LEGACY HEALTH SYSTEM

MATERIAL SERVICES

Policy #: LHS.800.17
Origination Date: 1/05
Last Revision 03/13
Next Review Date: 03/16

SUBJECT: New Supply and Equipment Procurement Policy

INTRODUCTION

Legacy Health is committed to providing high quality patient care, a safe environment for patients and employees, encouragement and support for clinical innovation while operating efficiently and within approved budgets.

A. PURPOSE

The purpose of this policy to is to ensure that new supplies and equipment are properly evaluated with respect to safety, efficacy, cost and reimbursement prior to being allowed for use.. This policy supports Legacy Health's operational and strategic objectives to:

1. Ensure quality patient care while ensuring staff and patient safety.
2. Standardize products and equipment system wide where possible
3. Leverage spend by contracting with carefully chosen, highly qualified supplier partners.
4. Establish productive working relationships among physicians, clinicians and administrative staff that support clinical innovation through collaborative decision making.
5. . Manage supply costs to budgets and improve margins whenever possible.

B. SCOPE

This policy applies to all requests for new clinical supplies and equipment, including capital equipment.

C. DEFINITIONS

FDA	Food and Drug Administration
Equipment or Product Standard	Product or equipment that is the preferred product or equipment for use within Legacy facilities as evidenced by contract, volume of purchases and/or clinical or user consensus.
New Product	Equipment or supply items that have not been previously approved for continuous use within Legacy Hospitals

New Supplier	A supplier that 1) has never done business with Legacy before or 2) has never provided the product/equipment under consideration before.
New Technology	A product or item of equipment that incorporates significant changes from its predecessor or is technology that has not previously been available on the health care market • New technology may require a change in procedure methodology and/or require credentialing • May have no established reimbursement Item or use of item is subject to an investigational device exemption (IDE) and therefore FDA allows use of the item only through an IRB protocol.
New Technology Assessment Committee	A Legacy cross-functional committee, physician or physician and/or clinical panel chartered with assessing new clinical technology.
PSP	Patient Specific Product
Value Analysis Executive Steering Committee	❑ A cross-functional board chartered as the final arbiter for approval of new products and system-wide standards that cannot be resolved by the value analysis process or require executive approval as determined by LH 800.17 ❑ Provides strategic direction, advocacy, and performance oversight of the Legacy Health Value Analysis program. .
IRB	Institutional Review Board
HDE	Humanitarian Device Exemption
IDE	Investigational Device Exemption

D. POLICY

REQUESTS AND INVESTIGATION

1. All requests for new clinical supplies and equipment will be initiated through the established new supply and equipment process as outlined in this policy. All requests for exceptions to this process must be reviewed and approved by the Director of Supply Chain Management, Director of Value Analysis and the Value Analysis Executive Steering Committee. All policy and process exceptions must be documented and approved for compliance and auditability,

All supply and equipment decisions will be made with respect to the whole of Legacy. All requests for new clinical supplies or equipment will first be referred to, and reviewed by, the appropriate Value Analysis Council or if none exists, an appropriate ad hoc committee that represent all stakeholders
Understanding clinical rationale for a product or equipment request is imperative to good decision-making. Physician, clinician and stakeholder input must be solicited and documented with every new product request prior to submittal of recommendation to purchase. A limited trial or evaluation may be conducted to validate clinical efficacy prior to forming a recommendation. Clinical Value Analysis and Supply Chain Management will facilitate the evaluations in accordance with policy LHS 800.03 Product Evaluation Policy

2. All new products and new suppliers must be reviewed by Legacy's Strategic Sourcing and Supply Chain Quality Departments prior to use. ; Screenings will include, but not limited to, FDA status, technical (capability and design), quality and safety reviews, supplier qualification and contract compliance status. Single exceptions to these e.g. emergent requirements require the prior approval of the Director of Supply Chain management.

3. In parallel with the Supply Chain reviews, Legacy's Information Services department must review any new product that will collect and store protected health information, access the Legacy network or interface with existing hardware or software. This is to ensure compatibility with existing systems, determine interface and/or interoperability requirements, ensure all such equipment is HIPAA compliant and assess support requirements as applicable. **Similarly, Clinical Engineering must review all requests for new capital equipment and select minor equipment to assess maintenance requirements and strategy.**

4.

.**APPROVALS**

1. After all reviews and evaluations are complete, a decision , to approve new products or equipment can be made by the by the respective Value Analysis Committee if:
    i. Addition of the supply or equipment is a result of an executive sanctioned patient care, safety or quality improvement initiative. Outcomes and financial impacts will be noted and tracked.
    ii. Reimbursement is established. Financial impact to margin is positive, neutral or has a negligible adverse impact to case cost.
    iii. Item is more expensive but other supply items are discontinued or reduced with a resulting neutral or positive impact on case cost and margin.
    iv. Does not result in a negative impact on existing contract compliance resulting in higher costs across the system.
    v. Does not represent a deviation from an established Legacy supply or equipment standard, or is intended to replace an existing standard.
    vi. Is capital equipment that introduces a significant new supply expense that can be managed within existing budgets.****
    vii. Approval will not result in a negative annual budget variance for Legacy at the general ledger line level..

viii. Item under consideration does not have an IDE or HDE designation or has and IDE or HDE designation and has received IRB approval (LHS 100.84 Tracking and Billing for Investigational Devices and Humanitarian Use Devices within Legacy Health System).
ix. The item is not new technology or is new technology and has been approved for use by the New Technology Committee, a designated physician liaison or physician panel.
x. Physician credentialing is not required.
xi. Item is requested for use as per FDA approval (is not being requested for off-label use)

2. All product or equipment requests that exceed the authority detailed in Section 1 must be presented to Value Analysis Executive Steering Committee for final determination. All requests must be submitted via a written synopsis of the clinical and financial considerations prepared with the collaboration and oversight of the requester, Value Analysis Council and Executive sponsor if applicable. A pro-forma may be required.

3. Clinical Value Analysis and Supply Chain Management will coordinate and facilitate all requests for submission to the Value Analysis Executive Steering Committee for consideration and decision.

   The Value Analysis Executive Steering Committee may pend a decision and may request additional information as necessary to gain clarification or may conduct further discussion as deemed necessary based on the complexity of the request.

   In the event a pending supply or equipment recommendation is determined to have a potentially negative impact, clinically or budgetary to another department or Legacy as a whole the product request will be escalated to the Value Analysis Steering Committee whereby the requestor will present the rationale for approval Mitigation strategies will be discussed and final approval will rest with the Steering Committee.

   Approval by the Value Analysis Executive Steering Committee for new products or equipment may be subject to completion of a formal evaluation per LHS 800.03 Product Evaluation Policy or may be provisional if approval is subject to realization of costs, quality, and utilization or outcome assumptions. Results of the evaluation, status reports, outcome updates as stipulated in the provisional approval will be presented to the Value Analysis Executive Steering Committee for final decision.

   If, in the judgment of the Value Analysis Executive Steering Committee further review or executive oversight is necessary, the request may be escalated to the Legacy Executive Council for final decision making.

REPORTING

Value Analysis Councils will establish annual cost and quality improvement goals as part of the strategic planning and budgeting cycle. On a quarterly basis, the Value Analysis Councils will submit or present to Operations Council and Value Analysis Executive Steering Committee a

report on progress to goals, activities, issues and accomplishments to the Value Analysis Steering Committee. .

All Legacy employees are responsible for managing the introduction of new products within the guidelines outlined in this policy. Non-adherence to this policy may result in corrective action.

Approval: Materials Management
Clinical Value Analysis
Executives Council,
Originator: *Director, Supply Chain Management*