Payment and Delivery System Reform Post-SCOTUS: Aligning Financial and Clinical Integration

Health Insights
Fall 2012 Conference

October 12, 2012

Doug Hastings
Chair, Epstein Becker & Green, P.C.
Past President and Fellow, American Health Lawyers Association
Member, Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Care, Institute of Medicine

The SCOTUS Decision

- Roberts court = court of one
- “You can’t be forced to eat broccoli, but you might be subject to a tax or fine if consumption of broccoli is found by Congress to be an important national interest, and you nonetheless refuse to buy it.”
- Four justices would have invalidated the whole ACA, including the payment and delivery reform provisions, which would have created potential misalignment between public and private sector payment reform.
- The ruling also preserves coordinated legal guidance given to health care providers by CMS, OIG, FTC, DOJ and IRS on ACO-related collaborative activities.

Why Clinical and Financial Integration Can Help Solve Policy and Legal Issues

- The law recognizes that collaborating providers that are “integrated” are acting like a single entity — i.e., single entities cannot pay themselves for referrals or conspire with themselves to restrain trade.
- This concept recognizes the importance of size and scale, but also the need for multiple, diverse participants.
- It also accommodates both collaboration and competition.
- Examples of the application of this concept in current law and enforcement policy include the academic medical center exception to Stark, the employee exceptions to Stark and the anti-kickback laws, and antitrust guidance on clinical integration and joint ventures.
- Where true provider integration is being sought and achieved, legal concerns should be lessened.

— Doug Hastings, “Addressing the Legal Issues in Achieving Quality and Cost Efficiency: The Need for a Rebuttable Presumption,” BNA’s Health Law Reporter, June 2009

Historical Legal Barriers to Provider Integration

- Federal and state regulatory schemes, particularly relating to antitrust, fraud and abuse, tax-exempt organizations, and medical liability, create barriers to provider integration.
- These laws all evolved in an era in which provider separateness was assumed to be appropriate and financial incentives and certain other agreements between providers generally were assumed to be improper.
- Government as purchaser and regulator:
  - Inherently, this dual role of government creates a duality of interest;
  - As purchaser, the goal is to pay less; as regulator, the goal is to require more;
  - As purchaser, the goal is to encourage financial incentives to improve quality and reduce cost; as regulator, the result is to view incentives with suspicion and declare some incentives illegal;
  - As purchaser, the goal is to encourage innovation and efficiency; as regulator, the result often is to discourage innovation and efficiency in an attempt to control behavior.

Value-Based Purchasing: The Market is Moving Away from Utilization-Based Reimbursement

- There is movement to “accountable care capable” entities:
  - Improving access to primary care resources;
  - Increasing patient satisfaction and engagement;
  - Increasing disease management and preventive care programs;
  - Reducing variation;
  - Building clinical management and care coordination capabilities;
  - Being able to track and report on quality measures and outcomes;
  - Improving cost-efficiency/lowering costs.
- Accountable care = improved patient outcomes, greater patient satisfaction, and enhanced cost efficiency.
- Pay-for-performance, bundled payment and global payment programs are among the value-based payment methods currently being utilized in both the public and private sectors.
- Providers are being asked to be better integrated both financially and clinically.

What Will it Take to Succeed?

- Providers with high quality standards and a focus on patient centered care.
- Providers that can manage additional cost reduction.
- Providers with medical management, care management and risk management competencies.
- Providers that are “financially sound” with the ability to cover at risk amounts and required investments.
- Providers that already have multi-provider network relationships ─ physician, hospital, post acute.
- Those who believe in the “spirit of the rule” vs. “another reimbursement game”.
- Providers with robust information technology and monitoring capabilities.
- Providers with a stable primary care patient base.
- Providers that have standardized clinical processes and protocols.
- Providers with strong governance oversight and change management structures.

Goals of Financial and Clinical Integration are Aligned

- This is more clearly recognized now than in the 1990s.
- Financial Integration
  - Shared financial data
  - Mutual dependency on financial outcomes
  - Aligned financial incentives among providers
- Clinical Integration
  - Shared data and patient relationships
  - Mutual dependency on clinical outcomes
  - Aligned clinical incentives among providers
- Both are required in today's value-based payment programs.

FTC/DOJ Definition of Clinical Integration – 1996

"(Provider) network joint ventures that do not involve the sharing of substantial financial risk may also involve sufficient integration to demonstrate that the venture is likely to produce significant efficiencies. Such integration can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network 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."

— U.S. Department of Justice and Federal Trade Commission. Statements of Antitrust Enforcement Policy In Health Care. Statement 8: Enforcement Policy on Physician Network Joint Ventures, August 1996

Subsequent Definitions of Clinical Integration

"So what does this mean? There is no single way to structure a clinically integrated network. This flexibility is an asset. Rather than a "one size fits all" approach, clinically integrated networks can conform to the demands and requirements of their respective communities and the other legal restrictions faced by providers, while also staying within the broad bounds of the antitrust laws. While there is no "cookie cutter" structure, in the Guidelines the FTC and DOJ do provide guidance on the structural pillars that clinically integrated networks often have."

— Brookings Institution ACO Toolkit, Part 6: "Legal Issues for ACOs", January 2011

"Clinical integration means that independent providers such as hospitals or health systems, physician practices, individual providers, and outpatient diagnostic centers integrate their services through shared electronic health record systems, clinical guidelines, unified practice management, and other techniques. In optimal systems-based care, each patient's health care needs are evaluated and treated comprehensively as part of a "system" of care for that person."

— Doug Hastings et al., "A New Quality Compass: Hospital Boards' Increased Role Under The Affordable Care Act," Health Affairs, July 2011

Key Clinical Integration Elements from Law and Regulation

- Shared EHR
- Care coordination; clinical teaming
- Selective network
- Monitoring and controlling utilization
- Evaluating and modifying practice patterns
- Enforcing protocols and taking remedial action
- Investment in infrastructure
- Board oversight of quality compliance program
- Performance measurement and improvement
- Transparency – reporting performance to payers and public

Legal Barriers to Delivery System Reform

- Legal barriers were identified early on as a potential brake on progress to a more coordinated health care system.
- The key legal issues are:
  - Antitrust law
  - Fraud and abuse law
  - Exempt organization tax law
  - Medical liability law
- The ACO Final Rule shows that, in CMS' view, even the minimum requirements for an ACO should be substantial.
- NCQA, which circulated ACO accreditation standards last year, agrees and is ready to begin accrediting ACOs.
- 2012 GAO report on antitrust policy related to collaboration among health care providers identifies various stakeholder perspectives.

Proposed Elements for Rebuttable Presumption - 2009

- A virtual or entity-based organizational structure that features clinical integration and supports quality and cost-efficiency.
- Adoption of appropriate evidence-based measures with outside verification.
- Clear documentation of structure, measures, and operational processes.
- A virtual or entity board in place, including independent board members, to oversee operations.

— Doug Hastings, “Addressing the Legal Issues in Achieving Quality and Cost Efficiency: The Need for a Rebuttable Presumption,” BNA’s Health Law Reporter, June 2009

CMS and NCQA ACO Criteria Require Clinical Integration

Criteria	CMS MSSP Participation Criteria	NCQA Accreditation Criteria
Governance	• 75 percent of the governing body must be controlled by ACO Participants and the governing body must include a Medicare beneficiary representative	• ACO must include the following stakeholders in oversight: primary care physicians, specialists, hospitals, consumers, and purchasers
Leadership	• ACO leadership must include a senior-level medical director	• ACO must include a designated physician or clinician leader with substantive involvement in the ACO
Evidence-Based Medicine	• ACO must define, establish, implement, evaluate, and periodically update processes to promote evidence-based medicine • ACO must develop an infrastructure for its ACO Participants to internally report on quality and cost metrics	• ACO must adopt evidence-based guidelines and disseminate decision support tools to clinicians • ACO must have a documented process to review the ACO's performance with the governing body
Patient Engagement	• ACO must have a process for evaluating the health needs of its population	• ACO must provide and engage patients in population health programs
Care Coordination	• ACO must define its methods and processes to coordinate care through an episode of care and during its transitions	• ACO must have a coordinated system to facilitate timely information exchange between multiple providers
Distribution of Savings	• ACO must indicate how it plans to use potential shared savings to meet the goals of the MSSP	• ACO must base at least a portion of participating providers' compensation on the performance of the ACO
Health Information Technology	• ACOs are encouraged to develop a robust EHR infrastructure	• ACO must use an electronic system to collect structured patient information and clinical data
Quality Measures	• ACO quality performance will be assessed against 33 measures	• ACO must annually monitor metrics from a set of 40 core performance measures

CMS ACO Financial Integration Models

MSSP Track One	• Shared savings only
MSSP Track Two	• Shared savings/limited shared losses
Pioneer	• Shared savings/shared losses in years one and two • Partial capitation in years three – five (if minimum annual savings rate achieved)

Coordinated Federal Agency Guidance - 2011

- The coordinated guidance issued with the ACO Final Rule from the DOJ, FTC, OIG and IRS shows a significant degree of inter-governmental agency cooperation and a respect for the substantial minimum requirements that CMS has established for ACOs.
- The guidance, taken together, suggests that a qualified – and effectively operating ACO – does gain a degree of legal protection (rebuttable presumption?) under these regulatory schemes through waivers, safety zones and announced agency protocols.
- The regulatory dialogue that has taken place around accountable care seeks to distinguish “good” collaboration from “bad” and relies heavily on clinical and financial integration as a basis for allowable collaboration.
- A key challenge remains realizing the cost-efficiency promise along with the quality promise – payment reform that drives financial integration along with clinical integration is part of the solution.

Fraud and Abuse

- In a companion document to the MSSP Final Rule, CMS and the OIG issued an Interim Final Rule regarding waivers from the various fraud and abuse laws that may create barriers to ACO formation and operation.
- In addition to the shared savings distribution waiver and the compliance with the Stark Law waiver that were contained in the proposed CMS/OIG issuance on March 31, there are three additional waivers in the Interim Final Rule:
  - An “ACO pre-participation” waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies to ACO-related start-up arrangements in anticipation of participating in the Shared Savings Program;

Fraud and Abuse

  - An “ACO participation” waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies broadly to ACO-related arrangements during the term of the ACO’s participation agreement under the Shared Savings Program and for a specified time thereafter; and
  - A “patient incentive” waiver of the Beneficiary Inducements CMP and the Federal anti-kickback statute for medically related incentives offered by ACOs under the Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimes.
- Again, it appears that the rulemaking process worked well here, and that CMS/OIG listened and provided additional flexibility in seeking to achieve the goals of the Affordable Care Act while also preserving their ability to conduct aggressive enforcement where warranted.

Exempt Organization Tax Law

- The IRS posted a fact sheet dated October 20, 2011 that references the Final Rule and provides a supplement to Notice 2011-20, which was issued on April 18 to address ACO activities in the exempt organization context.
- In this Q&A supplement, the IRS is more forceful than in Notice 2011-20 that not only is the IRS likely to view participation in the MSSP as consistent with charitable purposes, the IRS also is prepared to recognize that participation in a non-MSSP ACO also can be consistent with charitable purpose and exempt status under certain circumstances.
- Further, the IRS' responses to questions 18-21 specifically address clarifications to Notice 2011-20 and generally evidence flexibility in the IRS' view of ACO participation by exempt organizations.

Antitrust: Rule of Reason

- The most important component of the guidance is that the Antitrust Agencies acknowledge that CMS' definition of and requirements for ACOs align with their historical thinking about clinical integration and, therefore, the Agencies will accord rule of reason treatment to the commercial market activities of ACOs participating in the MSSP assuming that they basically operate in the same way.
- In other words, providers coming together to collaborate in ACOs that drive real change toward better outcomes and cost efficiency will not be subject to per se treatment.
- Many of the early participants in the Medicare ACO program are physician networks, which potentially enhances competition.

Antitrust: Safety Zone and Voluntary Review Process

- The Final Statement also provides a safety zone for lower market share ACO collaborations, although safety zones in many ways state the obvious and generally protect arrangements that most people would understand as not being a problem in the first place.
- More helpfully, the guidance provides examples of ACO-related behavior that potentially would be of concern to the Agencies, such as improper sharing of competitive information, tying sales and exclusive contracting – this gives ACO providers real guidance as to what to avoid.
- In addition, a voluntary expedited review process is provided for ACOs and their participants in the event that a specific, direct determination from the Agencies is desired.

Antitrust: Market Power Issues

- Notwithstanding the useful guidance in the Final Statement, market concentration and market power concerns remain the subject of an ongoing national policy debate – for example, the provider community generally cheered the removal of the pre-approval requirement for high market share ACOs from the Final Statement, while the payer and purchaser community was highly critical.
- DOJ and FTC clearly state that they will continue to protect competition in markets served by ACOs, using CMS data, and will "vigorously monitor complaints." And merger enforcement is not affected – the Agencies will continue to enforce under the current merger guidelines.

Antitrust: Market Power Issues

- There is the potential for new forms of contracting (rather than mergers) among providers, including in some cases high market share providers, working with payers, to accomplish accountable care goals through bundled and global payments to create antitrust-acceptable pathways (i.e., if payment is based on measurable value (quality over cost), where is the harm?).
- The private sector would benefit from greater payer-provider collaboration in this regard and acceleration of the movement to accountable care.
- Failure to do so will put more onus on government to regulate the prices of both and to micromanage the contract provisions between them.
- Payers and providers would be well served by adopting voluntary protocols relating to quality measures and cost efficiency, and the allocation of savings between them as well as with purchasers and consumers, including appropriate contract provisions.

Medical Liability

- Evidence-based medicine and consensus quality measures provide a basis to rationally determine proper use and identify overuse, underuse and misuse of medical services.
- This provides a credible basis for more rational legal treatment of liability claims, including, ultimately, a no fault, structured payment kind of system.
- Effectively clinically-integrated provider organizations should produce better health and better health care outcomes for patients, more cost efficiently, thereby reducing the incentives to practice defensive medicine.
- The tort liability laws and their application in the U.S. can and should be revised to follow suit.
- Again, the notion of a rebuttable presumption is helpful here.

Clinical Integration Imperative - 2012

- The momentum of change in health care payment and delivery is now mandating effective clinical integration among providers.
- Value-based payment requires managing populations and patients based on:
  - A culture of patient-focused care;
  - Systems and data which enable seamless coordination and continuity-of-care; and
  - Reinforcing aligned incentives.
- Legal barriers need to continue to be addressed to allow the benefits of integration while still protecting against harm, particularly as a result of high market share consolidation.
- The complementary nature of financial and clinical integration means that successful provider organizations can “do well by doing good”.

Contact Information

Douglas A. Hastings
(202) 861-1807
Dhastings@ebglaw.com