

## Chapter 21

# PROCEDURES FOR PURCHASING FDA APPROVED PRODUCTS

CAMC's Material Services is responsible for maintaining a database for all products (except pharmaceuticals, dietary foods, and maintenance materials) purchased at Charleston Area Medical Center. All products purchased for CAMC are FDA approved, with the exception of certain research items that may be reviewed and approved for use by the Institutional Review Board (IRB). In such cases a written directive from Administration is required before the item is purchased.

With the exception of pharmaceutical, dietary and maintenance sales representatives, all vendors must register in Purchasing prior to pre-scheduled visits with any CAMC/Camare department. (Dietary, Pharmacy and Maintenance vendor representatives are required to register in those particular procurement areas.) Purchasing validates the pre-scheduled visit and issues passes noting the pass the area(s) the sales representative is visiting. The sales representative is not authorized into any other area(s). Salesmen not in compliance with this policy may be denied the privilege of calling upon CAMC in the future.

Policies and procedures for procurement and/or evaluation of FDA approved devices and equipment can be found in the Purchasing Department section of the Corporate Material Services Policy and Procedure manual. A listing of the applicable policies is found at the end of this narrative. All FDA approved devices/equipment are purchased through the CAMC Purchasing Department. The Purchasing Department has responsibility to facilitate supply equipment standardization as well as to maintain supply contract compliance. For these reasons, it is important that all 'new' (previously unused at CAMC) FDA approved products be introduced through the Purchasing Department for appropriate action(s) prior to purchase of the product. Requests for product review are initiated utilizing the attached "Product Evaluation/Utilization Form".

Questions regarding purchase of new FDA approved products should be directed to CAMC's Director of Purchasing at 348-9542. Safety questions regarding the use of new FDA-approved products at CAMC should be directed to the Director of Safety at 348-8208 or to the appropriate administrative office.

### Applicable Material Services/Purchasing Policies:

<u>Policies</u>	<u>Policy Number</u>
Product Procurement	P-020
Purchasing Requisition Procedures (Non-Capital)	P-025
Capital Equipment Procurement	P-055
Product Evaluation and Utilization Committee	P-110
Requests for Product and/or Supply Evaluation	P-115
Evaluation of Equipment	P-120
Clinical Trials and Evaluation of Products, Equipment or Devices	P-125
New Products and Equipment	P-130
Sales Representative-Security and Unauthorized Solicitation	P-135
"Free" Equipment Offers to CAMC by Vendor	P-140
Vendor Product Displays	P-145

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