SCOPE: All Company-affiliated facilities including, but not limited to, hospitals, ambulatory surgery centers, home health agencies, physician practices, service centers, and all Corporate Departments, Groups and Divisions that perform services under research grants funded at least in part by vendors (“Research Programs”).

PURPOSE: To provide direction for the receipt of research grants from Vendors to help underwrite the costs of Research Programs and for payments to physicians or other potential referral sources for their participation in Research Programs sponsored by any Company–affiliated facility.

POLICY:

1. Payments to Researchers and Others Providing Services for Research Programs.
   All payments to physicians, other potential referral sources, and any other individuals (including members of their immediate family), providing services for any Research Programs, must be made in accordance with a written agreement. The amount of compensation must not exceed fair market value for the services performed. (See the General Statement on Agreements with Referral Sources; Approval Process Policy, LL.001.)

2. Grants from Vendors.
   A facility may only accept funds from a Vendor when the:
   • Facility and Vendor are both sponsors of the Research Program;
   • Facility and Vendor both benefit from the Research Program;
   • Facility and Vendor mutually agree on the Content of the Research Program;
   • Research Program content is not a marketing vehicle for the Vendor;
   • Research Program funds are not connected with any other business transaction;
   • Facility and the Vendor enter into a written agreement; and
   • Research Program is otherwise legitimate and bona fide.

DEFINITIONS

Research Programs, as used herein, are defined to include any program conducted by facility employees and medical staff for the purpose of testing or researching the use of a particular product or procedure for the purpose of providing feedback on the results to both the facility and the Vendor.

Vendors, as used herein, are defined as pharmaceutical manufacturers, medical device manufacturers, and other suppliers of medical products, equipment and services.

PROCEDURE:

A. Vendor Funding for Research Programs
   1. The primary purpose of the Research Program must be the promotion of objective scientific, research and educational activities, and not a marketing vehicle for Vendors. In no event is any request for, or acceptance of, a Vendor contribution for any Research Program to be connected in any manner, implied or express, with the conduct of business with a Vendor or the amount of business conducted with a Vendor.
2. Research Programs shall be conducted in accordance with generally accepted industry standards for medical research, the Company Clinical Research Policies (QM.RES.001 through QM.RES.007), as well as any requirements of the facility's IRB.

3. The facility must at least be a partial sponsor of the Research Programs (e.g., provides personnel, equipment, supplies and/or space).

Vendor funding may be received to underwrite part or all of the cost of Research Programs. A written agreement must indicate the amount of Vendor funding and its purpose, and any other relevant terms and conditions, with the goal of conforming to the requirements of the Personal Services Safe Harbor. This Safe Harbor requires:
   a. a written agreement between the parties;
   b. the services shall be specifically stated;
   c. if the services are not full-time, then the schedule needs to be stated;
   d. the term of the agreement must be for at least one (1) year;
   e. compensation is to be set forth in advance in the agreement, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any business transacted between the parties; and
   f. the services to be performed do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal Law.

4. Vendor funds must be used to pay legitimate expenses related to the Research Program, including, personnel and administrative costs, reasonable expenses, room and equipment rental, supplies, and handout materials. Payment must be by the Vendor directly to the sponsoring facility and not to any researcher or participant in the Research Program or other provider for the Research Program. Accounting for Vendor funding of Research Programs must comply with the requirements of Section B below.

5. The amount of Vendor funding must not be conditioned on the purchase of product by facilities, or related to the volume of business facilities conduct with a Vendor.

6. Payments to Physicians and other potential referral sources serving as researchers, faculty, or administrative support must be made using the one-time Physician Expense Reimbursement form (available on the Company’s Intranet at http://connect.medcity.net/c/document_library/get_file?uuid=c4a2fdd5-711f-4602-bbd6-774305aa7575&groupId=62961535 ). The facility CEO must certify that the payment represents fair market value and the services were rendered before payment is made. If the amount exceeds $150 per hour, an independent appraisal must be obtained to verify that the amount does not exceed the fair market value of the services received. If the hourly rate exceeds $250, the Division President must also certify that the payment does not exceed the fair market value of the services received. (See the General Statement on Agreements with Referral Sources; Approval Process Policy, LL.001.) Payments to non-referral sources must be made pursuant to a written agreement comparable to that used for potential referral sources.
B. Accounting Requirements for Vendor Funding of Research Programs

1. The Medicare rules do not provide adequate guidance regarding the specific treatment of funds provided by a Vendor to a facility for Research Programs. Accordingly, the Company has adopted the most conservative approach and treats such funds as discounts. For individual facilities receiving Vendor funds for Research Programs, the amount received must be offset against the cost of supplies by the particular facility. This requirement applies whether the payment is received directly from the Vendor or the Vendor directly pays provider of research program services or items. The preferred method, (and the method required by this Policy, is for the Vendor to make the payment to the facility and the facility to pay the Research Program participants. This insures that both the cost of the Research Program participants and expenses, and the funds received from the Vendor are separately recorded on the facility’s accounting records for proper treatment in the Medicare cost report. If the Vendor pays participants and expenses directly, the facility must obtain a copy of the payment documentation from the vendor and make an entry on the facility’s books to reflect the cost paid by the vendor and record a rebate for the same amount. These amounts must not be netted against other costs of the Research Program. This is important because the cost of the Research Program may be non-allowable but the rebate will be used to reduce the cost of the services or supplies that would otherwise be allowable.

2. If any Research Program is sponsored by a Division or the corporate office (or similar corporate subsidiary providing management or support services), the amount received by the Division or corporate office (or similar corporate subsidiary) will be allocated to the supply costs for all facilities within that Division, or all facilities nationally, respectively.

3. The facility must keep the Vendor funds received for specific Research Programs segregated in separate general ledger accounts to maintain adequate control of the receipt and use of the funds. All transactions must be supported by adequate documentation. Supporting documentation for withdrawals and expenditures should document the proper approvals and should also clearly document that the funds were used for the purpose intended.

4. Expenses for activities that are not related to patient care, as defined by Medicare, should be segregated in separate accounts to facilitate proper exclusion for Medicare cost reporting purposes. The following are some examples of activities which are not allowable for Medicare reporting purposes: charitable events and fund raising activities, health fairs, community education, educational events for non-employees, alcoholic beverages, gifts and entertainment. The facility should consult the appropriate Reimbursement Department representative regarding specific items. Expenses that are not allowable for Medicare reporting purposes must be excluded from cost reported to Medicare even if funds were received from Vendors under this policy relating to Research Programs. For Medicare reporting purposes, the funds received must be used to reduce the cost of supplies, the same as discounts and rebates.

5. All assets, liabilities, revenues and expenses for Research Programs must be properly reflected in the accounting records of the facility. Revenues received for Research Programs covered by this policy must not be used as a reduction of the Research Program expense, but reflected in “other revenue – rebates/research grants.”
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<thead>
<tr>
<th>DEPARTMENT: Materials Management</th>
<th>POLICY DESCRIPTION: Research Grant Funding from Vendors</th>
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<tr>
<td>PAGE: 4 of 4</td>
<td>REPLACES POLICY DATED: 8/1/04</td>
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<tr>
<td>EFFECTIVE DATE: January 1, 2009</td>
<td>REFERENCE NUMBER: MM.005</td>
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<tr>
<td>APPROVED BY: Ethics and Compliance Policy Committee</td>
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REFERENCES:

The fraud and abuse laws at 42 U.S.C. § 1320a-7b  
The Safe Harbors at 42 C.F.R. § 1001.952(a)-(v);  
Company Code of Conduct  
Business Courtesies to Potential Referral Sources Policy, EC.005  
Entertainment Policy, EC.006  
Vendor-Promotional Training, Business Associate-Sponsored Seminars and Honoraria Policy, EC.007  
Records Management, EC.014  
Agreements with referral sources Policy, LL.001  
Professional Services Agreements Policy, LL.002  
Non-Employed Physician Education Expenses Policy, LL.010  
Providing Free and/or Discounted Training and Equipment to Referral Sources Policy, LL.011  
Physician Access to the Internet Policy, LL.026  
Company Clinical Research Policies, CSG.RSH.001 through CSG.RSH.010  
Accreditation Council for Continuing Medical Education ("ACCME"):  
Standards for Commercial Support of Continuing Medical Education at  
http://www.accme.org/pdfs/disclosure_pol.pdf

The ACCME's Essential Areas and their Elements at  
http://www.accme.org/incoming/17_system98_essential_areas.pdf

Office of the Inspector General: OIG Compliance Program Guidance for Pharmaceutical Manufacturers:  
86 Federal Register 23731 (May 5, 2003) at 23735:  
http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf

Pharmaceutical Research and Manufacturers of America ("PhRMA"): PhRMA Code on Interactions with Healthcare Professionals:  

Advanced Medical Technology Association ("AdvaMed"): Code of Ethics on Interactions with Healthcare Professionals:  
www.advamed.org