December 13, 2017

TO: SCVMC Employees

FROM: Paul E. Lorenz
Chief Executive Officer, SCVMC

SUBJECT: Vendor Access, Conduct and Payments to SCVMC Personnel

REFERENCE: HHS #251.0, Photo Identification Badge/Access Card
HHS #701.0, Acknowledgment and Acceptance of Gifts to SCVHHS
HHS #578.0 Conflict of Interest
VMC #154.02 CME
VMC #154.03 CME Honorarium
June 28, 2017 Memo from Paul Lorenz, Chief Executive Officer, re Prohibition on Accepting Travel, Meals, Gifts and Other Payments from Vendors
HHS #585.18 Contracts with Business Associates

PURPOSE
To define the policy and procedures for all vendor companies and vendor representatives (collectively Vendors or Reps”) who do business within Santa Clara Valley Medical Center (SCVMC) hospital and clinics in order to comply with regulations and policies regarding patient safety and privacy and conflicts of interest while also safeguarding the resources and time of SCVMC employees, volunteers, contractors, medical staff and other personnel (collectively “SCVMC staff”) and Vendor Reps.

POLICY
In order to ensure accountability and control, all Vendor Reps must register with SCVMC and meet the visitation and conduct standards, policies, and requirements of SCVMC. The objectives of this policy include, but are not limited to:

- Compliance with SCVMC policies concerning security, health regulations, confidentiality, and badging
- Elimination of non-scheduled and or unannounced visits (cold calls)
- Establishment of pre-scheduled meetings between Vendor Reps and cost center managers, Hospital and clinical staff, or physicians. All house staff interaction with Vendor Reps must be supervised by appropriate hospital/clinical/physician staff
- Validation of Vendor Reps’ qualification credentials
- Establishment of permissible time frames of contact for Vendor Reps
- Description of acceptable Vendor Rep/staff interactions
- General rules of hospital conduct and for conducting business for Vendor Reps
- Compliance with laws and policies regarding gifts, meals, travel, compensation, consulting and other payments from Vendors to SCVMC staff
- Compliance with laws and policies re patient privacy including, but not limited to, the Health Insurance Portability and Accountability Act (HIPAA) and state and federal laws, and SCVHHS policies including HHS #585.18 Contracts with Business Associates, and all other HHS Policies relating to HIPAA, #585.01, et seq.
PROCEDURE

Vendor/Representative Registration

- All vendors and Vendor Reps currently serving SCVMC must complete an online registration process, managed by VendorMate, Inc. in order to continue their business relationship with SCVMC. Vendors must register separately from their representatives. All new vendors and Vendor Reps must complete this online registration at the beginning of their business relationship with SCVMC.
- An annual, per company fee must be submitted with the vendor’s first registration. This fee, based on the scope of a vendor’s business relationship with SCVMC, is paid to VendorMate to cover expenses such as continuous background checks, communication, and database maintenance.
- All Vendor Reps must have scheduled appointments. Cold calls are not accepted. Vendor Reps arriving at SCVMC without an appointment will be turned away. Vendor Reps are not allowed to loiter in halls, cafeteria areas, patient care areas, OR, or other SCVMC areas in order to meet with SCVMC personnel.
- Vendor Reps with scheduled appointments will be required to check in upon arrival and obtain a badge. Vendor Reps must complete a check-out process upon the completion of their visit.
- Vendor Reps may check in at the following points:
  - Protective Services
  - Resource Management
  - Main Entry Lobby
  - Operating Room Scheduling Desk

Overview of the Registration Process

To access the registration website directly, visit the following website: [www.vendormate.com]

The registration process consists of two phases:
- Registration of the vendor as a company with VendorMate
- Registration of each Vendor Rep and/or other persons acting on behalf of the vendor who visit SCVMC for business purposes

Each vendor and Vendor Rep will be required to provide contact information and upload documentation as specifically required to become a registered “vendor company” or a registered “Vendor Rep”.

Note: The registration process requires entry of the vendor company’s federal tax identification number. This number must be available to avoid delays in completing the registration process.

The vendor company registration process entails the following steps:
1. Business Identification:
   - Legal business
   - Type of business
   - Federal Tax Identification Number (FEIN)

2. Basic Business Information:
   - Business address and telephone
   - Catalog of products sold (identified using UNSPSC codes)
   - Estimated amount of business (in US Dollars) done with SCVMC during past 12 months
   - Vendor Reps’ information

3. Acknowledgment of SCVMC policies
   - HHS #251.0 – Photo Identification Badge/Access Card (subject to change with this policy)
- HHS #701.0 – Acknowledgment and Acceptance of Gifts to SCVHHS
- HHS # 578.0 Conflict of Interest
- VMC #154.02 CME
- VMC #154.03 CME Honorarium
- June 28, 2017 Memo from Paul Lorenz, Chief Executive Officer, regarding Prohibition on Accepting Travel, Meals, Gifts and Other Payments from Vendors

4. Payment:
Payment of annual “per company” registration fee to VendorMate, using a credit card. Note: This fee is paid only during the first registration a vendor completes. Each Vendor Rep registering thereafter will not be required to pay a fee.

<table>
<thead>
<tr>
<th>VENDOR GROUPS 1</th>
<th>ANNUAL FEE 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>High (companies with annual sales of $25,000)</td>
<td>$250</td>
</tr>
<tr>
<td>Medium (companies with annual sales of $5,000 to $25,000)</td>
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</tr>
<tr>
<td>Low/Potential (companies with annual sales of less than $5,000)</td>
<td>$25</td>
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</table>

NOTE: Fees are set by VendorMate and subject to change

5. Confirmation:
A confirmation email and click link to confirm email address and login information.

**Registration/Certification Requirements for Vendor Representatives**
Each Vendor Rep will be classified into one of the three aforementioned categories, based on the Vendor Rep’s product offerings, access to patient areas, and the scope of products and services marketed to SCVMC. There are certification requirements specific to each category; these requirements are consistent with standards set forth by the following:
- Health Insurance Portability & Accountability Act of 1996 (HIPAA)
- Association of Peri-Operative Registered Nurses’ (AORN) Standards for Health Care Industry Representatives in Operating Rooms
- The Joint Commission
- SCVMC and County Policies and Procedures

Regardless of classification, all Vendor Reps must acknowledge and abide by the following principles to conduct business with SCVMC:

1. **Conflict of Interest**
   Vendors Reps must provide a full disclosure about any conflicts of interest that exist or may exist with the County of Santa Clara, SCVMC or any SCVMC staff.

2. **Corporate Compliance Program, Deficit Reduction Act (DRA) of 2005, and False Claims Act**
   Vendor shall acknowledge and abide by SCVMC Compliance Program and agrees to disseminate information about SCVMC Compliance Program and DRA Provisions to its Vendor Reps, and shall require its Vendor Reps to abide by the same.
3. **Tobacco-Free Policy**
Vendor Reps agree not to use tobacco products while on SCVMC premises and abide by the County and SCVMC non-smoking policies.

4. **HIPAA and Patient Confidentiality**
The discussion, release, or use of any patient-related information viewed or overheard may not be used for any purpose other than that which is related to Vendor Rep job assignments and in compliance with patient privacy laws.

5. **Confidentiality of Business and Other Proprietary Information**
Any type of information generated in connection with SCVMC operations must not be accessed, downloaded, discussed, used, or disclosed for any purpose other than to conduct business with, or on behalf of, SCVMC. The agreement to not improperly disclose confidential information continues after termination of the vendor business partnership with SCVMC.

6. **Accompanying Guests**
At all times while visiting SCVMC facilities, Vendor Reps agree to escort any guests accompanying the Vendor Rep who are not registered with the SCVMC Vendor Program. Guests are NOT allowed into the Operating Room or patient care areas without prior approval by SCVMC Medical Staff and all guests must be in compliance with HIPAA and patient privacy laws.

7. **Conduct & Interactions with SCVMC Employees & Medical Staff**
When in SCVMC facilities and interacting with SCVMC employees and Medical Staff, Vendor Rep understands and agrees to comply with the following:
- Conversations with staff in patient care areas should be minimal, must be professional and case related only. No socializing.
- All patient education materials must be evaluated by the Patient Education Department prior to their use.
- Procedure rooms are to be entered only at the request of, and as directed by, the physician(s). The Vendor Rep cannot change or touch any equipment, carts, or sterile equipment. The Vendor Rep must follow the instructions of the Circulating Nurse and physicians at all times.
- Standards governing introduction of new products and the removal of expired or recalled products are abided by as a condition of doing business with SCVMC.
- All Conflict of Interest policies must be followed including, but not limited to, HHS #701.0 Acknowledgement and Acceptance of Gifts to SCVHHS, HHS #578.0 Conflict of Interest, VMC #154.02 CME, VMC #154.03 CME Honoraria, and June 28, 2017 Memo from Paul Lorenz and other policies regarding the provision of gifts, meals, and other payments from Vendors.
- Vendors may not provide any gifts, travel, meals, or other payments to SCVMC staff except as indicated in the June 28, 2017 Memo from Paul Lorenz, Chief Executive Officer. Vendors must read and agree to abide by this policy. Items and services provided at no charge or reduced charge to SCVMC must comply with all laws and policies governing the provision of such items and services.

8. **Contract Compliance**
SCVMC requires contracts with all suppliers when annual spending exceeds $25,000 per fiscal year. Contract compliance and the use of on-contract supplies is a requirement for business with the County of Santa Clara. In the event an off-contract supply or part is necessary, approval by the Director of Perioperative Services or designee is required in advance. If the approval is not received, the invoice will not be paid until the off-contract variance is remedied and pricing is established.
Compliance with the above standards, as well as those set forth in this Standards of Business Conduct Guide, shall extend to the Vendor Rep’s Company, co-workers, agents, and subcontractors. Failure to comply with these requirements could result in temporary or permanent exclusion from conducting business with SCVMC.

**Conducting Business with SCVMC**

**General Facility Access Standards**

Vendor Reps may enter SCVMC facilities for the purpose of conducting business only when the following conditions are met:

- **Vendor Reps New to SCVMC**
  A new Vendor Rep is required to make an initial appointment with Resource Management, Labs, IT, Facilities, or Pharmacy Department to become acquainted with SCVMC and to address any questions that the new Vendor Rep may have. Appointments will be coordinated through the Area Directors per their designated expertise. The Vendor Rep and the vendor must each complete the registration process and the Vendor Rep must attend the initial meeting prior to meeting with any other SCVMC personnel.

- **Scheduled Appointments**
  The Vendor Rep must have a scheduled appointment – a meeting or clinical case, for example – and must limit his/her business-related activities at SCVMC to the scheduled appointment(s). Under no circumstances will cold calls (visits without previously-scheduled appointments) be allowed. Drop-in visits to other departments are also not permitted. Scheduling of department appointments must be arranged by the department and the Vendor Rep.

**Badge and Check-In Process at Facilities Other Than SCVMC**

The Vendor Rep must check in, obtain a badge, and sign out at the conclusion of the scheduled appointment(s). This process is to be completed with assistance from Front Desk staff at the location where the appointment is occurring. With the exception of the introduction meeting that a new Vendor Rep must attend, it is not necessary for a Vendor Rep to report to Resource Management prior to attending a scheduled appointment at another SCVMC facility.

**HIPAA and Patient Confidentiality**

SCVMC respects the privacy of its patients and requires that all who conduct business with SCVMC share this commitment. All Vendors and Vendor Reps are expected to comply with HIPAA and other patient privacy laws and regulations, and with all SCVMC and SCVHHS policies governing compliance with HIPAA.

Where appropriate, Vendor contracts will include all appropriate HIPAA compliance provisions. In any event, the vendor must agree that any and all actions taken or authorized by the vendor regarding the transaction, goods, or services involving or relating to SCVMC shall comply with all applicable laws pertaining to standards for electronic transactions, including those set forth in HIPAA, and all rules promulgated there under. The vendor is also responsible for requiring all agents or subcontractors to comply with such applicable law. Upon the request of the SCVMC, the vendor will provide appropriate documentation of its agents’ or subcontractors’ compliance with such requirements.

**Conflicts of Interest**

SCVMC staff and Vendor Reps are expected to conduct business in an honest and objective manner and to comply with conflict of interest and related laws and policies. Vendor and Vendor Reps are prohibiting from giving, and SCVMC staff are prohibited from accepting, any payments from Vendors to SCVMC staff including gifts, travel reimbursement, meals, consulting, compensation and other payments except in limited
circumstances as set forth in SCVMC policy, including the June 28, 2017 memo from Paul Lorenz attached to this policy.

**Parking at SCVMC**
Vendor Reps may park in any visitor parking designated locations at SCVMC.

**Badge and Sign-In Process at SCVMC**
The Hospital’s Main Entrance is open from 6AM to 8PM and serves as the primary entrance for Vendor Reps and other visitors. For appointments at SCVMC occurring between 8PM and 6AM, the Vendor Rep must complete the check-in and badge process at the sign-in station located in the Protective Services or at a badging station identified by the department the Vendor Rep is visiting.

**Check-Out Process at SCVMC**
The check-out process must occur when the visit is complete. The department being visited is responsible for ensuring that the Vendor Rep’s arrival time and departure times are correctly reflected in the online Vendor Registration Program.

**Access to Patient Care Areas**
Vendor Reps are not allowed to enter patient care areas of SCVMC without specific permission from a director or manager of that department. While in patient care areas, the Vendor Rep shall be accompanied by an SCVMC employee at all times and must follow any internal policies of the respective department.

**Access to Common Areas of Hospital**
Excluding appointments, a Vendor Rep may spend **up to one hour** in SCVMC’s cafeteria, snack bar, lobby, and corridors. However, the Vendor Rep is **prohibited** from approaching physicians or SCVMC employees in these areas, as well as in elevators or patient care areas, for the purpose of conducting business discussions.

**Use of Cell Phones & Hospital Equipment**
A Vendor Rep is permitted to use wireless devices in posted designated areas only. Cellular phones and wireless cellular PC card use in permitted in most areas with the exception of the following prohibited areas, where phones **must be turned off**:
- All ICUs
- Operating Room
- MICC

Use of SCVMC equipment, such as telephones and computers, is prohibited unless the Vendor Rep is visiting SCVMC for the purpose of conducting business or the Materials Management department grants permission to the Vendor Rep.

**Use of Purchase Order**
All purchasing-related transactions require a purchase order – including those for which there is not an exchange of funds – in order for the Accounts Payable department to submit payment. Cost purchase orders are not required for no charge items on trial or for evaluation.

**Group Purchasing Membership**
Volume purchases must be reported through SCVMC’s Group Purchasing Organization. SCVMC is a member of Vizient. Additional information is available by contacting the Purchasing Department.
Non-Pharmaceutical Samples & Products for Trial Use
It is the policy of SCVMC that all new patient care products or substitute products (with the exception of pharmaceutical products) to be used at a SCVMC facility will be evaluated for cost and quality by the Value Analysis Committee or the Director of Perioperative Services or designee. This Committee will conduct a patient safety and product efficacy evaluation to ensure that there is a standardized review process before patient care products are recommended and purchased. The Director of Perioperative Services or designee will approve products and equipment for use in the Operating Room.

New Product Introductions
Vendor Reps are responsible for scheduling an appointment with Resource Management to introduce new products before these products can be discussed with physicians or SCVMC Medical Staff. The product must be left with Resource Management for review and evaluation by Product Value Analysis Committee whenever possible. Equipment/supplies furnished by the Vendor Rep must be in usable and unopened condition at the time it is brought into the hospital. SCVMC assumes no responsibility for supplies or equipment left in the organization by Vendor Reps for the purpose of evaluation. It is the responsibility of the Vendor Rep, unless agreed to by the requesting department, to deliver, install, and remove the equipment or supplies upon completion of the evaluation.

The Department wishing to use the new or substitute product is responsible for completing a “New Product Request Form” and forwarding it to the Value Analysis Committee Chair.

The Product Value Analysis Committee will be responsible for conducting product trials and for reporting the trial’s results back to the requesting department. If a product is accepted, the product will be assigned a Hospital number to be entered into the SCVMC system. The product may then be ordered and used with patients.

Vendor Reps performing maintenance service on medical equipment must deliver a customer-signed service report to the Staff Nurse or Requesting Department upon completion.

Clinical Equipment
Clinical equipment can only be brought in with a no charge purchase order and must go directly to Biomedical Engineering prior to the trial.

Removal of Product
The Vendor Rep cannot remove any supply, product, or equipment without authorization by Resource Management or Biomedical Engineering during visiting hours, and by charge personnel after business hours. A product return document shall be issued by the Vendor Rep when returning equipment for tracking purposes.

Product Recalls
Vendor Reps are required to notify the appropriate Resource Management and the Department Manager about product recalls, with such notification to include identification of the product (including lot numbers affected and quantities removed from SCVMC), the reason for the recall, and a copy of the recall or FDA information. Similar information about product substitutions must be provided to the Department Manager.

Contract Specifics for Services
Vendors and their Vendor Reps are expected to comply with all contract specifics involving scope, deliverables, performance standards, and applicable federal, state and local laws and regulations for all contracts and work
for services, normally delineated in a separate service contract. It is the responsibility of the service providing company to clarify and confirm any and all contract specific expectations with SCVMC.

**Vendor Interactions with SCVMC Employees & Departments**
SCVMC is committed to conducting business on the principles of honesty, fairness, and the merits of a vendor’s products or services. Neither the Vendor Rep nor anyone else working on behalf of the Vendor, may offer or give, nor may any SCVMC employee solicit, money, gifts, gratuities, favors, entertainment, the opportunity to earn money, or other items of value to any person associated with SCVMC or its Affiliates for the purpose of inducing such person to use, prescribe, or refer the Vendor Rep’s products or services, or for any other purpose.

**Meals and Gifts Provided to Employees**
SCVMC employees may not accept meals, food or gifts, travel reimbursement, consulting fees, compensation or any other payments from Vendor Reps or Vendors. See June 28, 2017 memo from Paul Lorenz attached to this policy.

**In-Service Training Sessions**
All in-service must be on formulary items and must be approved by the Department Manager in advance of the training being conducted.

**Hands-On Product Training**
Programs requiring “hands on” training about medical procedures, medical devices, or medical equipment must be held at training facilities, laboratories, hospitals, or other appropriate facilities conducive to learning. The training staff must possess the proper knowledge, skills, and certifications (if applicable) to conduct such training.

**Educational Conferences Sponsored by SCVMC**
Vendor Participation at Educational Conferences Sponsored by SCVMC must comply with SCVMC Policy. See VMC Policy #152.02 CME and 154.01 CME Honorarium.

**Pharmaceutical Manufacturer Representatives Conduct Policy**
Vendor Reps detailing pharmaceuticals, intravenous solutions, tubing or any item marked “Federal law prohibits dispensing without a prescription” shall deal directly with the SCVMC Department of Pharmaceutical Services.

1. Pharmaceutical Vendor Reps must schedule appointments by contacting the Pharmacy Secretary.

2. Pharmaceutical Vendor Reps must report to the Pharmacy Office, which is located at SCVMC. The Pharmacy Secretary will then verify the representative’s appointment and print a badge for the Vendor Rep.

3. Pharmaceutical Vendor Reps MAY NOT enter patient care areas, e.g.: Emergency room, Operating Room, Nursing Stations, and Anesthesia.

4. No samples, legend or over-the-counter product may be left in this facility. Any educational or promotional programs for prescribing medications must be registered in the Pharmacy prior to discussing with SCVMC Staff.

5. As new products become available, objective information shall be provided by Vendor Reps to the Pharmacy for further evaluation.
6. Only Formulary approved medications may be “Detailed” on SCVMC premises. The Formulary status of a medication may be determined by contacting the Pharmacy Department.

7. Displays are not permitted in public areas. Speaker programs may be arranged through the Pharmacy or Medical Education Departments.

8. SCVMC has a “closed” formulary system. Non-Formulary medications are not available for use on patients in this facility without appropriate medical director approvals. Requests for addition of items to the formulary must be initiated by a physician with privileges at SCVMC and must be reviewed by the Pharmacy and Therapeutics Committee. The requesting physician must contact the Pharmacy directly and provide appropriate documentation for P&T Committee consideration.

9. Violation of these policies by the Pharmaceutical Vendor Rep may result in exclusion from SCVMC and suspension of visiting privileges.

**Vendor Representatives in Procedural Patient Care Areas**

**General Standards**

SCVMC recognizes the need for education and introduction of new technology, procedures, and techniques to health care professionals in the perioperative setting. At the same time, a patient’s right to privacy and safety must be protected – particularly when a Vendor Rep is present during a surgical procedure. All Vendor Reps present in procedural areas must abide by the following general standards:

- A Vendor Rep may observe a procedure **only** at the request of a physician performing the procedure and in compliance with patient privacy laws
- If a new medical product is being used, the product **must** be approved **before** the product can be introduced to the physician and/or other clinical staff and before the product can be used with a patient.
- Vendor Reps are not permitted to:
  - **scrub in**
  - **assist with procedures** (other than technical assistance in the form of verbal consultation)
  - open sterile products,
  - load perioperative trays with non-contract products (unless approved by Perioperative Director in advance) or
  - have patient contact
- Vendor Reps or Technical Support Reps with specialized training may perform remote calibration of their company’s products – e.g., pacemakers and pain management devices – to the physician’s specifications.
- A Vendor Rep’s presence during a surgical procedure is to be recorded in documentation of a patient’s surgical procedure.
- Sales calls with physicians must be conducted in non-patient care areas only.

**Required Documentation & Competencies**

All Vendor Rep who are present in the operating room, catheterization lab, or other procedural patient care areas during a procedure are REQUIRED to maintain documentation of certain competencies, health status, and background checks on file.

The Vendor Rep must provide the following documentation in advance of being granted access to a procedure:

- Educational training and/or certification of the products/services the Vendor Rep is authorized to perform
- Competency assessments for the products/services provided: Evidence of the Vendor Rep’s comprehension and retention of the training received
• Pre-employment background checks, including criminal background checks and drug testing
• Liability (or Malpractice) Insurance Certificates
• Documentation of Education/Training for the following areas:
  o Aseptic Principles and Infection Control
  o Blood borne Pathogens
  o Sterile Techniques
  o Product Complaints and Medical Device Reporting (MDR) requirements
  o Product Recall Processes
  o Patient Rights, Confidentiality, and HIPAA
• Documentation of Vendor Rep’s Current Status for the following:
  o MMR (Measles, Mumps and Rubella) Vaccination
  o Hepatitis B Vaccination
  o History of Varicella (Chickenpox)
  o TB Testing (if positive, documentation of chest x-ray)

Operating Room Standards
Purpose
To protect the rights and confidentiality of SCVMC surgical patients and to eliminate unauthorized solicitation by Vendor Reps accessing the Operating Room. For the purpose of this policy, Vendor Reps are included in the group referred to as “non-medical advisors.”

1. Non-medical advisors may be present in the Operating Room only with the advance approval/request of the physician performing the procedure. No walk-ins will be accepted.
2. Non-medical advisors must first check-in with the Resource Management Department or at Operating Room Front Desk prior to arriving in the Operating Room area.
3. When entering the Operating Room non-medical advisors will:
   a. Approach the O.R. front desk.
   b. Leave a business card that is to be given to the appropriate Circulating Nurse.
   c. Have their SCVMC-issued badge displayed prominently at all times.
   d. Be suitably attired, according to SCVMC’s Operating Room policies.
   e. Leave brief cases/bags in the Assistant Director’s Office. They are not to be taken into the Center Core or Operating Rooms.
   f. Turn off cell phone. Cell phone use is not allowed anywhere in the Operating Room. A cell phone will affect some ventilators and monitors that are in use.
   g. Adhere to the SCVMC standards of confidentiality and Infection Control.
   h. Not be allowed to participate in the actual procedure or make any adjustments to equipment used during the cases.
   i. Not be allowed to open sterile supplies and implants.
   j. Enter the Operating Rooms through the scrub area.
   k. Enter the Operating Room only after induction of anesthesia or unless invited by the Surgeon prior to induction of anesthesia.
   l. As an invited guest, non-medical advisors will function under the direction of the Circulating Nurse and the Director of Surgical Services. Noncompliance with directions from either of the nurses could result in removal from the OR.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL
1. All Vendor Reps for Radiopharmaceutical doses shall hold a California Radioactive Materials license and they are inspected by the state of California.
2. The Radiation Safety Officer, or his/her designee, will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license, and that possession limits are not exceeded. The receipt area, room BM062, identified in the Item #11 diagram* is designed such that radiation levels in unrestricted areas do not exceed the limits specified in Title 17 CCR Section 30268.

3. During normal working hours, routine radioactive material deliveries will be directly brought to Nuclear Medicine "HOT LAB" by the pharmacy couriers. For after hours or weekend deliveries, the nuclear medicine key is obtained in the Protective Services Office.

4. If there is an expected non-routine delivery of radioactive material MSRD is notified. When the delivery has arrived, MSRD will call the Radiation Safety Officer/lead Nuclear Medicine Technologist. The RSO/or Nuclear Medicine Technologist must pick up the radioactive material in MSRD and deliver it to the Nuclear Medicine hot lab.

5. Personnel not trained in DOT Hazmat cannot accept packages containing radioactive materials. All radioactive packages will be secured against unauthorized removal.

6. Annual contract evaluation will be completed for each vendor to ensure compliance.

When delivered packages are wet or appear to be damaged, the RSO is to be immediately contacted.

**The carrier should be requested to remain until it can be determined that neither he nor the delivery vehicle is contaminated or if discovered after courier has left, call the radio-pharmacy immediately.

- Item #11 Diagram- located and displayed on the bulletin board in room BM067.
- See emergency list for current Radiation Safety Officer

Disciplinary Action
Vendor Reps who do not adhere to SCVMC policies will be subject to remedial actions ranging from suspension to permanent dismissal of rights to conduct business with SCVMC on behalf of their companies. Because SCVMC does not want to hinder the delivery of patient care, the Vendor Rep’s company may, subject to approval by SCVMC, assign another Vendor Rep to service SCVMC during the suspension or permanent dismissal of the Vendor Rep who has violated SCVMC policies. At the sole discretion of SCVMC, the following sequence of penalties for such violations may be imposed. Irrespective of the following sequence, SCVMC reserves the right to impose different actions or whatever disciplinary and remedial actions it deems appropriate.

- First Violation: Written notification of a 60-day suspension of facility visits and business interactions with SCVMC for the Vendor Rep committing the violation.

- Second Violation: Written notification of a one (1) year suspension of facility visits and business interactions with SCVMC for the Vendor Rep committing the violation.

- Third Violation: Written notification of a permanent ban of facility visits and business interactions at SCVMC by the Vendor Rep committing the violation.
Required Documentation Checklist for Vendor Reps

The following table represents a summary of documentation and competencies that are required for specific groups of Vendor Reps. Exact requirements are reflected in the vendor program. Vendor Reps may find it helpful to refer to this page in preparing their registration packages.

<table>
<thead>
<tr>
<th>Health Status or Immunizations</th>
<th>Pharmaceutical Reps Visiting SCVMC Campus</th>
<th>Reps in Procedural Areas (OR, Cath Labs, Etc.)</th>
<th>Medical Equipment Service Personnel or Clinical Service Techs</th>
<th>General Maintenance or Repair Personnel</th>
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</thead>
<tbody>
<tr>
<td>MMR (Mumps, Rubella, Rubeola)</td>
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<td>History of Chickenpox (Varicella)</td>
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<td>TB Skin Test (Chest X-Ray if positive)</td>
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<th>Education/Training</th>
<th>Pharmaceutical Reps Visiting SCVMC Campus</th>
<th>Reps in Procedural Areas (OR, Cath Labs, Etc.)</th>
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<td>Blood borne Pathogens</td>
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<td>Compliance/Ethics</td>
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<tr>
<td>HIPAA, Patient Privacy, Patient Rights Training</td>
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| Liability Insurance              | X                                        | X                                             | X                                                           |                                        |

| Photograph (Recent Head Shot) for Badge | X                                        | X                                             | X                                                           |                                        |
| W-9 Forms                          | X                                        | X                                             | X                                                           |                                        |
| Product Service Competency Statement | X                                        | X                                             | X                                                           |                                        |
Vendor Visitation to SCVMC Facilities and Access to SCVMC Personnel

Attachment:
1. June 28, 2017 memo from Paul Lorenz, Chief Executive Officer, regarding Prohibition on Accepting Travel, Meals, Gifts and Other Payments from Vendors

Issued: 07/31/81
Revised: 01/26/06, 05/02/06, 08/14/09, 10/10/12, 05/15/13, 4/13/16, Signature approval on file.
12/13/17
DATE: June 28, 2017

TO: SCVMC Employees and Certain Contractors, including Physician Contractors

FROM: Paul E. Lorenz, CEO
Santa Clara Valley Medical Center

RE: Prohibition on Accepting Travel, Meals, Gifts and other Payments from Vendors

This communication is a reminder that all SCVMC employees and certain contractors (collectively “staff”) are prohibited from accepting gifts, meals, travel reimbursement, consulting fees, or other payments from County vendors for any reason except as indicated below. This prohibition includes, but is not limited to, payment of travel expenses for staff to attend trainings and programs offered by the vendor, meals paid for or provided by the vendor, consulting engagements, and other gifts and payments regardless of whether the staff member attends on County time or his or her own time. It applies to all SCVMC employees and to those contractors who are involved or may be involved in the County contracting process, including decisions whether or not to recommend or purchase equipment or services.

Exceptions to this prohibition are: (1) payments that are specifically included in the County’s contract with the vendor, as determined by the contract manager in consultation with County Counsel; (2) certain honoraria and related payments to employed physicians for speaking engagements per the general guidelines attached; and (3) payments that have been approved in writing by the SCVMC Chief Executive Officer or the SCVMC Chief Medical Officer and which been reviewed for potential conflicts by County Counsel.

This prohibition exists for a number of reasons, the most important being that acceptance of such items could, for many staff, result in violations of state law and subject the staff member to personal liability and potential criminal prosecution resulting in significant fines and/or imprisonment. Under Section 1090 of the Government Code, County staff are prohibited from making contracts in which they have a financial interest. Receiving gifts, including meals, travel reimbursement and consulting fees, from a vendor can be construed as a financial interest especially if the staff accepting those gifts or meals are involved in the contracting process, including planning, negotiating, recommending or evaluating a contract, or any amendment or extension of a contract, with the vendor. In addition, the provision of gifts and payments can also be seen as a perk that could influence a decision whether or not to select a particular vendor. In addition, the Political Reform Act requires certain staff to report any gifts they receive in excess of $50 from any one vendor.

Any staff member that does not comply with the requirements of this communication or SCVMC or County policy may be subject to potential disciplinary action up to and including termination. Additional information can be found in relevant policies which include, but are not limited to: (1) HHS #578.0 Conflict of Interest; (2) VMC #530.1 Vendor Visitation; (3) VMC #154.02 CME; and (4) VMC #154.03 CME Honoraria.

SCVMC is in the process of revising travel authorization and leave request forms to ensure that appropriate disclosures are made and policies followed with regard to payment for travel expenses.

If you have any questions, please contact your manager or the Compliance Office. You may also report any potential conflict of interest violations or concerns to the Compliance Office at 408-885-3794 or complianceofficer@sccgov.org, or to the Compliance Office anonymous hotline at 855-888-1550.

Attachment: General Guidance: Acceptance of honoraria for employed physicians as Form 700 filers
General Guidance: Acceptance of honoraria for employed physicians as Form 700 filers

Background

In 1974, in response to the Watergate scandal, California voters passed the Political Reform Act (PRA) to “put an end to corruption in politics.” As a result of the PRA, the following individuals are required to file a Statement of Economic Interest (known as Form 700):

1. Officials and Candidates specified in Government Code Section § 87200
2. State and local government employees who have been identified as “Code Filers” by their employer via a unique Conflict of Interest Code.
   a. VMC physicians have been identified as “Code Filers” by the County of Santa Clara’s Conflict of Interest Code (click for link to document here)

Government Code Sections 89501-89502 define “honorarium” and specifically prohibit acceptance of an “honorarium from any source if the .... employee would be required to report the receipt of income or gifts from that source on his or her statement of economic interests.”

County-sponsored events

SCVMC policy prohibits the acceptance of honoraria by County employees at County-sponsored events.

Non-County sponsored events

Physicians are not allowed to “accept an honorarium from any source if the ... employee would be required to report the receipt of income or gifts from that source” on the Form 700 (Gov. Code, § 89502(c)).

In assessing whether a proposed payment/honorarium is permitted, two key questions must be asked:

1. Is the source of the proposed payment a reportable source on the employee’s Form 700?
2. Does the payment qualify as a prohibited honorarium?
1. **Reportable Sources**

Most VMC physicians are in Disclosure Category 4 as per the County's Conflict of Interest Code. This requires disclosure on Form 700 of all investments in, business positions in, and income (including gifts, loans and travel payments) from:

1. all sources that are health or mental health care providers, facilities, laboratories, clinics or nursing homes, or which provide goods, services, medication, or equipment to, or for the use by, health and mental health care providers;
2. all sources that provide, plan to provide, or have provided in the last two years, facilities, goods, treatment, medications, software, hardware, or related technology, equipment, vehicles, machinery, or services, including training or consulting services, to the Santa Clara Valley Health and Hospital System; and
3. all sources that receive, are planning to apply to receive, or have received in the last two years, grants or other monies (a) from or through the Santa Clara Valley Health and Hospital System, or (b) from or through the County of the type managed or administered by the Santa Clara Valley Health and Hospital System; and sources that receive referrals to provide assessments and/or treatments that are required or recommended by the Santa Clara Valley Health and Hospital System.

Certain physicians and other employees in Executive- and Director-level positions are in a higher disclosure category that requires them to report more items, so each employee should look up his or her own position at the link above and identify the applicable disclosure category.

2. **Honoraria Rule and Exceptions**

   An honorarium is defined as "any payment made in consideration for any speech given, article published, or attendance at any public or private conference, convention, meeting, social event, meal, or like gathering." (Gov. Code, § 89501(a).) The term "speech given" includes any "form of oral presentation" as well as "participation in a panel, seminar, or debate." (2 Cal. Code Regs., § 18931.1.) Thus, a payment or fee received from a reportable source for a speaking engagement, participation on a panel, etc. will generally qualify as a prohibited honorarium.

   The definition of an honorarium does not, however, include payments or reimbursements for travel in connection with a speaking engagement, nor does it include the cost of conference registration, meals, or beverages provided at a speaking engagement — although these items are generally subject to other reporting requirements, which are addressed below in section (3).

   The prohibition on honoraria is subject to several exceptions. The first is particularly relevant to physicians: the honorarium prohibition does not apply to "[e]arned income for personal services" if those services are customarily provided in connection with the practice of or employment in a bona fide business or profession, such as the practice of medicine. (2 Cal Code Regs., § 18932; see also Gov. Code, § 89501(b)(1).)

   To qualify for this exception, a physician's speaking activity must both be on a topic falling within the physician's practice or research area and be directed at other health care providers. **Under these rules, a physician who is invited to speak to other healthcare professionals on a topic within his or her practice or research area may receive a payment for that speech without violating the**
**honorarium prohibition.** But if a physician were asked by a pharmaceutical company to speak to its sales representatives, he or she could not accept a fee for doing so. If a physician qualifies for the earned income exception, he or she may accept the payment but must report it as income on his or her Form 700 if the source is a reportable source under the physician’s disclosure category.

Second, an honorarium that is not used by the recipient and, within 30 days, is either returned to the donor or delivered to the County General Fund, without being claimed as a tax deduction on the recipient’s income tax return, also is not prohibited. (Gov. Code, § 89501(b)(2).)

3. **Reporting of Travel Payments, Meals, Conference Registration, and Related Items**

Payments and reimbursements received for travel in connection with a speech – which includes transportation, lodging, and meals – are not honoraria. (Gov. Code, § 89506; 2 Cal. Code Regs., § 18932.4(g).) These payments are permissible, but are reportable as gifts on a physician’s Form 700. But they are not limited by the usual $460 annual cap on gifts from a single source if they are:

1. given “in connection with a speech”;
2. “reasonably related to a legislative or governmental purpose, or to an issue of state, national, or international public policy”; and
3. “limited to the day immediately preceding, the day of, and the day immediately following the speech.”

Many topics on which SCVMC physicians may be asked to speak are reasonably related to governmental purposes and issues of public policy relating to health care, but physicians who wish to accept transportation, lodging, and meals in connection with speeches should consult us for confirmation.

**Conference admission/registration fees at an event at which a physician gives a speech also are not prohibited honoraria.** (2 Cal. Code Regs., § 18932.4(e).) These fees need not be reported as a gift on the physician’s Form 700 if they are given by conference organizer (id., § 18942(a)(1), (11)), but should be reported if they are given by someone else who qualifies as a reportable source under the physician’s specific disclosure category.

Finally, informational materials (such as pamphlets and other written conference materials) are not honoraria and need not be reported as gifts. (2 Cal. Code Regs., §§ 18932.4(a), 18942.1.)

4. **Conflicts of Interest**

Under the PRA and Section 1090 of the Government Code, accepting an honorarium worth $500 or more, or travel payments or other items worth $460 or more, within a single calendar year limits a physician’s ability to be involved in official County decisions or contracts involving the source of the payment. The consequences for violations of the PRA and Section 1090 can be severe, including fines and criminal liability. Thus, we advise that any employee who is considering accepting an honorarium, travel payment, or similar benefit seek advice about potential conflicts of interest.

5. **Outside Employment Approval**

State law, Board Policy No. 3.6, and VMC policy require employees who are considering engaging in non-County work activities to obtain pre-approval from their supervisor by submitting an
incompatible activities/outside employment approval form. This requirement applies to **paid and unpaid** speaking work for non-County organizations. The relevant policy and approval form employees should use to request pre-approval of their outside work are available [here](#).

This advice is intended to be general in nature. If you have specific questions about a circumstance, please contact one of the following attorneys at the Office of the County Counsel for assistance.

**Kavita Narayan**, Deputy County Counsel  
Phone: (408) 299-5927  
[Kavita.Narayan@cco.sccgov.org](mailto:Kavita.Narayan@cco.sccgov.org)

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