Administrative Manual
Clinical Quality Product Value Analysis Policy

Objective / STATEMENT OF PURPOSE:

Clinical Quality Product Value Analysis (CQPVA) provides a framework and structure for the introduction, evaluation, standardization and utilization of products, new technology, and services at Covenant HealthCare.

Policy:

All products used at Covenant HealthCare will be subject to this policy. Any product introduced without a purchase order and/or prior approval through the CQPVA will be considered a gift.

Decisions made through the CQPVA process will include:

- Clinical problem evaluation and product criteria identification.
- Analysis of new products prior to adoption.
- Documentation of clinical soundness for new products.
- Analysis of cost reduction opportunities achieved through supply standardization, utilization, and process improvement.
- Cost impact/return on investment analyses.

Key areas that use the CQPVA process include, but are not limited to:

- Cardiovascular Services
- Interventional Radiology/Imaging
- Surgical Services
- Laboratory
- Pulmonary/Respiratory
- Emergency Department
- Nursing Services
- Support services area

The CQPVA Team's function is to review and evaluate products, and services for utilization that will best meet the needs of patients and staff at Covenant HealthCare. Major components of the process include:

- Selection of products/services that meet or exceed requirements of performance, quality, safety, and cost effectiveness.
- Reduction of cost through contract negotiations, standardization and proper utilization of products, services and equipment.
- Measurement of clinical and financial outcomes as appropriate for selected items.

Clinical Quality Product Value Analysis Processes

New Initiative or Product Request

- All new initiative and product requests must go through the Clinical Quality Product Value Analysis process prior to use at Covenant HealthCare.
- Exceptions to this policy will be:
  - Investigational drugs and devices that are being evaluated through the Institutional Review Board (IRB) process.
  - Replacement parts for existing equipment.
- All new initiative and product requests should be routed directly to the CQPVA Administrator for initial review.

Clinical Quality Product Value Analysis Evaluation

- The CQPVA Administrator will assign a CQPVA Team to evaluate and document the following in the course of its deliberations:
  - Clinical need or problem to be solved
  - Documentation of current product related issue
  - Reason for request
  - Stakeholder input
  - Objective clinical requirements
  - Evaluation/validation documentation (see detail below)
  - Pre and post clinical measurements for the evaluation/validation to ensure predicted outcomes
  - Related research or regulatory requirements
  - Education needs related to validation and/or implementation
  - All communication
  - Financial impact
- CQPVA documents have been provided to assist with documentation. If an area of documentation is not relevant to the particular initiative evaluation the team should indicate that the area does not apply.
- Attachments can be added to the CQPVA documentation as needed for any given evaluation.
- Once a full evaluation has been completed, the CQPVA Team will develop a recommendation related to the initiative request; this can include a full or limited adoption, postponement, decline, etc. and present to the Steering team for final approval.

Evaluation/Validation

- In the event that a product validation is needed, the following will be in place prior to initiation of the validation:
  - All participants have been properly trained and in-serviced.
  - Vendors will not participate in validations.
  - An evaluation form containing objective non-financial criteria will be developed, evaluation timeframe defined, and methodology approved by the CQPVA Team.
  - Appropriate safety checks will be conducted by individual departments.

Final Decision Process

- The recommendation from the CQPVA Team will be sent to the Steering team for a final decision.
- The CQPVA Administrator will communicate the outcome to the original requestor.

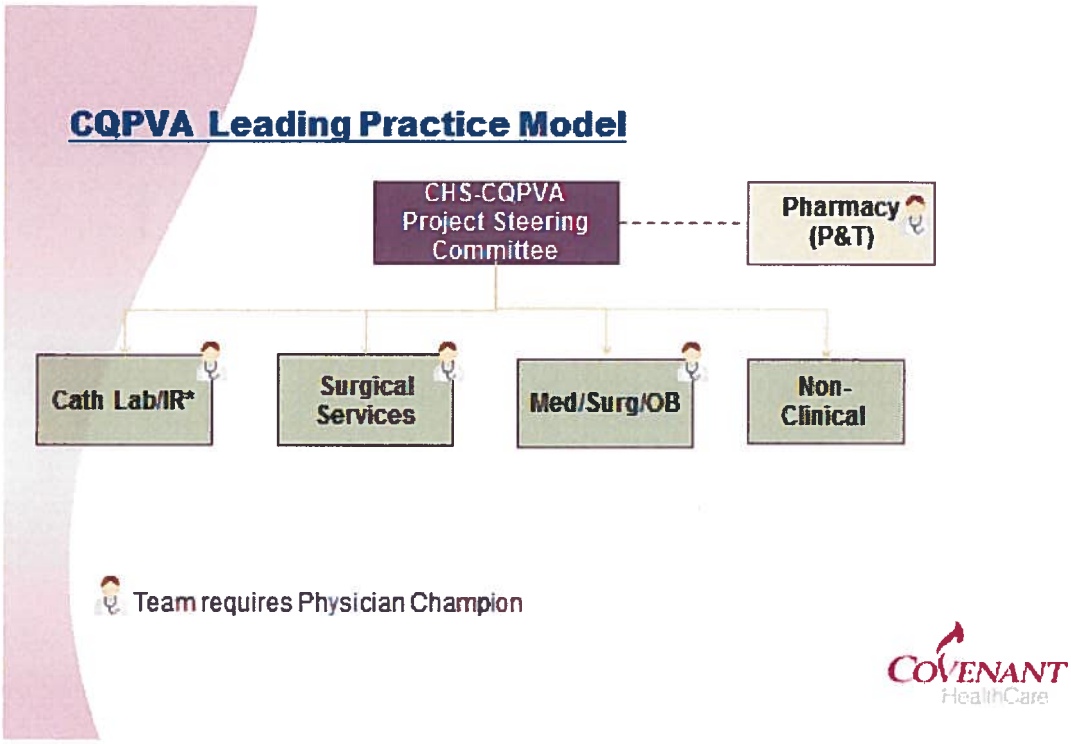
Initiative Implementation

- The Director of Supply Chain Management will note and coordinate changes as follows:
  - Negotiate and obtain best possible pricing and service based upon a bid and/or group purchasing contract and/or benchmark data to be obtained by Supply Chain Management.
  - Place item in Item Master per policy and procedure.
  - Place item into other databases as required.
- The CQPVA Administrator
  - The Coordinate acquisition of item or service in collaboration with the CQPVA team.
  - CQPVA Team leader will place savings on the team monthly report.
- The CQPVA Team or team leader will coordinate the following:
  - Conduct follow up utilization measurement to validate actual versus predicted use.
  - The CQPVA Team leader will place savings on the team monthly report.
  - The CQPVA Team will manage the conversion checklist to ensure a full and timely conversion of products.

Emergency Product Approval for One Time Use

- The Director of Supply Chain Management will be notified when a product is being requested for a one time or emergency need.
- Emergency use will be considered for consumable and or clinical products requested for an urgent patient need with possible adverse clinical outcome if not made available.
- The use of the Emergency product can also be approved by a senior administrator prior to use.
- A record will be kept for each request to include the vendor, product, physician, rational for use, and approving administrator.
- Any product used within Covenant HealthCare for an emergency situation will be automatically submitted to the CQPVA process for evaluation.
- Products that are introduced through the Emergency product process will be considered a donation to the organization and will not be billed to the patient or their insurance provider unless the product is ordered by Supply Chain Management one week prior to the procedure.
- Emergency use will not be utilized to "try" a product prior to submitting to CQPVA process.

Clinical Quality Product Value Analysis Organizational Structure



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