AdvaMed Best Practices Guidance on Value-Based Arrangements

March 15, 2022

Background

The U.S. health care system is transitioning from a fee-for-service and fee-for-product (volume-based) model to a value-based paradigm to deliver more coordinated, high-quality, affordable health care. Under the traditional fee-for-service / product framework, services and products are paid for on a utilization basis. The fraud and abuse laws – specifically, the federal Anti-Kickback Statute (AKS) – evolved under this framework, in which remunerative arrangements between providers and manufacturers were scrutinized for their potential to encourage overutilization, increase federal health care costs, and improperly influence medical decisions.

Arrangements to advance value-based care – also referred to as results-based, outcomes-based, or performance-based payment arrangements – are designed to increase shared accountability among shareholders for quality of, access to and/or the total cost of care. These arrangements often condition payment or modify pricing for health care items or services based upon clinical, economic, and/or patient-experience outcomes, and may include payor-driven reimbursement arrangements for providers, arrangements between or among providers, and arrangements between providers and manufacturers or other participants in the health care system.

Arrangements to advance value-based care also may involve payment for a "bundled" group of products and/or related services, software, equipment or similar items, such as bundles of medtech devices with provider process optimization consulting to improve patient care, increase efficiency and reduce costs, or may involve a single piece of medical technology. The related items and services provided under arrangements to advance value-based care may be provided to Health Care Professionals or patients for prevention, diagnosis, disease management, patient monitoring, or post-procedure or discharge care.

In some cases, there may be questions relating to the treatment of these types of arrangements under the AKS and its safe harbors, including the new and modified safe harbors finalized under the final rule published in the Federal Register on December 2, 2020, and effective January 19, 2021 (the Final Rule). The Final Rule

includes certain safe harbors that may apply to protect arrangements to advance value-based care. These safe harbors are designed to facilitate innovative value-based care and care coordination arrangements and to encourage a broad range of participation and business structures. Importantly, however, not all of the new and modified safe harbors under the Final Rule are available to Companies, or they may be available only to certain categories of Companies and/or with respect to specific types of products and services (i.e., digital health technology). Nonetheless, in the Final Rule, the U.S. Department of Health and Human Services Office of Inspector General acknowledged that these safe harbors do not address all beneficial value-based arrangements and even if a Company's arrangement may not be protected under one of the new or modified safe harbors, it may be protected under another safe harbor. And even if no safe harbor is available (or all of the conditions of a safe harbor cannot be met) for a particular arrangement, that does not mean the arrangement is per se in violation of the AKS. Instead, the arrangement should be analyzed for compliance with the AKS based on the specific facts and circumstances, including the intent of the parties.

In addition, questions may arise under the AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code" or "Code") relating to arrangements to advance value-based care.

This document provides AdvaMed's views of industry Best Practices relative to certain issues that commonly arise in connection with such arrangements. Please refer to the AdvaMed Code for the definitions of the capitalized terms (Health Care Professional, Company/Companies, and Medical Technologies) in this document.

Examples

Under the traditional fee-for-service models, device or medtech manufacturers were generally paid based on the number of units sold to a customer, such as a physician, hospital, health system, or other provider. Value-based methodologies focus instead on the value of the manufacturer's products in achieving patient care goals, sometimes in conjunction with other bundled items or services that measure or enhance the value of the care and/or enable the healthcare provider to obtain and deliver clinical information or clinical care more efficiently. The following are some examples of manufacturer arrangements with providers that promote value-based care:

- Bundled items and services with a rebate based on a clinical/economic outcome;
- Provision of items and services related to the achievement of a targeted outcome at no cost apart from the price for the medtech device;

- Provision of services under a risk-based compensation model; and
- Medical device manufacturers offering providers (1) managed equipment services and (2) department and/or staffing (co-)management.

Arrangements to advance value-based care may incorporate outcome targets to:

- Reduce occurrence of adverse events;
- Reduce protocol times;
- Reduce wasted consumables;
- Improve caregiver safety;
- Incentivize more efficient consumption and/or reduce energy costs or disposal costs; or
- Increase patient safety through dosage reduction.

Many medtech companies are uniquely poised to drive value-based care solutions with:

- Clinical solutions to improve outcomes;
- Data hub and analytics expertise - while many medical devices are inherently data driven, they also can work as part of a larger ecosystem – or on their own – to enable data collection, aggregation and analysis (e.g., value from population health-enabled data, including machine learning/AI applications); and
- Business Solutions to Reduce Costs and Time - medtech companies often have health care economics functions, reimbursement specialists, data analysts, and others who can contribute to designing value-based solutions that reduce the cost of care.

AdvaMed Code of Ethics on Interactions with Health Care Professionals (Effective January 1, 2020)

How does the AdvaMed Code apply to value-based solutions?

The Code applies with respect to interactions with Health Care Professionals relating to arrangements that promote outcomes or value-based care in the same manner as they apply to any other interactions with Health Care Professionals. However, inasmuch as arrangements that promote value-based care may involve several

types of interactions addressed by the Code (e.g., provision of coverage or reimbursement information, discussion or negotiation of sales or contract terms, provision of training and education, or consulting arrangements with Health Care Professionals), it is important to understand the applicable Code standard(s) for these interactions.

1. **Coverage, Reimbursement, and Health Economics Information**

   - Under Section XI of the Code, Companies may provide accurate and objective information about the economically efficient use of their Medical Technologies, including in the context of advancing value-based care arrangements.

   - A Company may also provide accurate and objective information regarding the manner in which new value-based reimbursement arrangements established with payors and other participants operate in order to facilitate a Health Care Professional's decision to buy or use the Company's Medical Technologies.

   - Section XI of the Code specifies that a Company may not "interfere" with an individual Health Care Professional's independent clinical decision-making or provide coverage, reimbursement, and health economics support as an unlawful inducement in the context of providing coverage, reimbursement, health economics Information, and consulting. In the context of an arrangement to promote value-based care, providing coverage, reimbursement, and beneficial health economics information regarding the use of a Company's Medical Technologies or regarding the arrangement to promote value-based care should not be considered interference in an individual Health Care Professional's independent clinical decision-making, nor should such assistance be provided as an unlawful inducement.

2. **Consulting Arrangements with Health Care Professionals**

   - While developing, evaluating, or implementing an arrangement to promote value-based care, Companies may retain a Health Care Professional as a consultant if the requirements under Section II of the Code are satisfied, including the requirement that the retention is intended to fulfill a legitimate business need and not constitute an unlawful inducement The following are examples of legitimate business needs, and accordingly, consulting undertaken for such purpose would be consistent with the Code:

- Helping in the development, evaluation, or implementation of protocols, procedures, operations, quality, efficiency, or the patient experience;

- Helping in the development, evaluation, or implementation of a solution to improve outcomes, quality, efficiency (including workflow), the patient experience; or

- Increasing the provision of rural health services and addressing any other emerging national or regional healthcare priorities.

- More generally, arrangements to advance value-based care are often complex and any engagement by a Company of a Health Care Professional as a consultant with respect to such an arrangement must be analyzed taking into account all applicable facts and circumstances. The following factors may be considered when engaging a Health Care Professional as a consultant with respect to arrangements to advance value-based care:

    - The Health Care Provider's experience or qualifications with respect to the purpose(s) of the arrangement to promote value-based care or with respect to products or solutions that are part of such arrangement.

    - The Health Care Provider's affiliations. It would generally not be appropriate for a Company to engage as a consultant a Health Care Professional affiliated with a provider to assist that provider in developing, evaluating, helping to implement, or managing an arrangement to promote value-based care, since such a payment could give rise to the appearance of an improper inducement. However, in circumstances where such a retention clearly would not involve such an inducement (e.g., the Health Care Professional is transparent with their employer as to their consulting activities, has no involvement in or influence on the provider's purchasing or use of the products or services at issue, and also regularly consults for the Company with respect to developing, evaluating or helping to implement for other providers arrangements that promote value-based care), such an engagement may be permissible.

    - The responsibilities or obligations of the Company related to the arrangements to advance value-based care. The consultant should be fulfilling such obligation or responsibility, as opposed to any obligations or responsibilities that belong to another party.

- Arrangements to advance value-based care could appropriately include Company-provided consulting services in support of the development, implementation and management of appropriate arrangement(s) to promote value-based care.

3. **Company Conducted Training & Education**

   - Arrangements to advance value-based care may include Company-conducted product training and education in accordance with Section III of the Code. Moreover, where an arrangement to promote value-based care involves both medtech product(s) and services, software, equipment or similar items designed to facilitate or measure given outcome(s), training and education may relate not only to the product but to the related services or items, as appropriate.

4. **Sales, Promotional, and Other Business Meetings**

   - Companies may conduct sales, promotional, and other business meetings with Health Care Professionals to discuss value-based solutions, services, or arrangements. These meetings may include presentations by or discussions with "key opinion leaders," "thought leaders" or other experts retained by the Company (subject to compliance with Section II of the Code, where a Health Care Professional is retained).