The compliance implications of value-based healthcare

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The compliance implications of value-based healthcare: questions you should be asking.

While advances in research and technology have led to global improvements in healthcare delivery, costs continue to grow at a rate outpacing changes in overall cost of living and inflation. Value-based healthcare (VBHC) is emerging as a possible solution to address rising costs. VBHC is intended to address inefficiencies resulting from the financial incentives in the current US healthcare system. It links healthcare expenditures to patient outcomes, rather than the volume of treatment provided or the number of interactions with the healthcare delivery system. The premise is that if providers of healthcare services and goods are incentivized in an integrated manner across the entire life cycle of care based on outcomes and results, costs may be reduced and patients may achieve greater, more sustainable benefits.

The impact of VBHC on healthcare stakeholders

With a shift to VBHC, stakeholders across the healthcare ecosystem must look at the patient care continuum more comprehensively than ever before. Costs and treatments that have historically operated within silos along the delivery chain must now be evaluated as part of an interconnected whole. Stakeholders, segmented here by manufacturers, payers and providers, must work together to understand how each of their roles impact patient outcomes and to agree on metrics to define reimbursement mechanisms. These new business models give rise to new legal requirements and compliance considerations. As your organization responds and adapts to fundamental changes in the delivery and reimbursement for healthcare services, are you asking the right questions to address potential legal and compliance issues?
Life sciences manufacturers must consider how customer satisfaction and overall health metrics are going to be defined, captured and incorporated into their product’s profile. New commercial models in the life sciences industry are quickly developing in response to VBHC market pressures. Manufacturers are now providing integrated services and offerings across the patient pathway, such as patient adherence programs and care delivery data analytics platforms to assess effectiveness, side effects and compliance with therapy. Contracting with payers (both government and commercial) and industry service providers is shifting toward outcomes-based models as well.

Accordingly, life sciences manufacturers will need to align their communications to payers regarding VBHC outcomes, such as the total “proven value” of the product. This proven value may include improved patient outcomes (including patient “satisfaction” and other subjective measures) resulting from the manufacturer’s product plus its patient care offerings. This messaging requires new and varied data sources to substantiate claims of product “value” beyond the traditional labeling and clinical product profile, as well as increased post-launch monitoring of clinical and real-world experience with a product to allow payers to adjust access based on patient outcomes.

In order to assess risk associated with these shifts, legal and compliance executives should ask:

- Have we structured our outcomes-based contracts with customers and our subsequent service agreements in a way that mitigates the risk that our payments could be viewed as an improper inducement?
- Have we assessed the scope of our patient services and the risk of:
  - Providing inaccurate reimbursement advice or advice beyond what is allowed?
  - Communicating unlawful promotional claims about our products, including “quality of life” claims that may not be supported by “substantial evidence”?
  - Engaging in the unauthorized practice of medicine?
- Are we protecting patient privacy in accordance with existing laws and regulations while sharing data to demonstrate value?
- How can we communicate about our products to demonstrate total value, while remaining compliant with existing promotional laws and regulations?

**Questions you should be asking**

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Commercial payers are beginning to enter into value-based purchasing contracts with providers and manufacturers. These purchasing agreements allow payers to share financial risk for treatment with providers and manufacturers and can range from quality reporting and performance, to bundled payments, “guarantees” related to measurable outcomes or upside-only incentive arrangements. Pay-for-performance arrangements with payers reward manufacturers for improved patient outcomes from successful use of devices or drugs (e.g., a reduction in hospitalizations), rather than paying based on sales volume.

Access to accurate and transparent data is essential to understanding how milestones can be defined for payment, as well as whether the agreed-upon targets are being met. To improve the cost efficiency of this shift from paying for treatments to paying for outcomes, some payers have begun to purchase providers in order to integrate healthcare delivery and reimbursement.

Each of these changes brings its own legal and compliance questions:

- What are the self-referral implications of a payer-provider agreement (e.g., Stark Law)? Do existing safe harbors provide the necessary guidance for your proposed transaction?
- What controls are in place for existing or potential value-based contracts to measure and validate the accuracy of quality outcomes?
- What are the antitrust implications in your market for a potential provider consolidation?
- How should manufacturer services that affect patient outcomes be negotiated under an outcomes-based purchase agreement?
- Are payer representatives properly trained to interact with patients and other stakeholders for the outcomes-based activities?
Providers are central to the shift in VBHC because their incentives are being realigned to reward managing costs, delivering successful health outcomes and maintaining quality of care, and away from payments based solely on the volume of services being provided under the traditional “fee-for-service” model. Often, VBHC payments require providers to assume downside risk in the form of withheld payments or rebates for not meeting quality of care standards. These arrangements encourage collaboration with payers, patients and manufacturers so that care expectations are met or exceeded.

Providers also own and manage health data across a population or episodes of care, which includes a multitude of stakeholders outside and within the provider’s network; therefore, provider data access and integrity is essential. As with payers, providers are looking to vertical integration as one solution, including sponsorship of their own health plans.

In order to assess risk associated with these shifts, legal and compliance executives should consider:

- What controls are in place within the provider network and in these risk-sharing agreements to affirm compliance with patient privacy laws, while providing necessary transparency to payers and manufacturers to demonstrate success and thus meet contractual obligations?
- Have risk assessment processes, as well as monitoring and auditing plans been updated to accommodate both fee-for-service and VBHC-based plans and agreements?
- Are process owners equipped to evaluate and adapt existing processes for VBHC-payment (e.g., provider tracking, eligibility determination, quality score calculation and reporting)?
- Are VBHC arrangements designed to fall within safe harbors or waivers of the Anti-Kickback Statute, Stark Law and Hospital-Physician Payment Civil Monetary Penalty Law?
- What are the Stark Law and antitrust implications of vertical integration?
VBHC has the potential to improve health outcomes through a more integrated delivery network and improved incentive structure, while reducing costs to individual, commercial and government payers. However, this shift faces operational challenges as well as a legal, regulatory and compliance framework that was largely designed for a fee-for-service market. Until the legal and regulatory regime catches up to the current and evolving market dynamics, legal and compliance professionals should increase their dialogue with each other and their business stakeholders, as well as regulators, to understand how to mitigate risk while remaining nimble in the changing environment.

Our team

Our multidisciplinary professionals are leaders in the health and life sciences sectors, drawn from both private industry and the enforcement community. Our professionals include former government prosecutors, pharmacists, corporate counsel, compliance officers and auditors.

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