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Brave New World: Compliance and the Transition to Value-Based Care

The U.S. health care system is in the midst of a fundamental shift, away from traditional “fee-for-service” models that reward providers for the quantity of services provided to patients, toward value-based models designed to reward the quality and efficiency of care provided to patients. This move to value-based care affects most sectors of the health care industry, including payors, providers, biopharma and medical device companies and other partner and support organizations, such as health information technology (“HIT”) companies, population health management experts and other consultants. In order to effectively transition payment and care delivery systems, many of these organizations are rapidly developing, acquiring and partnering together to obtain the expertise necessary to participate in value-based care initiatives.

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In a short time, value-based care initiatives have evolved from a set of initial programs sponsored by the Center for Medicare and Medicaid Innovation (“CMMI”) to innovative payment and service delivery models that involve private payors and other entities bearing risk for the provision of health care services. With this evolution, providers and others have had to grapple with a regulatory framework that is not inherently well-suited to value-based payment arrangements. Further, traditional compliance programs are often not structured or prepared to manage the regulatory risks presented by new value-based initiatives. While the Secretary of Health and Human Services issued waivers of fraud and abuse laws applicable to CMMI initiative participants, no such waivers exist for commercial value-based care initiatives. As a result, companies seeking to create or participate in value-based care initiatives must be aware of potential regulatory challenges, and should structure both their compliance programs and the initiatives themselves to mitigate these risks. We discuss below key regulatory challenges and mitigation strategies for consideration during the transition to value-based care.

- **Anti-Kickback Statute.** Fraud and abuse laws, and the Anti-Kickback Statute (“AKS”) in particular, often present the greatest challenge when structuring value-based care arrangements. The AKS prohibits the knowing and willful solicitation, receipt, offer or payment of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for either referrals of Federal health care program patients or the arranging, recommending, leasing or ordering of any item or service reimbursed by a Federal health care program.¹ Traditionally, providers, manufacturers and others have sought to structure arrangements to fit within one of the AKS safe harbors. This is often not possible with value-based care initiatives, in which some portion of the fees paid for services are “at risk” based upon a combination of cost savings, improved clinical quality, patient outcomes and/or patient satisfaction. In the absence of safe harbor protection, each value-based model is subject to a facts and circumstances analysis to determine whether the relevant sources of remuneration are intended to induce or reward referrals (and thus prohibited) or are intended solely to serve legitimate, “non-abusive” business interests (and thus permitted).² As a result, companies must carefully structure value-based arrangements to meet a facts and circumstances analysis—historically, by satisfying as many of the elements of an applicable AKS safe harbor as possible, with particular attention to ensuring the totality of the arrangement is at fair market value.

¹ 42 U.S.C. § 1320a-7b(b).

² *Cf. generally* 56 Fed. Reg. 35,952, 35,958 (July 29, 1991) (describing the statutory exceptions and AKS safe harbors as intended “to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements”).

Further, companies must implement safeguards sufficient to mitigate AKS risks posed by the risk-sharing portion of the value-based care initiative. There is limited sub-regulatory guidance available regarding the adequacy of safeguards in value-based care arrangements. Office of Inspector General (“OIG”) Advisory Opinion 12-22,³ which articulates OIG’s position on risk-based arrangements outside of formalized CMS risk-sharing programs, highlights certain safeguards that may mitigate risk in value-based care arrangements. Such safeguards include, among other things, ensuring that: (i) cost-savings and quality measures are objective and verifiable, clearly and separately identified, and transparent; (ii) any risk-sharing program does not incentivize inappropriate reductions or limitations in services; and (iii) the organization conducts periodic reviews to protect against any inappropriate results, such as reductions or limitations in services. Though this 2013 Advisory Opinion provides helpful insight, many in the industry desire further guidance to ensure that the private sector has the ability to develop compliant value-based care arrangements.

- **Civil Monetary Penalties Law and Stark Law.** The Civil Monetary Penalties (“CMP”) Law and Stark Law may be implicated by value-based care arrangements, particularly those involving “gainsharing” initiatives (*i.e.*, 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), on the theory that such arrangements could lead to a reduction in the provision of medically necessary services to individuals and inappropriately reward referral of Federal health care program business.⁴ The “Gainsharing CMP” prohibits hospitals from making, and physicians from receiving, direct or indirect payments as an “inducement to reduce or limit medically necessary services” to Medicare patients,⁵ while the Stark Law prohibits a physician from referring Medicare beneficiaries for the furnishing of “designated health services,” or DHS, to any entity with which the physician (or an immediate family member) has a financial relationship, unless the relationship meets the strict requirements of one or more of the exceptions enumerated in the statute or regulations.⁶ Over time, government agencies such as OIG and Centers for Medicare and Medicaid Services (“CMS”) have acknowledged that appropriately structured gainsharing arrangements may reduce hospital costs without causing inappropriate reductions in patient services or rewarding referrals of Federal health care program patients.⁷ Though companies seeking to structure or utilize gainsharing components in value-based arrangements may see this as an opportunity, any such arrangement must still comply with the Gainsharing CMP and Stark Law, and should adhere as closely as possible to sub-regulatory guidance issued by OIG regarding gainsharing. The most useful guidance on gainsharing is derived from over a dozen OIG Advisory Opinions on gainsharing issued from 2000 to 2012.⁸ As with OIG Advisory Opinion 12-22, these Advisory Opinions contain safeguards that may mitigate risk in gainsharing arrangements. Such safeguards

³ [OIG Advisory Opinion No. 12-22](#).

⁴ U.S. Government Accountability Office, *Physician Incentive Payments by Hospitals Could Lead to Abuse*, GAO/HRD-86-103 (July 1986), available at: <http://www.gao.gov/assets/150/144561.pdf>; OIG Special Advisory Bulletin, *Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries* (July 1999), available at: <https://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>.

⁵ Soc. Sec. Act Sec. 1128A(b); Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10 (2015).

⁶ See 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353.

⁷ See Testimony of Lewis Morris, Chief Counsel to the OIG (October 7, 2005), available at: <https://oig.hhs.gov/testimony/docs/2005/Gainsharing10-07-05.pdf>; series of favorable OIG advisory opinions issued between 1999 and 2012; changes to the Gainsharing CMP through the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”).

⁸ [Gainsharing Arrangements and CMPs for Medical Center Payments to Physicians to Reduce or Limit Services to Beneficiaries](#) (July 1999); [OIG Advisory Opinion No. 00-02 dated April 4, 2000](#); [OIG Advisory Opinion No. 01-1 dated January 11, 2001](#); [OIG Advisory Opinion No. 05-01 dated January 28, 2005](#); [OIG Advisory Opinion No. 05-02 dated February 10, 2005](#); [OIG Advisory Opinion No. 05-03 dated February 10, 2005](#); [OIG Advisory Opinion No. 05-04 dated February 10, 2005](#); [OIG Advisory Opinion No. 05-05 dated February 18, 2005](#); [OIG Advisory Opinion No. 05-06 dated February 18, 2005](#); [OIG Advisory Opinion No. 06-22 dated November 9, 2006](#); [OIG Advisory Opinion No. 07-21 dated December 28, 2007](#); [OIG Advisory Opinion No. 07-22 dated December 28, 2007](#); [OIG Advisory Opinion No. 08-09 dated July 31, 2008](#); [OIG Advisory Opinion No. 08-15 issued October 6, 2008](#); [OIG Advisory Opinion No. 08-21 issued November 25, 2008](#); [OIG Advisory Opinion No. 09-06](#).

include, among other things, utilizing objective historical and clinical measures to establish gainsharing arrangements, and ensuring that physicians have access to the same selection of items, supplies and devices as available before the gainsharing arrangement.

- **Data Sharing.** Providers and payors are often “covered entities” under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended, and are subject to privacy and security rules and requirements that limit their ability to share patient data with third parties. Other entities involved in value-based care initiatives (such as those performing data analysis, HIT or population management services) may be “business associates” under HIPAA subject to similar constraints regarding the use and disclosure of patient data. These constraints can be difficult to manage for any organization, but may prove onerous for organizations that also provide other health care products or services, particularly when such products or services may benefit from use of data collected when providing value-based care services.

For example, a medical device company that acquires a population health management business may find itself in possession of patient data that it must protect in accordance with HIPAA. To do so, the medical device company typically must ensure that only those within the population health management business who require access to patient data receive such information, and ensure that the HIPAA-protected population health management business patient data does not become intermingled with the medical device business patient data. This requires careful initial structuring of the acquisition (*e.g.*, considering whether to maintain the population health management organization as a separate legal entity), as well as ongoing training, auditing and monitoring to ensure that the population health management organization’s patient data is maintained separately from data collected in the ordinary course by the device company business and cannot be accessed by the device company personnel. This situation may be further complicated by any shared services between the medical device and population health management businesses (*e.g.*, information technology, human resources, billing) as well as the interest the sales force and others may have in intertwining the device and population health management businesses, despite restrictions established by HIPAA and other laws designed to protect the privacy and security of patient information.

- **Laws Regarding Risk Assumption.** Some states have insurance regulations that may apply to entities that bear risk under value-based care arrangements. In addition, certain states have begun to regulate providers that accept financial risk under value-based care models and to scrutinize network development that consolidates health care markets in a way that impacts health care prices. Although payors are accustomed to compliance with insurance and similar regulations, many organizations that are not ordinarily classified as risk-bearing entities may be required to comply with these state laws. Compliance requirements would vary but may include, for example, adherence to a minimum capital requirement for the risk-sharing business.
- **Conflicts of Interest.** With the expansion of value-based care, many organizations are providing, or seeking to provide, services outside their usual scope. While this necessarily requires an operational adjustment period, it also requires organizations to consider perceived or actual conflicts of interest in their traditional and new roles. For example, a post-acute care provider that manages a hospital palliative care department must consider how to manage the conflict of interest inherent in the manager’s evaluation and recommendation of post-acute care providers to hospital patients.

The list above is not intended as an exhaustive survey of all applicable regulatory issues related to value-based care arrangements. The initiation and revision of any value-based care arrangement requires consideration of these and other potential regulatory hurdles, including those related to antitrust, corporate practice of medicine and fee-splitting laws, and tax issues.

Any organization seeking to implement value-based care initiatives should, as an initial matter, develop or advance its health care regulatory and compliance program to focus on risks inherent in value-based care arrangements. The

organization's compliance department should be involved in the conception and structuring of any value-based care arrangement. The compliance department should focus on ensuring that, for each value-based arrangement, the company has established sufficient safeguards and has maintained documentation around the various components of the program. The compliance department should also monitor and audit each value-based care arrangement to ensure that it is continuing to operate consistent with applicable laws and legal guidance. An organization's effective development and deployment of its compliance program when structuring and monitoring value-based care initiatives will assist the organization in a smooth transition from a fee-for-service environment to one focused on value-based care.