Value-Based Health Care: Getting from Here to There

Healthcare Leadership Council

Hill Briefing

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Agenda

• Challenges of Fee-For-Service Health Care
• Current Fraud and Abuse Laws
  • Anti-Kickback Statute
  • Physician Self-Referral Law (Stark Law)
  • Interest in Fraud and Abuse Law Reform
• Proposals for New Value-Based Health Care Safe Harbor and Exception
Challenges of the U.S. Fee-For-Service Health Care System
Our Fee-for-Service World

Challenges Associated with Volume-Based Reimbursement Systems

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The Solution: Value-Based Health Care (VBHC)

Start by Putting the Patient at the Center of Care

At the heart of value-based healthcare is a shift to put the patient back at the center of care. What’s best for the patient should drive the system, not necessarily the volume of procedures, touch points, etc.
VBHC Is the Future, But the Shift is Ongoing

Existing Fee-for-Services-Based Laws are Seen as Major Impediment to Shift

VALUE-BASED HEALTH CARE

Outcomes-Based Payment Mechanisms

- Parties encouraged to be **financially aligned** to create incentives to encourage better coordination of care and other behaviors that improve outcomes and efficiencies

FEE FOR SERVICE

Volume-Based Payment Mechanisms

- Fraud and abuse laws needed to limit incentives among healthcare parties, keeping them **financially separated**
Current Fraud and Abuse Laws

Barriers to Value-Based Arrangements
Fraud and Abuse Laws – How They Work

Old Models that Do Not Accommodate Value-Based Health Care Arrangements

• Goal is to combat over-utilization and unnecessary care in federal health care programs and to keep parties financially separated
• Federal health care programs include Medicare, Medicaid, Medicare Advantage, and Medicare Part D
• Federal agencies can make incremental change through regulations, but these laws continue to be a significant barrier to health care innovation
• Value-based health care arrangements may include payments in exchange for making medically-valuable referrals or in-kind benefits to support care coordination or to improve quality. No existing safe harbors/exceptions protect these arrangements.

These laws were designed for a Fee-For-Service world, not the new health economy of integration, population health payments, and value-based arrangements.
Fraud and Abuse Laws – Anti-Kickback Statute

Prohibition Against Improper Remuneration

- Prohibits a party from providing anything of value to another party in exchange for:
  1. referrals of patients; or
  2. purchasing, leasing, ordering (or arranging for or recommending purchasing, leasing, or ordering) of any good, facility, service or item reimbursable in whole or in part by federal health care programs.

- Current safe harbors protect some arrangements including, but are limited in scope (e.g. managed care arrangements or discounts or warranties).

The AKS specifically provides that a violation constitutes a false or fraudulent claim under the False Claims Act.
Fraud and Abuse Laws – Anti-Kickback Statute

Prohibition Against Improper Remuneration

• AKS assumes all arrangements are for the sale of items and services.
  
  • AKS Warranty Safe Harbor is designed to protect provision of items and services due to a product defect, not a failure to achieve targeted clinical or economic outcomes
  
  • AKS Discount Safe Harbor is designed to protect discounts and rebates, not accounting for combined product/service offerings aimed as reducing adverse events and associated costs
  
• AKS is not waived for industry/provider/payer collaborations under new reimbursement models rewarding value
  
  • Limit ability of a non-provider to risk-share around improving health outcomes and lowering costs

AKS laws assume traditional reimbursement models rewarding volume, not value, are in play and do not provide flexibility to arrangements to achieve patient-centered clinical or economic outcomes
Fraud and Abuse Laws – Stark Law

Physician Self-Referral Prohibition

• Prohibits a physician from making a referral to an entity for designated health services payable by Medicare or Medicaid if the physician (or an immediate family member) has a financial relationship with the entity.

• “Financial relationship” includes an ownership or investment interest or compensation arrangement.

• “Designated Health Services” include, but are not limited to, inpatient and outpatient hospital services, clinical lab services, physical therapy, DME, home health services and outpatient prescription drugs.

Unlike the AKS, a violation of the Stark Law does not require any intent by the parties to enter the relationship in order to induce referrals. The presence of an improper financial relationship is enough.
Growing Consensus that Laws Need Reform

Seeking Clear Protections for VBHC Arrangements

Subjective Risk Analysis Required

GOAL:

Broaden protections for value-based arrangements among healthcare stakeholders while maintaining safeguards against fraud and abuse
Value-Based Arrangements
Safe Harbor and Exception Proposal
Value-Based Arrangement Safe Harbor & Exception

Addressing both the Anti-Kickback Statute and the Stark Law

- “Entity Agnostic” and “Payer Agnostic”
  - Less about who is involved and more about the types of financial and related arrangements to be protected
- Extends the landscape for such arrangements beyond proposals that are only protected under Center for Medicare & Medicare Innovation (CMMI) pilots and MACRA Alternative Payment Models (APMs)
- Emphasizes maintenance of protections for patients and federal health care programs

Provide opportunities for all stakeholders across the health care continuum, including providers, payers, and medtech manufacturers
What is a Value-Based Arrangement?

Parameters and Requirements to be Met

Value-Based Arrangement Goals
- Promotion of accountability for quality, cost, coordination, and overall care of patient populations;
- Improvement of management and coordination of care for patients; or
- Encouragement of investment in health care infrastructure and redesigned care processes for high-quality and efficient service delivery for patients.

Value-Based Arrangements to be Protected
- *Value-Based Risk Sharing Network Arrangements* – Network accepts capitation, revenue percentage for items or services, and/or financial risk parameters (upside or downside) related to the pursuit of value-based arrangement goals through utilization and cost-management.
- *Value-Based Risk-Sharing Transactions* - Arrangements whereby participants agree to specific preidentified clinical, quality, and/or economic metrics, including risk-sharing terms, as a determinant of future remuneration to the participants in the arrangement.

Drawn from existing federal VBHC program fraud and abuse waivers (e.g. Medicare Shared Savings Program)
Value-Based Arrangement Safe Harbor & Exception

Creating New Pathways for Compliance with Fraud and Abuse Laws

**Anti-Kickback Statute**

**Value-Based Arrangement Safe Harbor**

- Applies to “value-based risk-sharing network” or “value-based risk-sharing transaction” arrangements.
- Arrangement is set out in writing and specifies items and services covered by the arrangement, in advance of executing the arrangement.
- Remuneration between entities that further specific quality and cost savings goals can be protected (e.g., the bundling of an implantable along with consulting and post-discharge patient monitoring services)

**Stark Law**

**Value-Based Arrangement Exception**

- Mirrors the terms and conditions of the value-based arrangement AKS safe harbor
- Allow manufacturers and other entities to enter into value-based arrangements with physicians

HHS Secretary will also have authority to define additional value-based arrangements that should qualify for these protections.
Questions?

Thank You For Your Time
Value-Based Health Care

Tom Conniff
Law Department
Assistant General Counsel
June 14, 2019
Key Considerations

• What is value-based health care?
• Why is value-based health care important?
• How does the federal anti-kickback statute impede progress in implementing desirable value-based health care arrangements?
What is Value-Based Health Care?

• Basic Concept
  – Payment linked to *value provided*, rather than to *volume sold*
  – *Value* can be determined based on *cost savings* or *patient outcomes*
  – Manufacturers are held accountable for performance of their products

• Implementation
  – Specific structure of value-based health care arrangement is informed by expectations regarding a specific product and services
    • Arrangement seeks to align *costs* with actual *value* received
    • Adjust price or provide compensation if performance is not consistent with expectations
  
    – *Purchasers pay for only the actual value received*

Result is diversity in value-based health care arrangements
What Is Value-Based Health Care?

Diversity in Value-Based Health Care Arrangements

• **Examples of Potential Structures:**
  – **Price Adjustment:** Manufacturer pays a rebate if clinical outcomes are below expectations (e.g., outcomes are less successful than reported in clinical trials or alternative treatments) or clinical costs are higher than expected
  – **Indication-Specific Pricing:** Pricing depends on approved indication for a drug (higher if used for indication with stronger outcomes)
  – **Fixed Duration:** Payment is fixed for a standard duration of therapy, regardless of the duration required to achieve the desired outcome
  – **Caps:** Cap on total costs for which healthcare provider/third-party payor pays, with manufacturer funding all additional expenses
  – **“Make Whole”**: Reimbursement/compensation for costs to treat unexpected complications (e.g., cost of surgery to replace an implant that is not functioning correctly)
Why Is Value-Based Health Care Important?

• Value-based health care arrangements seek to “rationalize” payment for health care by *aligning value and payment* – Mechanism for addressing increasing healthcare costs

• General commitment by the federal government to implementing value-based arrangements and recognition that regulatory barriers impede implementation

“Regulatory Sprint toward Coordinated Care”

U.S. Department of Health and Human Services (HHS) initiative across HHS agencies to identify and address unnecessary regulatory burdens to care coordination and value-based health care
Why Is Value-Based Health Care Important?


“Upon taking office at HHS, I identified using the value-based transformation of our entire healthcare system as one of the top four priorities for our department … current interpretations of various well-meaning anti-fraud protections may actually be impeding useful coordination and integration of services.”
Why is Value-Based Health Care Important?

Centers for Medicare & Medicaid Services, Medicare Program; Request for Information Regarding the Physician Self-Referral Law (2018)

“To help accelerate the transformation to a value-based system that includes care coordination, HHS has launched a Regulatory Sprint to Coordinated Care … focused on identifying regulatory requirements or prohibitions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, encouraging and incentivizing coordinated care.”
Why Is Value-Based Health Care Important?

HHS Office of Inspector General (OIG), Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP (2018)

“[HHS] is working to transform the health care system into one that better pays for value ... [OIG] seeks to identify ways in which it might modify or add new safe harbors to the anti-kickback statute and exceptions to the beneficiary inducements civil monetary penalty (CMP) definition of ‘remuneration’ in order to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse.”
How does the federal anti-kickback statute impede progress in implementing desirable value-based health care arrangements?

Federal anti-kickback statute was enacted when federal health care programs generally paid for services on a fee-for-service based

– Statute and safe harbors do not contemplate arrangements that include adjustments to price or other transfers of value based on product performance
   • Value provided if product does not meet established performance expectations may not clearly represent traditionally protected value (e.g., may serve as a discount but not look like a traditional discount)

– Value-based arrangements often involve greater coordination with health care providers and the patients served by the providers
   • Encourages appropriate use of the product
     – Provider education
     – Supportive services and tools
   • Tracking and collecting performance data
   • Encourages compliance through patient education
How does the federal anti-kickback statute impede progress in implementing desirable value-based health care arrangements?

Examples:

Discount Safe Harbor
- Protects certain reductions in price
  - Typically up-front reductions or reductions based on factors such as volume
    » Value-based arrangements may incorporate requirements that products be used in certain ways in order to ensure that any performance failures relate to the product and not another cause
    » Other value provided or value that takes prices below cost if product does not perform as expected could be subject to challenge as other than a discount
  - Limited protection for discounts across bundled products and services
    » Value-based arrangements may cover various products and supporting services if must be used together to optimize performance
How does the federal anti-kickback statute impede progress in implementing value-based health care arrangements?

Examples:

**Warranty Safe Harbor**
- Protects payments if product does not perform to specifications
  - Historically interpreted as “product failure”
    » Value-based arrangements focus on failure to meet specific cost or quality performance metrics
    » Historically applied to situations in which particular product failed for a particular patient
  - Value-based arrangements may focus on performance metrics across a patient population (e.g., did use of the product reduce hospital re-admissions across a population as compared to use of a different product)
  - Value that can be provided to health care providers is limited to the cost of the product
    » Value-based arrangements may seek to address performance failures by covering other costs (e.g., cost of surgery on re-admission)
How does the federal anti-kickback statute impede progress in implementing value-based health care arrangements?

OIG Historical Response

- **Waivers**
  - Limited and do not always extend to participation by manufacturers of products
  - **Example:** Waivers for Accountable Care Organizations

- **Advisory Opinions**
  - Advisory opinions have supported value-based health care arrangements
    - **Example:** Recognition that warranty safe harbor can be applied to performance failures and not just product failures (*Advisory Opinions 17-03 and 18-10*)
  - Only parties to the specific arrangement covered by the advisory opinion can rely on the advisory opinion for protection
  - Each advisory opinion addresses specific value-based arrangement and value-based arrangements involve a diversity of structures
  - Seeking an advisory opinion is costly and time consuming; confidentiality concerns
How does the federal anti-kickback statute impede progress in implementing value-based health care arrangements?

Current Need

• Modernize the anti-kickback statute safe harbors to enable manufacturer engagement in more comprehensive value-based arrangements in a simpler, less time consuming and less costly fashion

• Clear and flexible standards that can be:
  ✓ understood and implemented
  ✓ appropriately tailored safeguards to prevent potential abuse
  ✓ applied to a diversity of value-based arrangement structures
Hypothetical Value-Based Arrangements

Arrangements Are Beneficial from Cost and Quality Perspective, But Require Greater Clarity and Certainty of Protection than the Current Law and Guidance Provide

None of the following hypothetical cases referenced in this presentation are squarely addressed by the federal anti-kickback statute, regulations or guidance or any case law. These situations promote lower costs and higher quality in the delivery of health care but greater clarity regarding permissibility is needed to support implementation.
Hypothetical #1 - Provision of Ancillary Items and Services at No Additional Cost

A medtech company offering to buyers of its products at no additional cost ancillary services (e.g., data analytics, follow-up lab testing, patient coaching, and mobile device applications to facilitate patient follow-up care) intended to measure and optimize the agreed-upon patient outcomes.

Example: Medtech company sells new variety of implant, and provides mobile device to permit patient tracking and information gathering.
Hypothetical #2 – Bundled Items and Services with Rebate Based on Clinical Outcome

A medtech company offering a hospital a bundle of items and services (e.g., technology, consulting, training, and ongoing patient monitoring) for a fixed price to achieve a specific clinical outcome (e.g., improvement in length of stay rates or a reduction of costly adverse events such as infections or readmissions), and, if the clinical outcome is not achieved, paying the hospital a rebate, thereby reducing the hospital’s net cost for the bundle.

Example: Medtech company sells a solution to a hospital that includes diagnostic equipment, analysis/consulting that aims to improve hospital’s clinical procedures for detection of pre-malignant lesion, and clinician education; if detection rates not increased to X%, the manufacturer will provide a 25% rebate.
Hypothetical #3 – Payment for Corrective Services if Targeted Clinical Outcome Not Achieved

A medtech company warranting its product will achieve a specific clinical outcome in a less invasive manner; and, if the clinical outcome is not achieved, offering to pay for a corrective surgery to accomplish the desired clinical outcome in the traditional manner.

Example: Medtech company sells new type of hip replacement to hospital that integrates certain care pathways (e.g., pre and post-operative clinical decision support tools) that can help optimize a patient's pre-post-intra surgical experience and recovery and warrants that its use with patients will reduce readmissions by a certain percentage; if readmission still occurs and new surgery is necessary, medtech company will fund replacement surgery.
Thank you

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Law Department
Assistant General Counsel
Tom Conniff
Assistant General Counsel

• Tom Conniff is an Assistant General Counsel for Johnson & Johnson with extensive health care experience in the medical device and pharmaceutical industries. Prior to joining Johnson & Johnson, Tom was an Assistant General Counsel for C.R. Bard, Inc. (now Becton Dickinson) and Lead Corporate Attorney for Stryker Orthopaedics’ global businesses. Tom’s practice primarily focuses on regulatory law supporting a number of the Johnson & Johnson Medical Device businesses including the Johnson & Johnson Medical Devices Strategic Customer Group.

• He is the Co-Chair of the AdvaMed Legal Committee Working Group on Advancing Value-Based Health Care and a member of the AdvaMed Joint Legislative Strategy Task Force to advance policy proposals developed by the AdvaMed Legal Committee Working Group on Advancing Value-Based Health Care with governmental agencies, Congress and the Administration. In this role, Tom has met with HHS, OIG, CMS, Senate and House Judiciary, Senate Finance and Ways and Means with other AdvaMed company-members to educate on the need for modernizing the Anti-Kickback Statute Safe Harbors.
Not-for-profit established in 1906

- For more than 110 years, Fairview Health Services has been a trusted care provider and community partner.

Academic partnership with University of Minnesota since 1997

- In 2018 we expanded our partnership with the University of Minnesota, with work underway to bring our joint clinical enterprise to market in 2019 under the brand M Health Fairview.

Expanding our reach to serve the Twin Cities metro and greater Minnesota

- In 2017 HealthEast Care System and Grand Itasca Clinic & Hospital became part of the Fairview system.

Mission
Fairview is driven to heal, discover, and educate for longer, healthier lives.

Vision
Fairview is driving a healthier future.

Values
Dignity • Integrity • Service • Compassion • Innovation
Our reach

We provide exceptional health care across the full spectrum of health care services.

With Fairview, our patients and communities can access our full continuum of care close to home.
Our system

34,000+ employees
5,000+ system providers
12 hospitals and medical centers
2,071 staffed beds
56 primary care clinics
100+ specialties
90+ senior housing locations
36 pharmacies
360,000 health plan members
Our 2018 impact

- 2.1+ million clinic visits
- 1,144,520 outpatient registrations
- 106,101 inpatient admissions
- 90,411 surgeries
- 13,699 births
- 326,198 emergency department registrations
- 11,527 behavioral inpatient admissions
- 236 blood and marrow transplants
- 331 organ transplants
- 2.3+ million pharmacy unit sales

$5 billion total assets
$5.7 billion total revenue
$771.8 million in community contributions (2017)
Barriers to Value-Based Care

Nonprofit Hospital Perspective on How the Stark Law and the Anti-Kickback Statute can Inhibit Value-Based Care
• Value-based payment arrangements which Congress/CMS promote typically require financial arrangements among multiple health care stakeholders that could implicate the Stark Law and AKS.

• Many policymakers and health care professionals cite the Stark Law and AKS as major reasons value-based care has not been widely implemented even with MACRA.

• Moreover, these laws pose barriers to activities of nonprofit providers like Fairview to improve the health of the communities they serve.
There are two major/overlapping categories of the laws’ issues:

1. There is a lack of exceptions or clarity for value-based payment models; and
2. A misaligned regulatory framework.

These two categories do not have to be mutually exclusive.
Barriers to Innovative Financial Arrangements

• Integrated care within a multi-disciplinary health care team is a reoccurring element of provider system and many value-based payment models.
  - Financial arrangements between hospitals and referring physicians implicate the Stark Law and AKS.
  - There are no broad exceptions from the Stark Law or AKS for value-based payment models.

• Public commenters have recommended an exception for entities that integrate care across multiple disciplines with various health care-related professionals as long as certain criteria is met and would apply to any stakeholder regardless of whether they participate in a Medicare alternative payment program.
Continued Barriers to Innovative Financial Arrangements

• However, under this approach, Congress and/or the Administration would have to establish:
  – Clear guidance for value-based integrated care and models that would be eligible for the exception; and
  – Clear guidance on how entities could distribute financial savings to support clinical and payment integration.

• Almost all current exceptions are based on a regulatory framework that is aligned with a FFS world.
  – Most exceptions involve financial arrangements that are based on a fair market value (FMV) exchange. Parties must get paid FMV for whatever service, item, or space they are providing.
  – Additionally, the laws generally prohibit arrangements that are based on or take into account the “volume or value” of patient referrals.
Continued Barriers to Innovative Financial Arrangements

• However, value-based arrangements generally reward activities that improve quality and generate savings, frequently focused on the physicians who are responsible for the applicable patient care – meaning those physicians are also responsible for referring patients.

• Payment for reducing medically unnecessary care, utilizing lower cost alternative treatments, and improving quality frequently do not satisfy traditional notions of a FMV exchange. And value-based payments to physicians who are involved in a patient’s care may be viewed as taking into account the volume or value of referrals.
Barriers to Activities of Nonprofit Providers

• Nonprofit providers engage in many community activities that embody or are consistent with value-based care.
  - As part of our mission, Fairview alone provided over $770 million in community services in 2017, and much of this represents activities to improve the health status of the communities we serve.

• These services can be provided at the community-wide level or the patient specific level.

• However, we face barriers to these efforts because of prohibitions of “beneficiary inducements” under the AKS and Civil Monetary Penalties (CMP) Law.
Example 1 – Activities to Improve the Health of the Community

• A hospital hosts free community-wide activities such as community-wide health fairs, health screenings, wellness programs or other health care education activities.

• ISSUE: These activities potentially could violate the beneficiary inducement prohibitions under the AKS and the CMP Law. There is a risk these activities could be viewed as steering patients to the provider.
Example 2 – Activities to Improve the Health of Patients

• A hospital provides free items and services to patients intended to improve patient health status such as transportation or lodging, coaches to promote adherence to treatment, or financial aid for medications through patient assistance programs.

• ISSUE: These activities potentially could violate the beneficiary inducement prohibitions under the AKS and the CMP law. There is a risk these activities could be viewed as steering patients to the provider. There also is a risk these activities could be viewed as improperly influencing a patient to take a specific treatment option.
Example 3 – Gainsharing in Hospitals

• A physician (non-hospital employee)-led care team based in a hospital successfully treats a patient that results in positive patient outcomes and significantly lower than expected costs for the hospital. The care team saved the hospital $10,000.

• The hospital gives $5,000 of those savings to the care team for their excellent work.

• ISSUE: This could potentially violate the Stark law prohibition against compensation based on volume or value of services rendered and/or be viewed as a payment above FMV. In addition, compensation targeted to care teams including referring providers could be construed as improper inducement of referrals to the hospital, potentially violating the AKS.
Example 4 – Accountable Care Organizations (ACO)/Payer Shared Savings

- A Hospital and Physician Group form an ACO through participation in the Medicare Shared Savings Program (MSSP). Subsequently, beneficiaries are experiencing improved outcomes and per-beneficiary costs decline.

- Hospitals extend the ACO for non-Medicare population (and commercial payers) where the Hospital and Physician Group would share any savings realized through care coordination.

- ISSUE: Depending on how it is structured, this could constitute a financial arrangement and potentially implicate the Stark Law/AKS. Distribution of savings from a payer to a hospital to a referring physician constitutes remuneration and a financial arrangement that could implicate Stark/AKS based on FMV and volume or value issues.

- There are no waivers or exceptions for non-Medicare MSSP initiatives.
Example 5 – Clinically Integrated Network

• A hospital-sponsored clinically integrated network (CIN) made up of multiple clinicians and stakeholders (i.e., specialists, hospitals, and post-acute care physicians) enters into a commercial payer arrangement to receive add-on reimbursement for satisfying certain metrics.

• The hospital (through its CIN entity) receives add-on payments and distributes to participating providers, who also refer patients to the hospital.

• ISSUE: The arrangement likely implicates the Stark Law and AKS for the same reasons discussed above – how is FMV determined in this context and are payment decisions that consider the referral source “taking into account” the volume or value of the referrals between the parties?