ACO²: Alternative Corporate Options for Accountable Care Organizations

Steve Shaber and Kim Licata
Poyner Spruill LLP
Raleigh, North Carolina

November 11, 2010
Triangle Practice Managers

Epigram

And don't throw the past away
You might need it some other rainy day
Dreams can come true again
When everything old is new again

"Everything Old Is New Again"
Peter Allen

Alternate Epigram

With a bit of a mind flip
You're there in the time slip
Let's do the Time Warp again

"The Time Warp"
The Rocky Horror Picture Show
Richard O'Brien

Debate on What Providers Must Be in an ACO to Participate in Shared Savings

- At present, there is no required composition of an ACO. There may be ACOs focused on particular aspects of care (physician services, acute care, full service)
- "All ACOs should have a strong base of primary care. Hospitals should be encouraged to participate . . . [b]ut in contrast to others' definitions, we believe that this need not be an absolute requirement for ACOs."
  - Elliott Fisher et al., A National Strategy to Put Accountable Care Into Practice, HEALTH AFFAIRS, May 2010, at 983.
- "[S]ome think that local hospitals must be included in an ACO. However, others think . . . we should allow separate outpatient and inpatient ACOs to develop. . . ."
  - Kelly Devers, Can Accountable Care Organizations Improve the Value of Health Care?, URBAN INSTITUTE, Oct.2009, at 4.

General Background on ACOs

What Are They? Do We Want to Become One? If so, How?

Introduction to Accountable Care Organizations

- Accountable Care Organizations (ACOs) are entities that become accountable for the overall cost and quality of health care services delivered to patients.
- Inherent in the concept of an ACO is that greater accountability will be encouraged through incentive payments or new forms of payments to the ACOs.
- The goal of programs involving ACOs is to **engage the stakeholders** in developing and producing a system that generates quality care for the lowest cost.

Eight Required Elements (under PPACA Shared Savings Program)

- Legal Organization
- 3 Year Commitment
- 5000 Beneficiaries
- Accountable for Quality & Cost of Care
  - Can collect and provide information
  - Can provide administration and clinical care
  - Offers evidence-based medicine and coordinated care
  - Is patient-centered
- The key is that CMS wants physicians (and other providers) to tell the Agency what works. We know what doesn't work!

"Beneficiaries"

- Under Shared Savings, this term means Medicare fee-for-service beneficiaries under Parts A and B.

- Beneficiaries do not include individuals enrolled in a Medicare Advantage plan or in a PACE program.

How Patients Get to the ACO

- Providers sign a participation agreement with an ACO(s)
- Exclusivity?
- PCPs v. Specialists

Patients are assigned to a PCP based on a majority of their outpatient E&M visits (according to insurance data)

p.s. Poyner Spruill LLP ATTORNEYS AT LAW

Considerations for Patient Assignment

- Assignment of patients will focus on:
  - Past provider-patient relationships,
  - Minimized cherry-picking or patient dumping,
  - Provider assignment for each patient, and
  - **Patient choice to use any provider regardless of participation in an ACO.**
    - Consider the impact of this on cost containment and accountability. How does one control costs when the patient can choose to go to anyone?

Considerations for Patient Assignment

- How many patients does an ACO need to have to be viable?
  - A provider may select the ACO in which to participate based on how many beneficiaries are assigned to that ACO and if care is likely to be needed for that beneficiary from a particular type of provider.
  - Will a particular ACO provide a provider with more/better business?
- What sort of acuity mix is needed/desired by providers?
  - Special needs ACOs?
- CMS has stated that patient assignment should be "**invisible**" to beneficiaries and be based on the provider from whom the patient receives the bulk of his or her health care services.
  - Statute is silent on how beneficiaries are informed of assignment and how members of an ACO can interact with assigned beneficiaries.

Compensation – Options

- Shared Savings.
  - ACO is eligible for "shared savings" payments (i.e., bonus payments) if:
    - it meets quality and performance standards and
    - the ACO's estimated Medicare costs are a certain percentage below a benchmark set by the Secretary.
- Capitation & Partial Capitation.
  - Secretary can choose to limit the capitation or partial capitation model to ACOs that are highly integrated systems of care and to ACOs capable of bearing risk.
- Other Payment Models Authorized by HHS.

Compensation Considerations Continued

- Providers will continue to receive payments under Parts A and B as any other provider would.
- Providers participating in an ACO are eligible for the "shared savings" payment if:
  - The ACO meets quality performance standards;
  - The ACO meets savings in excess of the benchmark set by CMS or said another way, care provided to ACO patients costs less than the benchmark by the percentage set by CMS.
- Currently there is no penalty for ACOs that fail to deliver. We don't expect that to be the case forever.

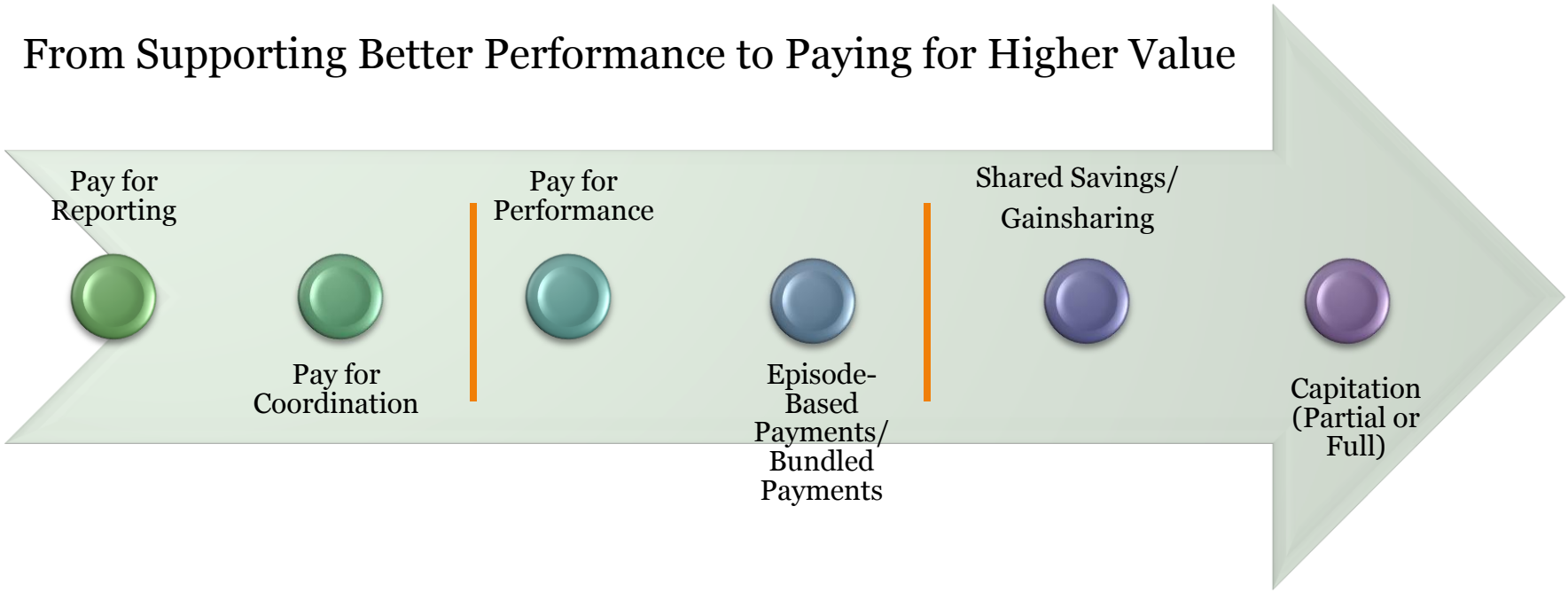
Show Me the Money

- Currently, it is unclear as to how payment will be made to providers and when shared savings payments will be made to a provider.
- Compensation may be treated differently than described for partial or full capitation models.
- The regulations should address this in greater detail.

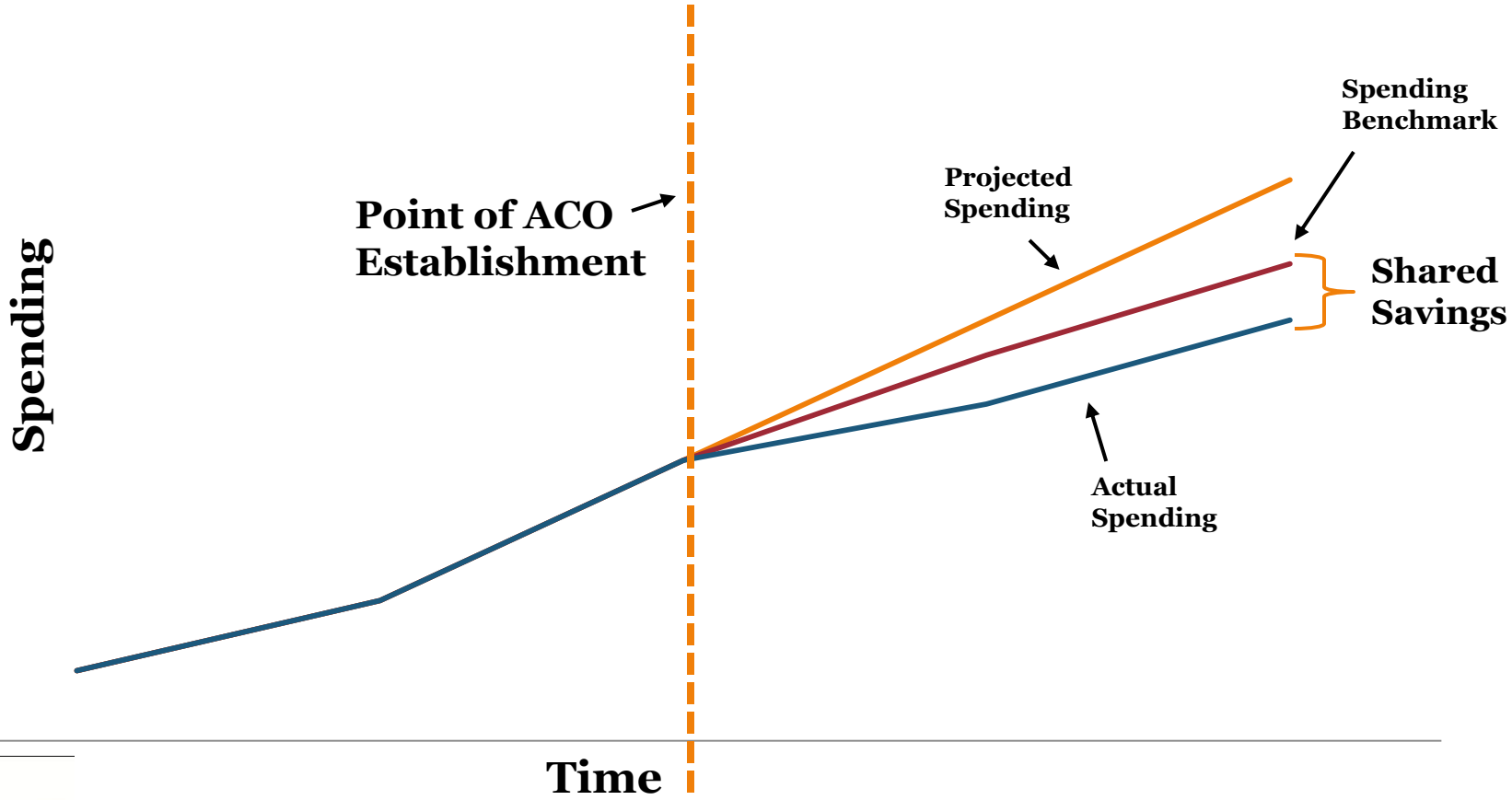
How to Stop Soaring Costs and Improve Quality in Health Care

Underlying Problems	Solutions
Lack of support for improvement, care management, and coordination.	Organizational support through integrated systems (virtual or real).
Failure to recognize role of various cost drivers, i.e. capacity.	Organizational accountability for total costs as well as capacity.
Assumption that quantity = quality, more is better, and less = rationing care.	Performance measurement assessed from outcomes and patient experience perspectives.
Reimbursement structure that rewards quantity, specialists, increased capacity, high margin treatments/procedures.	Reform reimbursement to focus on cost-savings, quality, shared savings or capitation payments.

Payment Reform to Shift Practices



Shared Savings



How Are Shared Savings Achieved?

- Quality and cost measurement
- Care coordination and chronic disease management
- Payment reform (bundled payments)
- Reduced complications and waste
- Informed patient decisions
- Internal process improvements (e.g., health IT)
- Workforce use and efficiency
- Capacity and distribution of resources

Key Challenges for ACOs

Participation of and Impact on Payers

- How ACOs work with Medicare beneficiaries may be very different from how they work with employees or health plan enrollees.
- What will be the impact of significant collaboration between providers and practitioners?

Quantity-Based Payment versus Value-Based Payments

- Some new payments models are being proposed, but there are still many incentives to provide more care than necessary from current reimbursement to defensive medicine.
- Major payment reform is still needed.

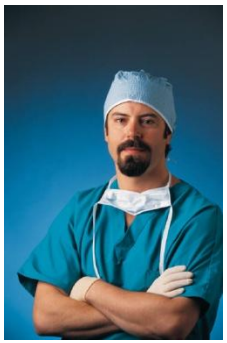
Overcoming the Specter of Past Failures

- Serious problems of execution in prior attempts, lack of trust from those who went down the road before and spent a lot of money, and weak incentives at best to reform patterns.
- If the program is successful initially, administration and bureaucracy will weigh improvements down.

Legal Issues in Forming ACOs

The Stark law, Anti-Kickback Statute, and Anti-Trust Considerations

The Stark Law and Regulations



Financial Relationship

Referral of DHS for Medicare or Medicaid patient

➔Under Stark, a physician is prohibited from referring Medicare patients to an entity for designated health services for which Medicare would otherwise pay, if the physician (or an immediate family member of the physician) has a financial relationship with the entity.

➔Stark is violated when the financial relationship does not fit a statutory or regulatory exception. Stark is a technical, bright-line statute, intent is irrelevant!

Potential Stark Exceptions

- Personal Service Arrangements.
- Bona Fide Employment Relationships.
- In-Office Ancillary Services.
- Personally Performed.
- Shared savings and incentive compensation?

- Remember Stark applies to ownership/investment interests and compensation arrangements, whether these are direct or indirect. The government will trace funds to see if there is a prohibited financial relationship.

Suggested Specific Changes to Stark

- Finalize, but simplify the proposed Stark Exception to allow for incentive compensation and shared savings payments to physicians (42 CFR 411.357(x)). This lengthy exception requires that the compensation arrangement (in cash or in kind) meets 16 specific requirements, including:
  - Compensation is part of a documented incentive payment or shared savings program to achieve actual cost savings, along with patient care improvement.
  - This program involves performance measures that are objective, reasonably related to practices with the patient population.
  - This program establishes baseline levels for performance measures and target levels with associated bonus payments.
  - At least 5 physicians must participate in each performance measure.

Suggested Specific Changes to Stark (2)

- The program requires independent medical review of the program's impact on the quality of care provided.
- Prior written notice to patients affected by the program.
- Written agreement signed by the parties with terms specified.
- Term of at least 1 year, but not more than 3 years.
- Payments are limited in duration and amount.

Suggested Specific Changes to Stark (3)

- Compensation over the term of the agreement is set in advance, does not vary during the term of the agreement and is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.
- The compensation can't be based on a reduction for LOS for a particular patient or in the aggregate for the hospital.
- The compensation must be paid directly to participating physicians or qualified physician organizations.
- The arrangement does not violate the antikickback statute or other federal or state law or regulation.

The Anti-Kickback Statute (AKS)

- The Anti-Kickback Statute prohibits the knowing and willful solicitation, offer, payment, or receipt of any remuneration, whether direct or indirect, overt or covert, in cash or in kind, in return for or to induce:
  - Referring or influencing the referral of an individual for the furnishing of any item or service;
  - Purchasing, leasing or arranging or recommending for the purchase, lease or ordering of any item or service.
- Paid in whole or in part under any federal health program.
- Basis for civil and criminal liability; also leads to liability under other federal statutes (False Claims Act, Civil Monetary Penalties).

The Anti-Kickback Statute (2)

- Just like Stark has exceptions, Anti-Kickback has Safe Harbors. Unlike Stark, there is no legal requirement that transactions with referral sources fit within a safe harbor and many do not. However, the OIG has said that substantial, as opposed to complete, compliance with a safe harbor is not sufficient to offer protection.

- How you structure an arrangement under the anti-kickback statute is often a function of how much risk you are willing to bear.

The Anti-Kickback Statute (3)

- The government's perspective on the failure to comply with a safe harbor can mean one of three things:
  - The arrangement does not fall within the ambit of the statute… so there is no reason to comply with the safe harbor standards, and no risk of prosecution.
  - The arrangement is a clear statutory violation and does not qualify for safe harbor protection. Prosecution would be likely.
  - The last category is the continuum of risk where the arrangement may violate the statute in a less serious manner. The government says that in this group, there is no way to predict the degree of risk and likelihood of prosecution.

Potential AKS Safe Harbors

- There are currently 22 safe harbors. Of course, a few may already protect arrangements likely to be used to distribute ACO savings and compensation, including:
  - Personal Services and Management Contracts.
  - Employees.
  - Managed care-related exceptions.

Suggested Specific Changes to AKS

- Advisory opinions, bulletins, and guidance have been useful, but specific to the reviewer and time-consuming.
- Either new or expanded safe harbors are needed.
  - Risk-sharing for cost savings arrangements.
  - Clarification of gainsharing issues (i.e. treatment under Civil Monetary Penalties Law).
  - Expansion of current managed care safe harbor.

Antitrust Law & Safety Zones

- Financial Integration is allowed where there is Limited Market Power.
  - *Arizona v. Maricopa County Medical Society*
  - *Statement 8*

- Clinical Integration is allowed where Clinical Benefits Justify Anticompetitive Bargaining.
  - Revised FTC *Statement 8*

Suggested Specific Changes to Antitrust Laws

- Confirm rule of reason approach to antitrust analysis (verbally has been done by FTC Chair).
- Clarify definition of "market" with respect to ACOs.
- Specify any limits on exclusivity/non-exclusivity.
- Provide clear guidance on arrangements that "lock up" a large market share to one ACO.
- Detail the requirements for clinical integration within the Statements of Enforcement.

Gainsharing as a Predictor of ACO Treatment

- Gainsharing is profit sharing between hospitals and physicians where FFS remains but a percentage of the cost savings gets passed on to the physician.

- The OIG has previously approved gainsharing arrangements on a case-by-case basis because of:
  - Substantial Structure
  - Accountability
  - Quality Controls and
  - Other Safeguards

Some Potential Physician-Led Structures for an ACO

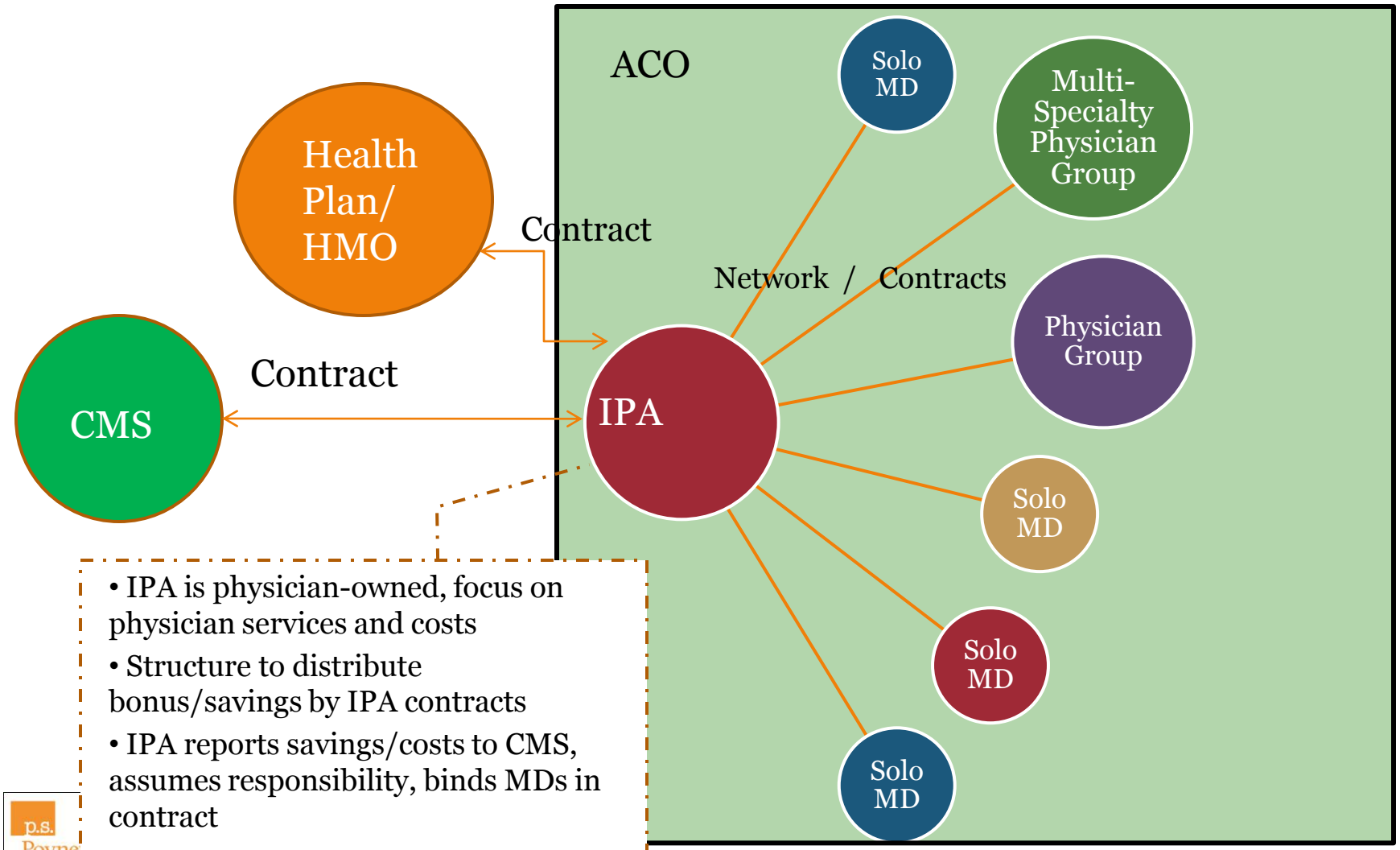
Based on statutory guidance

Potential ACO Models & Their Characteristics

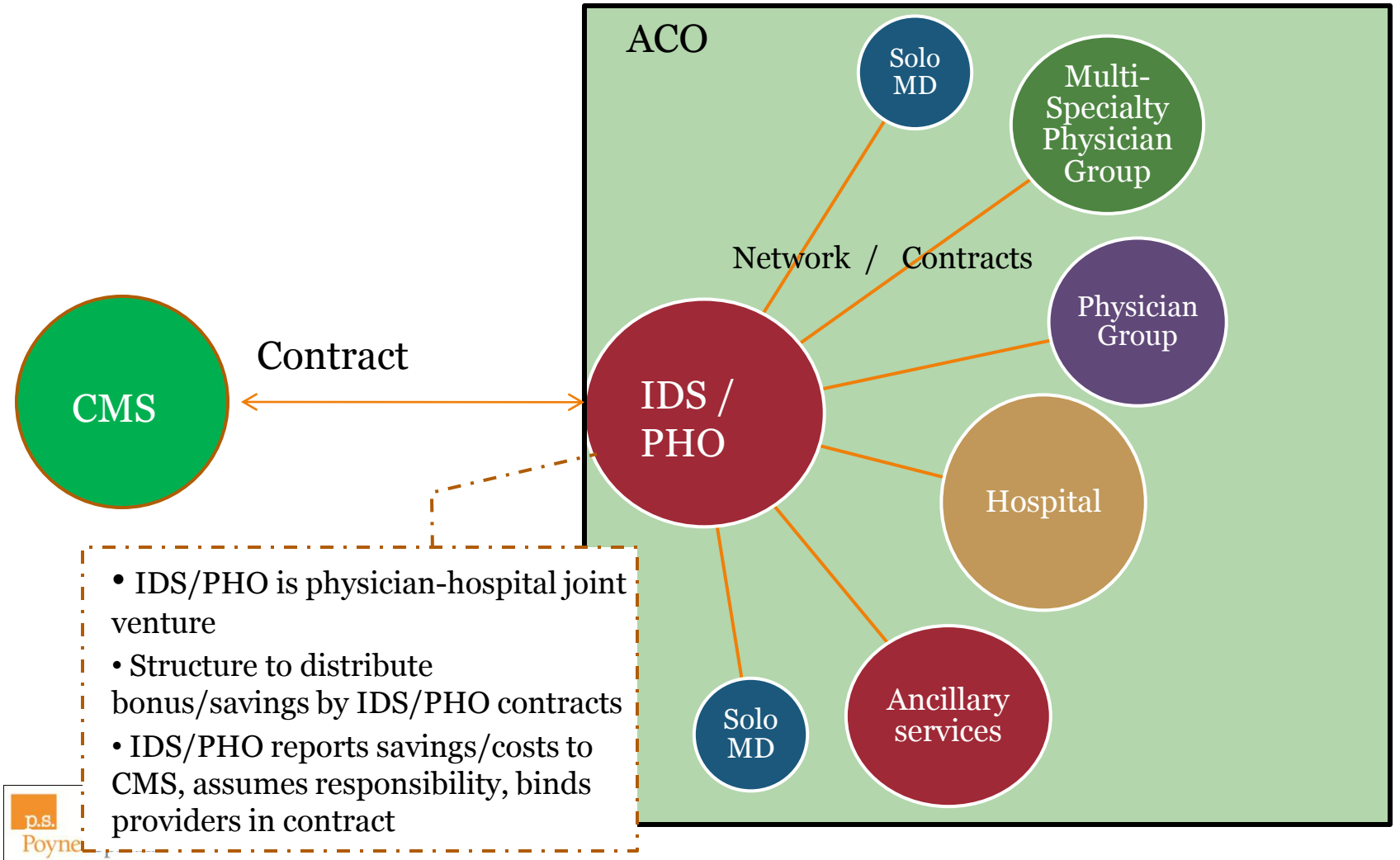
Provider Type	Ability to Provide or Manage Care across Continuum	Ability to Plan Budgets and Resource Needs (Accept and Manage non-FFS payment)	Provider Inclusiveness	Level of Performance Accountability
IPA	Low/Medium	Medium	High	Medium
Multispecialty Group	Medium/High	Medium	Low/Medium	Medium/High
Hospital Medical Staff Organization	Medium	Low/Medium	Medium	Low/Medium
PHO	Medium/High	Medium/High	Low/Medium	Medium/High
IDS	Medium/High	Medium/High	Medium	Medium/High
Virtual Approach-Extended Hospital Medical Staff	Medium	Low/Medium	High	Low

* Source: Kelly Devers & Robert Berenson, Robert Wood Johnson/Urban Institute, October 2009

IPA as Basis for an ACO

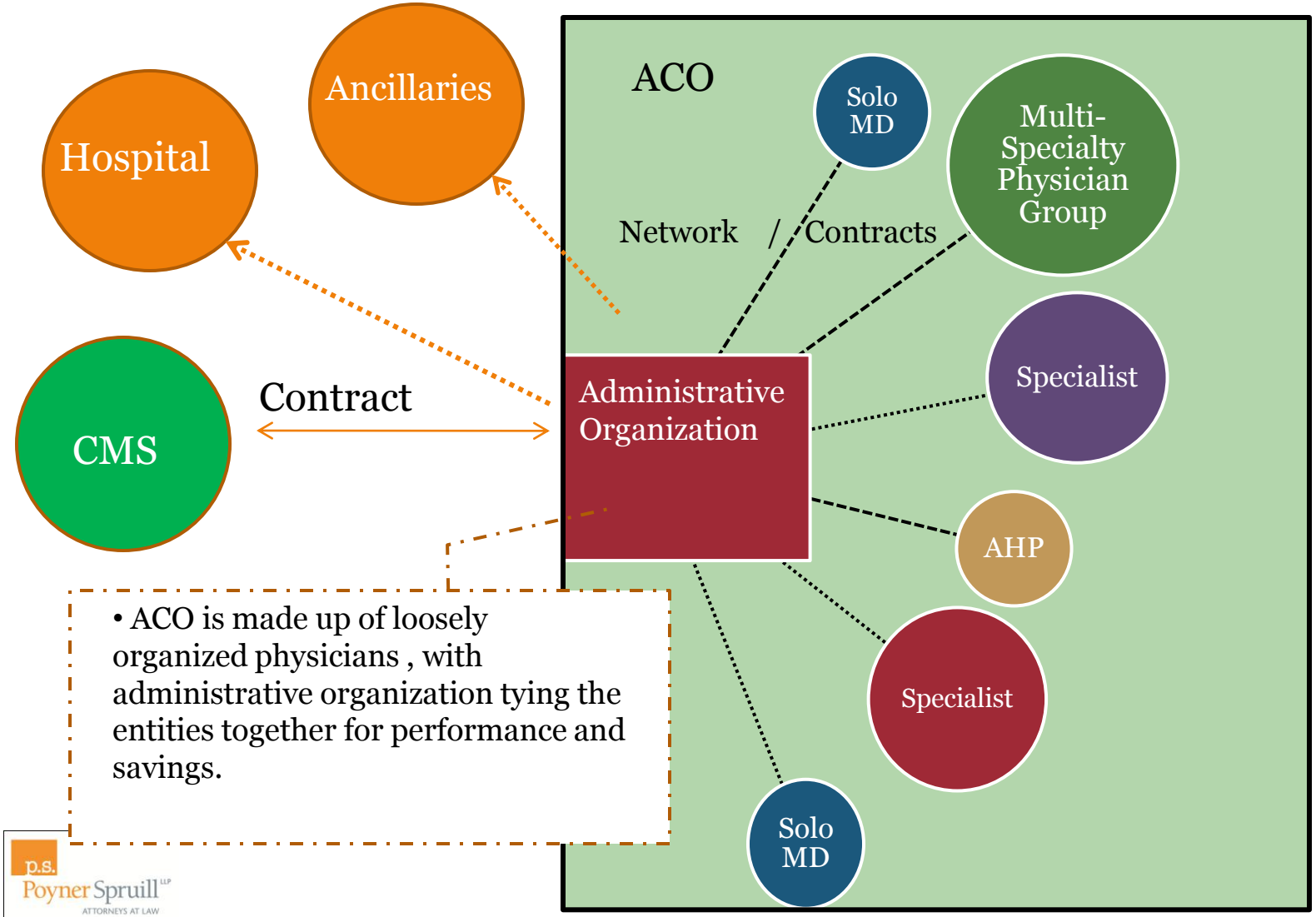


IDS or PHO as Basis for an ACO



- IDS/PHO is physician-hospital joint venture
- Structure to distribute bonus/savings by IDS/PHO contracts
- IDS/PHO reports savings/costs to CMS, assumes responsibility, binds providers in contract

ACO of Loosely Organized Physicians & Physician Organizations



- ACO is made up of loosely organized physicians , with administrative organization tying the entities together for performance and savings.

The Beauty of Waivers

- The PPACA allows the government to grant waivers (or exceptions, exemptions, safe harbors, and the like).
- Waivers could eliminate possible Stark, AKS, Anti-Trust, and organization problems.
- The regulations will (we hope) clarify this.

Special CMS Open Door Forum

Held on June 24, 2010

Highlights from the Open Door Forum

- Focus of Open Door Forum was to solicit opinions and experience from industry representatives, particularly physicians, to educate CMS on potential options for ACOs.
- CMS is asking physicians to tell the Agency how ACOs can work to be successful where past entities (i.e., HMOs) have failed to contain costs and promote quality care.
  - Physicians are in the driver's seat if they organize and provide comments to CMS.
  - If physicians do not take on this role, someone else (with potentially different interests) will.
  - Participants speaking at forum ranged from solo practitioners to large industry groups.
  - Additional opportunities for input are planned.

Highlights from the Open Door Forum

- CMS agrees that various organizational models meet the requirements of an ACO (IPAs, Multispecialty Groups, Hospital Medical Staff Organizations, PHOs, Organized/Integrated Delivery Systems, among others).
  - Statutory provisions identify several potential models and allow CMS to specify more details in regulation.
  - Models used can be loosely organized or more structured so long as the goal of cost containment and savings are achieved with accountability for care.
- Physician-led organizations (Mayo Clinic, Cleveland Clinic, Gunderson) have gained respect and notice for clinical and operational excellence.

Workshop on ACOs

Held on October 5, 2010

Highlights from the Workshop

- Focus of Workshop was to solicit opinions and advice from industry representatives, to address regulatory implications and hurdles faced by ACOs.
  - "Phenomenal interest" according to CMS Administrator Don Berwick.
  - "Triple Aim" of CMS: Better Care, Better Health, Lower per capita cost.

Highlights from the Workshop

- Each of the agency leaders (CMS, OIG, and FTC) emphasized their commitment to working together and to clearing hurdles for ACO development and innovation.
  - CMS- Stark law
  - OIG – Anti-kickback statute and CMPs
  - FTC – Anti-trust safety zones
- More sessions will be planned.

Highlights from the Workshop: FTC

- Antitrust perspective is focused on both creating safe harbors for collaboration and an expedited review process for those outside safe harbor. FTC in the Workshop looked for input on how to proceed.
- Mentioned examples of *Garfield County* case and *Grand Junction Co* case to show how FTC involvement and appropriate structuring can bring about lower cost and higher quality health care.
- The FTC recognizes that it may take years for an ACO to be robust and successful.

Highlights from the Workshop: FTC

- The FTC notes that there are benefits to the ACO Model and it needs to design accountability to make it a viable alternative.
  - Size matters. Pricing can be affected by large entities.
  - Dysfunction is driven by payment for quantity of services.
  - To what extent will exclusivity affect market power?
  - Mergers and joint ventures are on the rise…

    Because of or independent from ACOs?
- Must consider these implications for safe harbors and geographic area of competition.

Highlights from the Workshop: FTC

- ACOs will be analyzed under the fact-based **rule of reason** versus a *per se* approach.
  - First applied in the early 1900s, the rule of reason is that only combinations and contracts *unreasonably* restraining trade are subject to actions under the anti-trust laws, and that possession of monopoly power is not inherently illegal.
    - There are restraints that are *per se* illegal, such as price fixing agreements, group boycotts, and geographical market divisions.

Highlights from the Workshop: FTC

- FTC wants rules for ACOs that are flexible enough to allow decreased cost and increased quality without fixing prices and such.
  - Mentions potential models such as hospital-physician employment, IPAs, new ventures between independent providers.
  - **Clinical integration** is the key – you know it when you see it.
- Notes the tension between how high to set the bar as to who gets to be an ACO and how specific to define the bar.
  - Agreement that no one wants it to be so easy to qualify that there are many failed ACOs created.
  - Usefulness of giving the industry a framework for clinical integration and general expectations.

Highlights from the Workshop: FTC

- Incentivize innovation and fix payment methodology to promote desirable models of care.
  - FTC requires financial integration and sharing substantial risk on the upside and downside.
  - Weed out shams and incompetent organizations.
- Many providers are leery of collaboration because of past and current FTC guidance and enforcement activities.

Highlights from the Workshop: CMS

- One word says it all: WAIVER.
  - Fairly clear consensus that some changes need to be made to fraud and abuse laws and regulations for providers to embrace the concept of ACOs en masse.
    - Innovation is limited under current interpretations.
    - Changes are needed if ACOs are anything other than large integrated models.

Highlights from the Workshop: CMS

- **Option 1:** Say as little as possible in a broad waiver.
  - Not likely, too open for regulators to be comfortable.
  - Flexibility to experiment.
- **Option 2:** Don't start from the perspective fraud and abuse laws are impediments; craft specific exceptions to remove hurdles identified by existing entities that function as ACOs.
  - Concern that this will take too long.
- **Option 3:** Somewhere in between.
  - It's important to get it right from the start.

Highlights from the Workshop: OIG

- The OIG stated that fraud and abuse should not stand in the way of improving quality and decreasing costs.
  - This involves testing new payment and models, and the need to look at program integrity while achieving the goals of PPACA.
- Consideration should be given to other financial or business arrangements needed for ACOs, including start up capitalization, EHR, integration between various providers.

Highlights from the Workshop: OIG

- Two big issues:
  - Identifying the types of relationships that heighten the risk of fraud.
  - Managing the regulatory burden on small providers and others trying to become ACOs.
- We anxiously await the government's proposed solution to these issues!

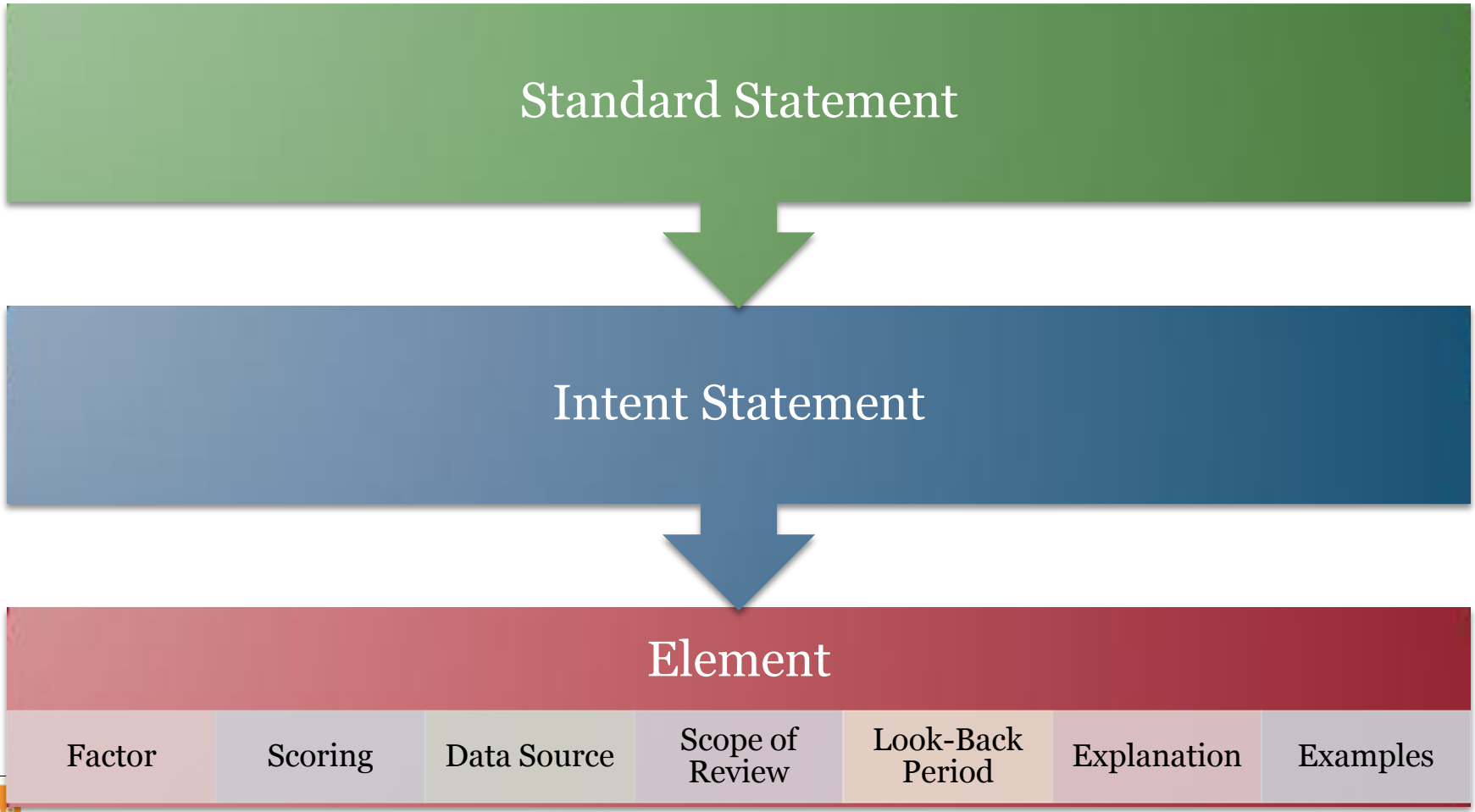
NCQA Draft 2011 Criteria for ACOs

Issued October 19, 2010 for Public Comment

Seven Categories

Program Structure Operations	• Clearly defined organizational and leadership structure. • Capacity to manage its resources effectively.
Access and Availability	• Sufficient numbers and types of providers and practitioners.
Primary Care	• Provide patient-centered care.
Care Management	• Collect and integrate data and assesses new patients' health, patients' needs. • Resources for patient care registries, e-Prescribe and patient self-management.
Care Coordination and Transitions	• Facilitate timely information exchange between providers for care coordination and transition.
Patient Rights and Responsibilities	• Policy commitment to patient rights, privacy, and has grievance process.
Performance Reporting	• Measures and reports clinical quality of care, patient experience, and cost. • Acts to improve these measures.

NCQA Approach for Each Standard



Example

PO 3: Health Services Contracting

The ACO arranges for pertinent health care services and determines payment arrangements and contracting.

Intent

The organization contracts with practitioners and providers to provide the full continuum care and foster open communication and cooperation with QI activities.

Element A: Arranging For Services

The organization arranges for the provision of the following health care services for its defined population:

1. **Primary care**
2. **Specialty care**
3. **Urgent and emergency care**
4. **Inpatient Care.**

Scoring	100%	80%	50%	20%	0%

Data source Materials

Scope of review

Explanation

Accountable care organizations are envisioned to be responsible for the full continuum of care for a defined population. Though significant impacts on costs and quality can be achieved through improvements in primary care; greater opportunities to reduce cost and improve quality can be gained through improved inpatient care and management of patients with complex conditions. These improvements require the involvement of and coordination with inpatient providers and specialists.

Organizations may include these entities in their legal structure or make provisions to have the services provided by these entities available to their defined population. Arrangements could be contractual, through collaborations, ownership arrangements or joint ventures.

NCQA reviews documentation to determine whether the organization has made arrangements to make these services available to its defined population.

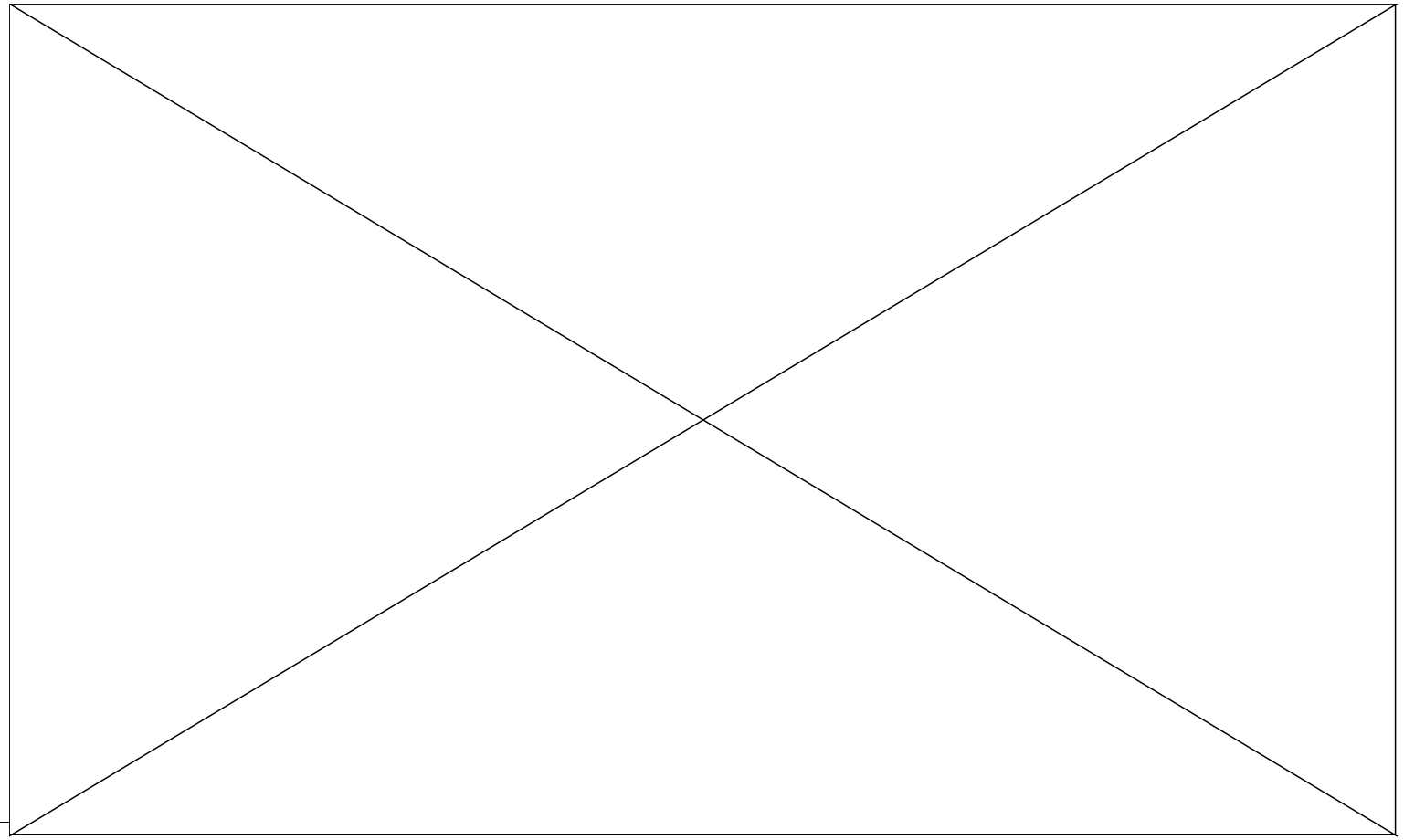
NOTE FOR PUBLIC COMMENT: Clearly this is not a comprehensive list of the health services likely to be required. We are interested in suggestions on which service types to list or alternative approach to assuring the organization has made the necessary arrangements for the types of services most likely to be needed.

Examples

- Contract with an urgent care facility (free-standing, hospital-based, or group-affiliated).
- Multi-specialty provider group including primary care practitioners included in

Final Thoughts

One Take on This Issue



Questions & Contact Information

- Steve Shaber, JD
- Poyner Spruill LLP
- 301 Fayetteville St., Ste. 1900
- Raleigh, NC 27601

- Office: (919) 783-2906
- Fax: (919) 783-1075
- Email: sshaber@poynerspruill.com

- Kim Licata, JD
- Poyner Spruill LLP
- 301 Fayetteville St., Ste. 1900
- Raleigh, NC 27601

- Office: (919) 783-2949
- Fax: (919) 783-1075
- Email: klicata@poynerspruill.com