Nebraska Medicine POLICIES AND PROCEDURES MANUAL ☒ System ☐ Department	Section: Medical Staff (MS) Subject: Disclosure Policy/Questionnaire Number: MS52 Attachments: Date Effective: 05/04 Date Reviewed: 09/06, 11/08, 09/10, 01/13, 04/13, 5/22/15

Policy:

Background: The members of the Pharmacy and Therapeutics (P&T) Committee must act on issues involving pharmaceutical and nutrition products, e.g., whether certain products should be added to the formulary or establishing criteria or restrictions for use of products. The Committee recognizes potential conflicts of interest may arise. A disclosure policy and questionnaire has been developed to guide members in determining if they have any personal interests in pharmaceutical and/ or nutrition companies which might represent potential conflicts of interest.

Policy: Members of the Pharmacy and Therapeutics (P&T) Committee shall identify potential conflicts of interest by its members. Member judgment is the ultimate criterion in a given case. The intent of the policy is to guide members in determining whether relationships with pharmaceutical or nutritional product companies appear to constitute a conflict of interest. Each member will sign acknowledgement of the policy and disclose relationships on an annual basis (on the back of this disclosure statement). The information will be kept in a confidential file by the secretary of the P&T Committee for three years.

Disclosing these relationships does not prevent the member from submitting a compound for consideration for formulary action nor participating in the discussion about drugs produced by the company(ies). It is Pharmacy and Therapeutics Committee policy that the following conditions constitute a potential conflict of interest in the decision to vote on formulary decisions. Members should abstain from voting on products from companies with which the conditions exist for conflict of interest.

Disclosure Criteria

It is the policy of the Pharmacy and Therapeutics Committee that a potential conflict may arise if any of the following conditions are met:

1. You or any member of your immediate family is a director, officer, partner, owner or employee of a pharmaceutical, biotechnology or nutritional company.
2. You or any member of your immediate family own securities (excluding mutual funds) or share in the profit of any pharmaceutical, biotechnology or nutritional company.
3. You or any member of your immediate family receive, or anticipate receiving, compensation from a pharmaceutical, biotechnology or nutrition company (e.g., for research support, lecturing, providing inservices or preceptorships, endorsement of products, publishing information or other grants).
4. You have any relationships with or receive any gifts from pharmaceutical, biotechnology or nutritional companies which you believe might influence your judgment in making decisions about products being reviewed for the formulary from the company.

I acknowledge receipt of the policy and agree to exercise my voting privileges with the committee giving due consideration to the criteria.

Signature: _____ Date: _____/_____/_____

PLEASE SIGN THE FORM, COMPLETE THE INFORMATION ON THE BACK AND RETURN THIS TO:
Administrative office (Zip 8138)- Department of Pharmaceutical & Nutrition Care

Department Approval		Administrative Approval	
Signed | s |:	Matthew Egbert, MD	Signed | s |:	Austin Thompson, MD
Title:	Chairman	Title:	Chief of Staff
Department:	Pharmacy & Therapeutics Committee		

Pharmaceutical and Nutrition Company Disclosure

Company[A]	***Type of Relationship***[B]

A. List companies with which you have had any relationship in the last three years.
B. Type of relationship: Investor; Research Grantor; Consultant; Sponsored Speaker; Sponsored publications; Product endorsement; Preceptor- Company Sponsored training

THE NEBRASKA MEDICAL CENTER
MEDICAL STAFF GOVERNANCE POLICY

March 19, 2008
Updated November 2008
Updated October 2009
Updated November 2010
Updated March 2012
Updated October 2013

ARTICLE 10

CONFLICTS OF INTEREST

(1) When performing a function outlined in this Governance Policy, the Credentials Policy or Organization and Functions Manual, if any Medical Staff Appointee has or reasonably could be perceived as having a conflict of interest in any matter involving another individual, the individual with a conflict shall not participate in the discussion or voting on the matter, and shall be excused from any meeting during that time. However, the individual may be asked, and may answer, any questions concerning the matter before leaving.

(2) The existence of a potential conflict of interest or bias on the part of any Appointee may be called to the attention of the Chief of Staff or applicable committee chair or Service chief by any other Appointee with knowledge of it.

(3) The fact that a Service chief or Appointee is in the same specialty as an Appointee whose performance is being reviewed does not automatically create a conflict. The evaluation of whether a conflict of interest exists shall be interpreted reasonably by the persons involved, taking into consideration common sense and objective principles of fairness. No Appointee has a right to compel a determination that a conflict exists.

(4) The fact that a committee member or Medical Staff leader chooses to refrain from participation, or is excused from participation, shall not be interpreted as a finding of actual conflict.

THE NEBRASKA MEDICAL CENTER™ CLARKSON & UNIVERSITY HOSPITAL POLICIES AND PROCEDURES MANUAL ☒ System ☐ Department	Section: Medical Staff (MS) Subject: Drug and Nutritional Samples Number: MS02 Attachments: Date Effective: 5/5/98 Date Reviewed: 10/00, 01/02, 07/04, 09/06, 12/08, 2/11, 06/13/13, 7/15

DRUG AND NUTRITIONAL SAMPLES

POLICY: To comply with medical staff policy and with State and Federal Laws of procurement, storage and distribution of prescription drugs and nutritionals.

I. Inpatient Care Areas

All pharmaceutical and nutritional samples are prohibited from use, storage, or distribution in any inpatient area (including the inpatient and outpatient operating rooms and PACU).

II. Outpatient Care Areas

A. **Pharmaceutical Samples: All pharmaceutical samples are prohibited from use, storage, or distribution in any outpatient area. This includes all hospital-based clinics, infusion centers, UNMCP clinics and offices.**

B. **Nutritional Samples:**

a. The Physician Manager/Medical Director or designee (mid-level/licensed medical nutrition therapist/registered nurse) determines which nutritional samples are acceptable for their patient population.
   i. The choice of nutritional samples in the clinics is independent of nutritionals listed on the inpatient formulary.
   ii. Nutritional samples may be distributed by a manufacturer representative upon request.

b. The Physician Manager/Medical Director or designee shall be responsible for the maintenance and control of nutritional samples in the clinics.
   i. Nutritional samples may be given to patients by a prescribing licensed practitioner, licensed medical nutrition therapist, or registered nurses in support of the overall plan of care.
   ii. Nutritional samples must be given to patients in their original manufacturer's packaging and labeling along with the patient package insert. Each individual sample must be labeled with full labeling content for individual sampling.
   iii. Immediately prior to the patient obtaining a nutritional sample, it must be inspected to assure that it has not expired.
   iv. All nutrition samples given to the patient in the clinic must be documented by a mechanism that can easily identify the patient registration number, product lot number, expiration date, product name, quantity and date (refer to attached example).

c. The Physician Manager/Medical Director or designee shall be responsible for receiving product recall notifications and for patient notification
   i. Recall notifications to be received from the vendor, FDA or other reliable source
   ii. In the event of a recall of a nutritional sample, patients who received the sample will be identified and contacted by the Clinic Physician Manager/Medical Director or designee.

Reviewed by: Pharmacy & Therapeutics Committee (7/7/15)
Bylaws Committee (7/2015)
Medical Staff Executive Committee (7/2015)
Board of Directors (7/2015)

(EXAMPLE ONLY)

NUTRITIONAL SAMPLE DISTRIBUTION LOG

Patient Reg. #	Lot Number Exp. Date	Nutrition Product Name	Quantity	Date

Department Approval

Signed | s |: Matthew Egbert, MD
Title: Chairman
Department: Pharmacy & Therapeutics Committee

Administrative Approval

Signed | s |: Austin Thompson, MD
Title: Chief of Staff

POLICIES AND PROCEDURES MANUAL	Section: Medical Staff (MS) Subject: Medical Staff Pharmacy and Therapeutics Committee
☒ System ☐ Department	Number: MS07
Supersedes MS 31	Attachments:
	Date Effective: 05/98
	Date Reviewed: 04/08, 01/10, 5/11, 09/12, 2/17/14

Policy:

The membership of the Pharmacy and Therapeutics Committee will consist of at least six (6) medical staff appointees, one of whom shall be concurrently a member of the medical staff of the Bellevue Medical Center, and representatives from Pharmaceutical & Nutrition Care, Nursing Services, and The Nebraska Medical Center management. The Committee will incorporate expert panels and a formal subcommittee structure including Formulary Committee and Medication Management Committee, and/or appropriate designee(s), to accomplish the required activities where applicable. The P & T Committee will report on a regular basis to the Medical Executive Committee and the Hospital Quality Committee. Before any actions are taken, the P&T Committee will need to obtain the approval of the Medical Executive Committee.

The Committee is accountable for ensuring safe and effective use of medications/nutrition for patients.

Note: The Medical Staff P&T Committee recognizes that some of the documents approved by the Committee include the use of a medical therapy that is not approved by the FDA in its dose, route of administration, frequency of administration, or medical condition for which it is intended to treat. As such, the individual licensed practitioner using this medical therapy in this manner assumes responsibility for its administration and has determined in his/her clinical judgment that the off label use of this medical therapy is appropriate for the patient's clinical condition."

Activities of the Committee will include:

1. Creation and oversight of the organizational Medication Safety Plan.
2. Develop and maintain policies and guidelines regarding drug and nutrition administration and use.
3. Review all research proposals involving investigational drugs or studying the effects of marketed drugs conducted at The Nebraska Medical Center sites.
4. Maintain a system for physician review of all adverse drug reactions and medication errors reported.
5. Develop and maintain Inpatient and Outpatient medication & clinical nutrition formularies. (Refer to Additions and Deletions to Formulary Policy MS 46)
6. Maintain a system for ensuring identification, review, analysis, and interpretation of drug use trends.
7. Maintain oversight of non-formulary medication use and provision of an evaluation and approval process for non-formulary medication requests for acute care areas (inpatients, infusion centers, outpatient procedure areas including the OR).
8. Review and act upon pertinent economic issues regarding drugs and drug therapy.
9. Provide oversight for review and approval of medication-containing order sets, order panels, ambulatory smart sets, therapy plans, and treatment plans for compliance with established drug policies and for safe and appropriate use and administration of medications. The Secretary of the Medical Staff P&T Committee or appropriate designee will maintain active membership on the organization's Multidisciplinary Order Set Team. This individual will facilitate appropriate review of order sets prior to implementation into the electronic health record. A monthly report of approved order sets, therapy plans, and/or protocols will be submitted to the Medical Staff P&T Committee by the Secretary or designee.
10. Review The Nebraska Medical Center Performance Improvement activities related to the activity of the P & T Committee.

Reviewed By:
P&T Formulary Committee (12/17/13)
Bylaws Committee (2/6/14)
Medical Executive Committee (2/11/14)
Board of Directors (2/17/14)

Department Approval		Administrative Approval	
Signed | s |:	Matthew Egbert, MD	Signed | s |:	Austin Thompson, MD
Title:	Chairman	Title:	Chief of Staff
Department:	Pharmacy & Therapeutics Committee		

Nebraska Medicine POLICIES AND PROCEDURES MANUAL ☒ System ☐ Department **Supersedes:**	Section: MEDICAL STAFF (MS) Subject: Vendor Policy Number: MS40 Attachments: Vendor Policy Attachment Date Effective: 1/14/03 Date Reviewed: 1/30/04, 6/19/06, 07/09, 02/10, 03/15

Pharmaceutical, Biotechnology, Nutritional Company, Pharmacy, and Healthcare Service Vendors – MS40

POLICY:
It is the policy of Nebraska Medicine (NM, as defined below) to create rules of conduct and guidelines for the interactions of NM staff and facilities with healthcare vendor representatives (HCVRs). While these interactions may be beneficial to NM and to its patients, they must directly support the clinical, research, and educational missions of the enterprise and be ethical, appropriate, and without actual or perceived conflicts of interest. HCVRs are guests of NM and shall provide their services in accordance with this policy, those of their employer, and all applicable and relevant professional guidelines, policy or code statements [e.g. Pharmaceutical Research and Manufacturers of America (PhRMA), American Medical Association], laws [Health Insurance Portability and Accountability Act (HIPAA)], rules, and regulations. Failure of HCVRs to adhere to this policy may result in termination of privileges of the individual and/or company or companies involved.

PURPOSE:
The purpose of this policy is to protect physician and NM staff efficiency and integrity, patient safety and confidentiality, NM proprietary information, and to support a culture of objective, evidence-based, cost-effective medical care. Furthermore, this policy seeks to identify HCVRs as visitors who are present in NM facilities for a legitimate business purpose and to assure their presence does not interfere with or unduly influence patient care and NM business practices.

SCOPE:
This policy applies to all NM facilities and entities, all NM staff (as defined below), and all HCVRs who provide services or products to or interact with NM or NM staff for business purposes. This policy does not limit nor is it a substitute for other related policies regarding conflict of interest, purchasing, etc. However, to the extent this policy is more stringent than other policies (including those of UNMC), this policy shall govern.

IMPLEMENTATION/RESPONSIBILITY:
Each NM staff member (see definition below) is responsible for adherence to and compliance with this policy as it applies to their respective areas and roles. Staff members should ensure that all HCVs meet NM requirements and follow all NM policies, procedures, and rules while on NM premises. Consistent policy compliance is vital to the integrity of this policy and NM entities and to patient safety and confidentiality. HCV compliance with this policy is a requirement for maintenance of vendor privileges at NM entities and facilities.

DEFINITIONS:
NM - For the purposes of this policy, NM shall mean all Nebraska Medicine organizations and sites, including but not limited to The Nebraska Medical Center, Bellevue Medical Center, UNMCP, and all affiliated NM clinics/sites
NM staff – All employees, professional healthcare staff (medical, nursing, pharmacy, laboratory, surgery, purchasing, etc.), contractors, students, trainees or volunteers acting on behalf NM or on NM premises
Healthcare Vendor Representative (HCVR) – Any representative of a pharmaceutical, nutritional, biotechnology, or pharmacy or other healthcare services provider, manufacturer, or company who visits NM for the purpose of soliciting, marketing, maintaining (including providing technical assistance), delivering or distributing products or information regarding the use of its products, equipment, services, and supplies to NM, its patients and physicians practicing at NM. This includes, but is not limited to, persons in sales, marketing, education, research, management, and scientific liaison professionals.
Protected Health Information (PHI) - Individually identifiable health information relating to the past, present, or future physical or mental condition of an individual; or payment for the provision of health care whether oral or reduced in any form or medium, created or received by NM
NM educational activities (EAs) – includes all educational programs and presentations, inservices, grand rounds, lectures, etc. regardless of whether educational credit is offered that take place on NM premises for the benefit of NM staff (excepting, consortia or symposia organized by NM or UNM entities that offer continuing education credits to registrants)
Gift – For the purposes of this policy, gift includes compensation, payment, or other things of value received by NM individuals and/or staff when performing NM functions, roles, and responsibilities (examples include, but are not limited to,

money, gift cards, samples for personal use, food, travel, tickets, free or discounted items [unless as part of an enterprise contract for products, services, or research], professional items [e.g., calipers, penlights], books, trinkets, or services). Vendor 'gifts' may be provided directly to an NM entity generally, but not to a specific individual.
REPtrax – the vendor credentialing system contracted by NM to capture, credential, and monitor vendors and individual vendor representatives
Samples – For the purposes of this policy, a 'sample' is a product unit not intended for sale and intended to promote the sale of the product.

PROCEDURE:

I. HCVR Visitation

A. Required Authorization/Appointments
1. An HCVR may visit NM staff members only as follows:
   a. At the request of the staff member and by appointment with written confirmation of appointment date, time, purpose, and location, or
   b. During an authorized NM educational program or
   c. At the request of the vendor and by appointment with written confirmation of appointment date, time, and location.
2. HCVRs should schedule appointments between the business hours of 8AM and 5PM, Monday through Friday, unless a specific exception is necessary for the convenience of the NM staff member with whom the visit will take place. All HCVR registration requirements in Section 2 must still be met.
3. While visiting NM, HCVRs shall not initiate contact with NM staff by telephone or pagers.
4. HCVRs shall schedule all appointments in advance and receive written confirmation with date, time, purpose, and location of the appointment. This written confirmation shall be required upon visit arrival. No HCVR shall request or receive confirmation of appointment with NM staff who has not been properly registered and credentialed in the REPtrax system.
5. Drop in visits are not permitted.
6. Generally, HCVRs should limit their appointments to no more than 20 minutes to be respectful of NM staff time and enterprise productivity. Should the HCVR require more than 20 minutes for their appointment this should be clearly noted and approved by the NM staff member in the written appointment confirmation.
7. Each visit is limited to contact with the NM staff member with whom the HCVR has a confirmed appointment only.
8. No open or standing invitations or appointments may be granted by NM staff to any HCVR.
9. No unregistered or uncredentialed individuals may accompany a registered HCVR on any visit.
10. Resource Control shall maintain a list of NM individuals or departments that do not want to be visited by vendors. NM staff wishing to be included on this 'no call' list shall contact Resource Control. Resource Control shall post an updated 'no call' list on REPtrax at least every 6 months, which all HCVRs will be required to review. HCVRs should not attempt to make appointments or to visit NM individuals or departments on the list.
11. HCVRs may not schedule individual appointments with medical housestaff (interns, residents, or fellows) or any healthcare professional trainee. HCVR interaction with housestaff or trainees may only occur incidental to approved and accredited institutional EAs or in the presence of an attending level and/or faculty staff member.
12. HCVRs should wear business attire and must park their vehicles in appropriate designated parking areas.

B. Registration and Checkout Procedures
1. Upon arrival to NM for a visit appointment with an NM staff member, all HCVRs must register in/at one of the following designated locations:
   a. Information/Access Services Clarkson Tower REPtrax kiosk (24/7)
   b. Information/Access Services Durham Outpatient Center (DOC) REPtrax kiosk (24/7)
   c. Purchasing Department (North Doctors Bldg, room 59) REPtrax kiosk (8am-3:30pm, Monday-Friday)
   d. Facilities Management and Planning (Clarkson Tower basement, room B8111) REPtrax kiosk (7am-5pm, Monday-Friday)
   e. OR Front Desk University Tower REPtrax kiosk "surgery representatives ONLY" (during normal hours of operation)
   f. OR Front Desk Hixson-Lied REPtrax kiosk "surgery representatives ONLY" (during normal hours of operation)
   g. Computing Center or Workstation Support Department (NM 4230 Bldg – Leavenworth St) for information-technology related business
   h. Biologics Production Facility (inside of south entrance) REPtrax kiosk (8am-5pm, Monday-Friday)
   i. Village Pointe Cancer Center (Radiation Oncology front desk) REPtrax kiosk (8am-4:30pm, Monday-Friday)
   j. All Off-site clinics : register with off-site clinic manager
2. An HCVR must complete the registration process for each individual visit appointment. Registration for an HCVR does **not** cover: 1) multiple appointments, 2) multiple visits on different days to the same NM staff member or location, or 3) multiple HCVRs from the same company.

3. During each visit, the HCVR will sign-in at the registration kiosk and be issued an orange badge. For The orange badge must be prominently displayed above the waist at all times during the visit. For off-site clinics, HCVRs shall show proof of their online RepTrax log-in when registering with the clinic manager for their visit. In addition, the HCVR must wear a name badge bearing his/her name and the name of the company he/she represents. These must be worn at all times while on NM premises.
4. Following HCVR registration/check-in, the HCVR will **promptly** notify the administrative staff at the appointment location of his/her arrival. Registered HCVRs are **not** permitted to loiter in clinic or patient waiting areas, halls or lobbies, cafeterias or restaurants, or the medical library either before or after scheduled appointments, for the purposes of informally or incidentally engaging NM staff. Administrative staff shall inquire with any HCVRs who are inappropriately loitering in such areas and politely redirect them to appropriate common areas or to leave the premises if they do not have an appointment or one is completed.
5. It is the responsibility of the NM staff member or area/location manager or administrator, upon the HCVR's arrival, to:
   a. Ensure HCVR is properly identified with NM and company badges, and
   b. Ensure HCVR provides appropriate written appointment confirmation (date, time, and location) from NM staff with whom appointment was made, and
   c. Ensure HCVR visit is conducted in a non-patient care location.

   Access to NM premises by an HCVR who is not appropriately registered and/or credentialed and who has not confirmed a previously scheduled appointment is prohibited.
6. Visits between HCVRs and NM staff shall **not** take place in patient care areas. Clinic or department managers will be responsible for designating appropriate non-patient care locations for HCVR visits. HCVRs are not permitted in the following areas: inpatient nursing units; clinics and other outpatient care areas; Emergency Department; procedure and/or operating rooms; pharmacy inpatient and outpatient waiting areas and dispensing and storage areas.
   a. If an HCVR needs to travel through or access patient care areas in order to reach the designated non-patient care location for the authorized visit, an NM staff member must meet and escort the HCVR to the visit location.
7. Upon completion of the visit, the HCVR shall checkout in REPtrax or at the location where the HCVR registered for the visit (per Section 2A), remove their visit badge, and leave the NM premises. Loitering on NM premises for the purposes of informally or incidentally engaging NM staff is prohibited.

C. Vendor Orientation and Certifications
1. New Vendors
   a. Before conducting any visit with an NM staff member, a new HCVR is required to:
      a. Register with REPtrax and complete all administrative requirements and training within REPtrax relevant to his/her vendor category(ies) at NM. This vendor credentialing process **must** be completed prior to any visit with an NM staff member.
      b. Complete a formal online orientation session in REPtrax that includes a review of NM policies and a **mandatory** slide show presentation. Elements include, but may not be limited to PHI and confidentiality, elements of the formulary selection process, and facility security/restricted areas.
      c. Sign a document pledging adherence to confidentiality and to abide by the terms of this vendor policy and others of NM that may be relevant. HCVRs may also be required to provide additional documentation (e.g. employer liability coverage, vaccination status, drug screening, etc.) applicable to his/her vendor category(ies).
2. Annual Certifications
   a. HCVRs will be required to review the online REPtrax orientation session and make appropriate certifications **annually** in order to maintain access to NM.
   b. Each HCVR individual or company is responsible for **timely** (within 30 days) notification to REPtrax of updated HCVR contact information/profile, any change in vendor category/requested access privilege, any termination or voluntary discharge from the company, or any change in competency or certification status for any reason.
3. Credentialing Compliance
   a. Failure of any HCVR to meet initial or annual credentialing requirements will result in suspension of privileges of the HCVR from REPtrax until required orientation and certifications are completed.
   b. Misclassification by an HCVR of his/her appropriate vendor category in REPtrax (e.g. selecting a vendor category that grants access to areas, such as the OR, that are not appropriate to the HCVR's role) will be considered a policy violation.

II. HCVR Activities

A. Educational activities (EA)
1. Whenever possible, the educational needs of NM or its staff should be met by appropriate NM resources and should not be requested to be met by HCVRs. This includes educational activities (EAs, includes inservices)

related to drugs, diseases, policy, or other products and services of interest or utilized at or by NM.
2. If educational needs are unable to be met by NM resources (e.g. unique and specialized education/training) then consideration shall be given to allowing an appropriate HCVR-supported/conducted EA.
3. HCVRs shall not solicit opportunities to conduct EAs. All requests for EAs shall be initiated by NM staff only.
4. All EAs, whether vendor-supported/conducted or not, for NM staff and on NM premises should be objective, unbiased, non-promotional, and aligned with NM practices, policies, and objectives. EAs regarding non-formulary drugs or products not formally approved or currently in use/purchased by NM are prohibited.
5. All vendor-supported/conducted EAs for NM staff on NM premises shall comply with ACCME standards for commercial support and shall be certified for continuing education (CE) credits appropriate for all expected/invited attendees. Exceptions to this provision may be made by department or area manager/director and should only occur when ACCME standards or certification for CE credits cannot be obtained or are not applicable.
6. HCVRs may **not** be present at or conduct the EA, unless a unique and specialized need/purpose has been identified in accordance with 1.B. above. Presence of the HCVR for the purposes of engaging NM staff or promoting a product or service is prohibited. Vendor promotional items or materials are not permitted at any EA. Non-branded training or instructional materials are permitted.

B. Food and drinks supplied by a vendor are considered to be 'gifts' and inducements for services and thus are prohibited. HCVRs may not distribute or deliver any 'gift' to any area, unit, or person on NM premises. Any refreshments for an EA must be paid for and provided by NM or by individual NM attendees. An exception to this provision would be refreshments provided as part of an NM or UNMC organized consortia or symposia taking place on NM premises at which food is to be provided for all registered attendees.

C. Sales/promotional activities
   1. Disbursement of information
      a. HCVRs shall not be permitted to post or ask NM staff to distribute any advertisements, promotional items, announcements of vendor-sponsored events, etc. on walls, doors, windows, bulletin boards, or for placement in reception areas or in NM staff offices or via email. No NM staff member shall provide names, email or address lists of NM providers or staff to any HCVR. Any notices of approved educational programs may be provided to an area administrator or supervisor for display in employee-only areas (i.e. break room).
      b. HCVRs may <u>not</u> leave marketing or promotional material of any kind in patient care or waiting areas.
   2. Promotional information/material
      a. Information or materials provided by HCVRs to NM staff regarding HCVR products or services shall:
         i. Be accurate and supported by balanced scientific literature
         ii. Include equal representation of the product or services advantages and disadvantages (e.g. safety concerns and efficacy benefits)
         iii. First be provided to appropriate representatives of the relevant department (i.e. Department of Pharmaceutical and Nutrition Care Services for pharmaceutical, nutritional, biotechnology or pharmacy services) **prior to** dissemination within NM
      b. Examples of acceptable and approved information for dissemination would include reprints from primary, peer-reviewed literature and unbiased promotional material. Examples of unacceptable information for dissemination would include abstracts, information regarding unapproved use of a drug or product, comparative cost analyses, and any information related to a non-formulary or non-NM approved product.
      c. HCVRs are responsible for communicating any and all changes in the legal or therapeutic status, labeling, safety, or product/service access (e.g. recall, withdrawal, shortage) of drugs, materials, products, or services in use within NM.
   3. Prohibited activities
      a. HCVRs related to any NM employee or staff member shall not call on that person in the course of their business. The vendor company must provide another HCVR to call on that NM employee or staff member.
      b. HCVRs are prohibited from providing cost information related to their product or service to any NM staff member, except to the directors and/or business administrators for the relevant department (i.e. drug pricing for Department of Pharmaceutical and Nutrition Care Services). HCVRs do not have access to actual acquisition prices of NM and therefore cannot provide accurate price comparisons or cost information about products or services.
      c. HCVRs shall not attempt to interpret or communicate policies of NM to any NM staff member. Any questions regarding NM policy(ies) should be directed to the appropriate area/department director.
   4. Unapproved products or non-formulary medications
      a. Promotion of the use of the items noted below is <u>not</u> permitted and shall be considered a violation of this policy:
         i. Unapproved products (e.g. services, products not purchased or approved by NM), or
         ii. Non-formulary medications (e.g. medications not yet reviewed by NM, medications which have been reviewed and denied addition, and off-criteria indications of restricted formulary medications), or
         iii. Products or medications restricted by NM outside of the scope and/or location of their approved

restrictions

b. If a physician provider needs medical literature or information (not promotional materials) regarding a non-formulary medication or use of a medication outside of the scope of its NM restriction, the physician should make such request to the Drug Information Center of NM. Such information should not be provided by an HCVR.

c. NM committees/subcommittees

i. HCVRs are not permitted to meet with voting members of applicable committees or subcommittees regarding products under consideration for addition/deletion for use at NM or during contract negotiations. Literature pertaining to such products may be provided, by request, to the voting member via mail or email. Exceptions to this provision may be made during product demonstrations or evaluations approved by the directors and/or business administrators for the relevant department.

ii. Information regarding applicable committees or subcommittees (including membership, meeting dates, agendas, meeting discussions) is strictly confidential and will not be shared with any HCVR. Actions taken regarding an HCVR's products will be communicated to such vendor by designated individuals **only** from the relevant department (i.e. formulary decisions by designated individuals from Department of Pharmaceutical and Nutrition Care Services).

III. Other HCVR activities and interactions with NM entities and staff

A. Other HCVR interactions with UNMC faculty , staff, students and other trainees, including but not limited to consulting, research, advisory boards, ghostwriting, shall be governed by applicable UNMC policies.

B. HCVR visits to NM administrators or NM staff for administrative purposes

1. HCVRs visiting NM administrators or staff to discuss business, research, or contracting opportunities related to pharmaceutical, biotechnology, or nutritional products or pharmacy or healthcare services shall comply with all requirements of this policy, MS40.

C. HCVR visits related to clinical trials

1. Pre-arranged and scheduled visits to NM facilities by an HCVR whose sole purpose is to discuss, evaluate, train, or conduct monitor visits for clinical trials approved by the NM Institutional Review Board and all applicable committees shall be permitted.
2. Such clinical trial-related visits shall occur with NM staff associated with the specific clinical trial only.
3. HCVRs conducting a clinical trial-related visit shall be required to obtain a free basic RepTrax membership and to sign-in in REPtrax for each visit. He/she should also wear a name badge bearing his/her name and the name of the company he/she represents.
4. HCVRs conducting a clinical trial-related visit shall be escorted by a NM staff member during the course of the visit and shall not be permitted in any patient care areas unless specifically required to conduct the work associated with their visit.

D. HCVR visits and activities related to medical equipment, supplies, and devices shall be conducted in accordance with the NM Vendor Policy (MI.06).

E. Samples

1. The use of pharmaceutical products and samples shall be governed the NM policy on Drug and Nutritional Samples (MS2).

F. Confidentiality

1. In general, HCVRs are prohibited from accessing or requesting any confidential PHI or NM proprietary information. As part of the initial and annual credentialing processes, HCVRs will be required to agree to and sign a confidentiality document.
2. HCVRs may not contact nor hold discussions with any NM patient, family member, or visitor while on NM premises.
3. Patient care rounding with providers and/or attendance at any conference at which patient information will be discussed/presented (e.g. tumor board, patient case conferences, etc.) by HCVRs is strictly prohibited.

G. Gifts/Money/Entertainment/Favors

1. HCVRs may not offer, and NM staff shall not accept from an HCVR, gifts or other things of value as defined above. Exclusions would include items provided as part of a NM contract, research project, unrestricted gifts, grants, or donations made to an NM entity (not to an individual), or reasonable honoraria for speakers participating in an accredited educational meeting or compensation for specific services as allowed by NM policies. Training or teaching materials may be accepted and should be unbranded (i.e. without corporate markings) when possible and compliant with Codes of Conduct authored by PhRMA.

H. Purchasing Authorization

1. Only purchases by personnel authorized by NM to issue and or approve purchase requisitions will be paid. Authorized personnel include designated purchasing staff and managers or above of their respective service lines. Physicians are not authorized to approve purchases or payment. NM will not assume responsibility for any loss or payment for products and services that were provided without adherence to the above requirements. Product that is provided without prior approval will be considered as a sample.

IV. Enforcement/Policy Compliance

A. HCVRs
   1. It is the responsibility of vendor companies to ensure that their HCVRs meet and adhere to all requirements of this policy and other applicable rules or regulations (e.g. FDA, PhRMA, Anti-kickback statute). HCVRS or their companies who violate any rules, policies, procedures and regulations, whether of NM or other applicable bodies (e.g. FDA), will be subject to removal, suspension, and/or refusal of entry by NM. Visitation or business privileges of any HCVR or vendor company may also be revoked or suspended by NM if such HCVR or vendor company practices conflict with or negatively impact NM business objectives or mission.

B. Compliance actions
   1. Assessment of and action regarding complaints about and/or policy violations by HCVRs shall be taken by the Executive Director of Pharmaceutical and Nutrition Care Services and will include:
      a. Verbal and/or written notification to the HCVR and the HCVR's manager (first infraction)
      b. Suspension of HCVR's privileges at all NM entities for up to 3 months (second infraction); ongoing business may be conducted by an alternative representative of the vendor company
      c. Suspension of HCVR's privileges at all NM entities for a minimum of 1 year (third infraction); reevaluation of the ongoing vendor company relationship with NM may occur
   2. Notwithstanding any other provision in this policy, NM will immediately terminate an HCVR's access and privileges at NM for any violation relating to the use, access, or disclosure of PHI.

C. NM staff
   1. It is the responsibility of NM staff and particularly directors, administrators, and supervisors to ensure that HCVRs meet all NM requirements and follow all NM policies, procedures, rules and regulations while on NM premises.
   2. NM staff must be vigilant regarding the presence of unauthorized personnel on NM premises, in order to protect the safety, health, privacy, and integrity of NM patients and entities as well as to assure NM regulatory compliance.
   3. Policy violations by NM staff shall be investigated and any disciplinary action taken shall follow established procedures of all applicable NM entities.

Reviewed by:
Pharmacy and Therapeutics Committee Pharmacy and Therapeutics Ad Hoc Committee -- 3/3/15
Nebraska Medicine Bylaws Committee
Nebraska Medicine Medical Executive Committee
Nebraska Medicine Board of Directors

Department Approval		**Administrative Approval**	
Signed | s |:	Matthew Egbert, MD	Signed | s |:	Austin Thompson, MD
Title:	Chairman	Title:	Chief of Staff
Department:	Pharmacy & Therapeutics Committee		

MS40Att.0412.doc

Return to Policy

Pharmaceutical Representative Policy Acceptance

Please cut and paste the following link into your browser and complete all of the training initiatives. Please return to this page upon completion and document completion of training and acceptance of our policies.

http://www.nebraskamed.com/Reptrax/PNCRslides/

The Nebraska Medical Center and UNMC Policy requires that you follow all policies and procedures while conducting business at any of our locations. Please read and accept the terms below when exiting this document. All Pharmaceutical Representatives must agree to the following:

1. I agree to comply with all Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals while conducting all business with this organization.

2. I have reviewed The Nebraska Medical Center/ University of Nebraska Medical Center policy MS 40 entitled Vendor Policy in its entirety and agree to abide by all content as it relates to pharmaceutical representatives.

3. I have reviewed the material contained in the Policy Training Slide show in its entirety and agree to abide by all rules as it relates to pharmaceutical representatives.

4. I understand that I may not reveal any Protected Health Information (including patient names, medical record number, medical condition or patient personal data) which I may become aware of during the course of my interactions with The Nebraska Medical Center/ UNMC staff. I further understand that I may not access any patient information available via information technology or medical records maintained by The Nebraska Medical Center/ UNMC.

5. I agree to abide by all policies and procedures and to protect the confidentiality and security of TNMC patients while visiting any The Nebraska Medical Center/ UNMC facilities.

THE NEBRASKA MEDICAL CENTER POLICIES AND PROCEDURES MANUAL ☒ System ☐ Department	Section: Medical Staff (MS) Subject: Additions/Deletions to Formulary Number: MS46 Attachments: Attachments A-B-C Date Effective: 1/30/04 Date Reviewed: 5/17/04, 10/16/06, 4/21/08, 7/19/10, 5/11, 09/12, 02/14

Additions / Deletions to Formulary

Background/Rationale:

The Medical Staff Pharmacy & Therapeutics (P&T) Committee, with Pharmaceutical and Nutrition Care is responsible for establishing and managing a formulary for The Nebraska Medical Center (MS-7; Bylaws article V. Section M. Part 2(a)). The Committee believes that the formulary represents a well-considered selection of evidence-based therapeutic options that above all ensures medication safety. Medication safety, broadly considered, should include not only avoiding medication errors, but also the selection of medications in the form that permits attainment of desired therapeutic outcomes in the least amount of time with the fewest adverse events. The Committee acknowledges that medicine is a dynamic field, which will require continuous review and thoughtful change to the formulary. However, the Committee also recognizes that change(s) to and management of the formulary represent considerable cost to the organization.

Policy:

This policy defines the standards and procedures for inclusion of pharmaceutical and nutritional products on The Nebraska Medical Center Formulary. Medications/nutrition products may be considered for addition to the medication/nutrition formulary at the request of an active or consulting staff physician or pharmacist/clinical nutrition therapist (for appropriate formularies) for The Nebraska Medical Center. The Nebraska Medical Center maintains two medication formularies to address the needs of patients: the Inpatient Formulary and the Outpatient Formulary (for the infusion centers and the clinics). The retail pharmacies associated with the organization have an open (yet conservative) formulary based on patient needs.

Definition:

A formulary is a collaborative, interdisciplinary effort to evaluate, appraise, and select the most clinically and economically effective and safe pharmacologic and therapeutic nutritional products for use in the care of patients.

Procedure:

I. Requesting an addition to the formulary

A. The requesting physician/pharmacist/nutrition therapist completes a "Formulary addition application" (Attachment A). The form is available by accessing the Pharmaceutical and Nutrition Care website via The Nebraska Medical Center Intranet at the following link: http://www.preceptor.com/other/pharmadm/rxhome/index.html. It is recommended that requestors cite primary literature or include FDA reviews (http://www.FDA.gov/cder) as part of the completed form. (see Attachment B for 'appropriate evidence') Full disclosure with regard to conflicts of interest on the part of the requestor is required. Incomplete forms will not be considered.

B. The requestor forwards the completed, signed form to the Pharmacist Co-Chair of the P&T Formulary Subcommittee via The Nebraska Medical Center Drug Information Services at Zip 8138 or via e-mail at TNMCDrugInfoSvc@spmail.nebraskamed.com, along with a supporting bibliography and/or references.

II. Formulary request review process

A. Upon receipt of the written request, personnel within Pharmacy Clinical Decision Support generate a preliminary review of the request against the criteria for adding a drug (Attachment B) to formulary. The preliminary review will be shared with The Nebraska Medical Center Formulary Subcommittee leadership and ACA P&T Committee chairs. Requests for addition to the formulary will all be reviewed via the review process described herein unless an

emergency review is required. In the case of emergency review (eg, emergent need for alternative addition(s) to formulary due to drug shortage), P&T leadership will be called upon to provide immediate review of the formulary request.

1. For requests not meeting criteria, the requestor will be notified as soon as possible by The Nebraska Medical Center P&T Secretary or designee to determine if there is additional information to be considered. If the request still does not meet criteria, the Clinical Decision Support pharmacist, or designee, will prepare the criteria review evaluation and present it to the Formulary Subcommittee Leadership for consideration. The Formulary Subcommittee Leadership will then provide a recommendation regarding the request. This recommendation will be presented to The Nebraska Medical Staff P &T Committees and the respective chairs of the ACA. If the drug is determined to not meet criteria for full committee review, the requestor will be notified by the Formulary Subcommittee Leadership or designee.

2. For requests that meet criteria, a monograph or other review document will be prepared by Clinical Decision Support personnel and pharmacists evaluating the request based upon published literature. (see Attachment B for 'appropriate evidence').
    a. When a request has met criteria, the requesting physician will be notified of the receipt of the request and the dates of the expected ACA P&T and Formulary Subcommittee reviews.
    b. Following the review of the request by the ACA P&T Committee, the requestor will be notified of the date, time, and location of the Formulary Subcommittee meeting at which the request is to be presented, and will be provided a copy of the prepared monograph for the requestor to review.
    c. The requesting physician may opt to be present for the presentation of the request to The Nebraska Medical Center Formulary Subcommittee. Votes by The Nebraska Medical Center Formulary Subcommittee on the request will be taken only after the requestor has been excused from the meeting.

3. The action request (addition or deletion) will be presented to and reviewed by the appropriate committees (see Section II, A, 4.). These committees will determine if their recommendation is to:
    a. Deny addition to the inpatient and/or outpatient formulary, or
    b. Approve addition to the inpatient and/or outpatient formulary, or
    c. Approve addition to the inpatient and/or outpatient formulary for restricted or conditional use as follows:
        i. Restricted use approval

        Agents may be added to the formulary with restrictions for their use <u>at the sole discretion of the approving committees</u>. Restricted agents should meet one or more of the following criteria:
        1) Has a limited therapeutic use and/or requires specific clinical or other expertise/knowledge to utilize the agent safely and appropriately
        2) Has the potential for significant inappropriate use that would lead to unnecessary medication exposure and/or excessive costs
        3) Is a high risk agent with the potential for serious adverse events or toxicities

        Agents may be restricted to a specific use/indication, by medical service or provider type, clinical/prescribing criteria, or location (specific area or unit within an institution, specific clinic, outpatient or inpatient, etc.). Alternatives for noncompliant requests may include obtaining a consult from an authorized prescribing service, transfer of patient to authorized area for use of the agent, or appeal to the P&T chair for special authorization of the restricted agent. Restricted drugs may not be obtained through the non-formulary drug process.

4. The reviewing committees and their respective review processes regarding formulary addition/deletion requests or drug class reviews are as follows:

    a. Action request will be reviewed initially by the ACA P&T Committee. The recommendation of the ACA P&T Committee will then be forwarded to The Nebraska Medical Center Formulary Subcommittee for consideration.
    b. Action request will be reviewed by The Nebraska Medical Center Formulary Subcommittee. The Formulary Subcommittee will vote to determine the disposition of the action request per the options defined in Section II, A, 3.
    c. The Nebraska Medical Center P&T (Steering) Committee will be informed of all Formulary Subcommittee actions on a regular basis.
    d. The P&T (Steering) Committee actions will be forwarded to The Nebraska Medical Center Medical Staff Executive Committee.

5. The requestor will be notified, in writing, of the P&T (Steering) Committee's action.

6. If a drug is on the formulary, it is approved for all FDA-approved indications and for all uses listed in CMS-approved compendia (AHFS-DI, Clinical Pharmacology, Lexicomp,, NCCN) unless otherwise specified in policy or unless otherwise restricted by the Formulary Subcommittee or P&T (Steering) Committee.

7. The P&T (Steering) Committee recognizes that some of the documents approved in the formulary review process include the use of a medical therapy that is not approved by the FDA in its dose, route of administration, frequency of administration, or medical condition for which it is intended to treat. As such, the individual licensed practitioner using this medical therapy in this manner assumes responsibility for its administration and has determined in his/her clinical judgment that the off label use of this medical therapy is appropriate for the patient's clinical condition.

III. Requesting a deletion from the formulary

A. The requesting physician/pharmacist/nutrition therapist completes a "Formulary Deletion Request" Form (Attachment C). The form is available by accessing the Pharmaceutical and Nutrition Care website via the Intranet. Refer to I.A.above.

B. Clinical Decision Support personnel conduct a preliminary review.
   1. Drugs and nutrition products may be deleted from formulary when:
      a. New evidence is available raising concerns regarding the product as a risk to patient safety or the product is considered inferior (less desirable due to stability, sterility, storage, or multitude of other concerns) to alternative (formulary) agents,
      b. Repeated regulatory recalls or shortages occur,
      c. Significant regulatory warnings concerning a product are issued,
      d. Excessive therapeutic overlap within a drug class exists,
      e. Non-utilization for a significant period of time indicates the drug need not be routinely available from pharmacy, and/or
      f. A product is removed from the market.

   2. Requests which meet the "criteria for deletion" (III. B. 1. a-f) will be reviewed by the appropriate Clinical Decision Support and Pharmacy Operations personnel. The action request will be presented to and reviewed by the appropriate committees (see II, 4 above).

      a. The appropriate committees will determine if their recommendation is to:
         i. Approve the request to delete the drug/nutrition product from the inpatient and/or outpatient formulary
         ii. Deny the request to delete the drug/nutrition product from the inpatient and/or outpatient formulary

C. The requestor will be notified in writing of the P&T (Steering) Committee's action.

III. Appeals of Formulary Decisions

Formulary decisions (regarding adding or deleting a pharmaceutical or nutritional products) made by the Formulary Subcommittee and P&T (Steering) Committee may be appealed, in writing, to the Chair, P&T Formulary Subcommittee. Such request for appeal shall include new additional evidence in published medical literature that should be considered by the Formulary Subcommittee and P&T (Steering) Committee.

Any denials of additions and deletions that can be appealed must be approved by the Medical Executive Committee.

Staff Accountability

Pharmacy & Therapeutics Formulary Subcommittee (12/17/13)
Pharmacy & Therapeutics Steering Committee (01/07/14)
By Laws Committee (2/6/14)
Medical Executive Committee (2/11/14)
Board of Directors (2/17/14)

Department Approval		Administrative Approval	
Signed | s |:	Matthew Egbert, MD	Signed | s |:	Austin Thompson, MD
Title:	Chairman	Title:	Chief of Staff
Department:	Pharmacy & Therapeutics Committee		

Attachment A
Nebraska Medicine
Application for Addition to Formulary

Please make certain the form is complete. Incomplete forms will be returned to the requestor. Note—there are 2 sides to this form. Attach any references you feel would assist the committee in reviewing your request. Requests for addition of a pharmaceutical, biologic, or nutritional agent to the formulary will be presented to the Medical Staff P&T Committee only when specific criteria are met. Please refer to Attachment B of this document for details.

1. Drug you wish to have considered for addition to formulary: Generic or Trade name, strength(s), route(s), dosage form(s) and formulation(s) desired:

_____

2. Intended indication(s) or use(s) for the requested drug:_____

_____

3. Indicate which area(s) the requested drug is likely to be utilized: ☐ Inpatient ☐ Outpatient Infusion Center ☐

☐ Clinic(s) _____(list) ☐ Retail Pharmacy

4. Are there currently agents on the formulary indicated for the same therapeutic or diagnostic uses as the requested drug?

If yes, please list: _____
(if unsure, please call Drug Information Services at 402-559-4114 for assistance)

5. Situation(s) in which the requested drug is superior to current formulary items (if applicable): Please select any of the below that apply and provide brief rationale:

☐ The agent is FDA approved or has significant literature to support proposed indication(s) where the others are not

_____

☐The agent is more clinically efficacious

_____

☐The agent has an improved side effect profile

_____

☐ The agent allows preferable route of administration, fewer potential complications, or less monitoring requirements

_____

☐ The agent is more cost effective

_____

☐ Other _____

6. Anticipated frequency of use (annual): <10 patients 10-30 patients 31-60 patients >60 patients

7. Are there current formulary agents that may be deleted if the requested drug is added? If yes, please list:

_____

8. How may the addition of this agent affect the prescribing patterns of other formulary agents? _____

_____

9. Should the agent be targeted toward specific patient populations and/or restricted in its use?
If yes, please describe proposed restrictions or criteria for use:_____

_____

10. Is this request supported by others in the department and/or institution/department leadership? yes no

PLEASE indicate financial or other relationships with the manufacturer or marketer of the requested drug that may be viewed as a conflict of interest (select any of the below that apply):

I am a consultant for the company that makes/markets this drug.	**yes**	**no**
I am a speaker for the company that makes/markets this drug.	**yes**	**no**
I have financial interests in the company that makes/markets this drug.	**yes**	**no**
I have had research funded by the company that makes/markets this drug.	**yes**	**no**
Industry representatives and/or drug information resources have assisted in the completion of this form.	**yes**	**no**

My signature below attests to the fact that the information provided above is accurate to the best of my knowledge.

_____ _____

Medical/Pharmacist/Nutrition Therapist Staff (please print name) Primary Practice Institution

_____ _____

Signature of requester Date

_____

Co-signature (if request supported by departmental/institution leadership)

A Clinical Decision Support Coordinator may need to contact you for further information about this request; please indicate your preferred method of contact below.

_____

Preferred method of contact (e-mail address, phone/pager number)

Please submit the application to The Accountable Care Alliance Medical Staff Pharmacy and Therapeutics Committee by returning the completed form to:

Nebraska Medicine Drug Information Services
988138 Nebraska Medical Center
Omaha, NE 68198-8138

or via e-mail to: TNMCDrugInfoSvc@nebraskamed.com

Please contact Drug Information Services at 402-559-4114 with questions.

Attachment B
Nebraska Medicine
Formulary Addition Request
Criteria for Consideration

Requests for addition of a pharmaceutical, biologic, or nutritional agent to the formulary will be presented to the Medical Staff P&T Committee only when the below parameters are met in a significant manner:

Efficacy— Agent must demonstrate efficacy for the indication(s)/disease state requested and, if there are other available formulary agents for the requested indication/disease state, appropriate evidence indicates that the agent requested provides equivalent or superior relevant clinical outcomes. The boundaries for consideration of 'appropriate evidence' are:

- Peer-review published literature (comparative or non-comparative trials; may or may not be randomized or controlled; meta-analyses; nationally recognized or professional societal guidelines) is strongly preferred
- For an agent with no other comparator for indication/disease state and/or is 'first in class'/new breakthrough medication, evidence in support of efficacy may include data from publicly-available FDA briefing documents/NDA submission, manufacturer package insert, medical meeting abstracts or presentations
- For an agent with no data for the specific indication/use/disease state being requested but with data for other indications/uses/disease states, then efficacy data in other settings will be of informational/supportive value only and will not be utilized as efficacy evidence in the absence of other data
- Experience from other institutions or colleagues (if not published) will be of informational/supportive value only and will not be utilized as efficacy evidence in the absence of other data
- Case reports and/or hypothesies will not routinely be accepted as alternatives for appropriate evidence

Safety— Significant safety concerns are not present for the indication(s) and patient population(s) requested. If there are other available formulary agents for the indication/disease state, literature indicates that the agent requested is as safe or provides enhanced safety.

Uniqueness/ease of use— The agent requested exhibits a unique pharmacologic property making it the only agent approved for the treatment or diagnosis of a specific disease state or the route of administration has fewer potential complications or requires significantly less patient monitoring when compared to other formulary agents for the indication(s) and patient population(s) requested.

Cost effectiveness— The drug requested and/or the associated non-drug costs are less than currently available formulary options and there is documented clinical evidence that the requested agent is both as effective and safe when compared to other formulary agents for the indication(s) and patient population(s) requested. In addition to acquisition costs, overall direct/indirect cost impact to the organization and reduction of unintended consequences will be addressed where appropriate and possible.

Attachment C
Nebraska Medicine
Request for Deletion of a product from Formulary

Please make certain the form is complete. Incomplete forms will be returned to the requestor. Attach any references you feel would assist the committee in reviewing your request.

Drug you wish to have considered for deletion from formulary: (Generic name, strength(s) and dosage form(s))

_____

Indicate which area(s) for the drug to be deleted: ☐ Inpatient ☐ Outpatient Infusion Center ☐

☐ Clinic(s) _____(list) ☐ Retail Pharmacy

CRITERIA FOR CONSIDERATION

A. **SAFETY/ REGULATORY WARNINGS**
Is there new evidence or regulatory warnings to suggest that this medication/product represents a safety risk? (please cite relevant references) _____**yes** _____**no**

Explanation/References: _____

_____

Is there evidence to suggest that this medication/product represents concern with respect to adverse events and/or drug interactions? (please cite relevant references) ____**yes** ____**no**

Explanation/References: _____

_____

B. **THERAPEUTIC REDUNDANCY/ NON-USE:**
Are there alternative formulary medications indicated for the therapeutic or diagnostic uses for which this product **is currently indicated?** **yes** **no** (If unsure, please call Drug Information Services at 402-559-4114 for assistance).

Explanation/ References: _____

_____

If yes, identify the current formulary drug(s) available and indicate whether each is more, equally, or less effective than the drug being requested.

Current Formulary Choice	Less Effective	Equally Effective	More Effective

_____/_____ _____

Medical/Pharmacist/Nutrition Therapist Staff (please print name and extension/pager number) Date

_____

Signature

Please submit the application to The Accountable Care Alliance Medical Staff Pharmacy and Therapeutics Committee by returning the completed form to:

Nebraska Medicine Drug Information Services
988138 Nebraska Medical Center
Omaha, NE 68198-8138

or via e-mail to: TNMCDrugInfoSvc@nebraskamed.com

Please contact Drug Information Services at 402-559-4114 with questions.