The Transition to Value-Based Health Care: Recommendations for Medical Device Manufacturers

April 27, 2017
Agenda

• Introduction
  • Shift to Value-Based Care
  • New Models of Medical Device Company Operation
  • Compliance Challenges and Risk Mitigation
  • Questions
Introduction

• Traditional models of medical device company operation focus on product sales
  – Advances focus on technological and product-related developments

• With shift to value-based care, medical device companies have new business opportunities with respect to the products and services they offer and the prices they charge
  – Medical device companies seek alignment with providers and payors, and look to provide support in governmental and private-pay initiatives
Introduction

• Medical device companies must consider and evaluate new value-based payment models as well as new delivery system models.

• As is the case throughout the health care industry, new value-based care models will present both organizational and compliance-related challenges.

• Medical device companies must assess strategies for mitigating legal and business risk related to these new models and for developing compliance programs that address value-based models.
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Traditional Model of Medical Device Company Operation

• Focus on product sale, parts, supplies and service

• Depends upon individual knowledge of product, sales representative experience and relationships with customers

• Provide discounts that align with provider payments, which reward providers for volume and internal cost controls
  – The government provides a pathway for protecting discounts under the Anti-Kickback Statute’s discount safe harbor
Shift to Value-Based Care

- Shift from fee-for-service to value-based reimbursement

- The Centers for Medicare and Medicaid Services (“CMS”) and its Center for Medicare and Medicaid Innovation (“CMMI”) led the foray into value-based reimbursement with innovative health care payment and service delivery models
  - Bundled Payments for Care Improvement (“BPCI”) Initiative
  - Comprehensive Care for Joint Replacement (“CJR”) Model
  - Proposed Episode Payment Models (“EPMs”)
  - Proposed Cardiac Rehabilitation Incentive Payment Model (“CRIPM”)

- Private payors continue to develop new value-based care models with providers, medical device and pharmaceutical companies
Value-Based Payment

• “Value-based payment” is a broad term used to address the variety of ways in which a medical device company may “share in the risk” with providers and payors
  – Bundled payments
  – Risk-sharing
  – Other methodology where payment is “at risk” based on outcomes

• May use with traditional product sale model as well as with new service models
  – The key is that the value-based payment is not just a discount – to be value-based, payment must be based in same way on quality of care, efficiencies, or patient satisfaction
Value-Based Payment

- Compliance issues/concerns around value-based payment depend upon the type of delivery model used.
- At a high level, however, value-based payment raises potential concerns around:
  - Anti-Kickback Statute
  - State insurance and similar laws for entities (including, potentially, providers and device companies) that bear risk
  - Conflicts of interest
  - Data sharing
  - Corporate practice and fee-splitting
- Risks may be muted when participating in government pay initiatives, which have waivers to address certain items.
- For private pay initiatives, must strategize to address risks when structuring the products, services and pricing in value-based arrangement.
• Hospital-based efficiency initiatives under which hospitals pay physicians a share of cost reductions attributable to physicians’ initiation and/or implementation of cost-savings measures
  – Though medical device companies, by definition, do not participate in gainsharing endeavors, as part of some delivery system models medical device companies may establish gainsharing arrangements

• Gainsharing arrangements are complex, and both hospital and physician partners have an interest in ensuring they are carefully structured to comply with current laws and guidance
Gainsharing

• The most useful guidance on gainsharing is derived from over a dozen Office of Inspector General ("OIG") advisory opinions on gainsharing issued from 2000 to 2012

• Gainsharing arrangements are often viewed as suspect by the OIG – however, OIG has made clear that gainsharing arrangements are not an enforcement priority unless the arrangement lacks sufficient patient and program safeguards
  – Structuring a gainsharing arrangement to comply with OIG advisory opinions reduces the risk of an adverse enforcement action or imposition of penalties

• There may also be other factors to consider, including whether the gainsharing partner participates in any federal or state bundled payment or risk-sharing programs
Transition Presents New Opportunities for Medical Device Companies

• Challenges yield opportunities for medical device companies seeking to serve as partners
  – Must think through new questions on discounts
  – Must also think beyond discounts, to new questions about the short-term and long-term value they can bring to payors and providers focused on value-based care
  – New value models inevitably bring new regulatory challenges

• Models seek to change the care delivery system and payment system, ultimately shifting financial risk based on outcomes
Delivery System Transformation and Payment System Transformation

• Delivery System Transformation
  – Focus on integration and coordination of care, alignment of resources and incentives
  – Maximize operational efficiencies and economies of scale
  – Balance care quality, efficiency, accessibility and cost
  – Use data to make key clinical and organizational decisions (e.g., measure outcomes and costs)

• Payment System Transformation
  – Payment for quality, not quantity, of care
  – Bundled payments
  – Shifting financial risk from insurers (Medicare, private pay) to providers
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Transition Presents New Opportunities for Medical Device Companies

• Medical device companies have unique expertise that can translate into valuable services for hospitals, e.g.—
  – Development of patient adherence tools
  – Health economics and outcomes information
  – Data analysis
  – Management or consulting services

• Legal risks depend on factors including the structure of the engagement, the medical device company’s ability to drive product selection and the separation (or lack thereof) between pricing of products and services
Continuum of Delivery System Transformation

• Moving from left to right, the continuum of delivery system transformation models increasingly offer opportunities for vertical integration and provider/payor alignment, but bring new compliance and regulatory challenges
Traditional Sale and Value-Based Payment Model

- Model adheres to the traditional device model for product sale, but adds as an overlay value-based pricing
- Advantage as an initial foray into value-based care for many medical device companies, as it requires a limited investment (in terms of money and other resources) in new models
- Potential for engagement with both provider and payor
- The next few slides are illustrative of this model, as well as potential risks that may accompany the model
Examples of Traditional Sale and Value-Based Payment Model

- In 2014, St. Jude Medical began offering to pay hospitals a 45% rebate on the net price of cardiac resynchronization therapies if a lead revision was needed within the first year of implantation as a result of four specified factors.

- In December 2014, Biosense Webster of Johnson & Johnson initiated a program under which Biosense Webster provided a credit to hospital customers if an enrolled patient with paroxysmal, drug-resistant atrial fibrillation (Afib) was treated with the Thermocool Smarttouch Catheter and returned for a repeat procedure within 12 months.
Traditional Sale and Value-Based Model: Compliance Concerns and Mitigation Strategies

- Potential regulatory challenges with a device sale and value-based payment
  - Anti-Kickback Statute
    - Discount safe harbor
    - Bundled discounts
  - Payor-provider relationship
    - Beneficiary of the value-based payment
  - State insurance and similar laws regarding risk-bearing entities
  - Potential complication from any government initiative in which provider is participating
Consulting / Episode Management Model

- Provide technology, consulting or episode management services around procedures using products similar to those the company sells (e.g., hospital orthopaedic surgery department)
  - Can be used with a variety of risk-sharing methods
  - Can also be used to create gainsharing models

- Big leap from the first model—this is a sea change from a product-focused model to a service-focused model
  - Operational questions (e.g., legal entity, personnel)
  - Scope of new skillset (e.g., develop, partner, acquire)

- May be used with provider or payor partners

- May be designed to complement governmental or private pay initiatives
  - Potential for model variation means variety of potential compliance risks
Consulting / Episode Management Model

• Data key new issue in consulting/episode management model
  – Data aggregation and de-identification services
  – Predictive analytics and artificial intelligence
  – Sharing data to improve quality of care, clinical outcomes and product development

• New data issues present various challenges
  – HIPAA
  – State laws regarding personal information
  – Contractual restrictions
  – Patient authorization and consent
Example of Consulting / Episode Management Model

• Some new technologies are designed to assist hospitals with targeted performance initiatives
  – In 2015, **Smith & Nephew**’s strategic business unit **Syncera** acquired Virtual Backtable and TrayTouch, software assets used by hospitals and ASCs to monitor instrument utilization data during surgery in order to streamline instrument assembly
  – Solutions designed to complement Syncera’s role in the hip and knee marketplace
• New technology not directly tied to a device company’s main product allows for development into new advisory space
Other new initiatives move beyond technology into consulting space

– In 2015, Boston Scientific announced strategic alignments with TogetherMD, a provider of health care data analytics software, and MedAxiom, a cardiovascular consulting company, with the intention of improving outcomes and reducing cost of cardiovascular care delivery as part of Boston Scientific’s Advantics service

– In 2016, Boston Scientific announced development of cloud-based, digital health solution with Accenture to provide insights into care coordination and patient population health patterns

Movement toward management of disease states, episodes of care and patient populations
Example of Consulting / Episode Management Model

- Solutions designed to manage an “episode” of care
  - In 2014, *Depuy Synthes Companies* of *Johnson & Johnson* announced its Geriatric Fracture Program, a hip fracture program focusing on treatment of patients from time of arrival through discharge
    - Early surgical intervention
    - Management of co-morbidities
    - Evidence-based care pathways
    - Prevention of delirium
    - Early supported discharge
    - Multi-disciplinary fracture program
    - Education, monitoring, communication with patients
  - *Depuy Synthes* supports hospital through implementation support, program materials and performance dashboard
  - In 2016, *Johnson & Johnson* announced that the program could help hospitals enrolled in mandatory CMMI programs
• For each of these technology, consulting and episode payment models, there may be a variety of value-based payment opportunities
  – For example, following the initial CMMI programs, a medical device company could use a bundled payment for each episode of care, with certain minimum quality-related thresholds
  – The medical device company payment could also be built upon a combination of a bundled payment for each episode, with goals related to quality, efficiency and patient satisfaction serving as bonus benchmarks

• In addition, the medical device company may be responsible for helping to design and establish gainsharing initiatives to incentivize physician participation
Example of Consulting / Episode Management Model

- Variety of payment options may also allow medical device companies to play greater role in payor initiatives
  - In September 2016, UnitedHealthcare launched a new program with Ortho Rhode Island, an orthopedic care group, dedicating resources to care coordination among Ortho Rhode Island care providers, as well as the primary care physicians and rehabilitation providers who contribute to patient care plans
    - Value-based effort involves population health support and data
  - In December 2016, UnitedHealthcare announced Spine and Joint Solution initiatives, involving bundled payment for defined episode of care (e.g., hip, knee replacement) at UnitedHealthcare-designated Centers of Excellence
    - Available to large and mid-sized companies with self-funded health plans
- Opportunity for technology, consulting, data analysis and other services to assist in implementation
Key question when assessing regulatory challenges is how medical device company will treat purchase of services versus purchase of products

- Anti-Kickback Statute
- Payor-provider relationship
- State insurance and similar laws regarding risk-bearing entities
- Potential complication from any government initiative in which provider is participating
- Medical ethics/hospital prudence
- Antitrust
- Medical malpractice
- Potential Stark Law, False Claims Act
Consulting / Episode Management Model: Compliance Concerns and Mitigation Strategies

• Medical device company may deploy a variety of risk mitigation strategies
  – Separate service payment from device payment
    • Track personal services/management agreement safe harbor as closely as possible
  • Safeguards and additional mitigation actions
    – Clear and transparent risk sharing tied to specific metrics
    – Objective quality metrics to ensure quality of care
    – Firewall with medical device company sales
    – Compliance program
      • Auditing
      • Monitoring
Management of Provider Business Line or Organization

• Enter into a management services contract to operate either a line of business using products like those the company sells (e.g., orthopaedic surgery department of a hospital) or a standalone provider organization

• Like the leap from traditional device sales to episode management/consulting, change to management of a provider organization is a large shift in medical device model
  – Increased alignment with provider
  – Operational questions (e.g., legal entity, personnel)
  – New skillset (e.g., develop partner, acquire)
  – Potential proof of concept requirement
Management of Provider Business Line or Organization

• Similar regulatory challenges as those in consulting model, exacerbated due to increased medical device company role
  – Anti-Kickback Statute
  – Institutional licensure
  – Corporate practice of medicine
  – Provider agreement
  – Payor-provider relationship
  – State insurance and similar laws regarding risk-bearing entities
  – Potential complication from any government initiative in which provider participates
  – Medical ethics/hospital prudence
  – Antitrust
  – Medical malpractice
  – Potential Stark Law, False Claims Act
A medical device company may deploy a variety of risk mitigation strategies

- Generally same common elements as consulting
- Avoid bundling products under management agreement (separate product/service contracts)
  - Track personal services/management agreement safe harbor as closely as possible
    - As with consulting, must establish safeguards and take additional mitigation actions
  - Value-based pricing (payment contingent on outcomes)
    - Outside the box; likely no safe harbor
    - FMV issues
Ownership of Provider Organization

• Medical device company acquires a provider of health care services using products like those the company sells

• This is the most vertically-integrated model and the furthest departure from the traditional model of medical device sales

• As with other models, there are new operational questions that arise with a provider ownership model
  – Given the potential loss of investment capital, questions regarding operational capabilities, proof of concept and partners take on increased importance

• There has been some movement toward this model, particularly overseas
Ownership of Provider Organization: Compliance Concerns and Mitigation Strategies

- Similar regulatory challenges as those in management model, exacerbated due to increased medical device company role
- With increased integration, must additionally consider separation between roles as owner, manager (if applicable) and device company
  - Conflict of interest questions
  - Personnel management
  - Data sharing
- Risk mitigation strategies essential
- Compliance program takes on increased importance, as it must handle new and challenging questions
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New Compliance Challenges and Risk Mitigation Strategies

• The current regulatory framework can be challenging for medical device companies seeking to develop new payment or delivery system models that align with value-based care initiatives
  – Established to allow for fee-for-service payments and discounts in line with the Anti-Kickback Statute discount safe harbor or similar

• Added difficulty with constant evolution of payment and delivery system models, as well as political uncertainty regarding the future of government initiatives
New Compliance Challenges and Risk Mitigation Strategies

• Robust compliance program is key to success
  – Must manage risks related to traditional role as device company and new partnership roles
  – Given variety of partnership roles, compliance program must be nimble and capable of adapting to new challenges

• Compliance programs should anticipate new value-based care changes and begin considering how to address challenges
  – Given rapid movement of deals in value-based care space, advance preparation important so that can assess and manage both acquisition and partnership transactions, and future movement of the business
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