# Transforming Healthcare Regulatory Practice:

## From Compliance to Consultative Innovation

### I. Executive Summary

The healthcare regulatory landscape is undergoing a fundamental transformation. Legal professionals who once focused predominantly on compliance and risk mitigation are now uniquely positioned to become strategic advisors, helping organizations innovate within regulatory boundaries. This whitepaper explores how value-based exceptions to the Physician Self-Referral (Stark) Law and value-based safe harbors to the Anti-Kickback Statute (AKS) can be leveraged to design innovative affiliation arrangements that:

- Align financial incentives between health systems, physician groups, ancillary service providers, digital health providers, and more.
- Reduce regulatory risk while expanding opportunities for collaboration.
- Capitalize on the flexibilities of the value-based framework without assuming substantial downside risk in payor contracts.
- Drive improved patient outcomes and cost efficiencies while ensuring compliance.

Despite these regulatory opportunities, many healthcare organizations have yet to take full advantage of the value-based frameworks due to:

1. Lack of familiarity with value-based enterprise (VBE) structuring and compliance requirements.
2. Misconceptions about the necessity of significant financial risk to utilize value-based models.
3. Concerns about disrupting existing compensation or referral arrangements.

Through real-world applications, case studies, and best practices, this whitepaper provides legal professionals with a strategic roadmap for:

| Key Takeaways |
| --- |
| Structuring compliant VBEs that align with business objectives. |
| Navigating risk and compliance challenges while fostering innovation. |
| Leveraging InHealth's knowledge and experience for expert guidance, risk management, and strategic implementation in the development of VBEs. |

The ability to effectively implement VBEs is quickly becoming a competitive advantage for healthcare legal professionals. By mastering these frameworks, attorneys can transition from compliance enforcers to strategic business consultants—ensuring their organizations thrive in a rapidly changing healthcare landscape.

## II. Introduction

### A. The Evolving Role of Healthcare Regulatory Lawyers

Traditionally, healthcare regulatory lawyers have operated as guardians of compliance—ensuring that organizations meet a maze of regulatory requirements. However, as the healthcare industry continues to adopt the new value-based frameworks, legal teams are uniquely positioned to play a broader role. Instead of merely preventing and responding to potential regulatory violations, progressive counsel can become strategic advisors who actively propel mission-critical affiliations, shape innovative care models, and drive operational efficiencies.

As discussed throughout this whitepaper, healthcare counsel possessing systematic understanding of the value-based exceptions and safe harbors to the Stark Law and Anti-Kickback Statute, respectively, can identify opportunities to tackle some of their organization's most significant challenges by deploying heretofore unviable affiliation strategies and compensation models.

### B. The Strategic Opportunity of Value-Based Frameworks

Central to this evolution are relatively recent changes to two key regulatory frameworks: the Stark Law and the AKS. Historically, these laws have served to prevent financial abuses in a fee-for-service environment. However, in 2021, the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) introduced value-based exceptions and safe harbors in order to spur innovation and provide a more accessible pathway to contemporary healthcare delivery models. To date, most health systems, physician organizations, and other providers of healthcare services have utilized these new models sparingly.

That lack of proliferation belies the utility of the value-based frameworks. By rethinking compensation and referral arrangements through a value-based lens, legal professionals can facilitate innovative business models that reward high-quality care, lower cost, and provide a better experience for both patients and providers. Used appropriately, value-based enterprise (VBE) structures can be utilized to address the following common challenges for healthcare organizations (among many others):

| Common VBE Strategic Objectives | |
|---|---|
| Align providers with value-based care contracts | Promote development and utilization of new care team models |
| Utilize compensation models that could vary with volume or value of referrals | Create better alignment between organizations or with providers |
| Alleviate FMV compliance concerns | Reduce provider burnout |
| Shift focus from production to improved outcomes and cost reduction | Enable a more robust compliance framework |
| Bolster health equity initiatives | Improve patient and provider experiences |

Furthermore, the "value-based" moniker connotes that an organization may need a substantial amount of revenue in risk-bearing value-based care contracts. In our experience, some of the most elegant and effective applications of VBEs have been undertaken by organizations that had very limited risk exposure in their payor contracts. They were either developing the institutional infrastructure and behaviors needed to succeed as they transitioned to such contracts, or they simply desired to achieve some of the required value-based purposes.

As such, counsel having an intimate knowledge of the value-based exceptions and safe harbors, emerging applications of these structures, and potential pitfalls associated with their use have extremely powerful new tools in their toolbox with which to assist their clients.

### C. Objectives and Structure of the Whitepaper

This whitepaper is structured to guide you through:

- An overview discussion of the value-based frameworks set forth in the Stark Law and the AKS.
- An exploration of how these frameworks can be applied to create innovative, risk-mitigated affiliation arrangements.
- Practical insights, examples, and best practices illustrating the benefits of a consultative, value-based approach.
- A roadmap for aligning these strategies with your organization's compliance requirements, business objectives, and operational realities.
- How InHealth's consulting services can support each step of this transformation—from risk assessment and process optimization to strategic implementation and change management.

By the end of this paper, you will have a clear understanding of both the need and the steps to take to transition from a reactive compliance role to a proactive, consultative partner—and why partnering with the experts at InHealth can help you accelerate that transformation.

## III. Understanding the Value-Based Enterprise Framework

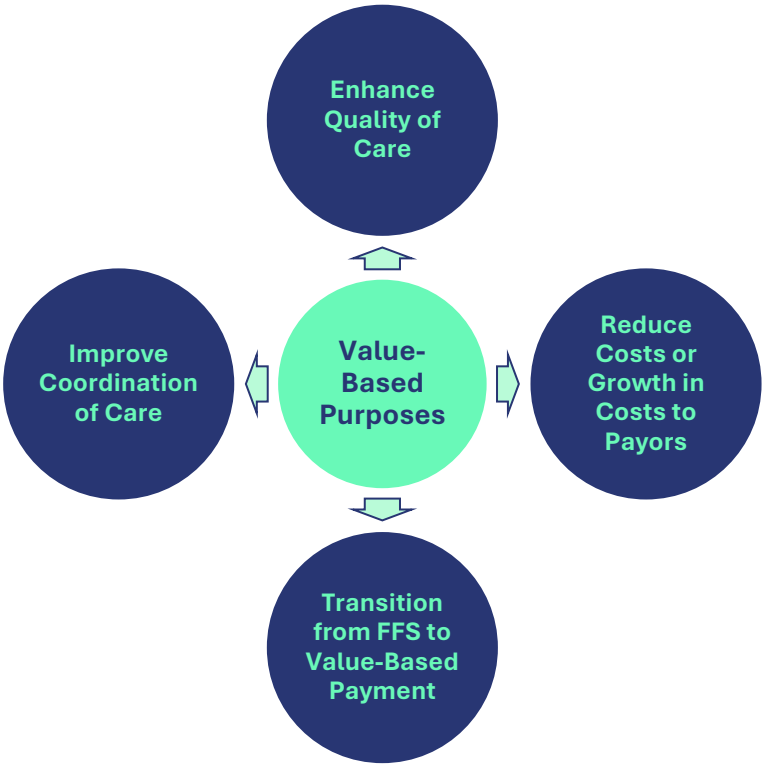
To support quality-driven, cost-efficient care models, CMS and HHS OIG introduced value-based exceptions to the Stark Law and value-based safe harbors to the AKS. These reforms introduced the concept of the VBE - a formal arrangement among providers and other entities to coordinate and deliver care in a way that supports a specified value-based purpose. Under the new framework, financial arrangements that meet all VBE criteria may be exempt from the traditional "big three" Stark Law and AKS prohibitions, namely FMV compensation, commercial reasonableness, and compensation that varies with the volume or value of referrals.

### A. The Value-Based Enterprise: Definition and Key Components

A VBE is a structured collaboration between two or more healthcare providers or entities that coordinate patient care and, in some cases, assume some level of financial risk. To assist your understanding, we have prepared a glossary of key terms and concepts related to VBEs and attached as an appendix to this document. To qualify for Stark Law exceptions or AKS safe harbors, a VBE must meet a number of proscriptive requirements. There are many other resources available that will more accurately and completely describe each of these requirements in detail. We provide links to several excellent sources of such information in the Resources section at the end of this document.

### B. Value-Based Purposes

In our experience, professionals who develop a comprehensive understanding of the value-based purposes set forth in the VBE frameworks are equipped to *identify opportunities* to deploy a VBE. If your client is trying to solve a problem, and the resolution of that problem is likely to accomplish one or more of the following goals, a VBE is likely to offer you a solution.




### C. VBE Risk Levels

Both the Stark Law and AKS offer three risk tiers for VBEs. Generally, the higher the risk level assumed by the VBE or its participants, the greater the flexibilities afforded in the remuneration exchanged between the participants. The following graphic provides an overview of VBE risk stratification.

| | |
|---|---|
| **Tier 1: Low / No Risk** | •Stark: Value-Based Arrangements<br>•AKS: Care Coordination Arrangements |
| **Tier 2: Some Risk** | •Stark: Meaningful Downside Risk<br>•AKS: Substantial Downside Risk |
| **Tier 3: Full Risk** | •Stark: Full Financial Risk<br>•AKS: Full Financial Risk |

## IV. Applications and Examples: Bringing the Value-Based Frameworks to Life

Armed with a solid understanding of the value-based frameworks set forth in the Stark Law and Anti-Kickback Statute, counsel is now prepared to identify practical applications for VBEs. This section will walk through several examples describing the current state of affairs, the value-based purpose that will be targeted by addressing the current challenges, and an overview of the structure of a VBE solution. We will also highlight the key areas in which InHealth can offer critical support for counsel.

### A. Restructuring Hospital – Independent Medical Group Collaboration into a VBE

- **Current State:** A regional health system has a long-standing partnership with an independent specialty physician group through:
    - A Professional Services Agreement (PSA) that compensates the group based on work RVUs (wRVUs) generated by its physicians.
    - A Co-Management Agreement under which the physician group provides management services for a particular hospital service line, receiving a mix of hourly fees and incentive-based compensation.
- **Challenge(s)**: While these agreements help align the group with the health system, they remain predominantly volume-driven and do not fully integrate value-based principles. Key challenges include:
    - The wRVU-based PSA incentivizes volume over efficiency and outcomes.
    - The Co-Management Agreement's hourly compensation structure does not strongly incentivize the physician group.
    - The Co-Management Agreement's incentive compensation is based on process improvement and does not align with the hospital's payor incentives.
- **Value-Based Purpose(s) Inherent in Solution:** The health system and physician group aim to improve the efficiency and quality of care delivery by reducing avoidable hospitalizations and enhancing patient outcomes in the service line.
- **Proposed VBE Solution:** The PSA and Co-Management Agreement are restructured within a VBE, aligning financial incentives with care coordination, quality, and cost efficiency.

    **1. Transitioning the wRVU-Based PSA into a Value-Based Compensation Model**

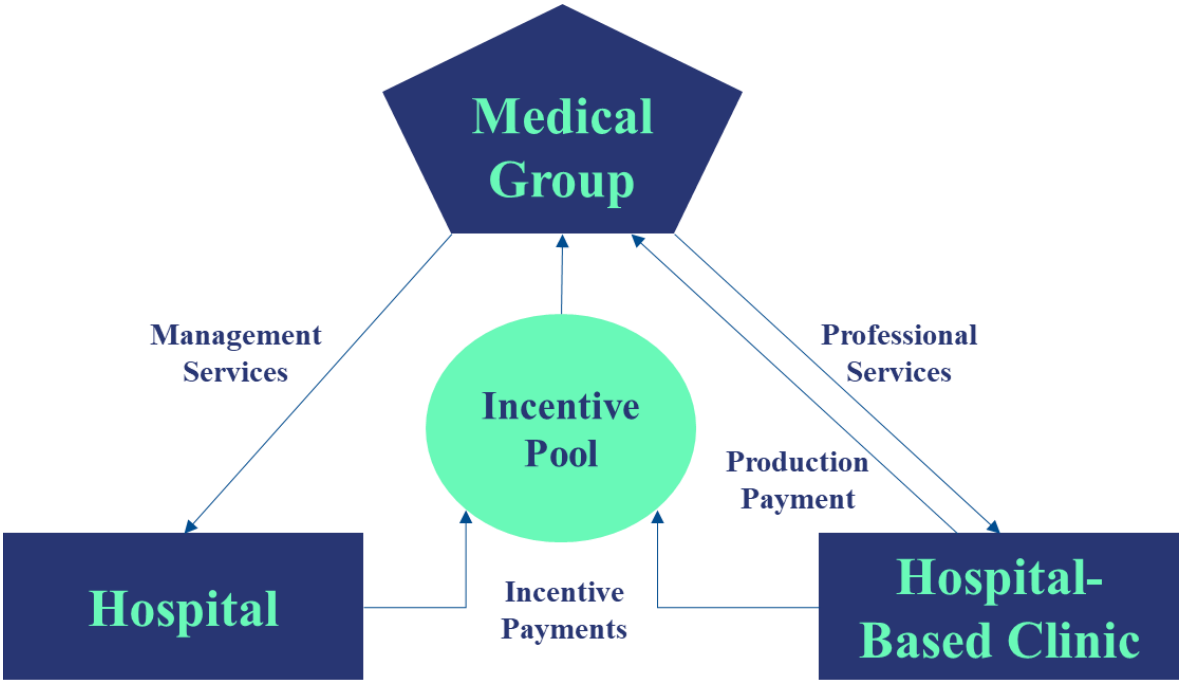
    - Instead of paying strictly based on wRVUs, the compensation model in the PSA is revised to incorporate quality and efficiency metrics into physician compensation.

    **2. Restructuring the Co-Management Agreement to Incorporate Shared Savings**

    - The co-management agreement evolves into a value-based arrangement, whereby the physicians continue managing the hospital service line, but the compensation is now solely funded by service line performance.
    - Performance-based incentives are tied to improvements in care coordination, reduced variations in care, and patient outcome metrics.

**3. Establishing a Formal VBE for Governance & Risk-Sharing**

- A VBE governance committee is created, including representatives from both the health system and physician group.
- The VBE committee oversees care coordination initiatives, tracks clinical outcome measures, and monitors the VBE's achievement of its value-based purpose.




- **How InHealth Can Assist Counsel:**

| | | |
|---|---|---|
| Developing compensation models for inclusion in PSA and Co-Management Agreement | Analyzing financial impact of VBE for both health system and medical group | Implementing monitoring and reporting systems to track performance of the VBE |

## B. Behavioral Health & Primary Care Integration Using a VBE

- **Current State:** A large primary care group wants to integrate behavioral health services into its practice to improve mental health access for patients.
- **Challenge(s)**: The primary care group would like to offer behavioral health services in-house, but they lack the expertise, staffing, and operational infrastructure to do so independently. They are faced with multiple obstacles.
    - Shortage of behavioral health providers, making it difficult for primary care physicians to find specialists willing to accept referrals.

- Limited patient follow-through, as many referred patients never schedule behavioral health visits or face long wait times for appointments.
- Fragmented communication between PCPs and behavioral health providers, leading to poor care coordination and suboptimal patient outcomes.

- **Value-Based Purpose(s) Inherent in Solution:** The primary care group and behavioral health practice desire to improve care coordination and expand behavioral health access.
- **Proposed VBE Solution:** A VBE is established between the primary care group and behavioral health group that meets the requirements of the AKS Care Coordination safe harbor and the Stark Law Value-Based Arrangements exception.

**1. The Primary Care Group Expands Its Behavioral Health Services**

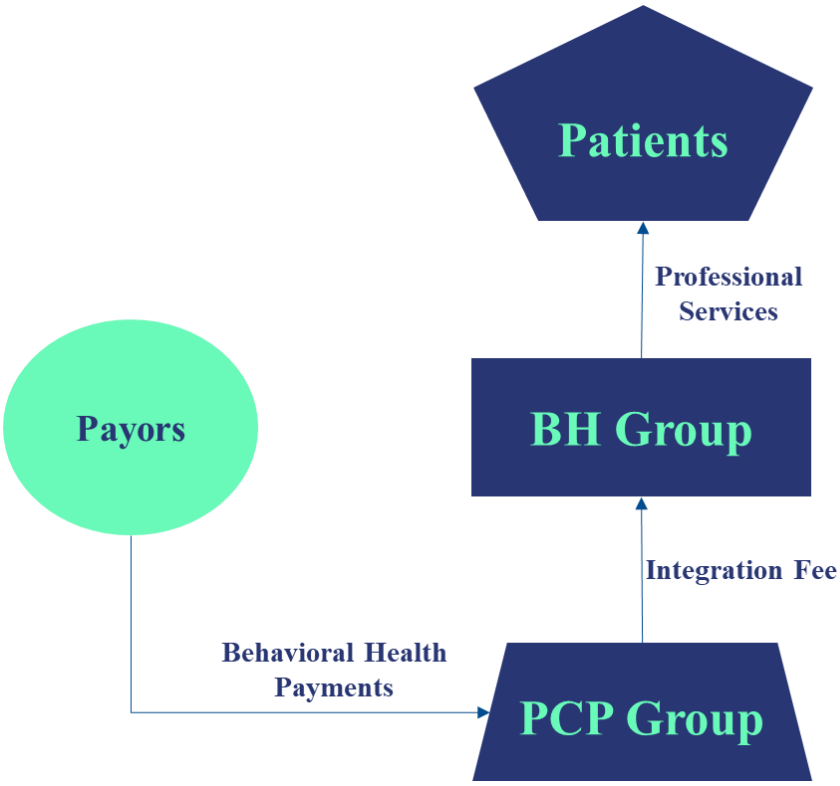
- Licensed therapists from the behavioral health practice are embedded inside the primary care clinics, enabling real-time interventions and ongoing management for depression, anxiety, and other behavioral health conditions.
- The PCP group bills directly for behavioral health services using Medicare's psychiatric collaborative care model codes or commercial behavioral health billing.
- The primary care group enhances its revenue while ensuring that patients receive timely behavioral health support within the PCP office.
- Complex patients are referred to psychiatrists within the behavioral health group.

**2. The Behavioral Health Group Supports the Primary Care Team**

- The behavioral health group provides and manages therapists, ensuring that high-quality licensed professionals are integrated within the primary care setting.
- The behavioral health group offers training for PCPs, helping them better manage mild-to-moderate behavioral health conditions in primary care.

**3. The Behavioral Health Group Charges the PCPs an Integration Fee**

- Instead of billing directly for behavioral health visits, the behavioral health group charges the primary care practice an "integration fee" equal to 50% of the total cost of the therapists.
- This flat, fixed fee structure meets the cash-in-kind remuneration requirements of the AKS Care Coordination safe harbor.



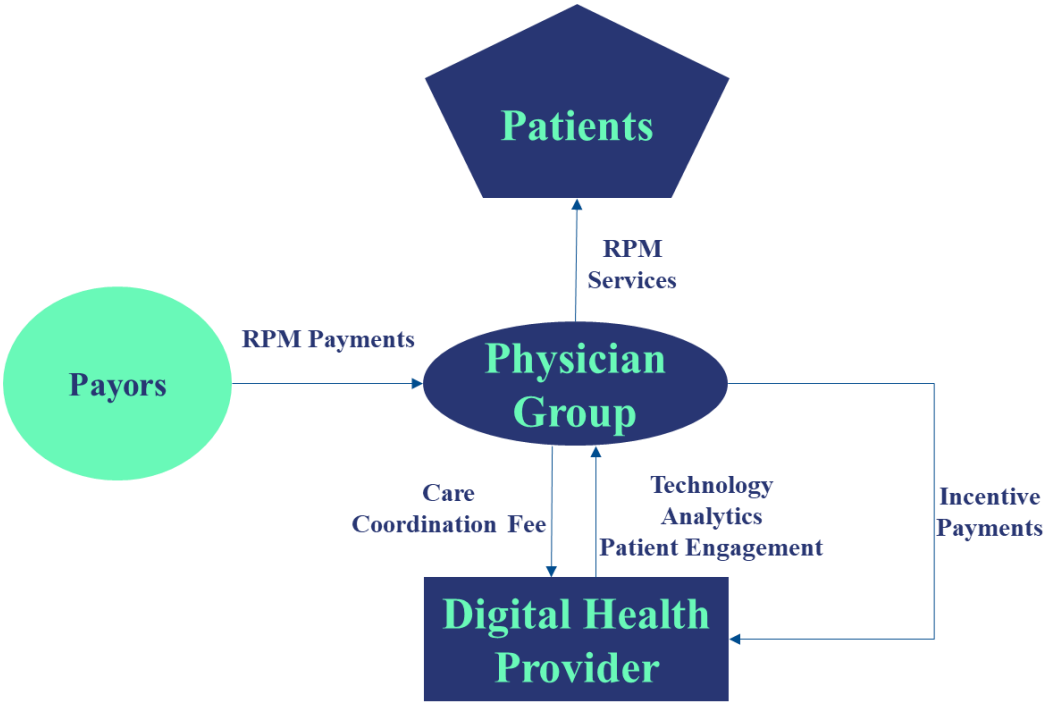

- **How InHealth Can Assist Counsel:**

| | | |
|---|---|---|
| Quantifying value of CoCM payments to PCP group relative to Integration Fee | Evaluating and recommending outcome metrics for inclusion in value-based agreement | Ensuring Integration Fee is consistent with requirements of AKS Care Coordination safe harbor |

### C. Developing a VBE for Remote Patient Monitoring

- **Current State:** A large physician group wants to integrate a digital health solution for remote patient monitoring (RPM) to improve chronic disease management and reduce emergency room visits. It has identified a digital health provider who has developed cutting edge technology for RPM.
- **Challenge(s)**: The physician group lacks the capital and technical infrastructure to implement the RPM program on its own. The digital health provider needs a business model that provides it substantial downstream cash flow with minimal upfront investment from its customers.
- **Value-Based Purpose(s) Inherent in Solution:** The physician group believes that the implementation of the RPM program will greatly enhance patient outcomes and ultimately reduce the cost of care.

- **Proposed VBE Solution:** The group and technology provider form a VBE, aligning financial incentives with success of the VBE in achieving its value-based purposes.
    - The digital health company provides RPM technology, analytics support, and patient engagement tools to the physician group at a significantly discounted upfront cost to comply with AKS Care Coordination safe harbor requirements.
    - The physician group implements the digital health solution and integrates RPM data into its chronic disease management protocols. The group bills payors for RPM services and reimburses the digital health provider through a care coordination fee.
    - The digital health company recoups its initial discount through an incentive compensation model from the group based on improvements in patient adherence, reductions in avoidable hospitalizations, and chronic disease outcome improvements.




- **How InHealth Can Assist Counsel:**

| | | |
|---|---|---|
| Developing model for funding incentive payments | Evaluating economics of arrangement for both participants | Develop measures and visualizations to track effectiveness of RPM program |

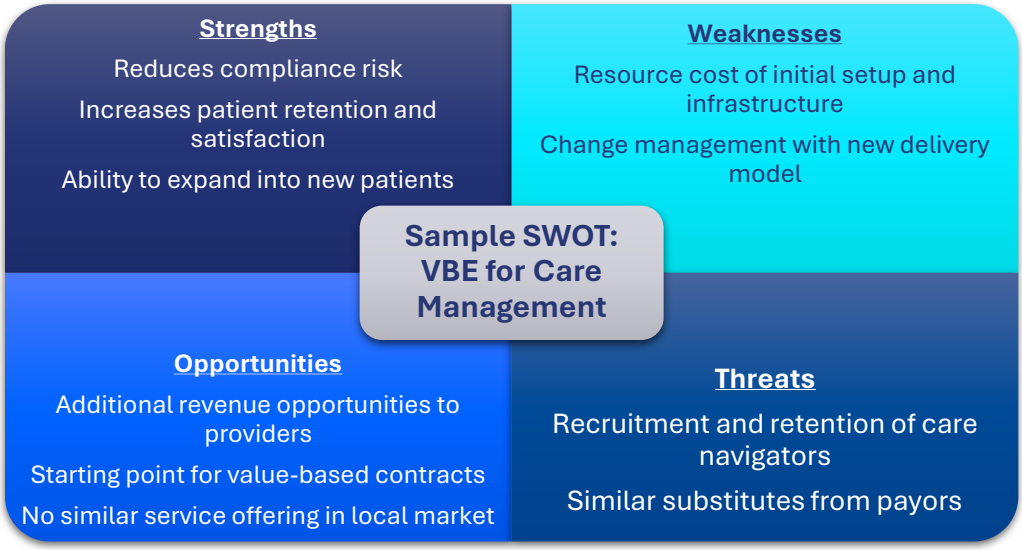
## V. Business and Legal Risk Management Considerations

As you assist your clients in the transition to value-based care, a disciplined approach to managing both legal and business risks is paramount. Through our work with healthcare counsel, front-line clinical operators, and organizational leadership, InHealth can share key insights developed by observing the intersection of these domains. This section outlines key strategies for maximizing the business impact of value-based innovations in regulatory compliance. We also highlight areas where InHealth's expertise can be leveraged as a supplement to your work.

### A. Assessing the Intersection of Business and Legal Risks with Valued-Based Care Strategies

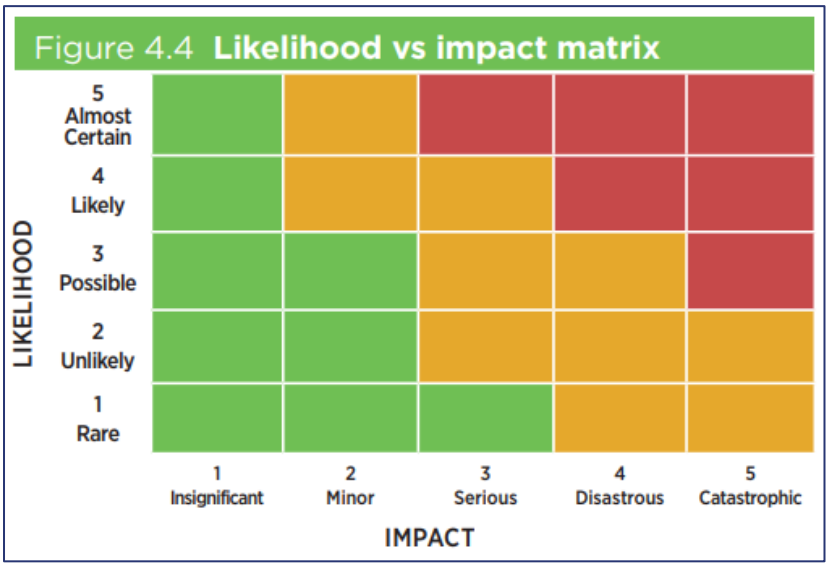
Prior to implementing value-based care strategies, counsel can improve the likelihood of success for their clients by performing upfront diligence. This essential work involves counsel working hand-in-hand with organizational leadership to identify the optimal pathways to implementing value-based care strategies. The adoption of these models of care inherently involves change and risk. Legal counsel is well suited to provide frameworks and guidelines that enable successful transitions while ensuring compliance. Below are a few of the key steps which counsel can take to fulfill this crucial role.

- **Risk Assessment Frameworks:** The exchange of funds for healthcare services is fraught with a cornucopia of federal and state regulatory concerns. Oftentimes, the ideal business idea implicates laws and regulations that pose significant liabilities to a healthcare organization. To help their business leaders make informed decisions, legal counsel can prepare the following risk assessment tools:
    - **Strengths, Weaknesses, Opportunities, and Threats (SWOT) Analysis**: The SWOT analysis is a tried-and-true framework for businesses that works well in the context of evaluating value-based care delivery models. By applying a lens to internal operations, legal counsel can highlight the existing Strengths and Weaknesses associated with value-based care models. For example, as discussed above the VBE framework can enhance organizational compliance (a Strength), though an organization must have the capacity to implement the documentation and monitoring process (a Weakness for resource-constrained organizations). When looking at external factors, legal counsel can underline the areas of topline and bottom-line Opportunity while flagging the Threats from the outside. As an example, organizations can utilize VBE protections to incentivize physicians to increase revenue streams through incentives for the deployment and operation of care management service lines (an Opportunity created through Medicare's expanding list of reimbursable care management services); by contrast, profitable operation of the service line requires diligent management of ever-growing costs among clinical support staff (a Threat). The diagram below provides a visual example of this analysis.




- **Compliance Checklists**: The complexity and length of healthcare regulations like the Stark Law and AKS can immediately overwhelm non-attorneys. Legal counsel can leverage their expertise to create checklists that delineate the key business needs that organizational leadership must meet in order to achieve compliance. The Stark Law alone creates a number of constructs that themselves have many moving parts (group practice exception, in-office ancillary requirements, professional services arrangement exception requirements, etc.). Checklist tools, ***tailored to key business needs***, offer a means to better inform key stakeholders; as an example of such a checklist, you can refer to the VBE Term Glossary included as a supplement to this document.

- **Enterprise Risk Management (COSO)**: The Committee of Sponsoring Organizations of the Treadway Commission (COSO) is dedicated to providing thought leadership through the development of comprehensive frameworks and guidance on enterprise risk management, internal control, and fraud deterrence. This work has carried over to compliance in the healthcare context. A useful tool developed by COSO for healthcare compliance programs is the likelihood / impact matrix; it provides a visual resource for placing potential business strategies into a color-coded matrix that weighs the likelihood of a risk against the magnitude of negative impact associated with the risk. Below is a blank template of the matrix produced by COSO.




- **Balancing Tests:** Borrowing a concept from the legal realm, legal counsel can guide operational leaders through "balancing tests" that weigh the compliance-related costs against the financial benefits of value-based care strategies. In our experience with value-based care models, legal counsel is well placed to help healthcare organizations understand the following cost components of the balancing associated with value-based care strategies:
    - **Self-Referral and Inducement Liability**: Given the structure of value-based care models, payments, in-kind remuneration, and other activities implicate federal and state regulations. Compliance with exceptions and safe harbors to these regulations have associated costs and pose different levels of risk.
    - **Documentation Requirements:** The forms of legal agreements, medical records, and other internal recordkeeping needed to comply with governmental and contractual value-based agreements.
    - **Counterparty Leverage**: Providers in value-based care models expose themselves to payment risk from payors. Legal counsel can help in understanding the leverage provider groups can bring to payment contracts to help mitigate these risks (e.g., the scope of covered lives to mitigate cost outliers, patient satisfaction and other community goodwill, and effective care team structures that enable practice at the top of license)
- **Change Management**: Most healthcare organizations have limited exposure to value-based reimbursement contracts. Accordingly, the process of building successful value-based care delivery models oftentimes represents a significant change from existing practice. The change management process can benefit significantly from counsel's input in the following domains:
    - Building sustainable **governance structures** to oversee operations and develop accountability to stakeholders.
    - Defining the **duties and responsibilities** among the business staff and clinical workforce involved in value-based care delivery.

- "Papering" innovative compensation structures into contracts **with clear definitions and an efficient process of adjudication**.

- **How InHealth Can Assist Counsel:**

| | | |
|---|---|---|
| Supplementing risk assessments with financial and operational benchmarking | Highlighting specialty-specific considerations for strategic planning | Developing implementation plans based on best practices |

### B. Monitoring Performance and Quality Assurance

Value-based care models create the opportunity for additional revenue through incentives for better performance across a wide range of quality domains. Accordingly, counsel must advise leadership and stakeholders regarding best practices to create a monitoring process that proactively drives success, while protecting against diminution of care quality. In our experience, counsel has led initiatives to substantially advance the following aspects of such processes:

- **Monitoring of Outcomes:** Most value-based care arrangements, be they external (e.g., from payors) or internal (e.g., employment agreements with clinicians) involve outcome measures that drive final payment amounts. As a result, a process for monitoring, reporting, and acting on the data associated with these outcome measures is essential to sustainable success. For example, while the VBE structure requires a monitoring process to ensure the value-based activities advance the agreed-upon value-based purposes, the structure also affords a large degree of flexibility regarding how the monitoring can occur. Legal counsel is well positioned to develop best practices tailored to fostering a successful monitoring program, which include:

    - **Monitoring Governance:** The structure of monitoring bodies, the scope of their responsibilities, frequency and form of meetings, and the voting framework for effectuating changes.

    - **Outcomes Measurement**: Developing formal definitions and monitoring processes that are embedded into value-based agreements that meet the dual needs of advancing quality, while also being easy to implement.

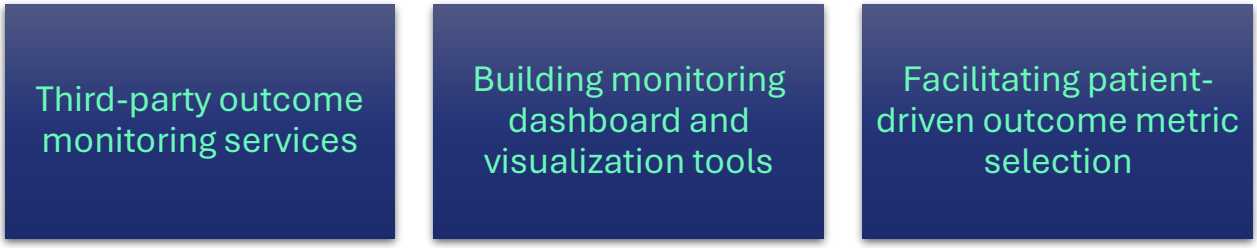
    - **Outcomes Reporting**: Actionable reporting requires timely and accurate data. Given the nature of the information involved in value-based care models (protected health information is often required), counsel has a central role in guaranteeing compliance, while ensuring a process for prompt reporting and resolution of data discrepancies.

- **Assessing Safeguards for Patient Safety and Experience:** Prior attempts at implementing managed care models failed due to their inability to center patient needs in an environment where cost savings are rewarded financially. Stated simply, capitated and shared-savings reimbursement models create an incentive for unscrupulous providers to stint on care. Most payors have since implemented safeguards against this practice by: (1) tying payment amounts to outcomes and patient satisfaction measures, and/or (2) requiring quality assurance from their provider partners.

In conjunction with clinical leadership, legal counsel can provide much-needed clarity around building operational safeguards.

- **Compliance Briefings**: Counsel can provide briefings that concentrate key takeaways from regulatory bodies regarding the essential components of patient quality assurance. The Innovation Models developed by the Centers for Medicare and Medicaid Services incorporate many safeguards that can serve as a template for specific specialty use cases. Furthermore, the HHS OIG has issued Advisory Opinions that discuss the components of managed care and gainsharing payment structures that mitigate concerns about patient care stinting. These resources are invaluable in helping organizations avoid "reinventing the wheel" and are linked to in our appendix.
- **Empowering Patient Advocacy**: Counsel can to serve as an advocate for patients treated by their clients. This role offers the uplifting opportunity to "do the right thing" while also contributing to financial and operational success of healthcare organizations. This advocacy can take the form of the following tangible steps: (1) facilitating adoption of patient-centric quality measures, such as patient reported outcome measures (PROMs), (2) incorporating patient feedback into quality assurance processes, and (3) including patient voices in the governance framework for outcomes monitoring.

- **How InHealth Can Assist Counsel:**

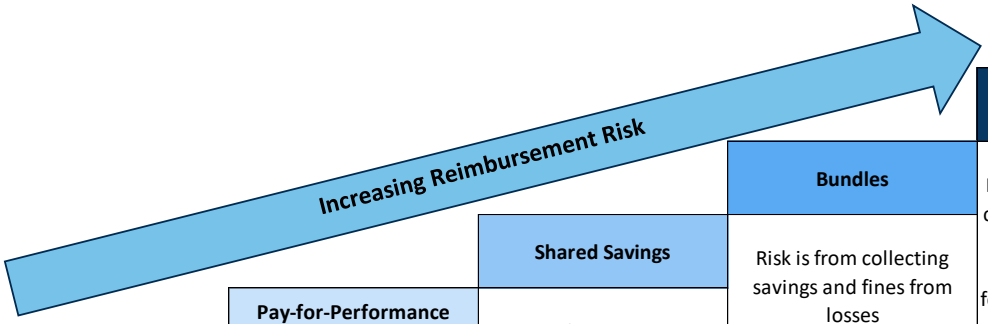



### C. Fostering Cultures of Continuous Improvement

To achieve long-term success within value-based care, healthcare organizations must have a robust culture of continuous improvement. Such a culture provides potent offensive and defensive capabilities. Organizations with a reputation for high-value care can leverage their position for favorable reimbursement contracts with private payors. From a defensive perspective, the goalposts used by payors to assess quality are often shifted, requiring further improvement to maintain revenue levels. We have observed legal counsel foster a culture of continuous improvement in the following ways:

- **Glidepaths to Risk:** Many healthcare organizations are initially unequipped to take a large plunge into heavily risk-based reimbursement models. Accordingly, they often wince at the thought of entering into value-based care. Fortunately, the VBE structure creates a pathway for gradually increasing reimbursement risk, while also taking advantage of the flexibilities related to directed referrals and provider compensation structure. This knowledge positions counsel to expand the potential strategic toolbox available to their clients, which is especially important in an era of stagnant reimbursement rates for physician professional services. Furthermore, counsel can help create an accretive roadmap for success in value-based care that allows their client to leverage prior wins into an expanding foundation for increasing opportunities in risk-based reimbursement.

For example, a thorough outcomes monitoring program can generate the data which fuels actuarially-valid studies of the value that their clients can deliver to payors. This information provides an edge in private payor contract negotiation and enables organizations to evaluate the potential benefit of participating in Medicare's value-based reimbursement models. As another example, the graphic below provides an overview of the spectrum of provider compensation models along the transition from fee-for-service to increasing risk-based reimbursement. It highlights tangible samples of compliant compensation structures counsel can present to help form a long-term plan for aligning physician incentives with greater risk-based reimbursement.




| Fee-for-Service (FFS) | Pay-for-Performance (P4P) | Shared Savings | Bundles | Global Capitation |
|---|---|---|---|---|
| Risk is in Volume<br><br>Compensation models incentivize higher volume for both PCPs and specialists<br><br>Examples:<br>Base + wRVUs<br>% of Collections<br>EBIT | Risk is from hitting quality targets, no fines from losses<br><br>Models incentivize higher volume with small bonuses tied to "quality"<br><br>"Quality" defined as min work reqts, citizenship, processes, outcomes<br><br>Examples:<br>Same as FFS models with small "quality bonus"; Base only | Risk is from collecting savings, no fines from losses<br><br>Models incentivize higher panel size with small bonuses tied to "quality"<br><br>"Quality" defined more tightly for PCPs to help meet quality measures; specialists generally unaffected<br><br>Examples:<br>Same as FFS models with quality/total cost of care (TCoC) incentives (passthroughs) for PCPs | Risk is from collecting savings and fines from losses<br><br>Models incentivize higher episode volume with small bonuses tied to "quality"; bonuses may move to be independent of production comp<br><br>"Quality" defined more tightly for PCPs and specialists to help meet payor quality measures<br><br>Examples:<br>Same as FFS models with quality/TCoC incentives (passthroughs) for both PCPs and specialists | Risk is from overall cost of care and stinting penalties<br><br>Models have increased focus on panel size, quality and TCoC with lower volume incentives for PCPs; specialist comp evolves to panel-based (medical specialists), episodic payments (proceduralists)<br><br>"Quality" for PCPs and specialists moves from process measures to outcome measures<br><br>Examples:<br>PCPs and medical specialists move to "panel" models; procedure-driven specialists migrate to episodic payment models |

- **Improving Contract Performance:** Value-based arrangements typically involve additional compensation provisions relative to payment arrangements on a fee-for-service basis. As a result, diligent counsel can provide much-needed advisory guidance around contract language and key terms to set their clients up for success. In the context of value-based care, contracts with payors for reimbursement and compensation arrangements with clinicians are subject to similar pitfalls. In the table below, we have outlined the essential desired objectives that our legal colleagues have been tasked with by their clients. We also provide sample solutions that counsel has developed in order to meet the objectives.

| Desired Objective | Sample Counsel-Led Solution |
|---|---|
| **Reducing the likelihood of contract disputes** | Incorporating robust contractual language around data sharing requirements and essential timeframes for data delivery. |
| **Minimizing the need for amendments and renegotiations** | Drafting robust formulas for outcome measures which tie directly to existing clinical workflows and data reporting capabilities. |
| **Enhancing regulatory compliance** | Creating optimized financial incentives that comply with VBE exceptions and safe harbors |

- **How InHealth Can Assist Counsel:**

Assistance with long-term value-based strategy for provider compensation

Supporting payor negotiations through financial and operational analyses

Contract review and term optimization

## VI. Conclusion and Next Steps

### A. Recap of Key Insights

This whitepaper has outlined how value-based exceptions and safe harbors can be utilized to:

- Transform physician compensation models to align with value-based care.
- Restructure existing provider agreements to support care coordination.
- Develop VBEs that drive quality, efficiency, and regulatory compliance.
- Mitigate legal and financial risk while fostering strategic innovation.

### B. The Future of Healthcare Regulatory Law

The shift from compliance-driven frameworks to value-based business models is accelerating. Legal professionals who embrace VBE structures will be at the forefront of:

- Advising on innovative care delivery models.
- Structuring legally sound, financially sustainable partnerships.
- Ensuring their organizations capitalize on regulatory flexibility to improve patient outcomes.

As healthcare organizations increasingly seek alignment between financial incentives and quality metrics, attorneys must not only interpret the law but guide their organizations in using it strategically.

### C. Next Steps: How InHealth Can Support Your Organization

InHealth Advisors provides expert consulting services to help legal professionals and healthcare organizations succeed in the adoption of the value-based frameworks.

| Summary of InHealth Capabilities |
|---|
| Plan and develop VBE models to support evolving strategies, existing arrangements, compliance challenges, and new affiliations / partnerships |
| Design and implement new compensation models to bolster VBE effectiveness |
| Identify, evaluate, and recommend outcome measures for inclusion in compensation models and value-based arrangements |
| Enable ongoing compliance through development of monitoring and reporting tools |
| Deliver valuation services focused on quality and outcomes-based payments |

For a personalized consultation on how your organization can leverage value-based regulatory frameworks, contact InHealth Advisors today.


**CONTACT**

www.inhealthadvisors.com

8 Inverness Drive East, Suite 245 Englewood, CO, 80112

719-224-0500

info@inhealthadvisors.com

## VII. Appendices and Supplemental Resources

### A. Glossary of Key Terms and Concepts: Value-Based Enterprises

To assist you in better understanding value-based enterprises, we assembled a table listing the definitions of key terms, as derived from the Anti-Kickback Statute.[1] While there are minor differences in the definitions listed in the Stark Law and Anti-Kickback Statute, we've found the latter to have the best starting point to understand key terms.

| Term | Definition |
|---|---|
| **Value-Based Enterprise (VBE)** | Two or more VBE participants:<br>(1) Collaborating to achieve at least one value-based purpose; |
| | (2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; |
| | (3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and |
| | (4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). |
| **Value-Based Arrangement (VBA)** | An arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are—<br>(1) The value-based enterprise and one or more of its VBE participants; or<br>(2) VBE participants in the same value-based enterprise. |
| **Value-Based Activities** | Any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:<br>(1) The provision of an item or service;<br>(2) The taking of an action; or<br>(3) The refraining from taking an action.<br>Value-Based Activities do not include the making of a referral |
| **Value-Based Purpose** | Means any of the following:<br>(1) Coordinating and managing the care of a target patient population;<br>(2) Improving the quality of care for a target patient population;<br>(3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or<br>(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population. |
| **Target Patient Population** | An identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that—<br>(1) Are set out in writing in advance of the commencement of the value-based arrangement; and<br>(2) Further the value-based enterprise's value-based purpose(s). |
| **VBE Participant** | An individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient acting in their capacity as a patient. |
| **Coordination and management of care (or coordinating and managing care)** | The deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population. |

[1] 42 CFR § 1001.952(ee)(14)

### B. References and Further Reading

To facilitate your review of the topics discussed in this whitepaper, we have compiled a list of resources and other further reading, organized in the order the subjects were addressed in this document.

- **Understanding Value-Based Enterprises:**
  - Federal Register Entry Detailing OIG Final Rule and Associated Commentary around Value-Based Enterprises Associated with the Anti-Kickback Statute: https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the
  - Federal Register Entry Detailing CMS Final Rule and Associated Commentary around Value-Based Enterprises Associated with the Stark Law: https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations
  - Summary of Key VBE Provisions and CMS/OIG Commentary, as summarized by Hall, Render, Killian, Heath & Lyman, P.C.: https://hallrender.com/2021/01/12/defining-opportunity-in-the-sprint-to-value-cms-and-oig-finalize-value-based-definitions-in-connection-with-new-stark-exceptions-and-anti-kickback-safe-harbors/
  - Summary of the Major Regulatory Changes Associated with VBEs, as summarized by King & Spalding LLP: https://www.kslaw.com/attachments/000/008/364/original/ca113020c.pdf?1606768658
  - Comparison Tables Associated with VBE Exceptions / Safe Harbors, as summarized by K&L Gates LLP: https://www.klgates.com/White-Paper-Value-Based-Safe-Harbors-and-Exceptions-to-the-Anti-Kickback-Statute-and-Stark-Law-2-24-2021
  - Case Study in Using a VBE to Integrate Primary and Specialty Care, as detailed by Nelson Mullins Riley & Scarborough LLP: https://www.nelsonmullins.com/insights/blogs/healthcare_essentials/corporate_and_transactional/using-a-value-based-enterprise-to-integrate-specialists-and-primary-care-taking-value-based-care-to-the-next-level
  - Case Study in Applying VBE Framework to CMS's TEAM Model, as detailed by Bass Berry & Sims PLC: https://www.americanhealthlaw.org/content-library/connections-magazine/article/6e700bbb-0723-4319-bc6f-ad3e8efea8a7/The-Value-Based-Dream-TEAM-How-CMS-s-New-Payment-M
- Resources to Support Business and Risk Management Services by Counsel
  - Committee of Sponsoring Organizations of the Treadway Commission (COSO) on Applying the COSO Enterprise Risk Management Framework for Compliance Risk Management: https://www.coso.org/_files/ugd/3059fc_5f9c50e005034badb07f94e9712d9a56.pdf
  - CMS Innovation Models Lookup Website: https://www.cms.gov/priorities/innovation/models
  - OIG Advisory Opinion 12-22 on Co-Management Arrangements: https://oig.hhs.gov/documents/advisory-opinions/658/AO-12-22.pdf
  - OIG Advisory Opinion 17-09 on Gainsharing Arrangements: https://oig.hhs.gov/documents/advisory-opinions/743/AO-17-09.pdf
  - Database Search Page of Patient-Reported Outcome Measurement Information System (PROMIS) Measures: https://www.healthmeasures.net/index.php?Itemid=992