UNITED STATES SENATE COMMITTEE ON FINANCE

“EXAMINING THE STARK LAW: CURRENT ISSUES AND OPPORTUNITIES”

JULY 12, 2016

STATEMENT FOR THE RECORD:

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

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The Advanced Medical Technology Association (AdvaMed) Supports the Transition of Health Care Delivery to Value-Based Payments and a Legal Framework that Protects Patients from Fraud and Abuse.

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide a statement for the record for the Senate Finance Committee’s July 12, 2016 hearing entitled, “Examining the Stark Law: Current Issues and Opportunities.” We applaud the Senate Finance Committee for addressing concerns with the federal fraud and abuse legal framework that are impeding a broader, more integrated transition to value-based health care delivery.

AdvaMed is a trade association that represents nearly 300 members, consisting of the world’s leading innovators and manufacturers of medical devices, diagnostic products, and health information systems. Together, our members manufacture much of the life-enhancing health care technology purchased annually in the United States and globally. Our members are committed to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. The devices AdvaMed members make help patients stay healthier longer and recover more quickly after treatment, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

AdvaMed supports the transformation of health care to value-based delivery and payments. Medtech manufacturers are key collaborators with providers and payers to improve outcomes, enhance the patient experience, and reduce costs. Medtech companies develop and heavily invest in technologies and services that are vital to realizing quality, clinical outcomes, patient satisfaction, and cost savings goals.

We stress that AdvaMed supports a legal framework that protects patients and the federal health care reimbursement programs from fraud and abuse. Our member companies further recognize the importance of ensuring ethical interactions between medtech companies and providers so that medical decisions are centered on the best interests of the patient. That is why AdvaMed developed a Code of Ethics (also known as the “AdvaMed Code”) to distinguish beneficial interactions from those that may inappropriately influence medical decision-making.

The Current Fraud and Abuse Laws Contemplate a Volume-Based Payment System (Fee-for-Service) and are Ill-Suited for Innovative Value-Based Payment Arrangements.

The existing fraud and abuse laws seek to prevent inappropriate medical decision-making and overutilization by ensuring that the financial interests of parties involved in the provision of care are not structured in a manner that creates inappropriate incentives to provide unnecessary services, leading to increased costs. Value-based payment arrangements generally lack overutilization concerns since payments are not directly tied to the volume of services provided. Instead frameworks such as risk-sharing, shared savings, and / or capitated payments are

1 Available at: http://www.advamed.org/CodeOfEthics
inherently designed to limit overall costs to the system with strong measurable quality goals to safeguard against underutilizing or withholding medically necessary services and limiting patient choice. Value-based arrangements align the financial interests of providers, industry, and payers to achieve clinical quality goals and manage costs. However, this alignment creates tension under the current fraud and abuse legal framework.

The federal Anti-Kickback Statute proscribes the “knowing and willful offer, payment, solicitation, or receipt of any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) in return for or to induce a referral of services or goods payable by Medicare or Medicaid.” Congress enacted the Anti-Kickback Statute in 1972, in the context of Medicare’s then-retrospective reimbursement system. In a fee-for-service environment, the Anti-Kickback Statute was intended to discourage overutilization of Medicare-reimbursed items and services by prescribers motivated by their own financial interest. Congress was further concerned with: (1) possible harm to beneficiaries; (2) increased Medicare and Medicaid costs; and (3) the potential of kickbacks to freeze competing suppliers from the system, mask the possibility of government price reductions, and misdirect program funds. The Anti-Kickback Statute originally prohibited only “bribes and kickbacks,” but Congress extended its reach in 1977 by substituting “any remuneration” for the “bribes and kickbacks” language and increasing the severity of the penalties from a misdemeanor to a felony. Congress recognized that the expansive reach of the Anti-Kickback Statute created uncertainty as to which routine commercial arrangements are permitted, and it excluded certain types of payments from consideration by the statute, including discounts. However, when the Office of Inspector General (OIG) promulgated final implementing regulations, the “safe harbor” for discounts/rebates was very narrowly drawn. For example, the regulation directs that supplying one good or service without charge or at a reduced charge to induce the purchase of a different

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2 42 U.S.C. § 1320a-7(b)(b); AdvaMed’s commentary on the Federal Anti-Kickback Statute serves to inform the discussion regarding its interplay with the Stark Law as reforms to the fraud and abuse laws are considered to advance value-based health care delivery.

3 59 Washington & Lee Law Review 3/1/02 (The Medicare Anti-Kickback Statute: In Need of Reconstructive Surgery for the Digital Age), citing Jost & Davies “The Law of Medicare and Medicaid Fraud and Abuse” 100 (2001-02 ed. 2000) (listing concerns that "patients will suffer, program funds will be unnecessarily depleted, and taxpayer dollars will be wasted" if kickbacks are permitted).

4 See 56 Fed. Reg., 35952 (July 29, 1991) (original safe harbors, citing United States v. Ruttenberq, 625 F.2d 173, 177, n.9 (7th Cir. 1980)).


8 See S. REP. 100-109, 27, 1987 U.S.C.C.A.N. 682, 707-08 (“It is the understanding of the Committee that the breadth of this statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed. The Committee bill therefore directs the Secretary, **708 in consultation with the Attorney General, to promulgate regulations specifying payment practices that will not be subject to criminal prosecution under the new section 1128B(b) and that will not provide a basis for exclusion from participation in Medicare or the State health care programs under the new section 1128(b)(7).”)

9 42 U.S.C. § 1320a-7(b)(b)(3).
good or service is not permitted unless the goods and services are reimbursed by the same Federal health care program using the same methodology. This has the potential to significantly restrict a value-based bundled offering of services and product if the reimbursement methodology for all discounted items or services is not the same. Further, there is ambiguity around protection for discounts linked to and/or premised on the performance of personal services since the safe harbor regulation excludes from the definition of a protected discount “services provided in accordance with a personal or management services contract.”

The OIG adopted similarly narrow safe harbors in other areas, also intended to protect Medicare from overutilization of reimbursable items/services. In promulgating the warranty safe harbor, the OIG explained:

“It is in the public interest to have companies offer warranties as an inducement to the consumer to purchase a product.” The OIG declined to protect broader warranties, including those relating to competitive warranties on other products, stating “We believe that safe harbor protection is proper where a replacement program honors the original manufacturer's warranty… and the agreement provides remuneration on the same terms as the original manufacturer's warranty without providing additional incentives or shifting additional costs to the Medicare and Medicaid programs.”

Under value-based payment arrangements, this restriction on competitive warranties to “terms equal to the agreement that it replaces” limits collaboration options that would add value. Another constraining element of the Warranties Safe Harbor is that to qualify for safe harbor protection a “manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.” This deters the formation of value-based arrangements that would include services and items among different manufacturers, as warranty remuneration between manufacturers is not protected.

The Personal Services and Management Contracts Safe Harbor includes the requirements that: (1) the agreement specifies exactly the schedule of service intervals, their precise length, and the exact charge for such intervals; (2) the term of the agreement be at least one year; and (3) the

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11 Id.
12 42 C.F.R. § 1001.952(h)(5)(vi).
13 Note 3, supra.
14 Id.
15 42 C.F.R. § 1001.952(g) (“the term warranty means either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6), or a manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item (which is covered by an agreement made in accordance with this statutory provision), on terms equal to the agreement that it replaces.)
16 42 C.F.R. § 1001.952(g)(4)
17 42 C.F.R. § 1001.952(d)(3)
18 42 C.F.R. § 1001.952(d)(4)
aggregate compensation paid over the term of the agreement be set in advance. These requirements do not account for risk-sharing, cost-savings, and performance-based payment models.

AdvaMed’s Priority Concerns in Advancing Value-Based Care are:

1. the Limitations in the Anti-Kickback Statute Safe Harbors for Discounts, Warranties, and Personal Services to Provide Protection for Bona Fide Value-Based Arrangements Among Collaborating Providers, Payers, and MedTech Manufacturers;

2. the Current Off-Label Promotion Enforcement Framework, which May Aggressively Construe the Sharing of Scientific and Health Care Economic Information to Develop and Operationalize Value-Based Arrangements as Implied Off-Label Claims; and

3. ensuring that the emphasis on value-based care does not create perverse incentives for hospitals and providers that compromise patient access to necessary care.

Medtech manufacturers want to comply with the fraud and abuse laws. However, there is no direct guidance from the government regarding the application of the fraud and abuse laws to value-based collaborations between manufacturers and providers and/or payors. Currently, value-based arrangements between medtech manufacturers and providers and/or payers are structured by cobbling together constructs within the discounts, warranties, and personal services safe harbors. However, this analysis necessitates the commission of immense resources, both in terms of time and legal costs. Because of the current regulatory limitations, these costs may be expended by all stakeholders without ultimately moving forward with a value-based collaboration given the uncertainty and concern for enforcement applying historic fee for service reimbursement principles as a framework. In short, regulatory uncertainty concerning the application of the criminal Anti-Kickback Statute chills value-based/outcomes-based collaborations.

Medtech company contributions to value-based health care arrangements can range from integrating data analytics infrastructure and services (to optimize care to achieve quality goals) to services that streamline the supply chain to reduce costs. These collaborations might involve bundling services, data collection and analytics, and medtech products to deliver high quality care, improved patient satisfaction, and cost reductions. Safe harbor protection is arguably afforded only to those arrangements that meet all of the conditions set forth in the safe harbor regulations. Unfortunately, as stated above, the Safe Harbor constructs are narrowly fashioned around fee-for-service payment models and no longer match the reality of value-based health care delivery and payment models. This serves to inhibit value-based frameworks designed

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19 42 C.F.R. § 1001.952(d)(5)
around quality care, which have the potential for greater impact. For example, the Discount Safe Harbor includes the limitation that the bundled good or service be reimbursed by the Federal health care program using the same methodology and the additional limitation that for cost-reporting entities, the discount must be earned based on purchases of that same good or service within a single fiscal year. The “same methodology” limitation can materially restrict the range of possible devices and services that may be integrated to deliver the best value. Uncertainty exists around what items or services would be considered to fall under the “same methodology.”

Finally, the single fiscal year limitation may prevent bundling items and/or services that are critical to supporting health care delivery frameworks which measure clinical outcomes and economic value over periods of time extending beyond the same fiscal year or that measure outcomes over multi-year periods that capture the long-term value of a value-based health care program, device or service. This is a major limitation of potential value-based care arrangements.

Integral to developing and executing value-based arrangements is the need for manufacturers to be able to communicate with providers, payors and other stakeholders on establishing clinical goals, efficiency measures, and economic performance terms. Starting points for these goals, measures, and terms may originate from economic and clinical data (with varying levels of support) that may not be specified in the approved or cleared label of the device. This scientific and health care economic information will be needed to both establish and optimize the clinical and economic goals of the value-based collaboration.

Medtech manufacturers support delivery reform models and their goals to achieve lower cost and higher quality health care. At the same time, we are concerned that the financial incentives inherent in the various delivery reform/alternative payment models can have the inadvertent effect of discouraging providers from (1) considering the full array of treatment options, due to concerns regarding exceeding “benchmark” threshold costs, or (2) using innovative treatments, technologies, and diagnostics that may bring value to the health care system over the longer term, but are more costly in the short run. The potential negative impact of the financial incentives of these models is magnified by the short payment windows used in the programs to compare actual spending against benchmarks in order to determine the level of savings that may be shared among providers. This is particularly concerning because many medical devices and technologies provide benefits over a long period of time spanning multiple years.

Additionally, gainsharing and other similar arrangements have created a major shift in incentives that have significant and potentially negative ramifications for patient care. AdvaMed continues to believe that “gainsharing” arrangements pose a risk of patient abuse and may violate the civil monetary penalty law prohibiting hospitals from offering remuneration to physicians for limiting medical care to their patients, § 1128A(b) of the Social Security Act (the “Act”). The Federal anti-kickback statute and the “Stark” physician self-referral law also prohibit certain financial relationships such as those created in gainsharing arrangements. As such, we recommend that alternative payment arrangements be implemented in a way that makes their operation

20 42 C.F.R. § 1001.952 (h)
transparent and that these arrangements be evaluated and assessed to determine their impact on patient access to necessary care.

**Recommendations to Advance Value-Based Care**

In light of the challenges noted above, AdvaMed offers the following recommendations for consideration:

- Create a new *Risk-Sharing Safe Harbor* for value-based arrangements between manufacturers and providers and/or payers that incentivize and reward improvements in clinical outcomes and/or reductions in cost.

  - This safe harbor should allow for:
    - sharing value-based rewards (e.g., ACOs sharing some of the benefits received from meeting benchmarks with a medtech manufacturer if its products contributed to meeting that goal);
    - shifting of risk over the course of an engagement so long as such risks are set in advance (e.g., the initial phases of a bundled device and services program are paid for by a manufacturer, but as benchmarks are reached, efficacy is shown and savings recognized, the hospital would share a portion of the savings generated with the manufacturer);
    - multiple entities to engage in a complex study where costs may shift from one company to another and then potentially to the hospital, as efficacy is proven.

  - Prior to proving that a system is efficient, the manufacturer would be in a better position to invest in the R&D of the engagement. However, once savings and efficiencies are proven, the manufacturer would also be able to share in the net benefit.

  - While there may be ways to construct these engagements currently, they do not offer the fluidity that is possible with a single agreement with benchmarks and shifting fees. The freedom and efficiencies afforded by a Risk-Sharing Safe Harbor would permit greater investments into value-based solutions.

  - The applicability of the Medicare Secondary Payer Statute to performance-based payments under this safe harbor should be clarified as well.

- Create a new *Safe Harbor for Bundling Services, Data Collection and Analytics, and Medtech Products in Value-Based Arrangements* (e.g., to determine whether clinical outcomes and cost savings metrics have been met, medical technologies are bundled with services to collect and monitor data, analytics, monitoring equipment, and IT infrastructure);
● Create a new Safe Harbor for Outcome Warranties that specifically addresses warranting an outcome instead of a product failure and protects payments for bundled products and services provided when an outcome is not met.

  o For example, this would provide a targeted approach to addressing scenarios where a medical device company agrees to reimburse a hospital not only its aggregate purchase price for the implant device acquisition costs, but also unreimbursed wound care products and services if a patient is readmitted to the hospital within 90 days following the surgical procedure because the surgical site is infected or a revision surgery is needed. Currently, when this occurs, there is arguably protection under the safe harbor warranty for only the device cost when the device fails. This may lead to litigation over whether there was a product failure. Litigation adds substantial costs, may not resolve in a timely manner, and may be upsetting to the patient. Permitting manufacturers to warrant the outcome, instead of against product failure, through the protection of a safe harbor would allow for more coordinated and timely management of post-operative complications.

● Issuing Guidance that expressly delinks the provision of scientific and health care economic information supporting the value-based health care goals to providers and payors from any regulated product promotional or labelling restrictions. This guidance should include:

  o clarification that communications on efficiency (e.g., performance/throughput claims), population outcomes/cost, and economics that are not specifically part of the product labelling are necessary and permissible to develop and operationalize value-based arrangements and that varying levels of supportive data are acceptable (e.g., case study, big-data analytics).

  o clear guidelines for industry to rely on in providing appropriate medical information to Health Care Professionals regarding medical technologies with only general claims in the product labeling; and

  o clarification on the scope of what may be discussed with payors and sophisticated providers about medical technologies and drugs undergoing review (e.g., 510(k) review) to facilitate planning.

● Consider directing the creation of 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.

● If there was a preference to work within the existing Anti-Kickback Statute Safe Harbors, we offer the following for consideration to advance value-based payment models:
o **Discount Safe Harbor** – we recommend that OIG issue guidance on the Medicare secondary payer statute’s applicability to performance-based payments.

o **Warranties Safe Harbor** - With regard to the Warranties Safe Harbor, we recommend:
  - expanding warranty coverage in value-based arrangements to permissibly include other direct costs, associated products, associated services, service as a product, and replacement outsourcing costs, which are all means of making the provider whole;
  - expanding competitive warranties to permit exceeding competitor’s terms; and
  - permitting warranty remuneration between manufacturers to allow for bundled items among different manufacturers to provide care.

o **Personal Services Safe Harbor** - With regard to the Personal Services Safe Harbor, we recommend:
  - allowing the parties to set the compensation formula in advance (e.g., percentage of savings or capitation), instead of being required to set the aggregate compensation paid over the term in advance;
  - removing the limitation that the term is for not less than one year (e.g. percentage of savings or capitation);
  - removing the interval schedule, length, and charge specificity requirement for services (e.g. percentage of savings or capitation);
  - expanding and revising the definition of fair market value to account for services/arrangements tied to new value based payment models that incentivize improved quality of care and cost effectiveness; and
  - issuing guidance that permits utilizing publicly available health care professional salary surveys as an acceptable methodology to determine fair market value.

**Conclusion**

In closing, we would like to reiterate our appreciation to Chairman Hatch, Senator Wyden, and the Senate Finance Committee for their work on this issue, and to also emphasize AdvaMed’s support for a legal framework that protects patients and the federal programs from fraud and abuse. We believe that targeted reforms to our fraud and abuse laws for value-based arrangements will maintain the protections for patients and the federal health care programs while allowing for greater involvement and investment in value-based payment models. AdvaMed welcomes opportunities to collaborate on advancing value-based care, especially where medtech may offer unique contributions to the value equation.