

Sanford New Product Introduction Process information

Sanford continually assesses new technology to improve clinical outcomes and patient care. To assist in managing the thousands of new products introduced in the market place each year the following guidelines are utilized to ensure clinicians are not constantly burdened with product conversions that do not result in improved patient care.

Revolutionary Products – Defined as new products that have recent FDA approval. These products have the greatest potential to greatly advance medical treatment. Sanford Health considers these types of products for evaluation at the request of Physicians. Physicians conduct initial product screening and request review by the standing Clinical Value Analysis Committees (VAT).

Evolutionary Products – All non-510(k) and IRB "me too" products new to the marketplace. These supplies and technology typically provide only minor or modest modifications to enhance existing products or company marketing strategies. Sanford reviews these types of products during regular supply contracting process to allow structured clinical evaluations, decision-making, staff education, and cost containment. Sanford Clinical Value Analysis Teams will only assess these types of products when requested by a Physician.

Value Analysis Teams (VAT) – Sanford Health strives to maintain a structured process to review the appropriateness of acquisition of supplies, equipment, and purchased services. Sanford VAT is charged with evaluating potential new purchases with a stringent value oriented methodology. The following components comprise this VAT value assessment:

- ~ Safety for Patient and Staff
- ~ Product Quality and Durability
- ~ Effectiveness
- ~ Comparison to Competitors Equivalent Products ~ Clinical Trials
- ~ Independent (or Company) Research, Studies and References
- ~ Education and Training Requirements
- ~ Ease of Use / Operation
- ~ Service and Repair
- ~ Product Availability, Storability, and Shelf Life
- ~ Infection Control
- ~ Cost and Value to Patient
- ~ Any Other Special Considerations

Under no circumstances will vendors introduce any new products or services without VAT approval. Doing so jeopardizes patient safety. In the event a vendor brings in a new product without VAT approval, Sanford Health nor with the patient be responsible for payment. Vendors will be provided with donation documentation for the product(s) and referred to Supply Chain Management for disciplinary action per the Sanford Vendor Relations and Certification Policy.

Sanford Health welcomes the opportunity to work with vendors to expedite the implementation of the most promising new technology to our patients.