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Learning from a diverse clinical background

an interview with **Lori Strauss**

by Ellis "Mac" Knight, MD, MBA

Comparing risks: Physician employment and clinical integration

» Employment of physicians and other providers by hospitals and clinical integration between hospitals and providers are two standard models of aligning hospitals, health systems, and providers.

» Clinical integration is becoming a more popular model for alignment, given that it places much less financial stress on the balance sheet of the hospital or health system than does provider employment.

» Employment of providers entails particular risks related to the Stark Law, the Anti-Kickback Statute (AKS), and HIPAA.

» Clinical integration's compliance risks predominantly revolve around antitrust rules and regulations; however, Stark, AKS, HIPAA, and medical malpractice risks are also inherent in this model.

» Neither employment nor clinical integration is free of compliance risks, and hospital or healthcare systems will have to scrutinize the risks and benefits of each before deciding which model they prefer to use to align and engage effectively with their providers.

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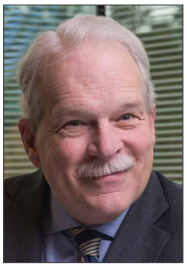
Most healthcare administrators and compliance managers are well versed in the risks related to hospital-physician employment models, for example, employed physician networks (EPNs). The Stark Law and the Anti-Kickback Statute (AKS) are also well understood by providers who must abide by these statutes once they go to work for hospitals and healthcare systems. What is not well known, however, are the compliance risks associated with participation in a clinically integrated network (CIN) and that these organizations may, in fact, be more perilous to traverse from a risk perspective than more traditional alignment models.



Knight

This article will explore the critical rules and regulations related to EPNs and CINS and compare and contrast these two organizational structures. The intent is to provide valuable information for those healthcare organizations (hospitals, healthcare systems, and physician practices) that are considering entering into one of these two models.

Employed provider networks (EPNs)

Hospitals or health systems now employ nearly one-half of US physicians.[1] In some specialties (e.g., cardiology), the percentage of employed physicians is much higher. In others (e.g., ophthalmology, plastic surgery), the numbers are much lower. Regardless of the specialties involved, specific stringent rules govern these relationships and must be followed to avoid serious legal or regulatory consequences.

The Stark Law is a set of statutes that address the fact that physicians and other providers, particularly those who participate with federal or state payer plans (e.g., Medicare, Medicaid), cannot self-refer to hospitals or other organizations with whom they have a vested interest (e.g., a hospital that employs providers and pays them significant compensation).[2] Although this does not mean that physicians do not or cannot refer patients to their employer organizations, it does mean that providers in such employment relationships may not receive direct compensation in return for these referrals. The practical result of this restriction is that hospitals and systems that employ providers must be very careful to:

- Limit their up-front payments to providers and pay only for hard assets (e.g., facilities, fixtures, furniture, and equipment) and avoid paying for things like goodwill or ancillary service operations;
- Pay only what is considered to be a commercially reasonable, fair-market value for the practice as determined by a non-biased third-party valuation; and
- Separate the revenues received for ancillary services ordered by the employed providers from those of direct patient care services (e.g., evaluation and management (E&M) or other current procedural terminology (CPT) services) used to capture provider work relative value units (wRVUs) that are then used to determine a provider's compensation.

The AKS is a criminal statute that prohibits organizations (e.g., hospitals) from offering payments or other rewards to providers in exchange for referrals within federal healthcare programs such as Medicare. Similar to the Stark Laws, the AKS must be considered when employing providers, and care should be taken to ensure that nothing is in the up-front payment for practice acquisition or the ongoing compensation models.[3]

The Health Insurance Portability and Accountability Act (HIPAA)* also comes into play with EPNs, because many of these networks are sharing IT systems, especially electronic medical records (EMRs).[4] Although it is, of course, entirely appropriate for providers who are actively involved in the care of a particular patient to access that patient's record on an EMR, it is not suitable for them to access the records of patients with whom they are not actively involved as a caregiver. Therefore, hospitals and other employers of large provider networks must be especially vigilant in maintaining the privacy of protected patient information.

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Finally, medico-legal risk remains a primary concern for all healthcare providers, including EPNs. Medical malpractice insurance coverage must be in place, and quality and patient safety efforts should be enacted to reduce both clinical and financial risk.

Clinically integrated networks (CINs)

With the increasing prevalence of value-based reimbursement models (e.g., shared savings, bundled payments, pay for performance, capitation) throughout the

healthcare industry, more providers of all types are joining together to form clinically integrated networks.[5] These networks focus on delivering high-value care delivery (i.e., quality per unit of cost) by providing the necessary infrastructure (e.g., IT systems and care management staff), initiatives (e.g., chronic care management, annual wellness visits, and transitional care management), and data (e.g., quality and cost measures) needed to deliver high-value care.

Organizing disparate providers, who may not all practice under the same tax ID number, into a CIN, which may also involve a hospital, however, raises its own set of compliance concerns.

Anti-trust regulations as defined and overseen by the Federal Trade Commission (FTC) have historically prevented heterogeneous groups of providers like those now being organized into CINs from jointly contracting with government or commercial payers.[6] Over the last decade or so, This prohibition has been lifted if CINS are explicitly formed to improve value (i.e. to increase quality and to lower costs). During this period, many precedent-setting legal cases and formal or informal opinions by the FTC have stated that CINs formed for value can jointly contract for services.

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As with many federal regulations, the criteria for clinical integration are not well defined by the FTC. Nevertheless, the following are generally considered to be essential attributes of a CIN if it is to avoid being deemed anti-competitive by the FTC and Department of Justice.

The CIN should be physician-led and physician governed

This matter is especially important in those networks that include hospitals or healthcare systems that may be providing the majority of the funding for the CIN. Apparently, the goal here is to make sure that the hospital or system does not use the CIN and its funding contributions to drive referrals from the CIN provider participants. Organizing in a way that allows physicians to play a dominant role is then looked at as a way of limiting any attempts by the sponsoring hospital/system to circumvent Stark.

The CIN should focus on quality and cost efficiency

Again, this issue is crucial and should be emphasized in all of the CINs organizing documents (e.g., operating agreement, clinical integration/business plan, participation agreements, and board/committee charters).

Note: Although the FTC does allow clinically integrated networks to jointly contract and share income from fee-for-service payments, capitation payments, bundled payments, and shared savings, or pay-for-performance (P4P) bonuses, it only allows tying these payments to provider performance (i.e., incentivizing performance through financial means) if other methods to drive performance have not been successful.[7]

The CIN should have in place a system to drive accountability, including a remediation plan for those providers who do not meet acceptable performance standards. This is important since more traditional structures,

such as the organized medical staff in a hospital, have not been especially capable when it comes to holding providers accountable for their actions. It is the FTC's goal, then, to drive more accountability within these networks by threatening to enforce antitrust regulations with CINs that do not include this component.

Risks and re-insurance

CINs often take on risk-based contracts where they assume both upside and downside risk with payers. In these two-sided risk models, CINs should consider ways to mitigate their risks from cases where, despite best clinical practice, budgets are overrun and paybacks are due to the payer (i.e., government or commercial plans). Re-insurance of outlier risk is the most common way to mitigate this risk. Other models, such as joining a provider-owned insurance captive, should also be considered as a way to manage risk in a CIN.

Finally, the medical malpractice risk of a CIN is equal to or perhaps more extensive than that seen in an EPN. Contributors to this increased risk include the fact that many CINs involve more than one clinical specialty, more than one type of provider organization (e.g., hospitals, ASCs, physician practices, ancillary service providers), and a wide variety of clinical services that span the continuum of care. The provider-owned insurance captive model mentioned above may be a way in which CINs can best manage their malpractice risk. Also, note that some malpractice insurance carriers are considering discounted premiums to those providers who participate in CINs and meet the performance standards for quality and patient safety set by these entities.

Conclusion

CINs are often a way for a hospital or healthcare system to achieve alignment and integration with providers without the risk to the balance sheet related to widespread physician/provider employment. However, CINs carry with them their own set of risks that all potential participants should consider. CINs don't offer a safe harbor from risk as compared to EPNs and, especially for those hospitals or healthcare systems unfamiliar with the unique risks related to clinical integration, they may indeed be a higher risk option for hospital systems looking to align more tightly and integrate with their providers.

** Corrected November 2, 2018*

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2. Callan Stein: "An Overview: The Stark Law Basics" Barrett & Singal website. Available at https://bit.ly/2xh1spo
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