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 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 adhering 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, UNMC, 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. 

REPtTrax – 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. 
A. HCVR Visitation 
   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 REPtTrax 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 REPtTrax 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 REPtTrax kiosk (24/7)
      b. Information/Access Services Durham Outpatient Center (DOC) REPtTrax kiosk (24/7)
      c. Purchasing Department (North Doctors Bldg, room 59) REPtTrax kiosk (8am-3:30pm, Monday-Friday)
      d. Facilities Management and Planning (Clarkson Tower basement, room B811) REPtTrax kiosk (7am-5pm, Monday-Friday)
      e. OR Front Desk University Tower REPtTrax kiosk “surgery representatives ONLY” (during normal hours of operation)
      f. OR Front Desk Hixson-Lied REPtTrax 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) REPtTrax kiosk (8am-5pm, Monday-Friday)
      i. Village Pointe Cancer Center (Radiation Oncology front desk) REPtTrax 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 symposiums 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 not 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 not 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 (M1.06).
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

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