

**CLINICAL INTEGRATION:
RESPONDING TO MARKETPLACE
REALITIES AND CHANGING
REIMBURSEMENT OPPORTUNITIES**

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CLINICAL INTEGRATION: RESPONDING TO MARKETPLACE REALITIES AND CHANGING REIMBURSEMENT OPPORTUNITIES

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Rarely has enhancing interest in the quality of healthcare services aligned squarely with the need to alter reimbursement methodologies of the marketplace. This opportunity to align the documented improvement of healthcare quality with an increase in market share and the attendant increase in reimbursement is a fundamental reason why "clinical integration" is increasingly gaining favor amongst providers and policymakers. This article discusses the potential advantages of clinical integration; its background; why providers should pursue clinical integration, including how a clinical integration program is responsive to the economic and quality demands being made of providers; and the key components of a clinical integration program. In particular, as private commercial payors and federal healthcare payment reform efforts increasingly reinforce quality and efficiency-enhancing mechanisms such as those that are available through clinical integration, failure to clinically integrate will likely result in missed opportunities for enhanced provider reimbursement through access to more favorable contracting terms and incentive payment methodologies.

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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. The U.S. Department of Justice and the Federal Trade Commission ("FTC", collectively, the "Agencies") recognize clinical integration as a mechanism for a multiprovider network that does not share substantial financial risk to produce efficiency benefits that justify joint pricing.ⁱ 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.ⁱⁱ

The significant efficiencies required by the Agencies prior to joint contracting result from otherwise independent providers collaborating to implement an active clinical integration program. A successful program will involve: (1) establishing mechanisms to monitor and control utilization of healthcare services that 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) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.ⁱⁱⁱ Pursuant to these objectives, each participant's performance will be evaluated and modified, as necessary, in order to achieve compliance with the requirements of the program. The result must be a high degree of interdependence and cooperation amongst participants.

As evident as the legal benefits available to clinically integrated entities are, the marketplace advantages are equally appealing. Joint contracting in lieu of messenger model contracting, as discussed below, affords clinically integrated entities the opportunity to access more favorable financial contracting terms, as well as pay-for-performance ("P4P") and other incentive pay opportunities. Lowered healthcare costs should result from clinical performance improvements such as reduced length of stay and fewer readmissions. 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. Achievement of quality and efficiency goals will allow providers the opportunity to garner higher ratings from industry oversight groups and to improve community visibility. Clinically integrated entities are better poised to compete in the marketplace with other provider entities. Further, 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.^{iv}

Moreover, clinical integration programs complement national healthcare reform initiatives that are currently under consideration. 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.^v As a result, regardless of whether, or the form of, comprehensive reform that comes to pass, providers should consider strategic options to position themselves for an organizational response to Medicare payment reform. Clinical integration offers providers an advantageous infrastructure to respond to such federal initiatives.

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.

ACOs are integrated hospital and physician delivery systems that allow for the distribution of financial bonuses for quality and cost saving achievements (and penalties where targets are missed). The Medicare Payment Advisory Commission ("MedPAC") has recommended broader use of ACOs.^{vi} ACOs are viewed as likely components of any federal reform initiative, particularly because government officials have identified ACOs as a potential producer of cost savings.^{vii} Because clinically integrated hospitals and physicians function in a manner consistent with the design of ACO, integrated providers will be able to take quicker advantage of ACO-based reimbursement initiatives.

Federal healthcare payment reform may also incorporate elements such as bundling. Bundling offers a single payment to hospitals and post-acute providers for an entire episode of care. Similar to the requirements of capitation, this risk-sharing arrangement holds all participating providers responsible for any cost of care above and beyond the bundled rate. MedPAC believes bundling will encourage provider interdependence and lower Medicare program costs. The creation of medical homes, a clinical setting focused around the PCP and designed to improve the coordination of care and disease management, has also been promoted. Relatedly, financial subsidies being offered under the American Recovery and Reinvestment Act of 2009 for adoption of electronic health records ("EHRs") will, by 2015, become payment reductions for providers who fail to become "meaningful users."^{viii} Additionally, there are ongoing hospital and physician Medicare and commercial P4P programs that reward documented quality improvement. That many of these concepts and initiatives are the subject of current CMS demonstration projects, including the Hospital Quality Incentive Demonstration, the Physician Group Practice Demonstration, and the Acute Care Episode Demonstration, suggests their traction.

Clinically integrated providers will be well poised to respond to federal reform initiatives that incorporate these concepts and initiatives, and will be eligible for associated incentive payments. Clinical integration dovetails with likely healthcare reform initiatives and goals by using or promoting:

- + The interdependence and cooperation of providers to encourage coordinated care for enhanced quality and efficiencies.
- + Adoption of evidence-based practice standards and clinical protocols, and provider benchmarking.
- + Creation of programs and mechanisms to monitor and control quality and utilization of healthcare services.
- + Use of an interoperative information management system, possibly including EHRs.
- + Credentialing aimed at selecting and maintaining a cost-conscious, high-quality provider panel.

Individual participating physicians share in the benefits of a clinical integration program. Physicians can participate in the opportunity to collaborate with peers and other providers during program development. Possibly for the first time, physicians will have readily-accessible comprehensive performance data across inpatient and outpatient delivery sites for self-assessment and improvement. 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. Physician participation in the Medicare Physician Quality Reporting Initiative program is complemented by clinical integration and enables physicians to access increased Medicare payments.^{ix} Not least of all, physicians are able to share in more favorable commercial payor contracting terms and increased P4P and bonus opportunities.

On the other hand, the Obama administration has indicated its intent to increase antitrust enforcement actions in many sectors, likely including healthcare. As a result, non-clinically integrated providers who are not employing the messenger model appropriately may be at increasing risk of investigation by the Agencies.

Antitrust Background

Section One of the Sherman Act states that "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce . . . is declared to be illegal."^x Section One violations such as price fixing are considered so harmful to competition that they may be considered *per se* violations. As recently as 1982, the Supreme Court held that it was *per se* illegal for physicians to agree on the maximum fee they would charge patients under healthcare plans because individual physicians are competitors in the market for the provision of services.^{xi}

While price fixing is typically *per se* unlawful, 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.^{xii} Anything not *per se* unreasonable is analyzed under the rule of reason balancing test to determine whether anti-competitive effects outweigh pro-competitive benefits.

Networks that are not substantially financially or clinically integrated can use the messenger model, as authorized by the Agencies, to facilitate contracting between competing providers and avoid price-fixing agreements.^{xiii} Under the messenger model, an independent administration literally "messengers" price and other contracting terms offered by payors amongst member physicians without advising or otherwise indicating the actions of other competitors in response to the same terms. This model has fallen out of favor for provider contracting with payors on a non-risk basis, particularly upon the Agencies' focus of enforcement through the advent of clinical integration, and a limited but growing number of FTC Advisory Opinions which have provided needed guidance on the specifics of clinical integration programs.^{xiv}

Considering a Clinical Integration Program

Due consideration to a number of factors prior to undertaking the development of a clinical integration program is necessary. The individuals and entity, or entities, that are clinically integrating, whether independent physicians, a PHO, IPA, hospital or health system, should consider undertaking a market share analysis. The analysis should assess provider market concentration across specialties. To the extent that the clinically integrated entity has the ability to exercise market power, its clinical integration program may be subject to increased antitrust scrutiny. Providers must remain cognizant of maintaining and enhancing competition in the market when designing and implementing the program. Local political and business issues and sensitivities should also be considered and appropriate outreach efforts undertaken, preferably in the program conceptualization stage.

Data collection methodologies, e.g., provider medical records and practice management systems, and the availability of hospital inpatient, outpatient, pharmaceutical, laboratory and ancillary service data, should be inventoried and assessed. Determining the data capabilities of the clinically integrating entities will guide the development of the healthcare information data system and repository that is necessary for

clinical integration, as discussed further below. Additionally state law protections for clinical integration activities, including peer review, should be analyzed.

Program Design, Development, and Implementation

After foundational considerations have been addressed, the design, development, and implementation of the clinical integration program can begin in earnest. Under the leadership of key physicians and staff dedicated, at least in part, to clinical integration activities, 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 physician participants.
- + Development of infrastructure in support of the program, including mechanisms to monitor and control utilization of healthcare services, through the:
 - + Establishment of clinical integration committee(s), and
 - + Initial and ongoing education and training of participating physicians and their staff, and the staff of the clinically integrating entity, if any.
- + Enhancing physician participation and membership requirements, including:
 - + Requiring clinical integration program participation and compliance, and
 - + Adopting an increasingly selective credentialing process.
- + Development and utilization of a centralized clinical data repository, patient registry 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, including:
 - + Execution of clinical integration physician participation contracts and Business Associate Agreements,
 - + Creation of clinical integration policies and procedures,
 - + Development of clinical integration governance and other documents, and
 - + Compilation of provider performance data.

The development and utilization of a clinical data repository, patient registry and management system with or without EMRs can be accomplished in-house or with the assistance of a third party vendor. The information system is essential to provider performance monitoring. As a condition of program participation, physicians will be required to report their clinical data to the centralized data system offered through a web based internet system. For those providers who cannot report data electronically, a manual reporting system of equal rigor as the electronic reporting system may need to be developed in order to appropriately address the care tendered by such providers. Additional sources of clinical data may be accessed from health plans, clinical laboratories, e-prescribing systems and other healthcare providers.

The regular review and update of Performance Measures, including based on the needs of payors and the patient community, is a necessary program component. Each practitioner will receive periodic individual and aggregate practitioner Performance Measure compliance reports. These "report cards" provide an ongoing assessment of provider performance for the benefit of the individual, the clinically integrated entity, and, ultimately, the patient and payor communities. Providers who do not achieve sufficient compliance with the Performance Measures must be subject to remedial efforts, including

training and education, and potential sanctioning and termination of membership in the clinically integrated entity. Assessment of performance by peers is a key component of any clinical integration program. The Agencies require that such programs have the "teeth" necessary to result in real consequences for providers who do not help achieve quality and efficiency goals.

Key Concepts

Regulators have identified a number of fundamental elements of a successful clinical integration program. First is the adoption of adequate Performance Measures. Performance Measures must be of sufficient clinical rigor. That is, clinical measures should not only be "low hanging fruit" but instead reflect clinical initiatives that address areas of community and payor concern in a manner that can achieve real quality or efficiency enhancements. Performance Measures should grow more rigorous and numerous over time. From the outset, however, Performance Measures should have applicability to all of the clinically integrated primary care physicians, specialists, and sub-specialists, in part to demonstrate to the Agencies that each participating physician has bought into the program. Further, the care of a substantial majority of the patients in the relevant community should be affected by the Performance Measures. An insufficient breadth or depth of Performance Measures leaves a jointly contracting entity at risk for regulatory review as a non-clinically integrated entity under the *per se* standard of review.

Second, clinical integration programs need to require physicians to participate in *each* payor contract entered by the clinically integrated physician panel. Individual providers cannot have the option of opting out of particular payor contracts. This requirement should be a condition of membership codified in each provider's participation agreement. This helps payors and patients to easily identify network participants and reinforces a third important component of a clinically integrated entity, wherein physician members are required to make referrals to other network members in most circumstances. Limited exceptions to this requirement are generally permissible; however, keeping referrals within the clinically integrated network whenever possible permits the entity to better track and coordinate the care received by patients, collect more comprehensive clinical data for assessment under the program, and achieve administrative efficiencies.

While referrals should remain in the network, regulators prefer a non-exclusive network as a fourth element of clinical integration. Participating physicians should not be restricted in their ability to contract with other payors or healthcare entities pursuant to this fourth component of a successful program. Nor should the clinically integrated entity and the payors with which it contracts be prohibited from contracting with other payors or contracting entities, as applicable.

Fifth, regulators seek demonstration of the "ancillarity" of the clinically integrated entity's joint contracting on behalf of its physician members to achievement of the overall goals of the program. The Agencies seek assurances 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.

Next the Agencies require adequate safeguards to prevent anti-competitive spillover. Spillover may occur between clinically integrated and non-clinically integrated providers, or by a clinically integrated physician in a context other than the clinical integration program. In the latter case, individuals who authorize or undertake joint contract negotiations on behalf of clinically integrated providers, such as through participation on a contracting committee, must be trained on the appropriate means of handling sensitive competitive data. For example, fee survey data provided to negotiators should be de-identified and limited in its use.

Finally, the operation of the clinical integration program must be thoroughly documented to ensure compliance with applicable legal requirements. This includes appropriate contracts, governance documents, policies and procedures, and, importantly, demonstration of the quality, cost-effectiveness, and efficiency enhancements achieved by the program.

Conclusion

Prior to engaging in joint contract negotiations, a legal assessment conducted by experienced healthcare counsel that audits the clinical integration program and determines the level of clinical integration that has been achieved should be performed. Such an analysis, however, does not end the entity's continuing need for ongoing program monitoring and enhancement, including through physician education efforts. The bar should be raised constantly, and the physician membership ever-more refined, to deliver on the efficiency and quality promises of the program and justify what should be increasingly-favorable contracting terms reached through the delivery and documentation of high quality care and efficient performance by participating providers. The heightened quality demands being made of providers by the federal government and private payors means that clinical integration is not only desirable, it is increasingly an imperative to achieve the important business goals of the participating providers.

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- ⁱ U.S. DEPT. OF JUSTICE & FED'L TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE §8.B (1996).
- ⁱⁱ *Id.* at §8.B.1.
- ⁱⁱⁱ *Id.*
- ^{iv} 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).
- ^v 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).
- ^{vi} MEDICARE PAYMENT ADVISORY COMM'N, IMPROVING INCENTIVES IN THE MEDICARE PROGRAM pp. 39-56 (June 2009).
- ^{vii} See e.g., Letter from Douglas W. Elemendorf, Dir., Congressional Budget Office, to Senator Max Baucus, Chairman, Comm. on Finance, U.S. Senate (Sept. 16, 2009).
- ^{viii} American Recovery and Investment Act of 2009, Pub. L. No. 111-5, § 4101 (2009).
- ^{ix} The Tax Relief and Health Care Act of 2006, Pub. Law. No. 109-432, 42 U.S.C. § 1305, required the establishment of a physician quality reporting system, including an incentive payment for physicians and other eligible professionals who satisfactorily report data on quality measures for covered services furnished to Medicare beneficiaries. The Physician Quality Reporting Initiative resulted from this initiative. The Medicare Improvements for Patients and Providers Act of 2008, Pub. Law No. 110-275, made the Physician Quality Reporting Initiative permanent. Qualifying practitioners who report quality measures data for services furnished in calendar year 2009 will earn an incentive payment of 2.0 percent of their total allowed charges for Physician Fee Schedule-covered professional services furnished during the year.
- ^x 15 U.S.C. §1 (2009).
- ^{xi} *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982).
- ^{xii} U.S. DEPT. OF JUSTICE & FED'L TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE § 8.B (1996).
- ^{xiii} *Id.* at § 9.C.
- ^{xiv} See, Letter from Markus H. Meier, Fed'l Trade Comm'n, to Christi J. Braun (Apr. 13, 2009) (TriState Health Partners, Inc.); Letter from Markus H. Meier, Fed'l Trade Comm'n, to Christi J. Braun and John J. Miles (Sept. 17, 2007) (Greater Rochester Independent Practice Association, Inc.); Letter from Markus H. Meier, Fed'l Trade Comm'n, to John J. Miles (June 18, 2007) and Letter from Jeffrey W. Brennan, Fed'l Trade Comm'n, to John J. Miles (Feb. 19, 2002) (MedSouth, Inc.).

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