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AHVAP POSITION STATEMENT ON STANDARDIZED PRODUCT REVIEW PROCESS

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As healthcare organizations strive to deliver the highest quality care while maintaining cost efficiency, the need for effective, evidence-based decision-making in product selection has never been more critical. The Association of Healthcare Value Analysis Professionals (AHVAP) recognizes that a standardized, systematic process for product evaluation is essential to support the strategic objectives of healthcare providers and ensure patient safety, clinical effectiveness, and financial sustainability. As a healthcare value analysis profession, we are committed to implementing a three-tier product evaluation framework that ensures timely, efficient, and patient-centered decision-making that is rooted on available evidence-based information, clinical guidelines and recommendations, and known best practices. This approach enables the specialty to differentiate between non-complex and complex requests, ensuring that each new product request receives an appropriate level of review. The focus of this Position Statement is to provide systematic guidance for the evaluation of all new products through **clinical, operational, and financial lenses**, with the patient remaining at the center of every decision made in healthcare value analysis.

A consistent, standardized approach to product evaluation allows for the objective assessment of new and existing products, ensuring that purchasing decisions are grounded in clinical outcomes, cost-effectiveness, and long-term value. By establishing clear, repeatable processes for evaluating medical devices, supplies, pharmaceuticals, and other healthcare products, organizations can minimize variability in decision-making, reduce waste, and drive more predictable and transparent outcomes. AHVAP is committed to advancing the practice of value analysis by promoting the adoption of these processes across the healthcare continuum, thereby empowering healthcare professionals to make well-informed, value-driven decisions that enhance both patient care and operational performance.

When evaluating a new product or technology, it is helpful to establish a product/technology champion within the targeted departments for implementation to facilitate a successful evaluation and potential implementation. Below is a standardized three-tier product evaluation framework that serves as a best practice for all healthcare facilities and industry partners to utilize when conducting a new product review in any setting. The timelines outlined below do not include the implementation of a new product, although we strongly recommend expeditious implementation to ensure that healthcare resources are managed appropriately, and patients can benefit as quickly as possible from new interventions and technologies.

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Three-Tier Product Evaluation Framework

Tier 1: Low Complexity Product Request

These requests involve products with minimal patient care impact which are generally considered commodities. The goal is to quickly evaluate and implement medical products of low complexity that have minimal if any impact to patient care. These products should be expedited through the healthcare value analysis process. Items within this category should be evaluated within **30 Days or Less**. There is generally no need to trial or evaluate products falling into this category. Products in this category will typically be evaluated by clinical end users through the review of a product sample to determine functional equivalence and clinical acceptability.

Examples of Low Complexity Items May Include the Following:

- Urinals
- Bandages
- Water Pitchers
- Incise Drapes
- Oxygen and Suction Tubing

Evaluation Process for Tier 1:

1. **Request Submission:**
   Submit through the institution's value analysis portal/process with product details, supporting product documentation, and pricing.

2. **Preliminary Review:**
   Initial screening by healthcare value analysis team and clinical representatives for completeness of submission. Review by value analysis team to determine Tier 1 classification is appropriate.

3. **Vendor and Data Comparison:**
   Review vendor history, usage data, and existing contracts.

4. **Rapid Clinical Review:**
   Confirm clinical appropriateness with limited stakeholder involvement (e.g., nurse, physician) and product sample to ensure clinical acceptability.

5. **Operational and Financial Impact Assessment:**
   Ensure the product aligns with current workflows and budgets.

6. **Decision and Communication:**
   Complete evaluation within 30 days. Communicate the outcome to stakeholders.

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Tier 2: Moderate Complexity Product Requests

These requests involve products with well-established usage and minimal clinical, operational, or financial impact. The goal is to **streamline the evaluation process** to enable fast decisions that support care delivery without unnecessary delays. Items within this category should be evaluated within **90 Days or Less**. A **focused trial** may be warranted in limited scenarios.

Examples of Moderate Complexity Items May Include the Following:

- Safety Venipuncture Collection Supplies
- Nasal Canula and Oxygen Delivery Masks
- Non-specialized gloves and masks
- Syringes and dressings
- Basic patient hygiene products
- Generic pharmaceuticals

Evaluation Process for Tier 2:

1. **Request Submission:**
   Submit through the institution's value analysis portal/process with product details, supporting product documentation, and pricing.

2. **Preliminary Review:**
   Initial screening by healthcare value analysis team for completeness of submission. Review by value analysis team to determine Tier 2 classification is appropriate.

3. **Vendor and Data Comparison:**
   Review vendor history, usage data, and existing contracts.

4. **Conduct Product Trial if Needed:**
   Conduct product trial if necessary. Review relevant peer-reviewed literature and clinical guidelines to ensure compliance.

5. **Operational and Financial Impact Assessment:**
   Ensure the product aligns with current workflows and budgets.

6. **Decision and Communication:**
   Complete evaluation within **90 days**. Communicate the outcome to stakeholders.

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Tier 3: High Complexity Product Requests

These requests involve products that may bring significant clinical innovation, require operational changes, or involve major financial investment. Items within this category should be evaluated within **120 Days or Less**. This tier necessitates a **detailed, multi-disciplinary review** to assess all implications effectively.

Examples of High Complexity Items May Include the Following:

- Peripheral Intravenous catheters
- Surgical robots or AI-powered diagnostic tools
- Implantable devices (e.g., cardiac stents, neurostimulators)
- Specialty pharmaceuticals (e.g., biologics, gene therapies)
- Ventilators
- Anesthesia Machines
- Medical equipment requiring infrastructure changes (e.g., CT, MRI machines)
- Any Device requiring a full human factors-validated review
- Products requiring new policies, workflows, human factors-validation, and/or staff training*

**Refer to the Food and Drug Administration Guidance on Applying Human Factors and Usability Engineering to Medical Devices*

Evaluation Process for Tier 3:

1. **Request Submission:**
   Submit product request through the institution's value analysis portal/process with comprehensive documentation (clinical studies, regulatory approvals, and cost details) and pricing.
2. **Preliminary Screening:**
   Initial screening by healthcare value analysis team for completeness of submission. Review by value analysis team to determine Tier 3 classification is appropriate.
3. **Stakeholder Engagement:**
   Assemble a multidisciplinary team (clinicians, finance, operations, supply chain, IT) to assess product impact.
4. **Conduct Product Evaluation if Needed:**
   If required, conduct product evaluation to assess patient outcomes and operational impact. Review relevant peer-reviewed literature and clinical guidelines to ensure compliance.
5. **Operational and Financial Modeling:**
   Evaluate changes to workflows, infrastructure, and long-term financial feasibility (e.g., ROI analysis, total cost of ownership).
6. **Formal Review and Approval:**
   Submit findings to value analysis committee or executive leadership.
7. **Decision and Communication:**
   Complete review and decision-making within **120 days**. Document outcomes and communicate the decision to all stakeholders.

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Guiding Principles for All Tiers

1. **Patient-Centered Focus:**
   The patient's safety, outcomes, and experience remain the highest priority.

2. **Triple-Lens Framework:**
   All decisions are evaluated through clinical, operational, and financial perspectives to ensure holistic alignment and adequate protection of the patient and healthcare team.

3. **Collaborative and Transparent Process:**
   Clear communication and collaboration across all departments ensure consistency, accountability, and alignment with institutional goals.

4. **Data-Driven Decisions:**
   Utilize evidence-based data, clinical trials, and usage patterns to support informed decision-making.

5. **Continuous Improvement:**
   Monitor product outcomes post-implementation to assess if initial expectations were met and identify areas for process refinement.

6. **Transparent and Proactive Communication:**
   Effective communication to all stakeholders regarding product change must take place to prevent breakdowns in care delivery and potential patient harm. AHVAP Industry Partners should be evaluated using the metrics outlined in the AHVAP Position Statement: Becoming a Strategic Industry Partner.

7. **Financial Stewardship/Fiscal Responsibility:**
   Financial Stewardship in healthcare value analysis is the commitment to managing an organization's financial resources in a way that maximizes their impact on patient outcomes and overall healthcare value. It involves taking a long-term, strategic view of resource allocation to ensure sustainable investment in products, services, and technologies that benefit both the organization and the patients it serves. Financial stewardship goes beyond mere cost-cutting to include practices that enhance value through efficiency, effectiveness, and innovation, ensuring that resources are used ethically and responsibly. By practicing financial stewardship, healthcare value analysis professionals aim to optimize resources in a way that supports organizational goals, advances patient care, and promotes trust and accountability within the healthcare system.

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Key Stakeholders in the Healthcare Value Analysis Process

A successful healthcare value analysis process requires collaboration among diverse stakeholders to ensure that all perspectives—clinical, operational, financial, and patient-centered—are adequately represented. Engaging the right stakeholders throughout the evaluation ensures informed decision-making, alignment with organizational goals, and optimized patient outcomes.

- **Clinical stakeholders**, such as physicians, nurses, pharmacists, and allied health professionals, play a critical role in evaluating the safety, efficacy, and clinical appropriateness of new products. Their expertise is essential to determine whether a product meets clinical standards, enhances patient care, and integrates seamlessly into existing treatment protocols. Specialty clinicians may be involved for more complex products like implants or advanced diagnostic equipment.

- **Operational stakeholders**, including supply chain professionals, clinical informatics staff, and department managers, are vital for assessing workflow impacts, implementation feasibility, and product logistics. They help identify potential bottlenecks and ensure that new products align with operational processes. For technology-driven products, IT involvement is necessary to evaluate system integration and data management requirements.

- **Financial stakeholders**, such as finance officers, reimbursement specialists, and procurement teams, focus on cost-effectiveness, return on investment (ROI), and budget alignment. Their role is essential in evaluating the total cost of ownership, reimbursement potential, and financial sustainability. Their input ensures that new product decisions contribute to the organization's long-term financial health without compromising patient care.

- **Leadership and governance teams**, including value analysis committees, executives, and quality assurance professionals, provide oversight and strategic alignment. They ensure that product decisions align with the organization's broader goals, quality standards, and compliance requirements. Leadership involvement is particularly crucial for complex products requiring significant financial investment or operational changes.

- **Patients and patient advocates** should be considered when relevant to provide a firsthand perspective on care experiences. Their input ensures that new products truly meet the needs of the populations served, promoting patient-centered care and trust.

By involving these key stakeholders in the value analysis process, healthcare organizations ensure thorough, balanced evaluations that drive innovation, optimize outcomes, and promote efficient resource use. This collaborative approach fosters accountability and transparency, ensuring that every product decision supports the organization's mission of delivering high-quality, patient-centered care.

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Ensuring Fair Evaluation and Minimizing Conflicts of Interest in Medical Product Evaluations

Evaluating medical products in a transparent and unbiased manner is essential to ensuring that healthcare decisions are based on clinical evidence, operational feasibility, and financial sustainability. **Mitigating conflicts of interest (COI)** and **fairly evaluating clinical evidence** helps protect the integrity of the healthcare value analysis process, promotes trust, and ensures that patient care remains the central focus.

Strategies to Minimize Conflicts of Interest:

1. **Disclosure of Conflicts of Interest:**
   All stakeholders involved in the product evaluation process—especially clinicians, committee members, and vendors—must disclose any financial, personal, or professional relationships that could influence their recommendations. A standardized disclosure form should be required at the beginning of each evaluation.

2. **Independent Review Committees:**
   Establishing **multidisciplinary value analysis committees** ensures that no single individual or department can unduly influence the decision. Committee members should come from different specialties and departments, ensuring diversity of thought and impartiality.

3. **Rotation of Stakeholders:**
   To prevent the development of biases over time, **committee memberships and leadership roles** should be rotated periodically. This practice helps maintain a fresh and objective perspective during evaluations.

4. **Industry Partner/Vendor Management Policies:**
   Industry Partner/Vendor interactions should be governed by **strict protocols** to avoid undue influence. These policies might include prohibiting gifts, restricting sponsored events, and limiting one-on-one meetings between Industry Partner/vendors and decision-makers.

5. **Blinded Evaluation Process:**
   When feasible, anonymize product information (e.g., brand names) to focus solely on the **clinical, operational, and financial performance** during the initial review stages. This helps reduce brand-related biases.

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Fair Evaluation of Clinical Evidence

1. **Require Peer-Reviewed and High-Quality Evidence:**
   Only clinical studies published in **peer-reviewed journals** or data from recognized healthcare research organizations (e.g., Cochrane, NICE) should be considered. Studies funded by manufacturers should be critically evaluated to assess potential bias.

2. **Use Standardized Evaluation Criteria:**
   Develop **checklists or scoring tools** to objectively assess clinical evidence, ensuring consistency across product evaluations. Key factors might include patient outcomes, safety, effectiveness, and ease of use.

3. **Incorporate Evidence Hierarchy:**
   Follow an **evidence-based framework** (e.g., GRADE system), giving higher weight to randomized controlled trials (RCTs) and systematic reviews while treating observational studies and manufacturer-sponsored research with caution.

4. **Seek Input from External Experts or Third Parties:**
   In complex or controversial cases, **external experts or independent advisory panels** can be consulted to provide an unbiased, third-party review of the clinical evidence.

5. **Pilot Programs and Real-World Evidence:**
   When appropriate, conduct **pilot programs or trials** to generate institution-specific data on how the product performs in real-world settings. This allows for an evidence-based assessment tailored to the organization's patient population and clinical practices.

Monitoring and Transparency

1. **Audit and Feedback Mechanism:**
   Periodically **audit product evaluation decisions** to ensure adherence to policies and identify any areas of improvement. Provide feedback to stakeholders on their role in the evaluation process.

2. **Transparency and Documentation:**
   All evaluation steps, including stakeholder input, clinical evidence assessments, and final decisions, should be **thoroughly documented and made available** to appropriate stakeholders. Transparency ensures accountability and builds trust in the process.

By following these strategies, healthcare organizations can minimize conflicts of interest, fairly evaluate clinical evidence, and ensure that product decisions are guided by **what is best for patients, aligned with operational goals, and financially sound**. This structured approach promotes ethical decision-making and strengthens the integrity of the healthcare value analysis process.

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How to Manage Delays and Roadblocks for Product Evaluation Samples

Healthcare value analysis professionals play a critical role in ensuring product evaluations are conducted efficiently and without unnecessary delays, especially when product sample availability may be limited or delayed. Product evaluations and trials, however, can be delayed due to unavailability of product samples from the manufacturer or lack of timely response from the Industry Partner personnel. These delays will hinder the ability for the evaluation process to remain on track. Here are effective strategies to manage and mitigate product sample delays during a new product evaluation:

1, Develop a Clear Evaluation Timeline with Contingencies

- **Set Realistic Timelines:** Establish a realistic evaluation timeline that includes buffer time to account for potential delays. Timelines detailed above are contingent upon the product evaluation and/or trial being completed in a timely fashion as to not lengthen the value analysis evaluation process.
- **Plan for Contingencies:** Anticipate possible delays and create a contingency plan to address them. This could involve early discussions with Industry Partners/Vendors regarding sample availability, anticipated lead times, and potential delays.

2. Communicate Early and Consistently with Industry Partners/Vendors

- **Engage Suppliers Proactively:** Begin conversations with Industry Partners/Vendors well in advance to understand potential supply chain issues, including production and shipping constraints. Healthcare value analysis professionals should establish their preferred distribution channel that can facilitate the product's delivery as needed.
- **Request Updates:** Maintain regular communication with the Industry Partners/Vendors to stay informed about the sample's status and any changes in delivery timelines. This proactive approach allows for quick adaptation to changes and helps prevent last-minute surprises.

3. Identify Alternative Evaluation Methods

- **Leverage Existing Data:** If sample delays are unavoidable, review available clinical data, case studies, and peer-reviewed research on the product's performance. This secondary information can provide insights that inform decision-making until physical samples arrive.
- **Conduct Virtual Product Demos:** Request virtual demonstrations from Industry Partners/Vendors or live-streamed walkthroughs of the product's use, which can offer valuable insight for stakeholders involved in the evaluation.

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4, **Prioritize Product Evaluation Criteria**

- **Determine Critical Factors:** Identify the most critical evaluation criteria for the product. For instance, if certain aspects (e.g., ergonomics, durability) require hands-on assessment, prioritize these elements once samples are available, focusing on preliminary reviews in the interim.
- **Use Comparable Products:** If the product is a newer version or has similar features to an existing product, consider evaluating comparable items to address non-unique aspects of performance while awaiting the sample.

5. **Engage Interdisciplinary Teams for Initial Assessment**

- **Involve Stakeholders Early:** Convene an interdisciplinary team, including clinicians, supply chain experts, and end users, to review the product's specifications, benefits, and projected outcomes before the sample arrives. Their expertise can help establish a strong preliminary understanding of the product.
- **Gather Feedback and Set Expectations:** Collect input on the most critical evaluation areas so that once samples arrive, the assessment can proceed efficiently with clear focus areas identified.

6. **Negotiate Partial Sample Shipments if Possible**

- **Request Partial Samples:** If possible, negotiate with suppliers to send partial shipments of the product. For multi-unit products, securing just one or two units can allow for initial testing while awaiting the full shipment, reducing potential delays.
- **Set Expectations for Full Delivery:** Establish expectations for when the full shipment will arrive and plan a phased evaluation if the sample is essential to completing the process.

7. **Keep the Evaluation Team Informed of Changes**

- **Maintain Transparent Communication:** Notify all relevant stakeholders of any anticipated delays and revised timelines. Providing regular updates ensures that the team remains aligned and that resources are scheduled effectively.
- **Reschedule as Needed:** If there are significant delays, consider rescheduling parts of the evaluation to avoid impacting other projects or creating gaps in product availability.

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8. **Document Delays and Adjust Timelines Accordingly**

   - **Track Delays and Impact:** Document each delay and its impact on the overall evaluation timeline. This record can be useful for future planning, as well as for discussions with suppliers regarding any recurring issues or potential improvements.
   - **Revise the Timeline:** Adjust the project timeline and expectations as delays occur, making sure to communicate changes clearly to avoid confusion and keep the project moving forward.

By employing these strategies, healthcare value analysis professionals can effectively manage product sample delays and ensure evaluations are completed as efficiently as possible. This proactive approach minimizes disruption, maintains alignment with organizational objectives, and helps secure the most appropriate products to support quality patient care.

Key Terminology:

In healthcare value analysis, **product sample, trial**, and **evaluation** are distinct stages in the process of assessing new products for use within an organization. Here's a breakdown of each:

1. **Product Sample**

   - **Definition:** A product sample is a single unit or limited quantity of a product provided by the vendor for initial inspection, examination, and basic assessment.
   - **Purpose:** The sample allows value analysis professionals, clinicians, and other stakeholders to get a hands-on look and feel of the product, examine its design, materials, and basic functionality.
   - **Scope:** The sample stage does not typically involve active use with patients or integration into clinical workflows. It's more of an introductory phase for stakeholders to determine if the product warrants further exploration.
   - **Outcome:** Based on this initial assessment, the team decides if the product is worth moving forward to a more comprehensive trial or evaluation. Product samples should be provided to the facility based on the institution's internal policies and procedures.

2. **Product Trial**

   - **Definition:** A product trial involves using the product within the healthcare setting on a limited basis and often in a controlled environment or specific cases.
   - **Purpose:** The purpose of the trial is to allow healthcare professionals to use the product under real conditions, assessing its performance, ease of use, and compatibility with existing systems or workflows.
   - **Scope:** Trials are usually short-term, with a defined start and end date or with a significant representation of feedback from the end users, and may focus on specific criteria like usability, efficacy, patient comfort, or clinician satisfaction. Trials may also include feedback forms, observations, and other data collection methods.
   - **Outcome:** The results of a trial determine if the product meets the initial expectations and requirements, providing evidence to support or refute its suitability for full adoption or further evaluation.

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3. **Product Evaluation**

- **Definition:** A product evaluation is a comprehensive and structured assessment that combines all findings from the sample and trial stages with an in-depth analysis of clinical efficacy, cost-effectiveness, safety, and long-term impact.
- **Purpose:** The evaluation aims to ensure the product aligns with clinical, operational, and financial goals. It assesses the overall value the product will bring to the organization.
- **Scope:** An evaluation is the final decision-making stage, often involving data from various sources, including clinical feedback, financial analysis, regulatory compliance checks, and comparisons to other products. It may also include reviewing peer-reviewed studies or benchmarking against similar products in use elsewhere.
- **Outcome:** The evaluation stage concludes with a recommendation for or against the product's adoption, based on thorough evidence that justifies the product's value, safety, and effectiveness for the healthcare organization.

In summary, **samples** are introductory, **trials** involve limited real-world use, and **evaluations** are comprehensive assessments used to make final decisions about product adoption. Each step plays a unique role in ensuring products meet organizational standards for quality, safety, and value.

Summary

This multi-tier product evaluation framework ensures that **low complexity products** are reviewed within **30 days, moderate complexity products** are reviewed within **90 days,** and **high complexity products receive the necessary analysis and engagement within 120 days**. By aligning with our patient-centered mission, we aim to balance speed, quality, and resource stewardship, fostering innovation and excellence in patient care delivery.

References:

Applying Human Factors and Usability Engineering to Medical Devices, electronically accessed from ***https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices.***

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	Low-Complexity	Moderate-Complexity	High-Complexity
Category Definition	These requests involve products with minimal patient care impact and that are generally considered commodities. The goal is to quickly evaluate and implement medical products of low complexity that have minimal if any impact to patient care. These products should be expedited through the healthcare value analysis process. Items within this category should be evaluated within 30 Days or Less. There is generally no need to trial or evaluate products falling into this category.	These requests involve products with well-established usage and minimal clinical, operational, or financial impact. The goal is to streamline the evaluation process to enable fast decisions that support care delivery without unnecessary delays. Items within this category should be evaluated within 90 Days or Less. A focused trial and/or evaluation may be warranted in limited scenarios.	These requests involve products that may bring significant clinical innovation, require operational changes, or involve major financial investment. Items within this category should be evaluated within 120 Days or Less. This tier necessitates a detailed, multi-disciplinary review to assess all implications effectively.
Review Time Frame	No More than **30 Days**	No More than **90 Days**	No More than **120 Days**
Sample Items	• Urinals • Bandages • Water Pitchers • Incise Drapes • Oxygen and Suction Tubing	• Venipuncture Collection Equipment • Nasal Canula and Oxygen Delivery Masks • Non-specialized gloves and masks • Syringes and dressings • Basic patient hygiene products • Generic pharmaceuticals	• Peripheral Intravenous Catheters • Surgical robots or AI-powered diagnostic tools • Implantable devices (e.g., cardiac stents, neurostimulators) • Specialty pharmaceuticals (e.g., biologics, gene therapies) • Ventilators and Anesthesia Machines • Medical equipment requiring infrastructure changes (e.g., MRI machines) • Any Device requiring a full human factors-validated review • Products requiring new policies, workflows, or staff training
Review Process	Product Sample	Product Trial	Product Evaluation