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Healthcare Update

Clinical Integration

Clinical Integration and its Relevance to Providers

Clinical integration is a type of collaboration amongst otherwise independent healthcare providers for the purposes of improving quality and containing costs, which is recognized by the U.S. Department of Justice and the Federal Trade Commission ("FTC", collectively, the "Agencies") as a mechanism to produce efficiency benefits that justify joint pricing for a multiprovider network that does not share substantial financial risk.¹ A successful program produces those required efficiencies by: (1) establishing mechanisms to monitor and control utilization of healthcare services, which are designed to control costs and assure quality of care; (2) selectively choosing participating physicians who are likely to further these efficiency objectives; and (3) investing significant capital, both monetary and human, in the infrastructure and capability necessary to realize the claimed efficiencies.² The result must be a high degree of interdependence and cooperation amongst participants.

The benefits of clinical integration are both legal and financial. While price fixing is typically *per se* unlawful under Section One of the Sherman Act,³ exceptions exist. The Agencies have outlined certain permissible pro-competitive conduct under Section One for providers who: (a) share substantial financial risk, or (b) are sufficiently integrated to create significant efficiencies, i.e., are clinically integrated.⁴ Clinically integrated entities that are subject to challenge for an alleged antitrust price-fixing violation are subject to review under the more lenient rule of reason standard instead of being deemed a *per se* antitrust violation.⁵

In addition to the legal benefits, there are several noted financial benefits to providers as a result of clinically integrating.

- Joint contracting: Joint contracting in lieu of messenger model contracting affords clinically integrated entities the opportunity to access more favorable financial contracting terms, as well as pay-for-performance ("P4P") and other bonus opportunities.
- Achievement of quality and efficiency goals: Clinical integration produces noted improvements in quality and efficiency, which can serve to:
 - o Garner higher ratings from industry oversight groups and to improve community visibility.
 - o Lower costs, from clinical improvements, such as reduced length of stay and fewer readmissions.
 - o Increasing ability to compete with other provider entities in the marketplace.
- Improved working relationships: The design and implementation of a clinical integration program reinforces the collaboration between, and the relationship of, the hospital or health system, and the independent practice association ("IPA"), or physician-hospital organization ("PHO") that may be a clinical integration partner, and its physician participants.
- Physician benefits: Participating physicians benefit from clinical integration by collaborating with peers and other providers during program development and having ready-access to comprehensive performance data for self-assessment and improvement. Additionally, satisfactory performance will afford participants the opportunity to identify themselves as quality providers with substantiating data and to increase their visibility in the payor and patient communities.
- Complement national healthcare payment reform initiatives: Central to healthcare payment reform is Medicare's incremental shift from fee-for-service payments to value-

based purchasing for the purposes of controlling cost growth and paying for quality.⁶ Clinically integrated entities present an established framework for the administration of value-based purchasing and quality-enhancing reform proposals and components such as Accountable Care Organizations (“ACOs”), bundling of services, electronic health records (“EHRs”), P4P, CMS demonstration projects and patient-centered primary care physician (“PCP”) medical homes.

Key Concepts

Regulators have identified a number of fundamental elements of a successful clinical integration program. First is the adoption of adequate Performance Measures of sufficient clinical rigor, reflecting clinical initiatives that address areas of community and payor concern in a manner that can achieve real quality or efficiency enhancements. Second, physicians must participate in *each* payor contract entered by the clinically integrated physician panel. Third, physician members are required to make referrals to other network members, in most circumstances. Fourth, regulators prefer a non-exclusive network. Fifth, entities must demonstrate that joint contracting is subordinate to and necessary for achievement of the goals of the clinical integration program, rather than be itself, the goal of the program. Sixth, adequate safeguards must be taken to prevent anti-competitive spillover. Finally, the operation of the clinical integration program must be thoroughly documented.

Program Design, Development, and Implementation

Under the leadership of key physicians and staff, the program will undertake a number of initiatives, including:

- Selection and adoption of evidence-based practice standards, clinical protocols, and performance benchmarks, or “Performance Measures.”
- Budgeting and investment of monetary and human capital by the clinically integrating entity (if any) and each physician participant.
- Development of infrastructure in support of the program, including mechanisms to monitor and control utilization of healthcare services.
- Enhancing physician participation and membership requirements.
- Development and utilization of a centralized clinical data repository and management system that may or may not include the initial use of EMRs.
- Generation of periodic individual and aggregate (peer) practitioner Performance Measure compliance reports.
- Documentation of the clinical integration program.

Considering a Clinical Integration Program

The benefits of a clinical integration program need not derive from wholly new undertakings. For example, hospitals participating in the Centers for Medicare and Medicaid Services (“CMS”) Reporting Hospital Quality Data for Annual Payment Update (“RHQDAPU”) program to receive the full annual Medicare market basket increase can build their clinical integration efforts upon initiatives that are already underway.⁷ The individuals and entity, or entities, that are clinically integrating should consider undertaking a market share analysis, with the intent of maintaining and enhancing competition in the market when designing and implementing the program; considering local political and business issues and sensitivities and appropriate outreach efforts to be undertaken; assessing data collection methodologies; and analyzing state law protections for clinical integration activities, including peer review.

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Conclusion

Hospitals and physicians need to objectively assess their current stage of clinical integration and, as necessary, embark on the path to the development of a robust and effective clinical integration program that mandates hospital and physician participation. Reimbursement modifications being considered and implemented by both governmental and non-governmental payors will make clinical integration an imperative strategic initiative for all healthcare providers. Our attorneys have been designing and developing successful clinical integration programs for a number of years.

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¹ U.S. DEPT. OF JUSTICE & FED'L TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE §8.B (1996).

² *Id.*

³ 15 U.S.C. §1 (2009).

⁴ U.S. DEPT. OF JUSTICE & FED'L TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE § 8.B (1996).

⁵ *Id.* at §8.B.1.

⁶ See e.g., Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub.L. No. 108-173, 42 U.S.C. § 1396u-5(c)); Deficit Reduction Act (DRA) of 2005, Pub. L. 109-171, title V, § 5001(a)-(b), 42 U.S.C. § 1305. The RHQDAPU program was originally mandated by Section 501(b) of the MMA. This section of the MMA authorized CMS to pay hospitals that successfully report designated quality measures a higher annual update to their payment rates. Initially, the MMA provided for a 0.4 percentage point reduction in the annual market basket update for hospitals that did not successfully report. The DRA increased that reduction to 2.0 percentage points. See also CENTERS FOR MEDICARE AND MEDICAID SERVS., U.S. DEPT. OF HEALTH AND HUMAN SERVS., REPORT TO CONGRESS: PLAN TO IMPLEMENT A MEDICARE HOSPITAL VALUE-BASED PURCHASING PROGRAM (Nov. 21, 2007).

⁷ See e.g., 74 Fed. Reg. 43754, 43861 (Aug. 21, 2009) (setting forth the most recent iteration of the RHQDAPU program pay-for-reporting requirements).

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