System-wide Policy: **Allina New Product Review**

Reference #: SYS-SC-ASCM-007

Origination Date:	September 2007
Revised Date:	July 2012
Next Review Date:	July 2015
Approval Date:	
Approved By:	Executive Leadership Team
System-Wide Policy Ownership Group:	Supply Chain Management
System Policy Information Resource:	Director, Purchasing

Stakeholder Groups
Finance Council
Executive Leadership Team (ELT)
Corporate Compliance
Peri-Operative Council
Clinical Service Line Executives

SCOPE:

Sites, Facilities, Business Units	**Departments, Divisions, Operational Areas**	**People applicable to (MD, NP, Administration, Contractors etc.)**
System Wide		

POLICY STATEMENT:

All Products supplied to Allina for use are required to be reviewed and approved prior to use by the appropriate New Product review process and approval forums. Non-approved products are not to be used at Allina. If Non-approved products are used at Allina the price paid for such unit will not exceed one dollar.

This policy will include all new products and technologies where "new" is defined as: Any Product that has not been used at the requesting Allina facility; including new generations of products that have been used at an Allina facility. The policy does not apply to new FDA approved substitutes for discontinued existing products if such substitutes do not offer new features or functionality

The policy applies to all Allina employees, medical staff (employed and affiliated) and suppliers doing business at Allina Health.

Purpose: 1) To establish processes enabling Allina to serve its patients through the acquisition of safe and clinically effective products and services at the most economical terms, 2) to work efficiently with our business partners to ensure the appropriate quality and quantity of products or services, and 3) to ensure supply-related operational and financial Considerations are addressed prior to use of new products.

DEFINITIONS: (Optional)

PROCEDURES:

Allina staff interested in having a product or technology reviewed for use at Allina will contact the Program Director at the Allina facility or the relevant Sourcing Manager/Senior Buyer at Allina Supply Chain Management. The Program Director, sponsoring physician, and Supply Chain Management will work together to acquire the information required for the review process.

Any Allina staff member (employees and affiliated physicians) may request new product reviews. Requests will not be accepted directly from suppliers without an Allina staff sponsor. Suppliers will be asked to assist in the completion of the New Product Request Form and/or vendor questionnaire. Supply Chain Management will manage the status of all requests to ensure expedited processing of all requests. Completed Request Forms, related documents, and Review Decisions will be retained by Supply Chain Management.

A New Product Review (NPR) Request form must be submitted through the specified on-line NPR software tool. Requestors are encouraged to forward supporting literature and reference contacts to Supply Chain Management.

As needed, a New Product Financial Impact Summary (FIS) will be distributed by Supply Chain Management to the appropriate New Product Review Committee, who will review the requests.

Products will not be allowed to be used until the New Product Review process has been completed. Expedited, one-time use approval may be obtained from the Vice President of Medical Affairs, Clinical Leadership Team executive, or their delegates if there is a unique patient circumstance that would justify such approval. If the Review Team determines that a trial will be authorized, the supplier will be asked to keep the cost of the trial item from exceeding the cost of the existing product(s) during the trial. If a product is brought in for use at Allina

without proper approval and without an agreed upon price, Allina will pay $1 for the product.

Reporting of the use of unapproved products, other than for the purpose of a formal trial or approved expedited/limited use, is the responsibility of all Allina staff. Reports should be directed to the Program Director, Clinical Service Line Manager, or their immediate supervisor.

Communication to the suppliers regarding new product decisions and implementation of new products will be the responsibility of Supply Chain Management.

Violations of this policy may lead to the suspension of the Supplier Representative's access to Allina facilities.

PROTOCOL: (optional) LINK

FORMS: (optional) LINK

ALGORITHM: (optional) LINK

ADDENDUMS: (optional) LINK

FAQ's (optional) LINK

REFERENCES:

Related Regulation and Laws:

Alternate Search Terms:

Related Policies:

Name of Policy	Content ID	Business Unit where Originated
Ethical Relationships with Industry	Ref #: 402-01.43	Corporate Compliance

Policies Replacing:

Name of Policy	Content ID	Business Unit where Originated