1. PURPOSE

The purpose of this policy is to establish clear and consistent rules governing the introduction of New Items (as defined in Section 3 below) into the Aurora Health Care system ("Aurora"). This Policy establishes requirements for Vendors seeking to have New Items purchased or used at any Aurora location, establishes requirements for staff seeking to have New Items introduced to Aurora, and establishes a formal evaluation process for these New Items.

2. SCOPE

This policy applies to Aurora Health Care, Inc. and any entity or facility owned and controlled by Aurora Health Care. With the exception of the items listed below, this policy applies to all New Items to be purchased, leased, rented, or otherwise acquired or utilized, including without limitation all New Items to be provided on a test, loan or consignment basis.

This policy does not apply to the following:

(a) Capital items (those items that meet the capitalization requirements outlined in CAPITALIZATION. Capital items must follow the AFE process in AUTHORIZATION FOR EXPENDITURES If, however, non-capital New Items are to be acquired in connection with the acquisition of a capital item, the non-capital New Items shall be subject to this policy.

(b) Items purchased with an Aurora Procurement Card, subject to the requirements of the Procurement Card program.

(c) Non-Medical items ordered less than 1 time per month through the MMIS/IREQ Special ordering process in PURCHASE ORDER

(d) Items purchased through a third party ASL approved website (ex. Staples, ABC, Grainger etc.)

(e) Food and meals.

(f) Books, magazines/periodicals and other similar subscriptions.

(g) Items acquired as part of a clinical trial or other research activity conducted with the approval of the Aurora Institutional Review Board.

(h) Any other categories approved in writing by Aurora's Senior Vice President and Chief Administrative Officer

3. DEFINITIONS

ASL: the Aurora System Logistics Department or Supply Chain.

Emergency NIRF: any New Item request that is designated by the submitter as an Emergency NIRF where the requested New Items must be acquired on an expedited basis in order to avoid harm to patients or other material risks.

Medical New Item: any New Item that is used to treat or otherwise provide medical care to patients.

MMIS: Aurora's Materials Management Information System.

New Item: any product or item that is not currently available for requisitioning within Aurora's MMIS.

NIRF: New Item Request Form.

Non-Medical New Item: any New Item that is not used to treat or otherwise provide medical care to patients.

PAM: the Purchasing Account Manager that work for ASL with the Sourcing Strategies team

Vendor: any individual or entity doing business with Aurora or soliciting business with Aurora.

Vendor Representative: any employee, agent or other representative of a Vendor.

4. POLICY

4.1 Required Approval. All New Items must receive approval through the processes described herein and must be added to MMIS prior to being acquired or used at Aurora. Under no circumstances will Aurora issue a Purchase Order or pay for any New Item that has not received prior approval pursuant to the processes described herein.

4.2 Requests for New Items. Aurora staff must complete a New Item Request Form (NIRF) for all New Items. The electronic New Item Request Form can be located on *Caregiver Connect.* NIRF training is be requested by sending an email to the IREQ administrator at IREQ.Administration@aurora.org

4.3 Review by ASL / Work Group. Based on the information provided in the NIRF, ASL will route each request as set forth below and will serve as the liaison between the requesting individual and the evaluating individual or team. Prior to proceeding with an analysis, the Compliance Department will be consulted as needed to determine if any individual/team/work group members disclose a potential conflict of interest that requires management in accordance with CONFLICTS OF INTEREST-CAREGIVERS.

a) Non-Medical New Items.

i. Are routed to the requestors one up manager for review for appropriateness. Once approved by the requestors manager the NIRF is routed to the ASL Purchasing team for final review. Purchasing will review to ensure the vendor is vetted; the price is correct, and duplicate items don't already existing in the item master. Both the manager and Purchasing can reject the request for appropriate reasons.

b) Medical New Items. All Medical New Items will be routed to the requestors one up manager for review for appropriateness. Once approved by the requestors manager the NIRF is routed to the ASL Supply Chain Manager to review for appropriateness then to the applicable PAM and if necessary to a corresponding Value Analysis Team for evaluation. At the discretion of the PAM, the request may be routed to a specific Work Group for additional evaluation. Once approved by the PAM the NIRF will be routed to Purchasing team for final review and approval. Any approver in the chain can reject the NIRF for cause.

c) Emergency NIRFs. Emergency NIRFs may be submitted to ASL on an exception basis, where existing circumstances prevented the NIRF from being submitted earlier and in a manner that would have permitted Aurora to evaluate the request pursuant to standard processes. All Emergency NIRFs must be approved by a Manager (or higher) with authority over the requesting area/department. ASL shall review Emergency NIRFs and, if approved, Emergency NIRFs will be approved for single use only and then routed to the applicable Value Analysis Team for evaluation if necessary.

4.4 Related Items. If a potential New Item is so closely related to an item that is currently available within Aurora's MMIS, such that an independent review of the proposed New Item is deemed unnecessary by ASL, the proposed New Item will be evaluated and approved or rejected by ASL. Examples of these related items include, but are not necessarily limited to, additional sizes of a pre-existing item and certain extensions of an existing vendor product line.

4.5 Evaluation and Approval / Rejection. Each NIRF will be evaluated based on a variety of factors, including but not limited to (i) product efficacy and the likelihood that the product will improve patient outcomes; (ii) product safety; (iii) product cost and the overall financial impact of adding the requested product; (iv) ease of use; (v) compatibility with other products; (vi) whether alternative products exist within MMIS; and other factors. After a NIRF is approved or rejected, ASL will communicate that decision to the requesting individual. If the NIRF is rejected, the reasons for the rejection will also be provided.

4.6 Vendor Information and Assistance. Vendors must provide information on New Item efficacy, safety, and clinical results when available. If requested by Aurora, Vendor will provide education and demonstrations with respect to the proposed New Item.

4.7 Product Evaluations. All trials or other evaluations of potential New Items governed by a Value Analysis Team must be arranged through the PAM.

4.8 Addition to MMIS. New Items approved through the process described above will be added to MMIS by ASL's Data Team.

4.9 Violations and Enforcement

a) The approach to applying certain portions of this policy may vary as stipulated in underlying contractual agreements or as stated elsewhere in this policy. ASL will serve as the arbitrator if any elements of this policy or its application are in dispute.
b) All Aurora caregivers are responsible for complying with this policy.
c) All Vendors and Vendor Representatives are required to comply with the terms of this policy as it relates to new products they wish Aurora to acquire or utilize.
d) Each Vendor is responsible to ensure that all of its Vendor Representatives are aware of, and comply with, this policy, and each Vendor shall be responsible for the conduct of its Vendor Representatives.
e) Aurora staff will monitor compliance with this policy and report any suspected violations of this policy to their supervisor and ASL, as appropriate.
f) ASL will investigate reported violations of this policy. Vendors and/or Vendor Representatives who violate this policy may be temporarily or permanently prohibited from visiting Aurora locations or conducting business with Aurora, as determined by ASL.

CROSS REFERENCES:

PURCHASE ORDER
VENDOR
AUTHORIZATION FOR EXPENDITURES CAPITALIZATION
AUTHORIZATION FOR EXPENDITURES
CONFLICTS OF INTEREST-CAREGIVERS
PROCURE TO PAY

REFERENCES: None

PRIOR REVIEW / REVISION DATES: 01/14, 01/16