Clinically Integrated Networks and Contracts with Commercial Payers: The New Frontier

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National health care reform and intense competition are pressuring hospitals and health systems to improve quality while reducing the overall cost of care. These improvements often require more-effective coordination with physicians and better arrangements with payers. Clinically integrated networks (CINs) can be a very effective vehicle for achieving these results.

This article provides insight into, and practical recommendations concerning, the structure and implementation of CINs, and includes an overview of legal, regulatory, and business issues. Importantly, CINs doing business strictly in the commercial arena do not have the same protections and waivers afforded to accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP); thus, providers should carefully structure CINs consistent with the legal and regulatory insights described in this article.

What Is a CIN?

Through CINs, hospitals engage independent and hospital-employed physicians to improve the quality of patient care and reduce costs; they then contract with third-party payers to receive additional incentive compensation as a result of providing such high-quality, low-cost care.[1] CINs are sometimes referred to in the industry as "commercial ACOs." The additional payments CINs receive from payers often are referred to as "value-based payments" as they reward providers for providing additional value (quality and cost savings) to health plans and consumers. CIN contracts with third-party payers are sometimes referred to as "population management contracts" and may involve value-based payments such as pay for performance, shared savings, shared risk, and tiered network arrangements. CIN contracts may be structured so that: (1) the providers' underlying participation contracts with payers continue unaffected, and incentive-based contracts are added on top of those underlying contracts; and (2) as CINs become increasingly clinically integrated, direct contracts with payers may supersede existing provider contracts.

Since a CIN pursues both improvements in quality of care and payer arrangements that reward this success, it can be a useful vehicle to drive improvements the hospital/health system views as strategically necessary. One of the advantages of CINs is that they seek to redesign the care delivery model on more of a "macro" basis for all patients before entering into population management contracts with payers, which simplifies physician administrative tasks. At the same time, the CIN can enter into several different types of payer arrangements, all of which will pursue quality and cost improvement (using the CIN's policies, procedures, and protocols for care improvement), but which may have varying degrees of risk and reward. An illustration of patient populations and potential contracts is provided below.

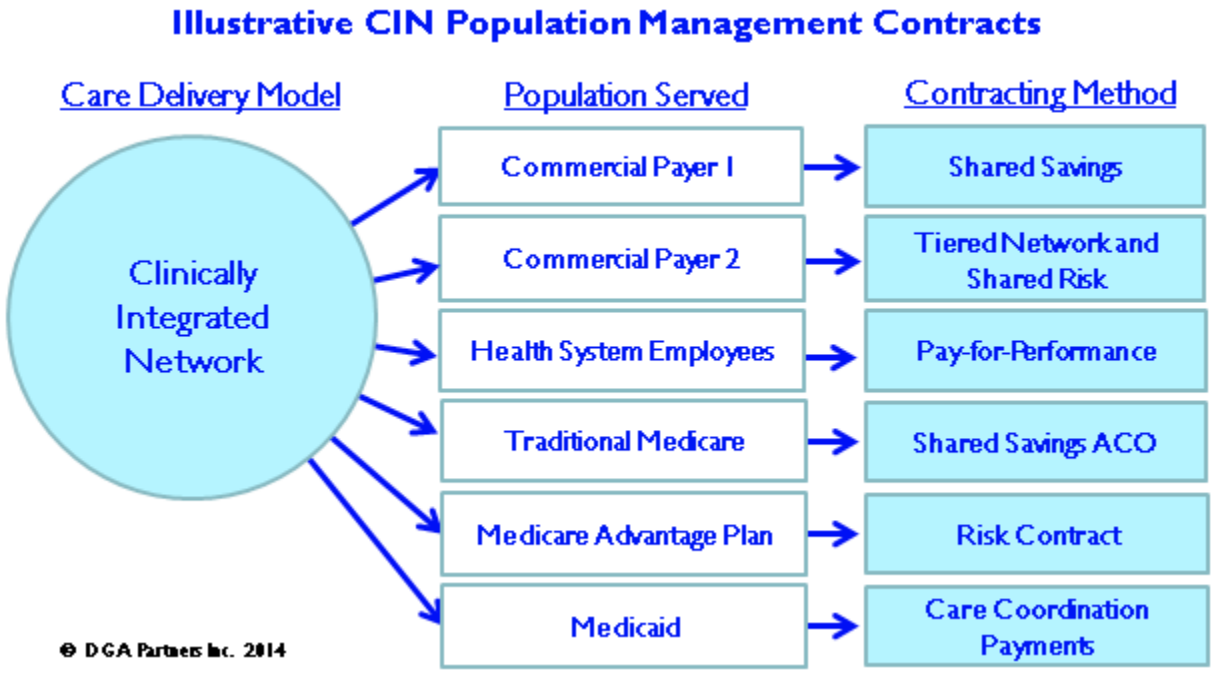
It is worth noting that CIN population management contracts often improve results for patients who are less "tightly managed" than previous payer-provider arrangements. For example, shared savings or pay-for-performance arrangements with commercial preferred provider organizations can allow CINs to drive improvements in a much larger population, without being restricted to a health maintenance organization population.[2]

CINs often focus on reducing utilization, especially of expensive services like avoidable hospital admissions. Though care improvements are positive for patients and typically support the hospital's mission, decreased inpatient volume can be a concern for hospital chief financial officers. The hospital's share of payer incentives often does not make up the difference in lost short-term revenue. However, a successful CIN can be an attractive choice for patients and can provide more-coordinated care for patients, making them more likely to seek follow-up care at the same hospital rather than a competing hospital. In addition, if a CIN successfully manages overall costs of care, insurers may offer lower cost insurance to subscribers who choose a network focused on the CIN's providers, or otherwise "steer" patients to CIN providers. This payer opportunity has become increasingly common as health plans search for cost-effective products to offer on public and private insurance exchanges or directly to employers.

Structure and Governance of CINs

Most CINs are organized as separate legal entities (either limited liability companies or nonprofit organizations). While in past years physician-hospital organizations were typically set up as joint ventures, most CINs are now established as subsidiaries of hospitals or health systems.

The CIN should be governed by its participants, who may include hospitals, physicians, physician groups, and other health care entities. It is important to engage the participation of a representative sample of participants in governance and leadership roles—including employed and independent physicians, primary care physicians, and specialty physicians, as well as members of the hospital entity and other participating entities, if any. A multi-class governing structure is helpful in giving representation on the "board" to the various participants. Many important decisions will require the "buy-in" of different stakeholder types by, for example, a majority vote of each class of stakeholder.



Moreover, physician leadership, input, and commitment will be key to the success of any CIN. Physician participants may or may not be required to contribute financially to the CIN, in which case capital will be contributed by the hospital or similarly situated entity. It is crucial that in situations where physician participants do not contribute financially, they contribute "human capital" such as their time and clinical expertise to achieve robust integration. With respect to financial incentives and bonus payments received from payers, the CIN will need to establish a reasonable method of allocating such incentive payments among participants, for example, by taking into account the achievement of quality benchmarks and adherence to evidence-based medicine protocols.

Participants in the CIN should work together to develop and implement a common set of clinical guidelines that will help participants clinically integrate to deliver high-quality, cost-effective care. Participants may use an information technology infrastructure to exchange electronic health records and clinical data to analyze quality and outcomes among participants and improve upon clinical policies, protocols, and procedures. Once clinically integrated, the CIN will be in a position to enter into population management contracts with third-party payers, with the goal of improving the quality of care for payers' patient populations, and in return, earning incentive compensation for delivering high-quality care.

Antitrust Concerns

CINs potentially implicate the federal antitrust laws[3] due to their interrelated structure and collaboration among various providers who may be actual or potential competitors.

The Federal Trade Commission (FTC) analyzes agreements among competitors under either the per se rule or the rule of reason.[4] The FTC will find "naked" agreements among competitors that fix prices or allocate markets per se illegal.[5] The FTC has recognized certain elements that demonstrate a CIN's anticompetitive nature, including (among other elements) an exclusive network comprising a very high percentage of local area physicians, and the presence of anticompetitive collateral agreements.[6] Thus, collaborating providers should refrain from anticompetitive activities, such as: (1) discussing competitively sensitive information (i.e., pricing terms of their respective payer contracts); and (2) individually or collectively deciding to terminate (or to threaten terminating) existing contracts if a payer offers unfavorable pricing terms for the CIN.

Absent per se anticompetitive conduct, the FTC (applying its rule of reason analysis) will determine whether, despite the presence of any anticompetitive effects, integration is likely to produce significant efficiencies that benefit consumers and whether joint pricing agreements with third-party payers are reasonably necessary to realize those efficiencies. Furthermore, to the extent that CIN population management contracts with payers sit on top of underlying individually negotiated provider-payer contracts, they may raise less risk of antitrust violations, provided that they are truly clinically integrated.

CINs are likely to produce significant efficiencies where collaborating providers are clinically or financially integrated.[7] Clinical integration can be achieved, for example, through robust participant involvement, evaluation and modification of practice patterns by participants, and the development and enforcement of clinical practice guidelines. Financial integration can be achieved through mechanisms such as capitated rates, or financial rewards/penalties based on group performance in achieving overall cost or utilization targets.

The safety zones described in the joint FTC/U.S. Department of Justice guidance for MSSP ACOs do not clearly apply to

non-MSSP commercial arrangements with payers; however, CINs can be informed by such guidance. To be conservative: (1) participating providers of a "common service" should have a combined market share of less than 30% for each common service in each participant's primary service area; (2) hospital or ambulatory surgery center participants should be non-exclusive, regardless of market share; and (3) participants having greater than 50% of the market share in any primary service should be non-exclusive to the CIN, and the CIN, in its population management contracts, should not require commercial payers to be exclusive to the CIN.[8]

Internal Revenue Service Issues

CINs should be aware of certain Internal Revenue Service (IRS) issues regarding tax exemption. They need to determine whether they should seek tax-exempt status, and if applicable, whether a participating provider's tax-exempt status would be affected as a result of participation in a for-profit CIN. In the latter situation, federal case law and IRS guidance discussed below can help guide a participating tax-exempt entity.

First, the activities of a CIN must further the charitable purpose of a participating tax-exempt entity. If not, a tax-exempt entity's status could be jeopardized if the CIN's activities represent *more than an insubstantial part* of the total activities of the tax-exempt entity. Guidance from the IRS suggests that less than 5% of revenue would be considered *insubstantial*, and between 5% and 15% of revenue would be riskier.[9]

Second, the CIN's activities should be *substantially related to the participating entity's tax-exempt purpose*. The IRS has expressed that many non-MSSP activities are not charitable activities, including negotiating with private health insurers on behalf of unrelated parties, regardless of whether the agreement negotiated involves a program aimed at achieving cost savings in health care delivery, because unlike MSSP activities, activities with commercial payers do not lessen the burden of government; however, improving the quality of health care to patients in the hospital's service area may arguably still advance some of the participating entity's stated tax-exempt purposes.[10]

Next, CINs must be certain that their revenues are not distributed *for the benefit of private individuals*. Any benefit flowing to private parties should be incidental to an organization pursuing tax-exempt charitable purposes.[11] IRS guidance for MSSP ACOs states that to protect against any impermissible private inurement or private benefit, a participating entity's share of economic benefits (and share of losses) derived from the ACO should be proportional to the benefits or contributions (including monetary and non-monetary contributions) the participating entity provides to the ACO.

Finally, a tax-exempt entity must retain control over decisions that could affect its tax-exempt status. "Control" may include retaining control over the governing body of the CIN, retaining the ability to exercise certain reserve powers if the entity's tax-exempt status is in jeopardy, or exercising control over the chief officer of the CIN.[12]

Health Care Regulatory Compliance

CIN participants should actively monitor and audit compliance with the health care laws and regulations described below.

The Anti-Kickback Statute and the Stark Law[13]

A CIN's participants will be working together toward establishing clinical integration, but nonetheless, they must ensure that their interdependence does not result in any payment or benefit in exchange for patient referrals. Participants should avoid threatening to cease or reduce patient referrals to physicians or entities that do not become members of the CIN, or otherwise conditioning referrals on participating in the CIN.

MSSP ACOs have the benefit of fraud and abuse waivers for activities that are "reasonably related to the purposes of the Shared Savings Program," which include: (1) promoting accountability for a patient population; (2) coordinating items and services provided to Medicare Part A and Part B beneficiaries; and (3) encouraging investment in infrastructure and redesigned care processes for high-quality and efficient service delivery.[14] The Centers for Medicare & Medicaid Services (CMS) has not expressly granted CINs the benefit of the MSSP waivers; however, in its Interim Final Rule regarding the MSSP ACO waivers, CMS explained that performance-based payments received from a commercial plan do not necessarily implicate the fraud and abuse laws.[15]

Civil Monetary Penalties Act[16]

The Civil Monetary Penalties Act (CMP Act) applies to Medicare and Medicaid beneficiaries. In working toward achieving cost savings, best practices suggest that participating providers in CINs comply with the CMP Act, which requires, among other things, that: cost-containment measures do not result in any adverse impact on the quality of patient care; cost-savings measures are not applied in clinically inappropriate circumstances; providers do not stint on care to patients; providers do not "cherry-pick" healthier patients or patients who cost less to treat; and providers do not inappropriately accelerate patient discharges.

Health Insurance Portability and Accountability Act and Health Information Technology for Economic and Clinical Health Act[17]

CINs will likely aggregate and share electronic health records and data across participating providers. Thus, CINs must comply with the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act, in addition to state privacy laws. CINs, acting as a business associate of each provider in the network, should execute business associate agreements with each provider. Furthermore, CINs should comply with the Electronic Health Records Items and Services Anti-Kickback Statute safe harbor and Stark exception.[18]

State Law and Payer Contract Issues

CINs should be structured to comply with state fraud and abuse, insurance, and corporate practice of medicine laws and regulations, and state privacy laws, as applicable. For example, state insurance laws may require that CIN participants providing certain services on behalf of a health plan obtain a license or certification from the state insurance agency. Moreover, state corporate practice of medicine laws may prohibit the CIN from controlling aspects of participating physicians' medical practices.

CINs must carefully structure their contracts with payers and ensure that such contracts clearly set forth certain key terms, such as: (1) the clinical benchmarks required to receive incentive payments and how such benchmarks will be measured (including sample calculations); (2) the patients covered under such contracts; (3) information technology, claims, and data-sharing requirements; (4) terms of payment; (5) audit and appeal rights; (6) communications with members; (7) any exclusivity provisions; and (8) termination rights and processes.

Conclusion

CINs may represent the future of multi-provider collaborations, increasing accountability among physicians, organizing and coordinating care among providers, and developing clinically integrated policies, procedures, and protocols to provide high-quality services while reducing overall health care costs. In some markets CINs face competition for the participation of independent physicians. CINs of competing hospitals may be trying to attract them to a different CIN, and some physician entities also may seek their allegiance. It is important that CINs are carefully structured to be attractive to physicians and functionally effective, while ensuring compliance with the legal and regulatory framework described above.

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1 CINs are similar to physician hospital organizations (PHOs). In fact, some PHOs consider themselves to be CINs as well. The concept of CINs first surfaced in the 1990s, when the Federal Trade Commission (FTC) recognized "clinical integration" as a way for providers to collaborate without violating federal antitrust laws. Bearing substantial financial risk is the other way to collaborate. Most recently, in February 2013, the FTC issued a favorable advisory opinion for a Norman PHO in Oklahoma, which shows additional flexibility in the government's approach toward health care delivery models that are consistent with health care reform.

2 Medicare Shared Savings Program ACOs are an example of one type of payer arrangement that can be pursued by a CIN and that serves a population that is not subject to typical health maintenance organization constraints.

3 The Sherman Act, 15 U.S.C. §§ 1-7 (2012); The Clayton Act, 15 U.S.C. §§ 12-27 (2012); The Federal Trade Commission Act, 15 U.S.C. §§ 41-58 (2012).

4 U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Policy in Health Care, Statement 9: Enforcement Policy on Multiprovider Networks (1996).

5 *Id.*

6 U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Policy in Health Care, Statement 8: Enforcement Policy on Physician Network Joint Ventures (1996).

7 Statement 9, *supra* note 4, and Statement 8, *supra* note 6.

8 Federal Trade Commission and Antitrust Division of the U.S. Department of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Oct. 20, 2011).

9 IRS Notice 2011-20.

10 *Id. See also* I.R.C. 501(c)(3) (2012) (Detailing a list of the different types of tax-exempt purposes).

11 *Redlands Surgical Servs. v. Comm'r*, 113 T.C. 47, 92-93 (1999), *aff'd* 242 F.3d 904 (9th Cir 2001).

12 *See* Rev. Rul. 2004-51(Tax-exempt university retained control of the activities of a joint venture with a for-profit entity by retaining control over its curriculum); *See also St. David's Health Care Sys. v. United States*, 349 F.3d 232, 236-237 (5th Cir. 2003) (The nonprofit partner must not have "ceded control" of its activities to its for-profit joint venturer in order to retain its tax-exempt status).

13 31 U.S.C. § 3729 *et seq.* (2012); 42 U.S.C. § 1320a-7b(b) (2012); 42 U.S.C. § 1395nn (2012).

14 76 Fed. Reg. 68002 (Nov. 2, 2011).

15 *Id.*

16 42 U.S.C. § 1320a-7a (2012).

17 Pub. L. No. 104-191; Pub. L. No. 111-5.

18 42 C.F.R. § 1001.952(y); 42 C.F.R. § 411.357(w).