ROPES & GRAY

ARTICLE

Health Care

May 8, 2017

Ten Things Investors Need to Know About Value-Based Healthcare

This article highlights key business and legal issues related to value-based healthcare for investors considering opportunities in the healthcare industry.

Attorneys
Deborah L. Gersh
Timothy M. McCrystal
Christina Bergeron

1. Value-Based Arrangements Are Here to Stay

Value-based healthcare ("VBH") arrangements are an alternative to traditional volume-based reimbursement methodologies. VBH payment models contemplate payment for healthcare services based on the quality and cost of care as measured against predetermined quality and efficiency metrics, such as clinical quality and outcomes standards, patient satisfaction, care coordination and cost savings and efficiencies (*i.e.*, reduced length of stay, reduced readmissions and improved rehabilitation outcomes).

VBH payment programs have been implemented by both government and commercial payers. The Centers for Medicare and Medicaid Services ("CMS") and its Center for Medicare and Medicaid Innovation ("CMMI") shifted industry focus and momentum towards value-based reimbursement by offering innovative healthcare payment and service delivery models, including both voluntary and mandatory programs. Although Tom Price, Secretary of the U.S. Department of Health and Human Services ("HHS"), has criticized VBH programs that mandate provider participation,[1] and in fact delayed the effective date of such mandated programs,[2] voluntary VBH programs, such as the Bundled Payments for Care Improvement Initiative (known as the "BPCI" program), have gained traction in the market. Currently, there are more than 7,000 organizations that participate in BPCI, including acute care hospitals, physicians, long-term care providers, skilled nursing facilities, inpatient rehabilitation facilities and home health providers. The BPCI program and other voluntary VBH arrangements continue to receive bipartisan support and are thus likely to remain intact under the Trump administration. Notably, the American Health Care Act, a bill recently passed by the House of Representatives to repeal and replace the Affordable Care Act, does not call for elimination of the CMMI or VBH payment programs.[3]

Similarly, the healthcare industry has generally embraced VBH arrangements, recognizing that improved quality of care and increased efficiencies are necessary to lower the cost of healthcare for all. On January 25, 2017, several of the nation's largest providers, payers, pharmaceutical companies and consumer groups sent a letter to President Trump and Congress in support of value-based healthcare and urged the President to build on and expand VBH models. A survey from the Health Care Transformation Task Force showed that 41% of its provider and payer members had implemented VBH reimbursement by the end of 2015, up from 30% in 2014.[4]

From an investment standpoint, VBH has become part of the healthcare landscape.

2. Value-Based Arrangements Are Not Just About Providers

VBH arrangements span the entire healthcare industry. Health plans, pharmaceutical companies, device manufacturers, and information technology companies are also heavily involved in VBH arrangements and are

[1] http://www.healthcarefinancenews.com/news/tom-price-says-cmmi-track-hints-changes-programs.
[2] https://www.federalregister.gov/documents/2017/03/21/2017-05692/medicare-program-advancing-care-coordination-through-episode-payment-models-epms-cardiac.
[3] American Health Care Act of 2017, H.R. 1628, 115th Cong. (as passed by the House, May 4, 2017).
[4] http://hcttf.org/releases/2016/4/12/healthcare-transformation-task-force-reports-increase-in-value-based-payments.

playing important roles in developing such arrangements. Important considerations in the following key industry sectors include:

- ***Health Plans:*** Commercial health plans are significant drivers of VBH arrangements. They are increasingly partnering with providers, medical device companies and pharmaceutical companies to implement VBH arrangements and share financial risk with respect to treatment of specific conditions and diseases. VBH payment models offered by payers can range from the simple quality reporting and performance, to upside only incentive arrangements, to payments based on bundled reimbursement, guarantees and other risk-sharing arrangements.

- ***Pharmaceutical Companies:*** Pharmaceutical companies are tying drug pricing to achievement of targeted clinical results. If the quality metrics are not met, the pharmaceutical company shares the financial consequence with the payer.[5]

- ***Medical Device Companies:*** Medical device manufacturers are expanding their offerings to include consulting services that leverage care delivery expertise and data analytics to assist providers in achieving better outcomes for patients.[6]

- ***Health IT Companies:*** Information technology companies are positioned to provide data analytics and related services that are integral to implementation of VBH arrangements and measuring their impact on quality, outcomes, cost and improving care pathways. The global healthcare analytics market is anticipated to reach $18.7 billion by 2020, an increase of nearly $13 billion from 2015, as the healthcare industry continues to focus on quality of care and cost reduction.[7]

3. Value-Based Healthcare Will Account for a Growing Segment of Industry Revenues

The shift in reimbursement from historical fee-for-service to VBH methodologies means that the healthcare industry will tie an increasing portion of its revenues to outcomes and performance rather than the simple delivery of products and services. Recently, the Health Care Transformation Task Force, a group of 20 major health systems and payers, pledged to convert 75% of their business to VBH arrangements by 2020.[8] Payers are among the industry leaders in the movement towards VBH arrangements. For instance, 45% of Aetna's 2016 overall health care spend was through value-based care models.[9] In 2014, Blue Cross Blue Shield plans spent more than $65 billion on value-based care representing approximately 20% of total medical claim dollars spent.[10] In 2017, Anthem announced that 58% of its total reimbursements were paid through value-based care models.[11]

---

[5] For example, see here to read about Amgen's agreement with Cigna and Harvard Pilgrim for the cholesterol drug Repatha, click here to read about Eli Lilly's agreement with Harvard Pilgrim for the diabetes drug Trulicity, click here and here to read about Merck's agreement with Aetna and Cigna for diabetes drugs Januvia and Janumet and here to read about AstraZeneca's agreement with Express Scripts for its lung-cancer drug Iressa. For more examples, see the Ropes & Gray article on value-based arrangements between the pharmaceutical industry and payers available here.

[6] For example, see here regarding Stryker Performance Solutions' approach to partnering with hospitals and other providers to help with quality improvement, revenue and patient satisfaction, and here for Johnson & Johnson's CareAdvantage offering that aims to consult with hospitals to achieve the goals of value-based care.

[7] "Healthcare analytics market to reach USD 18.7 billion by 2020," news release, Medical Market Research, August, 2016.

[8] Health Care Transformation Task Force, "Major Health Care Players Unite to Accelerate Transformation of U.S. Health Care System," January 2015.

[9] Bruce Japsen, "UnitedHealth, Aetna, Anthem Near 50% Value-Based Care Spending," Forbes, February 2, 2017.

[10] Medbill, "Blue Cross' $65 billion move away from fee-for-service medicine," July 14, 2014.

[11] Bruce Japsen, "Anthem Blue Cross Nears 60% Value-Based Care Spend," Forbes, April 27, 2017.

CMS, through CMMI, also anticipates spending billions of dollars for innovation efforts, including on the BPCI program and other VBH programs.[12] CMMI's $10 billion budget is the largest ever devoted to transforming care.[13] Over 4.7 million Medicare, Medicaid, and CHIP beneficiaries are, or soon will be, receiving care furnished by more than 61,000 providers participating in CMMI payment and service delivery models, including VBH arrangements.[14]

In 2018, CMS aims to spend 50% of its Medicare fee-for-service payments through alternative payment models and link 90% of its fee-for-service payments to quality.[15] In March 2016, CMS announced its progress toward this goal, with an estimated 30% of its Medicare fee-for-service payments made through alternative payment models as of January 1, 2016.[16] Similarly, Congress recently overwhelmingly passed The Medicare Access and CHIP Reauthorization Act ("MACRA"),[17] which repealed the sustainable growth rate formula for determining physician pay under Medicare and replaced it with baseline increases to Medicare reimbursement based on value-based outcomes such as quality and costs. In sum, value-based payment structures have bipartisan support and will therefore continue to account for a growing segment of revenue in the healthcare industry.

4. Care Redesign Will Be an Essential Ingredient of Success for Companies Participating in VBH Arrangements

VBH is not simply about how providers of a product or service will be paid. For many suppliers and providers, participation in VBH arrangements will require care redesign and coordination along the continuum of care. The quality and performance measures in VBH arrangements encourage alignment of resources, and create incentives to support treatment of a particular episode of illness or disease by coordinating on quality of care, efficiency, accessibility and cost. The expected growth of VBH programs has also led a number of providers to consider vertical integration of their organizations so that they are in a position to control the "end to end" delivery of products and services that are covered within VBH arrangements, as well as significant investments needed to implement operational modifications (*e.g.*, improved data analytics, retention of additional care coordinators, modifications to existing service lines, etc.).

From an investor's standpoint, key diligence issues will include review of a target's products and services to determine its VBH care redesign needs, the target's capability to adjust to changes in care delivery, and the target's ability to integrate its products or services with other providers involved in the specific episode of care. For example, in the context of VBH arrangements for comprehensive joint replacements, the management of a budget for the episode of care will require close operational coordination among pre-operative, surgical and post-operative service providers. Providers will be incentivized to avoid complications during surgery, lengthy recovery and rehabilitation periods, and to choose the most appropriate post-operative care for the patient. Investors will need to assess the care redesign readiness of a target along with its market position as a desirable partner for inclusion in care coordination arrangements.

5. Many VBH Arrangements Will Require Participants to Assume Financial Risk

The assumption of financial risk is inherent in mature VBH arrangements. Providers, pharmaceutical companies and medical device companies are assuming financial risk in the form of bundled payments, guarantees, fixed payments, and other arrangements that stake service fees and product prices upon the achievement of agreed-upon quality metrics and other measures.

---

[12] https://www.hhs.gov/about/budget/fy2017/budget-in-brief/cms/innovation-programs/index.html.
[13] The Affordable Care Act appropriated $10 billion to support CMMI activities initiated from FY 2011 to FY 2019. Section 3021 of the Patient Protection and Affordable Care Act, codified at 42 U.S.C. § 1315a(f).
[14] https://www.hhs.gov/about/budget/fy2017/budget-in-brief/cms/innovation-programs/index.html.
[15] https://www.healthit.gov/facas/sites/faca/files/Joint_DSR_slides_2015-10-06.pdf.
[16] https://innovation.cms.gov/Files/x/ffs-apm-goalmemo.pdf.
[17] Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 (codified as amended in scattered sections of 42 U.S.C.).

The financial performance of a target under VBH arrangements may also be impacted by other providers participating in a specific episode of care. VBH arrangements can be complex and investors will need to broaden diligence efforts to include both the target's financial responsibilities for services it provides, as well as its potential financial exposure related to the overall performance of the group or network of providers involved in the VBH arrangement.

Investors will also need to consider the business and legal implications of risk assumption by the target, including the potential applicability of state insurance and risk-bearing organization ("RBO") laws and regulations. If applicable, state insurance and RBO laws may require licensure, capital reserves, and other forms of approval to assume financial risk in the context of VBH arrangements.

6. Companies Participating in VBH Programs Will Need a Business Strategy that Aligns Provider Incentives with Value-Based Measurements

As a threshold matter, healthcare investors should review a target's VBH strategy in light of the specific services provided by the target and the prevalence of VBH arrangements in the target's market. In particular, investors should consider whether a target has a business strategy that aligns care redesign and achievement of advanced quality measures with provider financial incentives.

Recent developments in the medical device industry illustrate emerging business strategies designed to support and align the interests of parties participating in VBH arrangements. A number of medical device companies have adopted the strategy of providing consulting services that include, among other things, advanced data analytics capabilities, development of care pathways, and implementation of process improvement services. These offerings are designed to enable customers and providers using devices to improve outcomes and enhance provider performance under VBH arrangements. Some medical device and pharmaceutical companies are also implementing vertical integration strategies by entering into joint ventures and providing management services or acquiring healthcare providers so that they can impact more directly the performance of providers under VBH arrangements.[18]

Likewise, physicians, hospitals, health systems and other providers continue to form accountable care organizations ("ACOs") and other network arrangements through which participating providers develop the care management infrastructure necessary to implement VBH arrangements. These network arrangements also typically serve as the vehicle through which providers share and analyze clinical data and assume financial risk related to VBH arrangements.

7. Timely Access to Data and the Right Analytical Tools Are Necessary to Engage in Population Health Management

Success in VBH arrangements requires access to the appropriate information technology infrastructure designed to support VBH clinical decision-making. Companies participating in VBH arrangements will need to invest in electronic medical record systems and other data analytical tools to ensure they can develop evidence-based protocols and measure clinical outcomes.

In addition to appropriate IT investment, VBH participants will also need to ensure they have access to patient data. Appropriate collection and use of data is critical to the operations of clinical care networks and assessing population management. In the context of conducting business diligence, investors will need to review the target's capabilities and explore the target's readiness to conduct data analysis in support of clinical decision-making in accordance with applicable privacy laws.

8. Participants in VBH Arrangements Will Need to Engage Patients to Achieve VBH Objectives

Proactive patient engagement around clinical decision-making is an important component of VBH arrangements. Healthcare investors should consider whether a target has a care management team that includes the use of human

[18] See, for example, this article describing Abbott's acquisition of St. Jude Medical. See also this article describing Medtronic's purchase of Cardiocom, a provider of integrated telehealth and patient services for the management of chronic diseases.

capital and technological support for patient engagement, such as patient coaching, mobile/digital applications patients can use to communicate with their healthcare providers or log their symptoms, call centers and other forms of patient-focused engagement. Sophisticated VBH arrangements often use a number of different forms of patient interactions, as well as data analytics, to prioritize high-risk patients whose health will be most impacted by the target's outreach and patient care management.

9. Companies Participating In VBH Arrangements Will Need to Have the Commitment of Knowledgeable Clinical and Management Teams

To succeed in VBH arrangements, companies will need a dedicated team comprising both clinical and non-clinical personnel to manage the patient's entire care episode against agreed-upon quality benchmarks. Investors should consider whether the target has a committed clinical transformation officer and a seasoned team focused on care redesign and adaptation of the target's operations so that it can coordinate care with other providers.

10. The Structure of VBH Arrangements Raises a Host of Legal Issues

Participation in VBH arrangements raises a host of potential legal issues, including compliance with the federal Anti-Kickback Statute, the False Claims Act, the Physician Self-Referral Law and the Hospital-Physician Payment Civil Monetary Penalty Law. While CMS has granted waivers of certain laws related to participation in government programs, such as the BPCI program, the waivers are limited to the specific programs and would not apply in the commercial context. As such, it is important to evaluate, understand and mitigate these compliance risks in connection with structuring VBH arrangements.

VBH arrangements will also need to be reviewed for compliance with data privacy laws, including the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended, and other federal and state data privacy laws. As noted above, state insurance and RBO laws and regulations may also apply to certain VBH arrangements. Investors should review with transaction counsel the compliance of a target's VBH arrangements with applicable laws.

Despite the challenges presented by a regulatory framework that is struggling to keep up with the novel questions presented by VBH arrangements, and the current uncertainty surrounding the healthcare market, value-based care is likely to take a permanent place in the healthcare landscape. Investors should be prepared to take advantage of the opportunities offered by this momentous shift by ensuring that their portfolio companies or potential investments have a sound value-based strategy that is structured in a manner consistent with the myriad of legal and regulatory requirements that apply to such arrangements.