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UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

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Melony Williams Goodhand, JD, CPA, MS
Vice Chancellor for Finance
Chief Financial Officer

November 21, 2011

Dear (Interventional Radiology) Vendor:

The University of Arkansas for Medical Sciences (UAMS) is dedicated to promoting the highest ethical standards and is committed to making the care of our patients our first concern. In achieving this end, UAMS is dedicated to partnering with those vendors who are committed to improving patient care and the safety of our patients and staff, and reducing costs while controlling products introduced to UAMS through an established Value Analysis process.

As a reminder to you of our established policies, all orders for supplies, equipment or service must be covered by a formal purchase order, which has been authorized by the Procurement Department. UAMS will NOT pay for any supplies, equipment or services that have not been through our review and approval processes. Agreements made with physicians in their offices are not binding with UAMS as Physicians are not agents of UAMS. Any commitment or agreement made by any individual without prior knowledge and written approval from the UAMS Procurement Department is invalid and will not be recognized by UAMS.

Supplies delivered or brought into any entity of UAMS without an authorized purchase order will be returned to the vendor and not reimbursed by UAMS. UAMS will not assume any financial responsibility for unauthorized merchandise shipped to our facilities. Vendors who fail to comply with UAMS's expectations will compromise their business relationship with the UAMS.

We appreciate your cooperation in working with us to provide the best care to our patients. If you have any questions please contact Kara Otis R.N. Director of Value Analysis (501)686-8463. REFER to New Product Introduction Policy SC.1.04

Sincerely,

Phillip J. Kanney, M.D
Chairman, Professor of Radiology

Marvin T. Stricklin Director of Radiology

Melissa Fontaine
Associate Vice Chancellor for Clinical Programs

Melony Goodhand, JD, CPA, MS
Vice Chancellor Finance & CFO

David L. Ripa
Chief Supply Chain Officer

Number: SC.1.04
Policy Title: The Introduction of New Products

UAMS MEDICAL CENTER POLICIES & PROCEDURES
Number: SC.1.04
Policy Title: New Products Introduction (Supplies and Equipment)
Source: Supply Chain Management
Approved By: _____
Date Approved: August 19, 2009
Review/Revised Date: October 2011
Replaces Policy: MM.1.04

PURPOSE

I. University of Arkansas for Medical Sciences (UAMS) Medical Center is devoted to quality care and has determined that there is a need from a quality and patient safety perspective to establish a formal product evaluation process that will cross disciplines.

II. The intent of this policy is to provide a clear and understandable set of rules governing the introduction of new medical/ surgical products into UAMS supply chain formulary.

III. The purpose of this policy is to provide a documented process by which all new medical/ surgical products, product trials, and product replacements are reviewed, fully evaluated and formally approved prior to their use.

IV. That UAMS Supply Chain Management department holds itself to the highest standards to ensure the delivery of quality medical products that are safe for patient use at the most economic cost of ownership to the facility.

POLICY

I. This Policy Statement has been created to:

A. Establish requirements for vendors and sales reps seeking to have their products sold to and used at UAMS.

B. Provide guidelines for UAMS staff when seeking new medical/ surgical supplies for use in clinical care areas.

C. Establish a formal evaluation process for patient related new products, equipment, and clinical technology called Value Analysis. Refer to Supply Chain Policy SC.3.09 The Value Analysis Committee, for more information.

D. Establish guidelines for product standardization (when possible), to evaluate products for their effectiveness, safety, cost effectiveness, and compliance.

E. New equipment and technology will be formally evaluated through a formal trial process prior to purchase or change. Refer to Supply Chain Policy - New Technology Assessment Policy SC.3.08 and Clinical Equipment Safety Policy 2 for more information.

Number: SC.1.04
Policy Title: The Introduction of New Products

DEFINITIONS

1. Vendor or sales rep. A representative of a manufacturer or company who visits for the purpose of soliciting, marketing, or distributing products or information regarding the use of medications, products, equipment and/or services.
2. New product. A new supply that has been formally introduced on a new product request form and has been thoroughly evaluated and has been through the Value Analysis process and been accepted by the Value Analysis Committee.
3. Supply Chain Management Department (SCM) Encompasses the Procurement Department, Distribution Services, Value Analysis, Materials Management, Sterile Services & Supply, OR Materials Management, Linen Services and Equipment Management.

RESPONSIBILITY

Vendors are responsible for understanding and adhering to this policy as it relates to new products they wish UAMS to consider for product trial or consignment.

REQUESTING NEW MEDICAL SUPPLIES

1. The department that is requesting the new product or supply must fill out the electronic *add/change / delete form* that is available on the Supply Chain Value Analysis home page http://www.uams.edu/supplychain/valueanalysis/ all necessary fields must be filled out for the document to be sent to the Value Analysis Department for review.

2. Additions to the supply formulary or changes to the existing formulary will only take place after Departmental and Value Analysis Committee approval. All requests for new products will go through the department director and the Value Analysis team. **Exception**: New medications must go through the existing drug formulary evaluation and approval process.

3. All new product trials and evaluations of equipment will be brought in to UAMS under a no cost purchase order issued by the Supply Chain Management Department. If a new product is brought in to UAMS and used without the prior knowledge of the UAMS Supply Chain Management Department that item or supply will be considered a donation. All trials and evaluations of medical supplies will involve the Supply Chain Value Analysis department.

4. In an emergency situation a onetime purchase order/approval will be given for a non-formulary product. This product will not be used again until the on-line *add /change / delete request* form is completed by the requesting department and submitted to the Supply Chain Value Analysis department for review and consideration.

5. Technologies that are new to UAMS must be submitted using the on- line *add/ change /delete request* form. The request will be reviewed and if it is clinically supported go to the New Technology Assessment Committee for consideration. More information on this process is available in (TAC) Technology Assessment Policy #SC. 3.08

6. All new product requests will initially be screened for completeness and accuracy by the Supply Chain Value Analysis department before they are given to the appropriate Value Analysis Team for review and consideration. The Value Analysis Team will be made up of the Supply Chain Value Analysis Director or their designee, clinical staff and/ or subject matter experts. The Value Analysis Team will evaluate the request/s, review the cost/benefit analysis, and vote to approve or disapprove the use of a new supply item.

7. In rare occasions, the Director of Value Analysis has the ability to assign low cost or low impact conversions to the supply formulary without full committee review.

8. Equipment provided by a vendor for product evaluation must be tested and approved by the UAMS Clinical Engineering Department prior to the product evaluation. UAMS will not incur any cost for 3rd party equipment testing that may be necessary.

9. Physicians and other staff with a current financial or professional relationship with the manufacturer or distributor of the product to be evaluated, or a relationship that occurred in the most recent completed calendar year, will not evaluate the product and may only provide expert advice after their disclosure of the relationship. Requests must first go the appropriate department chair for approval. If the department chair has a current professional or financial relationship with the manufacturer or distributor, or a relationship that occurred in the most recent complete calendar year, the request must be approved by the chair's immediate superior.

10. All products if used by UAMS with permission from vendor must adhere to the Consignment /Loan Policy include policy #SC.3.10

EQUIPMENT ON LOAN OR TRIAL OR BROUGHT IN FOR DEMONSTRATION

1. Supply Chain must authorize prior to shipment, any equipment to be used on loan or trial.
2. Clinical Engineering should be notified in advance of the receipt of the equipment so that an inspection may be scheduled and performed. This will ensure that necessary personnel are available to perform the inspection.
3. Life support equipment brought in as a loaner, on trial, or for demonstration must have appropriate maintenance documentation submitted to Clinical Engineering during its inspection.
4. Clinical Engineering will inspect the equipment, including clinical alarms and will affix a Clinical Engineering inspection label in a visible location on the device. The device will also be evaluated for inclusion into the Equipment Management Program.
5. Equipment failing inspection cannot be used in the facility until the deficiencies identified have been corrected and appropriate safety tests completed.
6. Equipment brought in for a specific procedure and removed from the premises must be re-inspected each time it re-enters the facility.
7. It is the responsibility of the using department to coordinate any necessary training for staff on equipment brought in on loan, for trial, or for demonstration.

NEW PRODUCT APPROVAL PROCESS / NEW PRODUCT DENIAL PROCESS

1. Once a new item or supply has been properly submitted via the *add / change / delete request* form. The Supply Chain Management Contracting Department will analyze that product request for price competitiveness and alliance with our current GPO's product portfolio. It may be determined that the new product be on a local or national GPO contract, however all new products that are being considered for addition to the product formulary must first be on a contract. The Value Analysis Committee considers the product and looks at the total cost of ownership, quality and safety features of the item and makes the determination to add to the formulary or not.

2. The completed electronic form will be sent to the department director. The director will send the form via email/approval to the Value Analysis team. The team will verify usage, cost and/ or cost savings.

The VAT will present the information to the appropriate VAT Committee. The appropriate VAT committee will approve or deny the purchase.

a. If approved, the approval documentation is sent to Supply Chain management to be purchased. If the new product is an item that many departments will use, Staff Education and Training is contacted. If an item is used my many departments, the Value Analysis department of Supply Chain will create a flyer and post the conversion information of the change on the Supply Chain Value Analysis intranet page.
b. If denied, a letter will be sent to the requestor and Physician Department head (when applicable) within 7 days of denial explaining the reason for the denial.

PRODUCT EVALUATIONS/TRIALS

1. All evaluations or trials of supplies or equipment must be arranged through the Supply Chain Management department.
2. If the new item will be transported or utilized in the continuous care of the patient across multiple areas or departments, then an interdisciplinary evaluation team needs to be created to evaluate its use beyond the immediate department. This interdisciplinary team should include a member of the Hospital Risk Management Department, a physician in the inpatient and/or outpatient setting, an inpatient nurse and/or clinic nurse, an education representative, and other clinicians as needed. The Supply Chain Management Director of Value Analysis will be the facilitator of this determination and will facilitate pulling necessary team members together to review, if needed.
3. Physicians or other staff with a current financial or professional relationship with the manufacturer or distributor of the product to be evaluated, or a relationship that occurred in the most recent completed calendar year, will not evaluate the product and may only provide expert advice after disclosure of the relationship.
4. UAMS employees involved in product evaluation shall disclose any financial or professional relationships that have occurred within the past twelve months with the manufacturer or distributor of the product being evaluated and recues themselves from evaluation of the product. Such employees may respond to questions about the product from after disclosure of the relationship.

REFERENCES

UAMS Medical Center Policy and Procedures
Clinical Equipment Safety Policy 2
Value Analysis Policy SC.3.09
New Technology Assessment Policy SC.3.08
Additional information
Conflict of Interest for Academic Staff Members 4.4.10
Conflict of Interest for Non-Academic Staff Members 4.4.11

Additional Resources:
Assistant Vice Chancellor Supply Chain, (501)686-5802
Director of Materials Management, (501) 686-8429
Sr. Director Supply Chain Business Operations, (501) 686-6130
Director of Value Analysis, (501) 686-8463
Director of Clinical Engineering, (501) 686-7793
Hospital Risk Management, (501) 603-1150

Appendix A

Product Evaluation

Date:

Evaluation Item:

Manufacturer:

Current Product:

Please Circle Answers

1. Does the product perform the expected job required? Yes No
2. Is it functional and reliable? Yes No
3. Is the product safe for the patient? Yes No
4. Is the product safe for the user? Yes No
5. Is it easy to use? Yes No
6. What is your overall evaluation of this product? Yes No
    a. Satisfactory
    b. Unsatisfactory
7. What is your recommendation (please check on)
    a._____ I would like this product instead of current Product.
    b._____ I would like to use the product if it's less expensive than the current product
    c._____ I would like to evaluation another product.

Comments:

Name, Title, Department:

Please return to Office of Supply Chain, 686-8949

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Slot 571-1, Value Analysis Department,