth behavioral health services, the following protections must be in place:

(A) An appropriately trained staff member or employee familiar with the child's treatment plan or familiar with the child must be immediately available in person to the child receiving a telehealth behavioral consultation in order to attend to any urgent situation or emergency that may occur during provision of such service. This requirement may be waived by the child's parent or legal guardian. The medical record must document the waiver; and

(B) In cases in which there is a threat that the child may harm himself or herself or others, before an initial telehealth consultation the health practitioner must work with the child and his or her parent or guardian to develop a safety plan. Such plan must document actions the child, the health care practitioner, and the parent or guardian will take in the event of an emergency or urgent situation occurring during or after the telehealth consultation. Such plan may include having a staff member or employee familiar with the child's treatment plan immediately available in person to the child if such measures are deemed necessary by the team developing the safety plan.

004.06 TELECOMMUNICATIONS TECHNOLOGY COSTS. Telehealth services and transmission costs are covered by Medicaid when:

(1) The technology used meets industry standards;

(2) The technology is Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant; and

(3) The telehealth technology solution in use at both the originating and the distant site must be sufficient to allow the health care practitioner to appropriately complete the service billed to Medicaid.

004.06(A) STANDARDS. The standards above apply to any peripheral diagnostic scope or device used during the telehealth consultation.

004.06(B) COVERAGE. Coverage is available for teleradiology services when the services meet the American College of Radiology standards for teleradiology.

004.07 TELEMONITORING REIMBURSEMENT. Medicaid will reimburse for telemonitoring when all of the following requirements are met:

(1) The services are from the originating site;
(2) The client is cognitively capable to operate the equipment or has a willing and able person to assist in the transmission of electronic data;
(3) The originating site has space for all program equipment and full transmission capability; and
(4) The provider must maintain a client's record containing data supporting the medical necessity of the service, all transmissions and subsequent review received from the client, and how the data transmitted from the client is being utilized in the continuous development and implementation of the client's plan of care.

004.07(A) PER DIEM RATE. Telemonitoring is paid at a daily per diem rate set by Medicaid and includes the following:

(i) Health care practitioner review and interpretation of the client data;
(ii) Equipment and all supplies, accessories, and services necessary for proper functioning and effective use of the equipment;
(iii) Medically necessary visits to the home by a health care practitioner; and
(iv) Training on the use of equipment and completion of necessary records.

004.07(B) FIXED PAYMENT. No additional or separate payment beyond the fixed payment is allowable.

004.08 PRACITIONER CONSULTATION REIMBURSEMENT. Medicaid will reimburse a consulting health care practitioner when all of the following requirements are met:

(1) After obtaining and analyzing the transmitted information, the consulting health care practitioner reports back to the referring health care practitioner;
(2) The consulting health care practitioner must bill for services using the appropriate modifier; and
(3) Payment is not made to the referring health care practitioner who sends the medical documentation.

004.08(A) EXCLUSIONS. Practitioner consultation is not covered for behavioral health services when the client has an urgent psychiatric condition requiring immediate attention by a licensed mental health practitioner.

004.09 REIMBURSEMENT OF TELEHEALTH. Telehealth services are reimbursed by Medicaid at the same rate as the service when it is delivered in person in accordance with each service specific chapter in Title 471 NAC.

004.10 REIMBURSMENT OF ORGINATION SITE FEE. The originating site fee is paid to the Medicaid-enrolled facility hosting the client for telehealth services at a rate set forth in the Medicaid fee schedule or under arrangement with the Managed Care Organization (MCO).

004.11 OUT-OF-STATE TELEHEALTH SERVICES. Out-of-State telehealth services are covered if the telehealth services otherwise meet the regulatory requirements for payment for services provided outside Nebraska and:

(A) When the distant site is located in another state and the originating site is located in Nebraska; or

(B) When the Nebraska client is located at an originating site in another state, whether or not the provider's distant site is located in or out of Nebraska.

004.12 DOCUMENTATION. The medical record for telehealth services must follow all applicable statutes and regulations on documentation. The use of telehealth technology must be documented in the same medical record, and must include the following telehealth information:

(A) Documentation of which site initiated the call;

(B) Documentation of the telecommunication technology utilized; and

(C) The time the service began and ended.

005. CLIENT RESTRICTED SERVICES PROGRAM. This section applies to medical services in Medicaid fee-for-service and Managed Care.

005.01 RESTRICTED SERVICES CRITERIA. The Department may restrict a client to obtain Medicaid services only from a designated provider, or renew a period of restricted services, when the client has used Medicaid services at a frequency or amount that is not medically necessary. When evaluating whether a client has used services at a frequency or amount that is not medically necessary, the Department may consider any of the following criteria:

(A) Number, type, or dosage of prescriptions obtained by the client;

(B) Number of prescribers prescribing medication to the client;

(C) Number of pharmacies dispensing to a client;

(D) Number of clinic or emergency room encounters; or

(E) Whether the client displays at-risk behavior, as exhibited by any of the following:

(i) A client with a medical history of seeking and obtaining health care services at a frequency or amount that is not medically necessary; or

(ii) Behaviors or practices that could jeopardize a client's medical treatment or health including, but not limited to:

(1) Forging or altering prescriptions;

(2) Noncompliance with medical or drug and alcohol treatment;

(3) Paying cash for medical services that result in a controlled substance prescription or paying cash for controlled substances;

(4) Arrests for diversion of controlled substance prescriptions;

(5) Positive urine drug screen for illicit drugs or non-prescribed controlled substances;

(6) Negative urine drug screen for prescribed controlled substances; or

(7) Use of a client's Medicaid card for an unauthorized purpose.

005.02 DESIGNATION OF RESTRICTED SERVICES PROVIDER(S). The Department will designate a provider to provide services to a client placed into restrictive services. A designated provider must be located within a reasonable distance of, and must be reasonably accessible to, the client.

005.02(A) DURATION OF RESTRICTED SERVICES. A client placed into restricted services must obtain Medicaid services from the designated provider for a period of no more than 12 months. Upon the expiration of a period of restricted services, the Department may renew such period based upon the Department's review of the client's pattern of utilization.

005.02(B) DURATION OF PROVIDER DESIGNATION. A client placed in restricted services must remain with the designated provider, unless any of the following occur:

(i) The designated provider is no longer located within a reasonable distance of, or is no longer reasonably accessible to, the client;
(ii) The designated provider refuses to continue to serve the client;
(iii) The designated provider is no longer enrolled in Medicaid; or
(iv) A change is requested by the client and approved by the Department. A client may request a change of the designated provider no later than 90 days after a designation is made. Such request must be made to the Department in writing.

005.03 SERVICES BY PROVIDERS NOT LISTED AS RESTRICTED SERVICES PROVIDERS. Claims for services provided to a restricted services client by other than the designated provider will not be approved, with the following exceptions:

(A) Emergency care is defined as medically necessary services provided to a client who requires immediate medical attention to sustain life or to prevent any condition which could cause permanent disability to body functions;
(B) A primary care provider may refer a restricted services client to a non-designated provider for a specified length of time. Any referral made by a primary care provider to a non-designated provider must be approved by the Department prior to the non-designated provider providing services to the client. Referrals are not required for the following:
    (i) Non-emergent medical transportation;
    (ii) Home and community based services;
    (iii) Mental health and substance abuse services;
    (iv) Routine eye exams;
    (v) Radiology services;
    (vi) Laboratory services;
    (vii) Family planning;
    (viii) Obstetrics provider services only;
    (ix) Dialysis; and
    (x) Nursing home services; and
(C) Prescriptions will be covered if prescribed or authorized by a primary care provider, or within the setting of a hospital for non-emergency care if approved by a primary care provider.

005.04 RESTRICTED SERVICES NOTIFICATION. The client will be provided notice of the client's placement into restrictive services no fewer than 10 days before restricted services are imposed.

005.04(A) CLIENT APPEAL RIGHTS. A client may appeal the Department's decision to place the client into restricted services. Any appeal must be submitted in writing no later than 90 days after the client is placed into restricted services. If an appeal is submitted within 10 days after notice of the client's placement into restrictive services is mailed, the effective date of the restricted services will be stayed until the appeal has been decided.

005.04(B) CHANGE IN DESIGNATED PROVIDER. A client may appeal the Department's decision to deny the client's request to change a designated provider. Any appeal must be submitted in writing no later than 90 days after the Department's decision.

005.05 PHARMACY CLAIMS. Pharmacy claims submitted for prescriptions dispensed to a client in the restricted services program by providers other than a designated provider will not be paid except in a medical emergency. A pharmacy submitting a claim must provide documents indicating a medical emergency existed at the time the prescription was dispensed.

006. ADVANCE DIRECTIVES. An advance directive is a written instruction, such as a living will or durable power of attorney for health care, recognized under applicable law that relates to the provision of medical care if the client becomes incapacitated. Medicaid-participating hospitals, nursing facilities, providers of home health care or personal care services, hospice programs, and Managed Care Organizations (MCOs) must:

(A) Maintain written policies, procedures, and materials concerning advance directives;
(B) Provide written information to all adult clients receiving medical care by or through the provider or organization concerning their rights under applicable law to:
  (1) Make decisions concerning their medical care;
  (2) Accept or refuse medical or surgical treatment; and
  (3) Formulate advance directives, such as living wills or durable power of attorney for health care; and
(C) Provide written information to all adult clients on the provider's policies concerning implementation of these rights;
(D) Document in the client's medical record whether the client has executed an advance directive;
(E) Not condition the provision of care or otherwise discriminate against a client based on whether that client has executed an advance directive;
(F) Ensure compliance with requirements of applicable law concerning advance directives; and
(G) Provide for educating staff and the community on advance directives.

006.01 WHEN PROVIDERS GIVE INFORMATION CONCERING ADVANCE DIRECTIVES. Providers must give information concerning advance directives to each adult client as follows:

(A) A hospital must give information at the time of the client's admission as an inpatient;
(B) A nursing facility must give information at the time of the client's admission as a resident;

(C) A provider of home health care or personal care services must give information to the client in advance of the client's coming under the care of the provider;

(D) A hospice program must give information at the time of initial receipt of hospice care by the client; and

(E) A Managed Care Organization (MCO) must give information at the time of enrollment. If a managed care plan has more than one medical record for its members, it must document in all medical records.

006.02 INFORMATION CONCERING ADVANCE DIRECTIVES AT THE TIME AN INCAPACITATED CLIENT IS ADMITTED. A client could be admitted to a facility in a comatose or otherwise incapacitated state and be unable to receive information or articulate whether the client has executed an advance directive. In this case, to the extent that a facility issues materials about policies and procedures to the families or to the surrogates or other concerned persons of the incapacitated client in accordance with applicable law, it must also include the information concerning advance directives. This does not relieve the facility from its obligation to provide this information to the patient once the client is no longer incapacitated.

006.03 PREVIOUSLY EXECUTED ADVANCE DIRECTIVES. When the client or a relative, surrogate, or other concerned or related client presents the facility with a copy of the client's advance directive, the facility must comply with the advance directive to the extent allowed under applicable law. This does not preclude a facility from objecting as a matter of conscience, if it is permitted to do so under applicable law.

006.04 INFORMATION CONCERNING ADVANCE DIRECTIVES ABSENT CONTRARY LAW. Absent contrary applicable law, if no one comes forward with a previously executed advance directive and the client is incapacitated or otherwise unable to receive information or articulate whether the client has executed an advance directive, the facility will note that the client was not able to receive information and was unable to communicate whether an advance direct.

TITLE 471
NEBRASKA MEDICAL ASSISTANCE PROGRAM SERVICES

CHAPTER 1-000 ADMINISTRATION

1-001 Introduction: This title addresses services provided under the Nebraska Medical Assistance Program (also known as Nebraska Medicaid).

1-001.01 Legal Basis: The Nebraska Medical Assistance Program (NMAP) was established under Title XIX of the Social Security Act. The Nebraska Legislature established the program for Nebraska in Neb.Rev.Stat. §68-1018. NMAP is administered statewide by the Nebraska Department of Health and Human Services Finance and Support (HHS Finance and Support or the Department).

1-001.02 Purpose: The Nebraska Medical Assistance Program was established to provide medical and other health-related services to aged, blind, or disabled persons; dependent children; and any persons otherwise eligible who do not have sufficient income and resources to meet their medical needs.

1-001.03 Title XIX Plan: The State Plan for Title XIX of the Social Security Act - Medical Assistance Program is a comprehensive written commitment of the state to administer the Nebraska Medical Assistance Program in accordance with federal requirements. The Title XIX Plan is approved by the Federal Department of Health and Human Services. The approved plan is a basis for determining federal financial participation in the state program. The rules and regulations of NMAP implement the provisions of the Title XIX Plan.

1-002 Nebraska Medicaid-Coverable Services: The Nebraska Medical Assistance Program covers the following types of service, when medically necessary and appropriate, under the program guidelines and limitations for each service:

1. Inpatient hospital services;
2. Outpatient hospital services;
3. Rural health clinic services;
4. Federally qualified health center services;
5. Laboratory and x-ray services;
6. Nurse practitioner services;
7. Nursing facility (NF) services;
8. Home health services;
9. Early and periodic screening, diagnosis, and treatment (HEALTH CHECK);
10. Family planning services;
11. Physician services and medical and surgical services of a dentist;
12. Nurse midwife services;
13. Prescribed drugs;
14. Services in intermediate care facilities for the mentally retarded (ICF/MR);
15. Inpatient psychiatric services for individuals under age 21;

16. Inpatient psychiatric services for individuals age 65 and older in an institution for mental diseases;
17. Personal assistance services;
18. Clinic services;
19. Psychologist services;
20. Dental services and dentures;
21. Physical therapy services;
22. Speech pathology and audiology services;
23. Medical supplies and equipment;
24. Prosthetic and orthotic devices;
25. Optometric services;
26. Eyeglasses;
27. Private duty nursing services;
28. Podiatry services;
29. Chiropractic services;
30. Case management services;
31. Medical transportation, including ambulance services;
32. Occupational therapy services;
33. Emergency hospital services;
34. Screening services (mammograms); and
35. Home and community-based waiver services (see Title 480 NAC).

(Certain services covered under the home and community-based waivers may not meet the general definition of "medical necessity" and are covered under the NMAP.)

1-002.01 Nebraska Medicaid Managed Care Program: Certain Medicaid clients are required to participate in the Nebraska Medicaid Managed Care Program also known as the Nebraska Health Connection (NHC). The Department developed NHC to improve the health and wellness of Nebraska's Medicaid clients by increasing their access to comprehensive health services in a way that is cost effective to the State. Enrollment in NHC is mandatory for certain clients in designated geographic areas of the state. The client's participation in NHC will be indicated on the client's NHC ID Document. NHC clients will receive a Nebraska Medicaid Identification Card. Participation in NHC can be verified by accessing the Department Internet Access for Enrolled Providers (www.dhhs.ne.gov/med/internetaccess.htm); the Nebraska Medicaid Eligibility System (NMES) at 800-642-6092 (in Lincoln, 471-9580) (see 471-000-124); the Medicaid Inquiry Line at 877-255-3092 (in Lincoln 471-9128); or using the standard electronic Health Care Benefit Inquiry and Response transaction (ASC X12N 270/271) (see Standard Electronic Transaction Instructions at 471-000-50).

NHC utilizes two models of managed care plans to provide the basic benefits (medical/surgical) package; these models are health maintenance organizations (HMO's) and primary care case management (PCCM) networks. NHC also provides a mental health and substance abuse services (MH/SA) benefits package that is available statewide to all clients who are required to participate in NHC. See 471-000-122 for a list of NHC's plans.

Services included in the benefits package that are provided to a client who is participating in NHC must be coordinated with the plan. The requirements for provision of services in the NHC benefits package are included in the appropriate Chapters of this Title. Services that are not included in the benefits package will be subject to all requirements of this Title.

For clients enrolled in an NHC plan for the basic benefits package, copayments are required only for prescription drugs. Clients enrolled only in the NHC mental health/substance abuse plan are subject to copayments required under 471 NAC 3-008 ff.

1-002.02 Limitations and Requirements for Certain Services

1-002.02A Medical Necessity: NMAP applies the following definition of medical necessity:

Health care services and supplies which are medically appropriate and -

1. Necessary to meet the basic health needs of the client;
2. Rendered in the most cost-efficient manner and type of setting appropriate for the delivery of the covered service;
3. Consistent in type, frequency, duration of treatment with scientifically based guidelines of national medical, research, or health care coverage organizations or governmental agencies;
4. Consistent with the diagnosis of the condition;
5. Required for means other than convenience of the client or his or her physician;
6. No more intrusive or restrictive than necessary to provide a proper balance of safety, effectiveness, and efficiency;
7. Of demonstrated value; and
8. No more intense level of service than can be safely provided.

The fact that the physician has performed or prescribed a procedure or treatment or the fact that it may be the only treatment for a particular injury, sickness, or mental illness does not mean that it is covered by Medicaid. Services and supplies which do not meet the definition of medical necessity set out above are not covered.

Approval by the federal Food and Drug Administration (FDA) or similar approval does not guarantee coverage by NMAP. Licensure/certification of a particular provider type does not guarantee NMAP coverage.

1-002.02B Place of Service: Covered services must be provided at the least expensive appropriate place of service. Payment for services provided at alternate places of service may be reduced to the amount payable at the least expensive appropriate place of service, or denied, as determined by the appropriate staff of the Medicaid Division.

1-002.02C Experimental or Investigational Services: NMAP does not cover medical services which are considered investigational and/or experimental or which are not generally employed by the medical profession. While the circumstances leading to participation in an experimental or investigational program may meet the definition of medical necessity, NMAP prohibits payment for these services.

Within this part, medical services include, but are not limited to, medical, surgical, diagnostic, mental health, substance abuse, or other health care technologies, supplies, treatments, procedures, drugs, therapies, and devices.

1-002.02C1 Related Services: NMAP does not pay for associated or adjunctive services that are directly related to non-covered experimental/investigational services (for example, laboratory services, radiological services, other diagnostic or treatment services, practitioner services, hospital services, etc.).

NMAP may cover complications of non-covered services once the non-covered service is completed (see 471 NAC 1-002.02L).

1-002.02C2 Requests for NMAP Coverage: Requests for NMAP coverage for new services or those which may be considered experimental or investigational must be submitted before providing the services, or in the case of true medical emergencies, before submitting a claim. Requests for NMAP determinations for such coverage must be submitted in writing to the NMAP Medical Director at the following address by mail or fax method:

Medical Director
Nebraska Department of Health and Human Services Finance and Support
Medicaid Division
P.O. Box 95026
Lincoln, NE 68509-5026
Fax Phone Number: (402) 471-9092

The request for coverage must include sufficient information to document that the new service is not considered investigational/experimental for Medicaid payment purposes. Reliable evidence must be submitted identifying the status with regard to the criteria below, cost-benefit data, short and long term outcome data, patient selection criteria that is both disease/condition specific and age specific, information outlining under what circumstances the service is considered the accepted standard of care, and any other information that would be helpful to the Department in deciding coverage issues. Additional information may be requested by the Medical Director.

Services are deemed investigational/experimental by the Medical Director, who may convene ad hoc advisory groups of experts to review requests for coverage. A service is deemed investigational/experimental if it meets any one of the following criteria:

1. There is no Food and Drug Administration (FDA) or other governmental/regulatory approval given, when appropriate, for general marketing to the public for the proposed use;

2. Reliable evidence does not permit a conclusion based on consensus that the service is a generally accepted standard of care employed by the medical profession as a safe and effective service for treating or diagnosing the condition or illness for which its use is proposed. Reliable evidence includes peer reviewed literature with statistically significant data regarding the service for the specific disease/proposed use and age group. Also, facility specific data, including short and long term outcomes, must be submitted to the Department;
3. The service is available only through an Institutional Review Board (IRB) research protocol for the proposed use or subject to such an IRB process; or
4. The service is the subject of an ongoing clinical trial(s) that meets the definition of a Phase I, Phase II, or Phase III Clinical Trial, regardless of whether the trial is actually subject to FDA oversight and regardless of whether an IRB process/protocol is required at any one particular institution.

1-002.02C3 Definition of Clinical Trials: For services not subject to FDA approval, the following definitions apply:

Phase I: Initial introduction of an investigational service into humans.

Phase II: Controlled clinical studies conducted to evaluate the effectiveness of the service for a particular indication or medical condition of the patient; these studies are also designed to determine the short-term side effects and risks associated with the new service.

Phase III: Clinical studies to further evaluate the effectiveness and safety of a service that is needed to evaluate the overall risk/benefit and to provide an adequate basis for determining patient selection criteria for the service as the recommended standard of care. These studies usually compare the new service to the current recommended standard of care.

1-002.02D Cosmetic and Reconstructive Surgery: NMAP limits reimbursement for cosmetic and reconstructive surgical procedures and medical services that are performed when medically necessary for the purpose of correcting the following conditions:

1. Limitations in movement of a body part caused by trauma or congenital conditions;
2. Painful scars/disfiguring scars in areas that are visible;
3. Congenital birth anomalies;
4. Post-mastectomy breast reconstruction; and
5. Other procedures determined to be restorative or necessary to correct a medical condition.

1-002.02D1 Exceptions: To determine the medical necessity of the condition, the Department requires prior authorization for cosmetic and reconstructive surgical procedures, except for the following conditions:

1. Cleft lip and cleft palate;
2. Post-mastectomy breast reconstruction;
3. Congenital hemangioma's of the face; and
4. Nevus (mole) removals.

1-002.02D2 Cosmetic and Reconstructive Prior Authorization Procedures: In addition to the prior authorization requirements under 471 NAC 18-004.01, the surgeon who will be performing the cosmetic or reconstructive (C/R) surgery shall submit a request to the Medical Director. This request must include the following:

1. An overview of the medical condition and medical history of any conditions caused or aggravated by the condition;
2. Photographs of the involved area(s) when appropriate to the request;
3. A description of the procedure being requested including any plan to perform the procedure when it requires a staged process; and
4. When appropriate, additional information regarding the medical history may be submitted by the client's primary care physician.

Prior authorization request for cosmetic and reconstructive surgery must be submitted using the standard electronic Health Care Services Review – Request for Review and Response transaction (ASC X12N 278) (see Standard Electronic Transaction Instructions at 471-000-50) or in writing by mail or fax to the following address:

Medical Director
Nebraska Department of Health and Human Services Finance and Support
Medicaid Division
P.O. Box 95026
Lincoln, NE 68509-5026

Fax Telephone Number: (402) 471-9092

1-002.02E Preventive Health Care: To ensure early detection and treatment, to maintain good health, and to ensure normal development, NMAP provides the HEALTH CHECK program to clients age 20 and younger. HEALTH CHECK is a program of early and periodic screening, diagnosis, and treatment (EPSDT) designed to combine the health services of screening, diagnosis, and treatment with outreach, supportive services, and follow-up to promote and provide preventive health care. See 471 NAC 33-000.

~~Other preventive health care services covered by NMAP are listed in the individual provider chapters.~~

1-002.02F Family Planning Services: NMAP covers family planning services, including consultation and procedures, when requested by the client. Family planning services and information must be provided to clients without regard to age, sex, or marital status, and must include medical, social, and educational services. The client must be allowed to exercise freedom of choice in choosing a method of family planning. Family planning services performed in family planning clinics must be prescribed by a physician, and furnished, directed, or supervised by a physician or registered nurse.

Covered services for family planning include initial physical examination and health history, annual and follow-up visits, laboratory services, prescribing and supplying contraceptive supplies and devices, counseling services, and prescribing medication for specific treatment.

1-002.02G Services Provided Outside Nebraska: Payment may be approved for services provided outside Nebraska in the following situations:

1. When an emergency arises from accident or sudden illness while a client is visiting in another state and the client's health would be endangered if medical care is postponed until s/he returned to Nebraska;
2. When a client customarily obtains a medically necessary service in another state because the service is more accessible;
3. When the client requires a medically necessary service that is not available in Nebraska; and
4. When the client requires a medically necessary nursing facility (see 471 NAC 12-014.04) or ICF/MR (see 471 NAC 31-003.05) service not available in Nebraska.

1-002.02G1 Prior Authorization Requirements: Prior authorization is required for services provided outside Nebraska when -

1. The service is not available in Nebraska (see 471 NAC 1-002.02G, items 3 and 4); or
2. The service requires prior authorization under the individual chapters of this Title.

1-002.02G2 Prior Authorization Procedures for Out-of-State Services: The referring physician shall submit a request to the Department using the standard electronic Health Care Services Review Request for Review and Response transaction (ASC X12N 278) (see Standard Electronic Transaction Instructions at 471-000-50) or by mail or fax to the following address:

Medical Director
Nebraska Department of Health and Human Services Finance and Support
Medicaid Division
P.O. Box 95026
Lincoln, NE 68509-5026

Fax telephone number: (402) 471-9092

~~**For prior authorization procedure for nursing facility services, see 471 NAC 12-014.04.** For prior authorization procedures for ICF/MR services, see 471 NAC 31-000.~~

The request must include the following information or explanation as appropriate to the case:

1. A summary of the client's physician's evaluation of the client and the determination that the service is not available in Nebraska, or if available, the service is not adequate to meet the client's needs;
2. The name, address, and telephone number of the out-of-state provider;
3. An indication of whether the out-of-state provider is enrolled or is willing to enroll as a Nebraska Medicaid provider and accept the Medicaid allowable payment as payment in full for the services;
4. A description of the client's condition. The physician must certify, based on a thorough evaluation, that the services being requested are medically necessary and not experimental or investigational;
5. Identification of the physician who will be assuming follow-up care when the client returns to Nebraska;
6. Any plan for follow-up and return visits, including a timeline for the visits (for example, annually, every six months, as needed), and an explanation of the medically necessity for the return visits;
7. If the client is requesting assistance with transportation, the type of transportation appropriate for the client's condition, and when ambulance, air ambulance, or commercial air transportation is being requested, the request must provide an explanation of medical necessity; and
8. The client's name, address, and Medicaid recipient identification number, or date of birth.

1-002.02H Sales Tax: The State of Nebraska is tax-exempt; therefore, providers shall not charge sales tax on claims to the Department or Medicaid. Sales tax may be an appropriate inclusion on cost reports.

1-002.02J Services Not Directly Provided For Treatment or Diagnosis: Medicaid does not cover services provided to a client that are not directly related to diagnosis or treatment of the client's condition (for example, blood drawn from a client to perform chromosome studies because a relative has had problem pregnancies, paternity testing, research studies, etc.). Exception: For transplant-donor-related services, see 471 NAC 10-005.20 and 18-004.40.

1-002.02J1 Autopsies: Medicaid does not pay for autopsies.

1-002.02K (Reserved)

1-002.02L Services Required to Treat Complications or Conditions Resulting from Non-Covered Services: Medicaid may consider payment for medically necessary services that are required to treat complications or conditions resulting from non-covered services.

Medical inpatient or outpatient hospital services are sometimes required to treat a condition that arises from services which Medicaid does not cover. Payment may be made for services furnished under these circumstances if they are reasonable and necessary and meet Medicaid requirements in 471 NAC.

Examples of services that may be covered under this policy include, but are not limited to -

1. Complications/conditions occurring following cosmetic/reconstructive surgery not previously authorized by Medicaid (for example, breast augmentation, liposuction);
2. Complications from a non-covered medical transplant or a transplant that has not been previously authorized by Medicaid;
3. Complications/conditions occurring following an abortion not previously authorized by Medicaid; or
4. Complications/conditions occurring following ear piercing.

If the services in question are determined to be part of a previous non-covered service, i.e., an extension or a periodic segment of a non-covered service or follow-up care associated with it, the subsequent services will be denied. For example, when a patient undergoes cosmetic surgery and the treatment regimen calls for a series of postoperative visits to the surgeon for evaluating the patient's prognosis, these visits are not covered.

1-002.02M Drug Rebates

1-002.02M1 Legal Basis: These regulations govern the Drug Rebate Program, established by Section 1927 of the Social Security Act, attached and incorporated by reference. The definitions and terms in Section 1927 of the Social Security Act apply to these regulations.

The Nebraska Medical Assistance Program, also known as Nebraska Medicaid, covers prescribed drugs only if the labeler has signed a Rebate Participation Agreement with the Secretary of Health and Human Services, Centers for Medicare and Medicaid Services (CMS). Coverage of prescribed drugs is subject to 471 NAC 16-000, Pharmacy Services.

1-002.02M2 Rebate Dispute Resolution: If, in any quarter, a manufacturer discovers a discrepancy in Medicaid utilization information that the manufacturer and the Department are unable to resolve in good faith, the manufacturer must provide written notice of the discrepancy by National Drug Code (NDC) number to the Department within 30 days after receiving the Medicaid utilization information.

If the manufacturer, in good faith, believes that the Medicaid utilization information is erroneous, the manufacturer must pay the Department that portion of the rebate amount claimed that is not disputed within 30 days after receiving the Medicaid utilization information. The balance due, if any, plus a reasonable rate of interest as set forth in Section 1903(d)(5) of the Social Security Act must be paid or credited by the manufacturer or by the Department by the due date of the next quarterly payment after resolution of the dispute.

The Department and the manufacturer must use their best efforts to resolve the discrepancy within 60 days of receipt of notification. If the Department and the manufacturer are not able to resolve a discrepancy within 60 days, CMS requires the Department to make available to the manufacturer the Department's administrative hearing process under 465 NAC 6.

The hearing decision is not binding on the Secretary of Health and Human Services, CMS, for purposes of his/her authority to implement a civil money penalty provision of the statute or the rebate agreement.

Nothing in this section precludes the right of the manufacturer to audit the Medicaid utilization information reported or required to be reported by the Department.

Adjustments to rebate payments must be made if information indicates that either Medicaid utilization information, average manufacturer price (AMP), or best price is greater or less than the amount previously specified.

1-002.02M3 Manufacturer Right to Appeal: Every manufacturer of a rebatable drug that has a signed rebate agreement has the limited right to appeal to the Director of Finance and Support for a hearing. This appeal right is limited to any discrepancies in the quarterly Medicaid utilization information only. No other matter relating to that manufacturer's drugs may be appealed to the Director, including but not limited to the drug's coverage status, prior authorization status, estimated acquisition cost, state maximum allowable cost, or allowable quantity.

A manufacturer must request a hearing within 90 days of the date the Department gives notice to the manufacturer of the availability of the hearing process for the disputed drugs.

1-002.02M4 Filing a Request: If the manufacturer wishes to appeal an action of the Department, the manufacturer must submit a written request for a hearing to the Director of Finance and Support. The manufacturer must identify the basis of the appeal in the request.

1-002.02M5 Scheduling a Hearing: When the Director receives a request for hearing, the request is acknowledged by a letter which states the time and date of the hearing.

1-002.02M6 Hearings: Hearings are scheduled and conducted according to 465 NAC 6-000, Practice and Procedure for Hearings in Contested Cases Before the Department.

1-002.02M7 Supplemental Drug Rebates: In addition to the requirements for drug rebates as described and defined in 471 NAC 1-002.02M Drug Rebates, the NMAP may negotiate and contract for supplemental rebates with labelers of prescribed drugs. The negotiations and contracts may be between the labeler and the Department or an entity under contract with the Department to negotiate these supplemental rebates, including a single or multi-state drug purchasing pool. Any entity under contract with the Department shall be fee based, and there will be no financial incentives or bonuses based on inclusion or exclusion of medications from the Preferred Drug List.

Only those drugs meeting the requirements under 471 NAC 1-002.01 and which are otherwise eligible for coverage by NMAP are eligible for coverage .

Supplemental drug rebate agreements between the Department and/or the entity under contract to negotiate these agreements will be required as described under the provisions of 471 NAC 16-004.03 Preferred Drug List and Pharmaceutical and Therapeutics Committee.

1-002.02N Requirements for Written Prescriptions: The Nebraska Medical Assistance Program will not pay for written prescriptions for prescribed drugs unless executed on a tamper-resistant pad as required by federal law. This includes written prescriptions:

1. For otherwise covered prescription-only and over-the-counter drugs.
2. When Medicaid is the primary or secondary payer.
3. For drugs provided in Nursing Facilities, ICF/MR facilities, and other specified institutional and clinical settings (inpatient and outpatient hospital, hospice, dental, laboratory, x-ray and renal dialysis) when the drug is separately reimbursed.

1-002.02N1 Exclusions: The following prescriptions and other items are not required to be written on tamper-resistant prescription pads:

(1) Orders for drugs provided in Nursing Facilities, ICF/MR facilities, and other specified institutional and clinical settings (inpatient and outpatient hospital, hospice, dental, laboratory, x-ray and renal dialysis) for which the drug is not separately reimbursed, but is reimbursed as part of a total service;
(2) Refills of written prescriptions that are presented at a pharmacy before April 1, 2008;
(3) Faxed prescriptions;
(4) Telephoned, or otherwise orally transmitted prescriptions;
(5) E-prescribing, when the prescription is transmitted electronically;
(6) Prescriptions for Medicaid recipients that are paid entirely by a managed care entity; and
(7) Co-pays covered by DHHS funds for prescriptions for drugs covered by Medicare Part D, for certain dual eligible persons.

1-002.02N2 Effective April 1, 2008, a written Medicaid prescription must contain at least one of the following characteristics:

(1) An industry-recognized feature designed to prevent unauthorized copying of a completed or blank prescription form, such as a high security watermark on the reverse side of the blank or thermochromic ink;
(2) An industry-recognized feature designed to prevent erasure or modification of information written on the prescription by the prescriber, such as tamper-resistant background ink that shows erasures or attempts to change written information; or
(3) An industry-recognized feature designed to prevent the use of counterfeit prescription forms, such as sequentially numbered blanks or duplicate or triplicate blanks.

1-002.02N3 Effective October 1, 2008, a written Medicaid prescription must contain all three characteristics listed in 471 NAC 1-002.02N2.

1-002.02N4 Emergency Fills: NMAP will pay for emergency fills for prescriptions written on non-tamper resistant pads only when the prescriber provides a verbal, faxed, electronic, or compliant written prescription within 72 hours after the date on which the prescription was filled. In an emergency situation, this allows a pharmacy to telephone a prescriber to obtain a verbal order for a prescription written on a non-compliant paper. The pharmacy must document the call on the face of the written prescription.

1-003 Verifying Eligibility for Medical Assistance: Providers may verify the eligibility of a client by viewing the client's current Medicaid eligibility document (see 471-000-123 for examples). Clients participating in the Nebraska Medicaid Managed Care Program will have an NHC Identification Document (see 471-000-122). Eligibility may also be verified by contacting the Nebraska Medicaid Eligibility System (NMES) (see 471-000-124) or the client's local HHS office (see 471-000-125), or by using the standard electronic Health Care Eligibility Benefit Inquiry and Response transaction (ASC X12N 270/271) (see Standard Electronic Transaction Instructions at 471-000-50).

When a client initially becomes eligible for medical assistance, s/he may not possess a Medicaid eligibility document until the following month. The provider shall verify the eligibility of the client(s) by contacting NMES or the local office or by using the standard electronic transaction (ASC X12N 270/271).

1-004 Federal and State Requirements: The Department is required by federal and state law to meet certain provisions in the administration of the Nebraska Medical Assistance Program.

1-004.01 Medical Assistance Advisory Committee: The Director of the Department appoints an advisory committee to advise the Director in the development of health and medical care services policies. Members of the committee include physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care; members of consumers' groups, including NMAP clients; and consumer organizations, such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; the Director of Regulation and Licensure and the Director of Health and Human Services. Members are appointed on a rotating basis to provide continuity of membership.

1-004.02 Free Choice of Providers: An NMAP client may obtain covered services from any provider qualified to perform the services who has been approved to participate in NMAP. The client's freedom of choice does not prevent the Department from -

1. Determining the amount, duration, and scope of services;
2. Setting reasonable and objective standards for provider participation; and
3. Establishing the fees which are paid to providers for covered services.

Clients participating in the Nebraska Medicaid Managed Care Program are required to access services through their primary care physician.

1-004.03 Utilization Review (UR): The Department or its designee perform utilization review activities related to the kind, amount, and frequency of services billed to NMAP to ensure that funds are spent only for medically necessary and appropriate services. The Department or its designee may request information from clients' records as part of the utilization review process. In the absence of specific NMAP state UR regulations, Medicare UR regulations may apply.

1-005 Medicare Benefits (Title XVIII) Buy-In: The Department pays monthly premiums for Part B of Medicare only for clients who -

1. Are 65 years of age or older; or
2. Meet the eligibility requirements of disability in Nebraska's Assistance to the Aged, Blind, or Disabled Program.

See 471 NAC 3-004 for further information on Medicare/Medicaid crossover claims and Medicare managed care plans.

1-006 TELEHEALTH FOR PHYSICAL AND BEHAVIORAL HEALTH SERVICES

1-006.01 Implementation Date: These regulations will be become operative January 1, 2017.

1-006.02 Definitions

Child: An individual under 19 years of age.

Comparable Service: A service provided face-to-face.

Distant Site: The distant site is the location of the provider of the telehealth consultation.

Originating Site: The originating site is the location of the client at the time of the telehealth consultation.

Telehealth Consultation: Any contact between a client and a health care practitioner relating to the health care diagnosis or treatment of such client through telehealth. For the purposes of telehealth, a consultation includes any service delivered through telehealth.

Telemonitoring: The remote monitoring of a client's vital signs, biometric data, or subjective data by a monitoring device which transmits such data electronically to a health care practitioner for analysis and storage.

1-006.03 Health care practitioners providing telehealth services must follow all applicable state and federal laws and regulations governing their practice and the services they provide.

1-006.04 Originating Sites: Health care practitioners must assure that the originating sites meet the standards for telehealth. Originating sites must provide a place where the client's right for confidential and private services is protected.

1-006.05 Informed Consent: Before an initial telehealth consultation, the health care practitioner shall provide the client the following written information which must be acknowledged by the client in writing or via email:

1. Alternative options are available, including in-person services, and these alternatives are specifically listed on the client's informed consent statement;
2. All existing laws and protections for services received in-person also apply to telehealth, including:
    a. Confidentiality of information;
    b. Access to medical records; and
    c. Dissemination of client identifiable information;

3. Whether the telehealth consultation will be or will not be recorded;

4. ~~The client has a right to be informed of all the parties who will be present at each telehealth consultation and has the right to exclude anyone from either the originating or the distant site;~~

5. For each adult client or for a client who is a child but who is not receiving telehealth behavioral health services, a safety plan must be developed, should it be needed at any time during or after the provision of telehealth. This plan shall document the actions the client and the health care practitioner will take in an emergency or urgent situation that arises during or after the telehealth consultation;
6. For each client who is a child who is receiving telehealth behavioral health services:
   a. An appropriately trained staff member or employee familiar with the child's treatment plan or familiar with the child shall be immediately available in person to the child receiving a telehealth behavioral consultation in order to attend to any urgent situation or emergency that may occur during provision of such service. This requirement may be waived by the child's parent or legal guardian. The medical record shall document the waiver.
   b. In cases in which there is a threat that the child may harm himself or herself or others, before an initial telehealth consultation the health practitioner shall work with the child and his or her parent or guardian to develop a safety plan. Such plan shall document actions the child, the health care practitioner, and the parent or guardian will take in the event of an emergency or urgent situation occurring during or after the telehealth consultation. Such plan may include having a staff member or employee familiar with the child's treatment plan immediately available in person to the child if such measures are deemed necessary by the team developing the safety plan;
7. The written consent form shall become a part of the client's medical record and a copy must be provided to the client or the client's authorized representative; and
8. If the client is a child or otherwise unable to sign the consent form, the client's legally authorized representative shall provide the consent.

1-006.06 Telecommunications Technology: Medicaid coverage is available for telehealth and transmission costs when, the technology used meets industry standards and is HIPPA compliant.

1. The telehealth technology solution in use at both the originating and the distant site must be sufficient to allow the health care practitioner to appropriately complete the service billed to Medicaid. These same standards apply to any peripheral diagnostic scope or device used during the telehealth consultation.
2. Coverage is available for teleradiology services when the services meet the American College of Radiology standards for teleradiology.

1-006.07 Telemonitoring

1. Medicaid will reimburse for telemonitoring when all of the following requirements are met:

a. Telemonitoring is covered only when the services are from the originating site;
b. The client is cognitively capable to operate the equipment or has a willing and able person to assist in the transmission of electronic data;

c. The originating site has space for all program equipment and full transmission capability; and
d. The provider must maintain a client's record containing data supporting the medical necessity of the service, all transmissions and subsequent review received from the client, and how the data transmitted from the client is being utilized in the continuous development and implementation of the client's plan of care.

2. Telemonitoring is paid at a daily per diem rate set by Medicaid and includes the following:
   a. Health care practitioner review and interpretation of the client data;
   b. Equipment and all supplies, accessories, and services necessary for proper functioning and effective use of the equipment;
   c. Medically necessary visits to the home by a health care practitioner;
   d. Training on the use of equipment and completion of necessary records.

3. No additional or separate payment beyond the fixed payment is allowable.

1-006.08 Practitioner Consultation:

1. Reimbursement: Medicaid will reimburse a consulting health care practitioner when all of the following requirements are met:
   a. After obtaining and analyzing the transmitted information, the consulting health care practitioner reports back to the referring health care practitioner;
   b. The consulting health care practitioner must bill for services using the appropriate modifier;
   c. Payment is not made to the referring health care practitioner who sends the medical documentation.

2. Exclusions: Practitioner Consultation is not covered for behavioral health when the client has an urgent psychiatric condition requiring immediate attention by a licensed mental health practitioner.

1-006.09 Reimbursement Rate of Telehealth: Telehealth is reimbursed by Medicaid at the same rate for the service when it is delivered in person.

1-006.010 Reimbursement of Transmission Costs: Transmission cost rates are set forth in the Medicaid fee schedule and include reimbursement for all two-way, real-time, interactive communications, unless provided by an Internet service provider, between the client and the physician or health care practitioner at the distant site which comply with the federal Health Insurance Portability and Accountability Act of 1996 and rules and regulations adopted thereunder and with regulations relating to the encryption adopted by

~~the federal Centers for Medicare and Medicaid Services and which satisfy federal requirements relating to efficiency, economy and quality of care.~~

1-006.11 Reimbursement of Originating Site Fee: The originating site fee is paid to the Medicaid-enrolled facility hosting the client for telehealth at a rate set forth in the Medicaid fee schedule.

1-006.12 Out-of-State Telehealth is covered if the telehealth otherwise meets the regulatory requirements for payment for services provided outside Nebraska and:

1. When the distant site is located in another state and the originating site is located in Nebraska; or
2. When the Nebraska client is located at an originating site in another state, whether or not the provider's distant site is located in or out of Nebraska.

1-006.13 Documentation: The medical record for telehealth must follow all applicable statutes and regulations on documentation. The use of telehealth technology must also be documented in the same medical record, and must include the following telehealth information:

1. Documentation of which site initiated the call;
2. Documentation of the telecommunication technology utilized (e.g. real-time two-way interactive audio-visual transmission via a T1 Line); and
3. The time the service began and ended.