CAHIR MEDTECH · EXECUTIVE BRIEF

Hospital VAC Dossier Pack: executive brief

What hospital Value Analysis Committees (VACs) review before they buy a new device, and how the Cahir MedTech VAC Dossier Pack organizes the evidence, budget impact and stakeholder work.

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Why it matters

FDA clearance or approval allows a device to be marketed. It does not mean hospitals will buy it. Most hospitals send new products to a Value Analysis Committee, often clinicians, supply chain and finance, before purchase.

A complete, honest dossier shortens review and keeps every claim within the cleared or approved indications.

The ten dossier elements

Element	What the committee expects	Typical evidence
Product summary	Indication, regulatory status and how it differs from current practice.	One-page VAC submission
Regulatory status	Clearance or approval letter and labeled indications.	FDA database record
Clinical evidence	Key studies with design, population, endpoints and limitations.	Evidence dossier
Safety profile	Adverse events and recalls disclosed accurately.	FDA MAUDE and recall databases
Economic impact	Budget impact using the hospital's own volumes and costs.	Budget Impact sheet
Coding and reimbursement	Codes and payment by setting, with uncertainty stated.	Reimbursement summary
Workflow and training	Training, setup time and workflow changes.	Implementation plan
Supply chain and contracting	Pricing, GPO status, lead times and returns terms.	Contracting terms
Clinical champion	Requesting physician and department, with rationale.	VAC request form
Trial or evaluation plan	Evaluation period, success metrics and review date.	Evaluation plan

What the workbook adds

- **Budget impact:** for each cost element, annual impact = (current cost per case – new cost per case) × annual cases. Positive values are savings. Use hospital data and name the source of every number.
- **Stakeholder map and objection log:** record each committee member's main concern and the evidence-based response, so follow-up is consistent.
- **Device-type checks:** extra prompts for software (IT security, SBOM, data privacy), diagnostics (lab validation, CLIA), implants (surgeon evidence, inventory model), capital equipment (total cost of ownership, biomedical engineering) and consumables (conversion, standardization savings).

Official sources

- FDA medical device databases
- FDA MAUDE database
- CMS Medicare Coverage Database

Workbook + guide · $299 USD one-time · Applicable taxes may apply. Companion guide: https://medtech.cahir.ai/go-to-market-guide · Toolkit dashboard: https://medtech.cahir.ai/workspace

Planning aid, not legal, coding or reimbursement advice. Confirm current cycles and requirements on official CMS, AMA and FDA pages.