



Medtech companies are uniquely poised to drive Value-Based Health Care (VBHC) solutions as the health care system moves away from paying for care based on the quantity of services to paying for care based on outcomes, such as those identified in the Triple Aim (better outcomes, lower cost, and patient satisfaction).

- *Clinical Expertise to Improve Outcomes* – Medtech companies are experts in how their technologies may affect clinical outcomes. This expertise derives from years of testing and scientific studies on device performance and gives them the specialized knowledge necessary to design offerings that can improve outcomes.
- *Clinical and Business Solutions to Reduce Costs* – Medtech companies often have dedicated medical, clinical, and quality specialists, a health care economics function, reimbursement specialists, data analysts, and others who can support the health care delivery network’s ability to effect positive change.
- *Data Hub and Analytics Expertise* – Medtech companies are in a unique position to collect, aggregate and analyze data that is used to improve health care, reduce costs, and improve the patient experience. VBHC is largely driven by data. Many medical devices are inherently data driven and generate data—either generating data on their own or work in an ecosystem to contribute to data collection and aggregation.

Who better to support hospitals, physicians and their patients that are undergoing treatments with medical devices, than the people who designed the technologies?

- *Expertise with Medtech and Disease States* - The medical device industry is particularly well-positioned to collaborate with providers’ and payers’ efforts to improve patient care because medtech manufacturers are experts in how their technologies may improve clinical outcomes.
- *Specialized Knowledge to Design Medical Devices and Related Capabilities*- This expertise provides the specialized knowledge necessary to design offerings that can improve patient outcomes, reduce costs, create efficiencies (e.g., improving care pathways) and improve the patient experience (e.g., increasing patient engagement & feedback throughout the continuum of care via mobile apps).

The current Anti-Kickback Statute (AKS) and safe harbor regulations challenge medtech companies’ ability to enter into value-based contracts with providers and payers.

- Although existing AKS safe harbors may protect some limited value-based offerings, changes are needed to make it easier for the participants to effectively engage in value-based health care arrangements and to allow for more comprehensive and efficient solutions.

Create New Value-Based Safe Harbors – To promote medtech companies entry into value-based health care arrangements, AdvaMed recommends creating VBHC-specific safe harbors for:

- *Value-Based Pricing Arrangements* - A new safe harbor for value-based pricing arrangements would allow for price adjustments, and for services to be bundled with the product being sold or leased, subject to appropriate safeguards, where the arrangement is dependent upon the achievement of a measurable clinical and/or value outcome.
- *Value-Based Warranties* - A new safe harbor for value-based warranties would allow manufacturers of products to make certain clinical and/or outcome assurances, and provide an appropriate remedy where such outcomes are not achieved. The outcome warranty would allow a manufacturer to share risk by providing a payment, item, or service when a targeted clinical or economic outcome is not achieved, instead of limiting the manufacturer to providing a payment, item, or service for an established product defect only (as contemplated under the current law.)
- These would both allow for bundling data collection and analytics to help determine if better clinical outcomes and cost savings have been met.

Create a Fast Track Guidance Process (that is less formal than the advisory opinion process) that would apply across all safe harbors for value-based considerations. Ideally, a multiagency commission with OIG, DOJ, FDA and CMMI jointly engaged.