

Value Analysis Supplier Handbook

Welcome!

Thank you for partnering with Spectrum Health (SH) in our vision of providing personalized, affordable, and exceptional healthcare to our patients and community.

The purpose of this handbook is to be informational to our suppliers, not a legally binding document to align with Spectrum Health's high standard of care. Review of supplier quality, supplier diversity and expectations are the key points.

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What is Value Analysis?

Value analysis (n.) – a systematic, objective process for providing an evidence-based methodology to evaluate current and emerging technologies to reduce/manage expenses by considering alternate products, services and practices which meet, but do not necessarily exceed, the clinical and end-user’s specifications while maintaining or improving safety and quality of patient care.

Value Analysis is evidence-based, patient-centered, customer-focused, process-oriented and data driven.

– Adapted from the Association of Healthcare Value Analysis Professionals

Responsibilities of Value Analysis Team

- ◇ *Product and service selection across 14 hospitals and 150 ambulatory sites*
- ◇ *Clinical and financial evaluation of new product requests*
- ◇ *Orchestrate new clinical product trials*
- ◇ *Coordination of new product implementation*
- ◇ *Review existing products for:*
 - *Clinical efficacy*
 - *Standardization opportunities*
 - *Cost savings opportunities*
- ◇ *Consideration of cost avoidance and revenue enhancement*

Definitions

- ◇ **Value Analysis Team** – A team based on standardizing processes, focused on cost savings without compromising patient quality care.
- ◇ **Value Analysis Program Specialist** – Clinically focused position held by a Registered Nurse (RN) verifying requested products, research, collaboration with sourcing and implementation of products.
- ◇ **Service Lines:**
 - Orthopedics
 - Neuroscience
 - Surgical Specialties
 - Cardiovascular
 - General Products
 - Radiology
 - Laboratory
- ◇ **Executive Value Analysis Team** – A steering committee comprised of service-line Value Analysis Team leaders and key stakeholders to guide and direct the VA program to achieve system alignment with top priorities and goals.
- ◇ **Sponsorship** –
 - Physician-use products require a physician sponsorship.
 - Clinical commodity items require a clinician sponsorship.

Supplier Representative Responsibilities

Compliance

Spectrum Health Team Members

Failure to comply with this policy or report violations made by Supplier Representatives may result in performance correction up to and including termination.

Supplier

Supplier is responsible for upholding Spectrum Health values and following the guidelines within the Supplier Representatives Policy. If supplier does not comply with these guidelines, they be formally reprimanded in the process below.

Process

Internal team members will report the issue to their internal Sourcing Specialist within supply chain. A corrective action report will be created by our internal teams and then a reprimand will be issued. The reprimand level is dependent on the amount and severity of violations the representative has had.

Violation Levels

- Level 1: First written warning email documenting violation sent to Supplier Representative and their upline
- Level 2: Suspension of the Supplier Representative for a period up to three months
- Level 3: Termination of access of the Supplier Representative.

Any violations of the policy may affect future Supplier relations with Spectrum Health, at Spectrum Health's sole discretion.

Responsibilities

Supplier

All Supplier Representatives will adhere to Spectrum Health policies and will abide by local, state, and federal laws and any other regulations including HIPAA (Health Insurance Portability and Accountability Act) and those made by any regulatory body such as The Joint Commission, CHAP, CARFF, and all other regulatory standards of practice. If a Supplier Representative is suspended or terminated from Spectrum Health, it is the responsibility of the Supplier to provide adequate coverage and backfill.

Spectrum Health Team Members

It is the responsibility of all Spectrum Health team members, including medical staff, who interact with Supplier Representatives to comply with this policy and to report any Supplier Representative who violates or attempts to violate this policy to the appropriate sourcing specialist or buyer.

Sourcing Department

It is the responsibility of the sourcing department to investigate, record and administer supplier reprimands. As appropriate, sourcing will collaborate with the legal and compliance departments.

Policy

Requirements Applicable to All Suppliers and Supplier Representatives for All Spectrum Health Locations, including Patient Care and non-Patient Care Facilities

Meeting with Spectrum Health Team Members - All Supplier Representatives must have a scheduled appointment with a specific individual. Unscheduled visits are not permitted. Regardless of appointment status, all Supplier Representatives must check in prior to proceeding to the individual's office or work area. Meetings with Suppliers are to be conducted by Spectrum Health team members in their respective office or designated areas. Meetings should be held during normal business hours. Supplier Representatives should be escorted by a Spectrum Health employee and not left unattended.

Product Delivery

Prior to any electrical equipment being brought on site for trial or purchase, the equipment must be inspected and approved for use by Clinical Engineering (otherwise known as Bio-Med) or Maintenance. Supplier should contact their designated procurement representative to determine the department and designee that will be responsible for conducting the inspection. Loading and unloading arrangements must be made with the appropriate department beforehand. Suppliers must abide by Spectrum Health's parking policies and procedures at all times.

Conflicts of Interests

Supplier Representatives shall disclose any actual or perceived conflict of interest in their business relationship with Spectrum Health to all involved Spectrum Health team members, ensuring a thorough description of the influence the potential conflict may have on the product or service sourcing process. Specifically, any family, personal, or financial relationships that may exist between the Supplier Representative and Spectrum Health or its team members must be disclosed.

Additional Requirements Applicable to Suppliers and Supplier Representatives for All Patient Care Facilities and Clinical Staff Interactions:

Meeting with Clinical Staff

Supplier Representatives must schedule appointments with physicians through the medical staff office or the physician office. Supplier Representatives may not enter any patient care or administrative areas without a scheduled appointment.

New Products

Supplier Representatives shall present all new products and technological improvements to procurement before presenting them to other Spectrum Health physicians/team members. New products will be reviewed by Spectrum Health value analysis team or an alternative review committee, as determined by Spectrum Health. Supplier Representatives are required to obtain a purchase order for all goods and services prior to delivery including, but not limited to, equipment and product trials.

Post Case Billing

Supplies approved for use in surgical procedures may require a post case purchase order. Supplier Representatives are required to submit a request for purchase order in a timely fashion in accordance with the following:

- Purchase order requests are due by noon the next business day after the procedure was completed.
- For cases occurring on Friday, Saturday, and Sunday, PO requests are due by noon on Monday.
- For cases occurring on holidays (New Year's Day, Memorial Day, 4th of July, Labor Day, Thanksgiving, and Christmas), POs are due by noon on the following business day. If a Supplier Representative does not submit a request for purchase order in a timely fashion, Spectrum Health may withhold payment to Supplier.

Patient Care-Related Services

It is acknowledged that a limited number of Supplier Representatives may be specifically requested by Spectrum Health staff or physicians, pursuant to a Spectrum Health policy or procedure, to be involved with Spectrum Health staff's or physician's provision of hands-on patient care via (i) conducting staff or physician training, (ii) consulting with staff or physicians concerning a specific patient, or (iii) calibrating a device (collectively, "Patient Care-Related Services").

Patient Care-Related Services may only be provided upon compliance with the below criteria. Patient Care-Related Services must, at all times, be conducted under the supervision, direction and responsibility of a licensed Spectrum Health healthcare professional or physician.

Only Supplier Representatives providing Patient Care-Related Services may enter nursing units or patient Care Areas within Spectrum Health for business purposes and then, only by appointment or with authorization by the department management. Suppliers shall complete the authorized business task and immediately leave the area and return to registration. Suppliers are not authorized to enter staff or physician lounges or proceed into other offices or areas without prior authorization.

Use of any device to record or transmit audio and/or take photographic images or videos are strictly prohibited.

Prior to entering a Patient Care Area, or providing Patient Care-Related Services, a Supplier Representative must sign into the supplier access system as instructed per section 6 below. Minimum requirements for access to Patient Care Areas include proof of all required vaccines, including but not limited to, Chicken Pox, Hepatitis B, MMR, TB and influenza. Other requirements such as proof of relevant training, proof of liability insurance, proof of drug screen, criminal background check and acceptance of Spectrum Health policies will be communicated via the supplier access system.

Suppliers are not allowed to operate any equipment for a procedure unless it is explicitly stated in an active and executed contract. Suppliers are permitted to calibrate programmable devices under the direction of the attending physician. These devices include, but are not limited to, pacemakers, internal cardiac defibrillators, nerve stimulators and lasers.

Patient consent should be obtained and documented in the patient's medical record regarding the presence and role of the Supplier Representative, if that person will be present during treatment, care, or a clinical procedure.

Suppliers will be solely responsible for personal and professional belongings brought into Spectrum Health.

Education

In-Service Education may be scheduled through the pharmacy, patient care department, or operational department with the approval of the department designee (and the pharmacy for medication-related in-services). For education and in-services suppliers are expected to function in accordance with the Sunshine Act.

Facility Access and Identification

Spectrum Health Hospital Group, including surgical sites, uses a supplier access system. All Supplier Representatives must sign in and print a Supplier identification badge from the supplier access system. This badge must be worn in plain sight. If a Supplier Representative has a permanent Spectrum Health issued badge, the Supplier Representative is still required to sign into the supplier access system. All Supplier Representatives are also required to wear their company identification badge. The sign-in process will print a badge with the date, amount of time in the facility, individual to be visited, Supplier Representative's name and company. Supplier Representatives will also be required to comply with any specific departmental registration processes that may exist in addition to the supplier access system.

Non-hospital sites (i.e., physician groups, designated pavilions, and health plan sites) requires all Supplier Representatives to wear their company badge when entering any facility for appointments. The Supplier Representative is required to check in at the front desk area for the appointment. Supplier appointments must be scheduled in advance with each department visited.

Supplier Diversity

As an anchor institution imbedded in our communities, we understand the impact of our purchasing practices. Spectrum Health is committed to building a comprehensive and innovative supplier diversity program to align with our mission, vision, and values. In an effort to improve the economic health of the communities we serve; a formal goal has been set to double our 2020 spend with women and minority owned businesses by 2025.

Spectrum Health defines a diverse supplier as a business at least 51% owned, managed, and operated by women or protected minorities: *African Americans, Native American, Asians, Individuals with Disabilities, Latinos, LGBTQIA, Pacific Islanders/Native Hawaiian, or Veterans.*

To be considered a diverse supplier at Spectrum Health, two requirements must be met:

- 1) Your organization identifies with one of the below demographics:
 - *Minority-Owned Enterprise (MBE) that is at least 51 percent owned, controlled, operated, and managed by members of an ethnic/racial minority group.*
 - *Women-Owned Enterprise (WBE) that is at least 51 percent owned, controlled, operated, and managed by one or more women.*
 - *Veteran-Owned Enterprise (VBE) that is at least 51 percent owned, controlled, operated, and managed by U.S. Military Service Veterans.*
 - *Business Enterprise that is at least 51 percent owned, controlled, operated and managed by individuals with disabilities (DBE).*
 - *Lesbian, Gay, Bisexual, Transgendered- Owned Enterprise (LGBTBE) that is at least 51 percent owned, controlled, operated, and managed by members of the LGBTQIA community.*
- 2) You can provide proof of certification via a reputable third-party certification agency. Agencies recognized by Spectrum Health include, but are not limited to, the following:
 - *National Minority Supplier Development Council (NMSDC) or a regional affiliate council*
 - *Women's Business Enterprise National Council*
 - *Various State or Local government agencies or chambers of commerce*
 - *Small Business Administration – Veteran or Disability Certification*
 - *National LGBT Chamber of commerce or a regional affiliate council*

As we continue to mature our supplier diversity program in pursuit of achieving our goals, additional requirements will be expected of our existing supply base. Beginning in 2022, we will require our top 20 Tier-1 suppliers to submit their Tier-II MWBE spend data. In the future, this request may become more extensive to our broader supplier base. Together, we can improve the economic health of our community.

For questions, please reach out to your dedicated Sourcing Specialist.

Third Party Risk Management and Business Continuity

It is the policy (#24891) of Spectrum Health to manage its third-party relationships in accordance with applicable regulation and industry leading practices, to fulfill the organization's fiduciary and risk management responsibilities as they pertain to third parties through a comprehensive Third-Party Risk Management (TPRM) Program.

The TPRM program takes a risk-based approach to supplier assessment, due diligence, monitoring and management. The TPRM program is intended to help our healthcare leaders navigate supplier relationships in a risk-informed manner.

TPRM involves managing the risks associated with contracts, performance, and relationships with third parties throughout the entire supplier lifecycle: evaluation, negotiation, onboarding, monitoring and management, and reevaluation and offboarding. This may include vendors or suppliers that provide products, services, business professional services and information systems. The TPRM program addresses risks across several domains: strategic, operational, legal, compliance, reputation, information security and data privacy. Operational risk includes continuity of product and service delivery.

Spectrum Health recognizes supply disruptions of lifesaving and life-sustaining products are perhaps the greatest external threat to the continuity and quality of patient care. We seek to do business with suppliers willing to be transparent regarding business continuity practices and show evidence toward maturing those practices on an ongoing basis.

We define a resilient supplier as one that:

- Improves end-to-end resiliency of critical products
- Demonstrates reliable performance and outcomes
- Provides prompt communication and alternative solutions as needed
- Shares supply continuity strategy with customers
- Enables shared visibility of critical locations
- Increases business continuity program maturity
- Communicates resiliency KPI metrics

Healthcare Industry Resilience Collaborative

Spectrum Health is a member and Co-Founder of the Healthcare Industry Resilience Collaborative (HIRC). The Healthcare Industry Resilience Collaborative is a community of healthcare providers and their suppliers who have united to improve healthcare supply chain resiliency.

HIRC members share a common vision for understanding, measuring, and building stronger end-to-end value streams across the provider-supplier spectrum for practical, scalable, and self-reinforcing change.

To fully comprehend the value of a product, a supplier's resiliency must be considered. Our resiliency approach includes partnership, communication, and transparency within a trusted relationship.

Suppliers providing the following resiliency information will be given greater consideration. The preferred method of delivery is via our third-party, Supply Risk Solutions (SRS). SRS provides a secure portal for data management. Supplier maintains full control and ownership of the data.

Standard	Description	Action	Value
Supply Chain Mapping	Minimum Tier 1 production and distribution facilities for contracted portfolios	Provide locations, product categories, and emergency contact(s)	Increase visibility and proactive planning
Event Communication	Proactive communication of potential supply disruptions	Respond to periodic third-part hazard alerts	Increase timely coordination and mitigation if impact
Business Continuity Maturity (BCM) Assessment	BCM self-assessment	Complete assessment and remediation as needed Provide live discussion, address gaps or concerns	Promote supply chain resiliency maturation
Resiliency KPI	Standard measures to assess supply chain continuity and preparedness	Self-report order fill rate, backorder rate , raw fill rate, # recalls / quality issues Completion of above on periodic basis	Promote supply chain resiliency performance

We believe this information is strategic to our business continuity program and seek your support. Transparency increases mutual preparedness and confidence. With the patient as the center focus of our work, we believe resiliency information is in the best interest of patient care.

Recalls

The FDA defines recalls as an action taken to address a problem with a medical device that violates FDA law. Three classes categorize the products; when a medical device is defective, is a risk to health, or when the product is both defective and a risk to health. All equipment and pharmaceutical recalls are paralleled with the three classes from the FDA.

- Class I Recall: Dangerous or defective products that predictably could cause serious health problems or death.
- Class II Recall: Products that might cause a temporary health problem or pose only a slight threat of a serious nature.
- Class III Recall: Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws.

As Spectrum Health provides a high standard of care to our patients, families, and community we expect the same from our suppliers. This information is shared for knowledge purposes and is not considered a legally binding acknowledgement.

Back Orders

When medical supplies are on backorder, suppliers should notify Spectrum Health immediately. It is expected that the supplier will proactively provide the Purchasing team at Spectrum Health with appropriate substitute product recommendations and cross-matching alternate manufacturer information when able.

Members of Spectrum Health's Purchasing team partner with Value Analysis Program Specialists to clinically evaluate potential substitute products to ensure clinical efficacy and equivalency and assess the need for clinician education. In the event, education is required, it is expected that the supplier will partner with Value Analysis to ensure safe patient care is provided.

Supplier Quality

Managing health care costs in an economically sustainable manner is a priority at Spectrum Health. The Supplier Quality Notification (SQN) program works to recover administrative costs and lost operational activity resulting from recalled or defective products, medical devices, equipment, and pharmaceuticals purchased by Spectrum Health. We are committed to our SQN program while equally dedicated to maintaining our relationships with our supplier partners.

Spectrum Health is proud of our strong partnerships with suppliers and confident that suppliers will be proactive in the identification, communication, and termination of products that meet the above qualifications. We thank you in advance for addressing recalls in a safe and efficient manner to better protect our community.

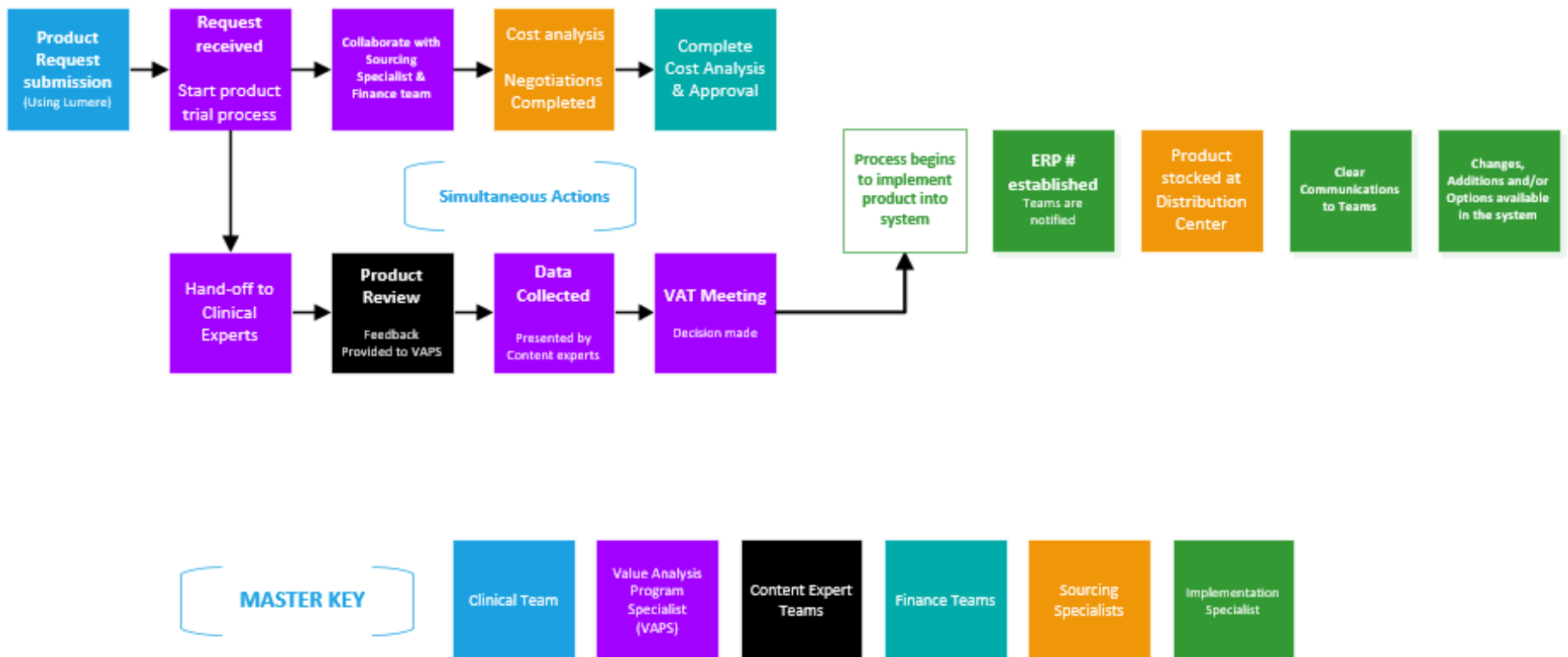
SQN program development, collaboration with other health systems, and strong supplier partnerships will drive resilience, enable growth, and help to define industry-wide expectations.

New Product Request Workflow

Our goal is to ensure that safe and effective products are available to clinicians, keeping patient outcomes at the center of all we do. Value Analysis at Spectrum Health applies objective, standardized processes which allow our service-line leaders to make informed decisions about medical supplies, technologies, and patient care services within the context of safe, evidence-based care.

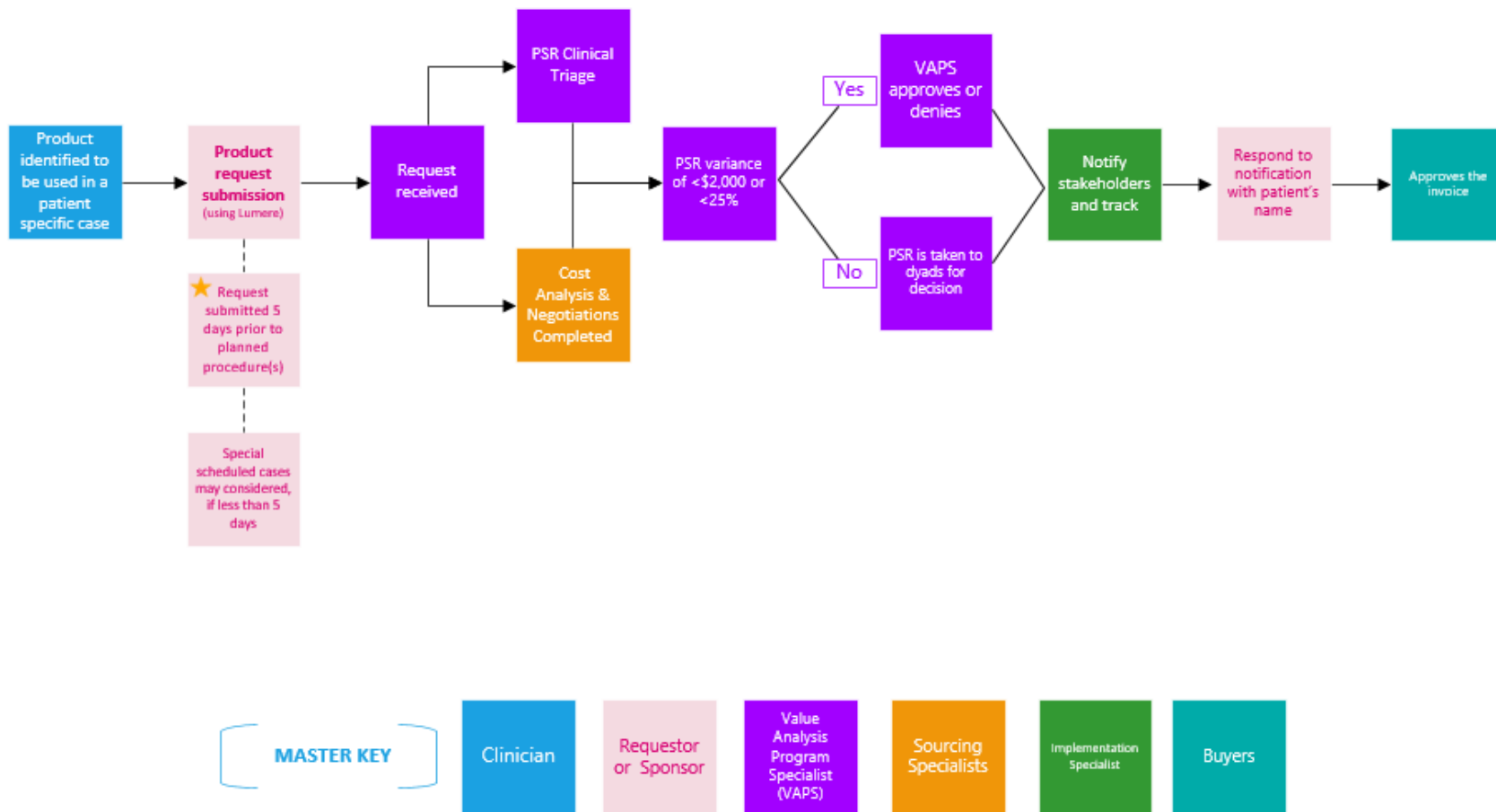
We take a multidisciplinary approach to evaluating new product requests, partnering with Supply Chain Sourcing, Financial Analysts, and clinical content experts. Our Value Analysis Program Specialists (RNs) conduct a thorough evaluation of the requested product, securing feedback from Sourcing, Finance, and others to partner with the requesting provider/clinician. New products are presented at a Value Analysis Team (VAT) monthly meeting.

If approved, our team's Implementation Specialists orchestrate a seamless transition into our system, ensuring our clinical end-users have all the training and resources they need to successfully transition to the new product. The New Product throughput at Spectrum Health has a rolling average of approximately 27 days. Post approval, our procurement team will work with SH legal dept to finalize agreements. Suppliers may be contacted at any point within the New Product Request process for additional information.



Patient Specific Request (PSR)

When a medical device or supply is required to provide individualized care to a patient, our providers submit a Patient Specific Request to Value Analysis. Value Analysis Program Specialists (VAPS) conduct a clinical evaluation of the request while Sourcing conducts a cost analysis. This information is used to determine if the system-approved product would be appropriate for use or if the patient scenario warrants a non-catalogue item. PSRs are to be submitted 7-10 business days prior to the case unless an emergency. PSRs submitted within 24 hours before or post-case are subject to non-payment.



Product Trial Process

All product trials must be approved by the service-line’s Value Analysis Team (VAT). The product requested to trial undergoes the same rigor as the New Product Request process. If approved for trial, Value Analysis Program Specialists orchestrate the trial from start to finish, working with key stakeholders at every step. Trials are only approved if clear metrics outside of user-preference can be established, measured, and reported upon. Trial results are reported out during monthly VAT meetings. Final trial outcomes are presented at VAT for decision-making by service-line VAT leaders.

