Key Takeaways

• The aggregation of providers into Accountable Care Organizations (ACOs) can help a community meet the triple aim, but if not done right, it can drive up prices. Regulators, health plans and employers are concerned about the aggregation of healthcare providers. Without assurances that the purpose, structure and activities of a provider organization are aimed at producing better care at lower cost, aggregation could lead to higher prices with no improvement in quality or increase in value.

• Existing regulatory structures may not readily apply to today’s innovation in provider relationships. States and the federal government are actively encouraging the formation of ACOs. At the same time, regulators recognize that existing regulations broadly apply to managed care activities traditionally performed by insurers. As provider organizations engage directly in managing care, and ultimately assume financial risk for the care of a population, the distinction between provider and insurer blurs. One approach to fill the regulatory gap is to create new regulation. But there is danger in creating regulation when the organizations and activities being regulated are immature. Imbedding new rules into existing regulation or creating a new regulatory scheme guides future growth based on structures and activities that have not yet been tested. But absent new regulation, how do communities create innovative healthcare solutions with assurance that new ideas and processes are successful, or at the very least cause no harm?

• Oversight of ACOs through an accreditation process has the potential to guide, direct and validate in an evolving marketplace. Accreditation focuses on achieving desired outcomes with standards that can move as structures, processes and systems evolve. Progress is not impeded by the creation of laws, in a fluid environment, that tend to reflect current day and current thinking. Laws and regulation are difficult to change. Accreditation standards are developed with multiple stakeholder appeal, guided by successful organizations seeking to raise the bar on quality. Clinical integration and accountable care standards validate performance in four key areas: leadership and governance; alignment of providers; clinical management and coordination; and integrated infrastructure. Consumer safeguards and achievement of the triple aim are central to an accredited clinically integrated network or ACO.

Passage of the Affordable Care Act Has Sparked Innovation in Healthcare Delivery

In 2014, over 20 million individuals were receiving care through an ACO [Leavitt Partners]. That number will rise as new ACOs are forming and established ACOs are growing and changing. In theory, ACOs form to improve quality and health outcomes of a defined population while lowering total cost. In reality, individuals and groups of providers aggregating to form an ACO find achieving the triple aim difficult and without proper oversight the outcome of ACO development could be higher cost with no demonstrable improvement in outcomes. Lawmakers, policy makers and regulators need to embrace rules and guidelines.
that promote the development of successful ACOs while safeguarding against the formation of networks that could leverage greater market power without creating value, or fail, causing potential harm or disruption to the local healthcare delivery system and higher prices for consumers.

Provider Consolidation or Aggregation May Lead to Serious Anti-Trust Issues

Hospital and provider consolidation and aggregation and the potential for anti-trust issues has long been a concern of the Federal Trade Commission and the Department of Justice. In 1996, the two agencies jointly released regulatory guidance (Statements of Antitrust Enforcement Policy in Health Care) that set clear requirements for what constituted anti-competitive activities with respect to provider mergers and collaboration.

In 2011, the Federal Trade Commission and Department of Justice provided anti-trust guidance to address the formation of ACOs participating in the Medicare Shared Savings Program. The initial phases of the formation of ACOs under the Medicare Shared Savings Program did not meet the level of shared risk to qualify for the safe harbor for the shared risk exception established in 1996. The foundation of the 2011 revised guidance was provider market share, not the level of risk assumed. The substitution of market share for risk as the determinant of potential anti-trust, and the level of permissible market share of 30 percent is still untested.

The anti-trust guidance was updated to reflect that the Medicare Shared Savings Program created a comprehensive framework that required provider (ACO) acceptance of risk over time. The framework also mandated reporting quality measures and a host of other requirements to assure the triple aim. It also required the ACO to have a formal legal structure. However, this framework only applies to ACOs that are part of the Medicare Shared Savings Program. ACOs forming for other purposes may not have to meet the test for market share, may not be assessed for market share, and absent an organized framework such as that required for MSSP, there is little to assure that the ACO has the structure and capabilities to meet the triple aim. ACO accreditation can be the framework that ACOs need.

A 2012 Robert Wood Johnson report, The Impact of Hospital Consolidation, found that provider consolidation in an already concentrated market consistently led to higher prices. At times the price increases were so dramatic that they led directly to anti-trust concerns. Without proof of improved quality and lower costs, i.e. clinical integration, health plans and employers remain concerned about provider consolidation.

States Face Regulatory Uncertainty

There are serious anti-trust concerns for state regulators to consider when supporting the development of ACOs. Even with the strict requirements for participation in the Medicare Shared Savings Program, the Federal Trade Commission and Department of Justice are unwilling to grant a safe harbor for every participating ACO.

How can state regulators responsibly protect consumers from provider aggregation that may do harm, and still meet the triple aim?

Clinical Integration: Demonstrating Value

Regulators need guidelines and validation of clinical integration to protect consumers.

Financial integration through risk sharing is key to the triple aim, but alone it is insufficient. ACOs must be built on a foundation of clinical integration. The clinically integrated network must demonstrate that it is delivering cost efficient high quality care while improving the overall health of the population it serves.

URAC standards and accreditation process assures an organization, either a clinically integrated network or an ACO, has the proper structure, governance, tools and infrastructure to demonstrate it can manage its population.
Components of a Clinically Integrated Network

Regulators should look for evidence of fundamentals of a network to determine whether it is sufficiently clinically integrated. This oversight can be done through an accrediting process using existing accreditation standards that change with the future. These fundamentals include:

**Interdependence:** There must be information-sharing and collaboration among providers.

**Care Coordination:** There must be linkages between primary care and specialty care, across multiple settings with the consumer at the center.

**Clinical Guidelines:** Evidence-based clinical guidelines covering a broad spectrum of conditions must be established and endorsed by the providers who are collaborating.

**Clinician Responsibility:** Network clinicians must hold individuals and their group accountable to the use of clinical guidelines and perform peer evaluation, instruction and support.

**Infrastructure:** The network must provide processes and systems for clinical decision-making and documentation, and training for use.

**Information Technology Integration:** Information technology and clinical decision support tools must be used in the collaborative effort.

**Performance:** There must be a system for monitoring, measuring and improving, including feedback and action plans.

**Outcomes:** Health outcomes for the population must be measured and tracked to assess progress and inform quality improvement efforts.

**Results:** The clinically integrated network must demonstrate improvement on quality performance, utilization and cost through systematic measuring and reporting.

URAC promotes continuous improvement in the quality and efficiency of healthcare management through processes of accreditation, education and measurement. For more information, contact us at info@urac.org or (202) 326-3943, or visit www.urac.org