The ACO Legal and Regulatory Environment: An Update and Framework for 2011

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The Case for Payment and Delivery Reform

- **The Problem:**
  - Fragmented care
  - Uneven, unsafe practices
  - Unsustainable costs

"Our fee-for-service system, doling out separate payments for everything and everyone involved in a patient's care, has all the wrong incentives: it rewards doing more over doing right, it increases paperwork and the duplication of efforts, and it discourages clinicians from working together for the best possible results."

— Atul Gawande, "Testing, Testing," The New Yorker, 12/14/09

The Case for Payment and Delivery Reform

- **The Solution:**
  - Better coordinated care, more transparent to the consumer, using evidence-based measures to achieve better outcomes, greater patient satisfaction and improved cost efficiency
  - Or, in other words, “accountable care”
  - An “accountable care organization” (“ACO”) is a provider-based organization comprised of multiple providers with a level of clinical integration sufficient to deliver accountable care
  - Both the payment system and delivery system (in both the public and private sectors) need to change together to achieve accountable care
  - There is widespread agreement as to the current problems and the end goals — the challenge is the transition

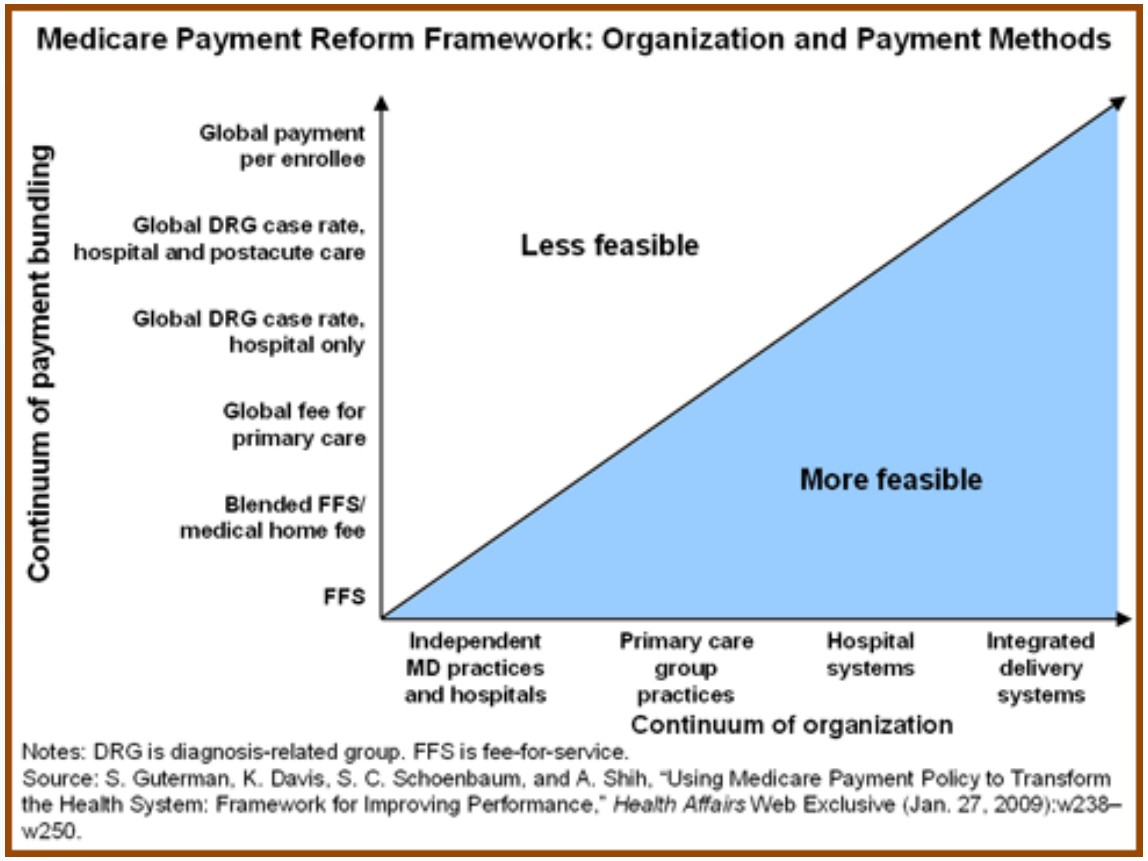
In Search of Accountable Care – Part II

- Why might ACOs work now when similar concepts did not in the 1990s?
  - There is greater recognition of the urgency of the cost and quality problems
  - The applicability of evidence-based medicine is more widely understood and accepted
  - There is greater understanding that good outcomes, patient satisfaction and cost-efficiency are linked
  - We have learned from past experience with provider integration efforts and risk contracting
  - Consensus measures and IT infrastructure have advanced significantly
  - Early pilots and demonstrations have shown promise

In Search of Accountable Care – Part II

- Potential Pitfalls
  - " Accountable care" and the triple aim get lost in the structural and legal debate
  - The Medicare ACO program is unsuccessful and dominates the focus
  - Patients are left out of the equation
  - Quality measures are not widely agreed upon or accepted
  - Cost savings are not realized
  - It feels too much like managed care and capitation of the 1990s

The Accountable Care Framework



"To change the way health care is organized and delivered, we need to change the way it is paid for — to move from fee-for-service payments to bundled payments."

– Gutterman, Davis, Schoenbaum and Shih, 2009

Recent Proposals to Divide ACOs Into Tiers

- **Level I -** No financial risk, but eligible to receive shared savings; minimum number of PCPs; able to report basic set of measures
- **Level II -** Greater upside on savings, but some risk for higher costs and/or bundled payments; more comprehensive performance measures; minimum cash reserves
- **Level III -** Full or partial capitation; full public reporting on comprehensive measure set; more stringent financial requirements and reserves

ACA Accountable Care: Innovation Opportunities

- **Sec. 3021. Establishment of Center for Medicare and Medicaid Innovation within CMS.**
  - Creates a Center for Medicare and Medicaid Innovation ("CMI") within CMS to test innovative payment and service delivery models to reduce program expenditures while preserving or increasing the quality of care
  - Instructs CMI to use open door forums or other mechanisms to seek input from interested parties
  - Models to be tested include medical homes; risk-based contracting; coordinated care models like ACOs; and improved post-acute care models
  - $10 billion in funding, 2011 to 2019
  - To be up and operating by January 1, 2011
  - Formation of CMI recently formally announced, but no specific guidance yet

ACA Accountable Care: Innovation Opportunities

- **Sec. 3022. Medicare Shared Savings Program.**
  - Directs the Secretary to create a shared savings program by January 1, 2012 that will promote accountability, coordinate services between Parts A and B
  - ACOs that feature shared governance and meet quality performance standards can receive payments for shared savings
  - Eligible ACOs include:
    - Physicians and other professionals in group practice arrangements;
    - Networks of individual physicians;
    - Partnerships or joint ventures between hospitals and physicians;
    - Hospitals employing physicians; and
    - Other groups the Secretary deems appropriate
  - Savings to be shared based on actual costs compared to the benchmark set by the Secretary
  - Allows the Secretary discretion in implementing a partial capitation model for ACOs
  - Draft regulations already late; expected any time, but exact date is uncertain

ACA Accountable Care: Innovation Opportunities

- **Sec. 3023. National Pilot Program on Payment Bundling.**
  - Creates a voluntary pilot program implementing bundled payments surrounding hospitalizations in order to improve coordination, quality and efficiency of care
  - To be established by January 1, 2013
  - Can be expanded if it is found to improve quality and reduce costs
  - Bundle to include acute, inpatient hospital services, physician services and post-acute services for episode of care beginning 3 days prior to hospitalization and 30 days post-discharge

ACO Criteria – ACA Section 3022

- Agree to become accountable for overall care of assigned Medicare fee-for-service beneficiaries
- Enter into 3-year agreement with HHS
- Have a formal legal structure that will allow the organization to receive and distribute payments to participating providers
- Include sufficient primary care physicians for at least 5,000 Medicare fee-for-service beneficiaries
- Have arrangements in place with sufficient specialist physicians
- Have in place a leadership and management structure including clinical and administrative systems
- Define processes to promote evidence-based medicine, report on quality and cost measures, and coordinate care
- Demonstrate patient-centeredness

ACO Criteria – Brookings/Dartmouth

- The ACO can provide or manage the continuum of care for patients as a real or virtually integrated delivery system
- The ACO is of sufficient size to support comprehensive performance measurement and expenditure projections
- The ACO is capable of internally distributing shared savings and prospectively planning budgets and resource needs

ACO Criteria – NCQA

- 2011 Draft Accountable Care Organization Criteria (released October 19, 2010)
  - Program Structure and Operations
  - Access and Availability
  - Primary Care
  - Care Management
  - Care Coordination and Transition
  - Patient Rights and Responsibilities
  - Performance Reporting

Questions for CMS Related to the ACO Program

- How will “formal legal structure” and “shared governance” be defined?
- How will beneficiaries be assigned to ACOs?
- How transparent will the ACO-patient relationship be?
- How will the ACO benchmarks be set?
- How will savings be allocated between the ACO and Medicare?
- What quality measures will be used?
- Will CMS use partial capitation or other alternative payment methods?
- How will this program relate to the value-base purchasing program and to CMI?
- Will there be guidance to states regarding the potential regulation of provider risk sharing?

ACO Major Regulatory Issues

- Fraud and Abuse (Stark, Anti-kickback, CMP)
- Antitrust
- Corporate practice of medicine
- State regulation of risk transfer
- Quality reporting, auditing and compliance

Board Fiduciary Duty and Quality

- Medicare fee-for-service payments are declining
- Payment changes will further reduce reimbursement to hospitals with high readmissions and poor scores on quality measures
- Shift to bundled or global payments will require infrastructure investments
- Increasing focus on quality reporting may result in “fraud and abuse” enforcement against providers making claims to public payers for care deemed substandard
- Greater quality data reporting and transparency will require oversight, including assurance that reporting is accurate

Key Fraud and Abuse and Antitrust Questions

- Do we need a new definition of fraud and abuse?
- Will the Secretary use the waiver authority conferred in the ACA?
- Will federal qualification as an ACO serve as formal legal recognition that the ACO provider components are clinically integrated?
- How will market power issues be resolved?
- October 5 CMS, FTC, OIG, workshop on ACOs

A Note on the “ACOs and Market Power” Debate

- Recent volley of cross-allegations as to who is at fault for price increases
- Aggregation does not equal accountability; but some size and scale is necessary for effective care coordination and quality reporting
- As long as the payment system rewards volume, unit pricing and billable transactions, this issue will be difficult to resolve
- New forms of contracting (rather than mergers) among competing providers to accomplish accountable care goals through bundled and global payments may help create antitrust-acceptable pathways
- The private sector would benefit from greater payer-provider collaboration and acceleration of the movement to accountable care
- Failure to do so will put more onus on government to regulate prices of both parties and potentially micro-manage contract provisions
- If the promise of accountable care is realized, purchasers, payers, providers and consumers all will benefit

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