Presentation Overview

1. Current Health Care Regulatory Trends
2. Overview of Potential Changes
3. Industry Segments
   1. Revenue Cycle Management
   2. Payors
   3. Pharmaceuticals
   4. Medical Device Manufacturers
4. Ropes & Gray Resources
The Patient Protection and Affordable Care Act (ACA) impacted the health care sector in several ways:

• Value-based care has become an increasing focus of both Congress (which created a cost and quality based payment modifier for physicians groups) and CMS through its Innovation Center (commonly known as CMMI) to save federal dollars and improve care quality

• Under VBC models, health care entities need to improve efficiency, reduce waste, and resolve uneven quality concerns because of limited available dollars and economic pressure

• To succeed under VBC models, most providers incur infrastructure costs such as adopting electronic medical record systems, updating facilities, implementing clinical integration, and developing evidence-based protocols to track quality measures and redesign care

• Health care entities have partnered to share these expenses and gain economies of scale
Difficulties under the ACA

The ACA also contributed to stressors for the health care industry:

• Insurance mandates and exchange requirements drove the growth of high deductible, high copayment plans, which have contributed to growth in hospital bad debt

• Reductions in inpatient and select downstream provider reimbursement rates have decreased provider revenue
  – Medicare and Medicaid reimbursement rates have not kept pace with hospital expense growth

• Increased emphasis on post-acute care rather than traditional hospital-based care

• Increased scrutiny on patient outcomes and “unnecessary” services

• Reduced payor competition in individual marketplace as several insurers have left the exchanges
Current Health Care Regulatory Trends: Value-Based Care

- Public and private payors are moving away from traditional fee-for-service payment models. Instead, they are increasingly utilizing payment methodologies that (i) put providers at financial risk and (ii) reward providers for improving quality of care, efficiency, and patient satisfaction
  - Key areas of focus will be high-cost and high-utilization services
  - Providers with experience in managing risk over a defined population have a significant advantage in the new reimbursement landscape

- Growth in downside risk for institutional and downstream providers
  - CMS introduced voluntary and mandatory bundled payment programs that push downside risk to hospitals and network partners (with the future of mandatory bundled payment programs now in some doubt)
  - CMS increasingly seeking ACO participants that assume higher risk
The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) changed how Medicare will pay physicians and other clinicians. MACRA created two payment tracks:

- **Advanced Alternative Payment Models (APMs) participation:** Clinicians may participate in certain CMS-administered value-based payment programs or federal demonstration projects
  
  - Participants in Advanced APMs will receive an annual 5% lump sum increase in Medicare Part B reimbursement beginning in 2019

- **Merit-Based Incentive Payment System (MIPS):** Adjusts clinician payments based on quality, cost, improvement activities (i.e., patient safety, care coordination, increased access), and use of health IT
  
  - MIPS participants will receive an annual performance-based upward or downward adjustment in Part B reimbursement, ranging from ± 4% in 2019 to ± 9% beginning in 2022
  
  - New Medicare Part B participants and participants that serve few patients are excluded
Current Health Care Regulatory Trends: Provider Consolidation

- Because of (i) low reimbursement rates and (ii) growth in value-based care, health care providers have consolidated at a dramatic rate to increase efficiencies and maximize benefits from economies of scale

  - **Provider consolidation:**
    - Vertical integration of physician groups, hospitals, and non-acute care providers
    - Horizontal integration of systems acquiring free-standing, high-risk hospitals

  - **Geographic consolidation into metropolitan areas**
Current Health Care Regulatory Trends: Payor Consolidation

• Recently, health plans have also sought to consolidate to achieve economies of scale, gain negotiating power with providers, and reduce risks through diversification

• Critics have argued health plan mergers reduce competition and lead to less consumer choice and higher premiums

• Following suits by the DOJ, federal courts blocked proposed mergers between Aetna and Humana, and Anthem and Cigna
Current Health Care Regulatory Trends: 21st Century Cures Act

• 21st Century Cures Act was enacted in Dec. 2016 with strong bipartisan support

• The Cures Act makes numerous changes to laws governing FDA programs, clinical research regulations, and Medicare coverage and reimbursement rules to advance biomedical innovation
  – Promotes drug development, including expansion of the types of data the FDA will consider and increased clinical trial design flexibility
  – Promotes use of electronic health records and health information technology by promoting interoperability and reducing burdens on providers
  – Increases incentives for development of drugs for rare diseases
  – Expedites review for breakthrough devices and expands humanitarian device exemptions
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Regulatory Changes on the Horizon from the Trump Administration

• The Trump administration and Republican-controlled Congress have sought to repeal and replace the ACA
• The Trump administration has also sought to reduce regulatory burdens on industry
  – FDA Commissioner, Scott Gottlieb, has discussed reducing the requirements necessary for bringing drugs to market
  – On August 10, 2017, CMS proposed a rule that would cancel the Comprehensive Care for Joint Replacements and cardiac care payment bundles
    • The Office of Management and Budget is currently reviewing this proposed rule, which followed two delays of the bundles’ implementation
    • Experts predict that the voluntary bundled payments program will survive, along with the ongoing CCJR demonstration
ACA “Repeal and Replace” Efforts Appear to Have Stalled for Now

• “Repeal and replace” efforts in both the House and Senate have stalled
  – The House passed the American Health Care Act on May 4, 2017, but the Senate declined to vote on the bill before effecting substantial changes to it
  – The Senate floated several versions of their own ACA replacement, called the Better Care Reconciliation Act, but failed to attract enough support for any of its iterations
    • After narrowly voting to proceed to debate on the bill on July 25, 2017, the Senate ultimately rejected the version Republican leadership put up for a vote on July 28
• Future congressional action on health care reform is uncertain
Regulatory Changes on the Horizon from the Trump Administration

• Prior policy priorities of Trump healthcare appointees (including Representative Tom Price as Secretary of HHS and Seema Verma as Administrator of CMS) indicate the following regulatory changes may be on the horizon:
  – CMS could grant state Medicaid waivers that impose additional state eligibility requirements (such as work requirements) and costs (such as premiums and copays) on Medicaid beneficiaries
  – CMS could decrease the amount of federally driven value-based care programs if the scope of CMMI programs are narrowed
Value-Based Care: Potential Changes

• Despite recent political changes, value-based care and alternative payment methodologies have bipartisan support, and it appears likely that VBC initiatives will be central to the viability, growth and profitability of providers in the healthcare industry.

• However, HHS under Secretary Price could scale back or eliminate mandatory CMMI demonstrations:
  – Experts have speculated about a policy shift away from mandatory programs and into voluntary ones, but CMS’s recent move to cancel two payment bundling programs could indicate that the administration is taking a harder line.
Secretary Price could ease regulatory burdens on physicians imposed by MACRA

- Sec. Price voted for MACRA, but has objected to the complexity of MIPS and has pushed to make the system more physician-friendly

- If HHS scales back the number of CMMI models, there would be fewer Advanced APMs for physicians to participate in, and more physicians could have to participate in the more burdensome MIPS track
  - Perhaps in part to address this challenge, CMS issued a proposed rule on June 20, 2017 that appears designed to make MACRA requirements less burdensome for physicians, including by exempting more doctors from MIPS participation
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Payors: Introduction

VBHC Considerations for Payors

- MLR vs Admin Spend
- Medical Device Bundles
- Medication Management Services
- Data Analytics and Consulting
- Provider Network Support
Payors: VBHC Programs Overview

<table>
<thead>
<tr>
<th>Type of Program</th>
<th>Medicare ACOs</th>
<th>BPCI</th>
<th>CJR/EPMs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population-Based</td>
<td>Episode-Based</td>
<td>Episode-Based</td>
<td></td>
</tr>
<tr>
<td>Mandatory?</td>
<td>Voluntary</td>
<td>Voluntary</td>
<td>Mandatory*</td>
</tr>
<tr>
<td>Participant Type(s)</td>
<td>Medicare Providers</td>
<td>Acute Care Hospitals, SNF, Physician Groups, HHAs, IRF, LTCH</td>
<td>Acute Care Hospitals</td>
</tr>
<tr>
<td>Risk-Sharing?</td>
<td>Required, except for Track 1</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Payment Method</td>
<td>FFS with retrospective reconciliation</td>
<td>FFS with retrospective reconciliation or global cap</td>
<td>FFS with retrospective reconciliation</td>
</tr>
</tbody>
</table>

* Now called into question with potential for cancellation of certain mandatory bundled payment programs
## Government Payors - Medicare

<table>
<thead>
<tr>
<th>Type of Program</th>
<th>Comprehensive Primary Care+</th>
<th>Part D Enhanced MTM</th>
<th>Medicare Advantage VBID</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mandatory?</strong></td>
<td>Voluntary</td>
<td>Voluntary</td>
<td>Voluntary</td>
</tr>
<tr>
<td><strong>Participant Type(s)</strong></td>
<td>Private Payors and Primary Care Physicians</td>
<td>Part D Sponsors</td>
<td>Medicare Advantage (“MA”) and MA-Part D Plans</td>
</tr>
<tr>
<td><strong>Risk-Sharing?</strong></td>
<td>Required</td>
<td>None (may spend more on MTM items/services)</td>
<td>None (may modify services or cost sharing)</td>
</tr>
<tr>
<td><strong>Payment Method</strong></td>
<td>FFS + PMPM care management fee + at risk incentive payment</td>
<td>Standard Part D reimbursement</td>
<td>Standard Medicare Advantage reimbursement</td>
</tr>
</tbody>
</table>
## Payors: VBHC Program Examples

### Government Payors - Medicaid

<table>
<thead>
<tr>
<th></th>
<th>Arkansas</th>
<th>Massachusetts</th>
<th>Ohio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Program</strong></td>
<td>Episode-Based</td>
<td>Population-Based</td>
<td>Episode-Based</td>
</tr>
<tr>
<td><strong>Payor Types</strong></td>
<td>State Medicaid and Private Payor</td>
<td>MassHealth-contracted MCOs</td>
<td>Ohio Medicaid MCOs; input from private payors</td>
</tr>
<tr>
<td><strong>Providers</strong></td>
<td>Varies by episode</td>
<td>ACOs that include PCPs; certain hospitals receive additional funds</td>
<td>Varies by episode type; participation mandatory</td>
</tr>
<tr>
<td><strong>Risk-Sharing?</strong></td>
<td>Required reconciliation at end of performance period</td>
<td>Yes – extent varies among participation options</td>
<td>Yes for highest cost episodes</td>
</tr>
<tr>
<td><strong>Payment Method</strong></td>
<td>Fee for services with reconciliation against price benchmark</td>
<td>PMPM capitation or FFS with shared savings/losses</td>
<td>Fee for service with retrospective gain/risk sharing</td>
</tr>
</tbody>
</table>
# Payors: VBHC Program Examples

## Commercial/Private Payors

<table>
<thead>
<tr>
<th>Providers</th>
<th>Type of Program</th>
<th>Risk-Sharing?</th>
<th>Payment Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCBS MA AQC</td>
<td>Population-Based</td>
<td>Optional</td>
<td>Modified 5-year global budget with quality incentive payments</td>
</tr>
<tr>
<td>Humana</td>
<td>Population-Based</td>
<td>Yes</td>
<td>Fee for service with gain/risk sharing for performance on quality and health outcomes</td>
</tr>
<tr>
<td>Walmart, GE, Boeing, Lowes</td>
<td>Episode-Based</td>
<td>Yes</td>
<td>Fixed global payment for each procedure, including non-hospital services</td>
</tr>
</tbody>
</table>
Payors: Legal Considerations

Medical Loss Ratio ("MLR") Requirements

\[
MLR = \frac{\text{Health Care Claims} + \text{Quality Improvement Expenses}}{\text{Premiums} - \text{Taxes, Licensing & Regulatory Fees}}
\]

Allowable Expense Categories

- Improve outcomes: quality reporting, care management/coordination, care compliance
- Readmissions prevention, including patient education and counseling
- Patient safety and reduction of medical errors
- Implement wellness and health promotion activities

Requirements for All Expenses

- Must be designed to improve care quality
- The desired positive outcomes must be objectively verifiable and calculable
- The spending should be directed towards enrollees or a population that includes enrollees
- Grounded in evidence based medicine, widely accepted clinical best practices or criteria
## The Anti-Kickback Statute ("AKS")

<table>
<thead>
<tr>
<th>Scope</th>
<th>Prohibits the knowing and willful solicitation, receipt, offer or payment of any remuneration in return for either referrals of federal health care program business or recommending items or services reimbursed by a federal health care program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managed Care Safe Harbor</td>
<td>Protects price reductions by first tier contractors offered to qualified managed care plans; would not cover services offered by a payor to providers; also requires contractor to have “substantial financial risk” which is narrowly defined</td>
</tr>
<tr>
<td>Personal Services Safe Harbor</td>
<td>Protects certain personal or management services; however, requires compensation to be at fair market value, which is difficult to determine when “value” is determined by outcomes and is therefore not set in advance (and may change over time)</td>
</tr>
<tr>
<td>Advisory Opinions</td>
<td>HHS-OIG endorsed safeguards include objective and verifiable cost savings and quality measures, no inappropriate reductions in services, and periodic reviews</td>
</tr>
</tbody>
</table>
Payors: Legal Considerations

Responses to FY 2017 HHS-OIG Safe Harbor Solicitation

- Suggests modification of existing warranty, discount and personal services safe harbors
- Also recommends modifying managed care safe harbor to protect VBHC relationships with PBMS
- Requests development of a new, VBHC-specific safe harbor
Payors: Design & Implementation

- Target Population Identification
- Performance Measures
- Provider Incentives
- Operational Challenges
- Continuous Improvement
- Care Transformation
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Pharma: Value-Based Care

• Significant Interest
  – Pharmaceutical industry interested in exploring value-based contracting with both payers and providers
    • Meet strategic objectives
    • Respond to perceived customer need
  – Appearance versus reality

• Potential Opportunities
  – Mitigate market access restrictions or support higher prices (particularly for products that payors may be reluctant to cover on launch)
  – Differentiate from competitors by demonstrating value
  – Generate real-world evidence about a product

• Legal and Operational Challenges
  – Many concerns the same for payer v. provider arrangements but some key distinctions
• Potential Value-Based Contracting Approaches
  – **Price Adjustment**: Manufacturer pays a rebate if clinical outcomes are below expectations (e.g., outcomes are less successful than reported in clinical trials or compared to patients taking competitor drugs) or clinical costs are higher than expected
  – **Shared Savings**: Manufacturer shares in any cost savings attributable to the drug
  – **Shared Payment**: Manufacturer shares in any enhanced payments from payers attributable to impact of drug use
  – **Make Whole**: Reimbursement for costs to treat complications (e.g., above baseline number/percentage)
• Potential Value-Based Contracting Approaches

  – **Trial**: Trial period during which the drug is jointly funded, or provided without charge, and outcomes are monitored
  – **Indication-Specific Pricing**: Pricing depends on approved indication (higher if used for indication with stronger outcomes)
  – **Fixed Duration**: Payment for a standard duration of therapy, regardless of the duration required to achieve the desired outcome
  – **Caps**: Cap on total costs or number of doses for which payor pays, with manufacturer funding all additional expenses

*Legal Concerns May Vary Depending on General Approach and Particular Structure*
# Pharma: Legal Challenges

## Key Fraud and Abuse Laws

<table>
<thead>
<tr>
<th><strong>Key Fraud and Abuse Laws</strong></th>
<th><strong>Summary</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anti-Kickback Statute</strong></td>
<td>Prohibits knowing solicitation, offer, payment, or receipt of anything of value whatsoever in order to generate business reimbursable (directly or as part of a service) under “federal health care programs”</td>
</tr>
</tbody>
</table>
| **False Claims Act (FCA)** | Prohibits knowingly presenting or causing to be presented a false claim for payment to the federal government  
*Additional mechanism to enforce the Anti-Kickback Statute* |
| **CMP Law (Gainsharing)** | Prohibits payments by hospitals to physicians to induce reduction or limitation of *medically necessary* services to hospital patients covered under “federal health care programs”  
*Law does not apply to pharmaceutical manufacturers but government guidance may provide analytical framework for assessing risk-sharing arrangements* |
| **Transparency Laws** | Requires manufacturers to track and report payments and other transfers of value to certain health care providers  
*Discounts/rebates are generally exempt from reporting and most manufacturers apply exemption to all commercial transactions involving the sale of products/services* |
## Pharma: Legal Challenges

<table>
<thead>
<tr>
<th>Other Laws</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Privacy</td>
<td>Limits the ability of health plans, health care providers and their respective business associates to use and disclose individually identifiable health information</td>
</tr>
<tr>
<td>Medicaid Drug Rebate Program</td>
<td>Requires manufacturers to provide specific rebates to state Medicaid programs for outpatient prescription drugs dispensed to Medicaid patients in exchange for state Medicaid program coverage</td>
</tr>
<tr>
<td>Antitrust</td>
<td>Prohibits pricing discrimination or exclusive contracting in connection with sale of products that could result in competitive harm</td>
</tr>
<tr>
<td>State Insurance Laws</td>
<td>States vary in how they regulate the sharing of health insurance risk between insurance companies and providers or other entities</td>
</tr>
</tbody>
</table>
| Corporate Practice of Medicine   | State corporate practice of medicine laws generally prohibit corporate entities from practicing medicine or employing physicians to provide medical services, as such entities are not themselves licensed to practice medicine
Consider including contract provisions to ensure that independent clinical decision-making is maintained |
# Pharma: Legal Challenges

<table>
<thead>
<tr>
<th>Other Laws</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government Value-Based Payment Programs</td>
<td>Limits who may participate in programs and what financial arrangements among participants and third parties are permitted</td>
</tr>
<tr>
<td></td>
<td>Government may address legal risks with agency guidance or waivers (if authorized) (e.g., Medicare Shared Savings Program)</td>
</tr>
<tr>
<td></td>
<td>Government may not always include pharmaceutical companies in programs or extend waivers/interpretive flexibility to manufacturers (e.g., Comprehensive Care for Joint Replacement Model)</td>
</tr>
<tr>
<td>FDA Promotional Restrictions</td>
<td>Limits the ability of manufacturers to make communications inconsistent with approved labeling about products</td>
</tr>
<tr>
<td></td>
<td>Requires that communications be truthful, not misleading, objective and balanced</td>
</tr>
<tr>
<td></td>
<td>Permits exchange of scientific information</td>
</tr>
<tr>
<td>FDA Adverse Event Reporting</td>
<td>Requires manufacturer reporting to FDA of adverse drug experience information</td>
</tr>
<tr>
<td></td>
<td><em>Manufacturer has enhanced access to adverse event data generated in connection with the measurement of outcomes</em></td>
</tr>
</tbody>
</table>
**Pharma: Future Opportunities & State Initiatives**

- Many state Medicaid programs have implemented some form of value-based payments
  - The most common models are a per member per month payment tied to meeting performance expectations, episode-based payment schemes, and population-based payments where providers are held accountable for spending targets

- Episode-based and population-based models vary from state to state in their coverage of pharmaceuticals
  - *Example:* The New York Delivery System Reform Incentive Payment Program uses MCOs and both episodic and continuous alternative payment systems to drive cost efficiency and quality outcomes. New York providers may choose from several value-based payment arrangements, all of which include the costs of drugs

- In 2016 Medicaid Drug Rebate Program Notice (#176), CMS encourages state Medicaid agencies to enter into value-based purchasing arrangements involving drugs and outlines how manufacturers should seek CMS guidance on these arrangements
Pharma: Future Opportunities

• Potential Considerations to Enhance Opportunities
  – Alignment with existing payor/provider initiatives
    • Consider common health care quality measures
  – Ability to demonstrate short-term impact
  – Payor/provider need to differentiate
    • Crowded disease state
  – Simplicity
    • Simple to measure treatment effects (e.g., cholesterol level or blood pressure)
    • Clearly defined outcomes (e.g., tumor’s response to treatment)
  – Leverage existing infrastructure
    • Data already collected by providers in routine course
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Industry Trends for Medical Device Manufacturers: Introduction

• Traditional models of medical device company operation focus on product sales
  – Advance 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
• 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
Medtech: Shift to Value-Based Care

• Shift from fee-for-service to value-based reimbursement
• Private payors continue to develop new value-based care models with providers, medical device and pharmaceutical companies
Medtech: Gainsharing

• 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
Medtech: 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
Medtech: New Opportunities

• 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
Medtech: New Opportunities

• 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
Medtech: Traditional Sale and Value-Based Payment Model

- Traditional Sale and Value-Based Model: Compliance Concerns and Mitigation Strategies
  - 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
Medtech: 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)

• This is a sea change from a product-focused model to a service-focused model

• May be used with provider or payor partners

• May be designed to complement governmental or private pay initiatives
Medtech: 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
Medtech: Consulting/Episode Management Model

• For each of these technology, consulting and episode payment models, there may be a variety of value-based payment opportunities

• In addition, the medical device company may be responsible for helping to design and establish gainsharing initiatives to incentivize physician participation
• 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
Medtech: 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
Medtech: 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
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Resources & Tools

We compile and produce resources to help you navigate the transition to value-based care.

Contact Our Team for Research materials

Complimentary offerings

- CLE Presentations
  - CLE Presentations on value-base health care topics

- Research Binders
  - Electronic collection of information related to CMS Innovation Models, including general overview, participation requirements, FAQs and more

Offerings at a fixed fee

- State Survey of RBO Laws
  - A time-saving tool that allows you to look up and compare RBO-related laws and regulations for across the country

- Hotline/Help Desk
  - Monthly bank of hours dedicated to counseling on value-based payment models

- Template Agreements
  - Provider participation agreements, management and administration services agreements for value-based payment models

Insights & Analysis

Ropes & Gray regularly examines trends, developments and issues in value-based health care to provide guidance on this rapidly evolving topic.

- Experts Tout Value-Based Contracts, RWE, Patent Reform As Pricing Fixes (June 16, 2017)
- Video - Value-based health care: fraud & abuse (June 13, 2017)
- Video - Value-based health care: issues for pharmaceutical companies (June 9, 2017)
- Video - Value-based health care: data & technology (June 2, 2017)

https://www.ropesgray.com/Value-Based-Health-Care-Initiative