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Accountable Care Organizations: Proposed Regulations Finally Released

Preparing for Significant Regulatory Changes and
Anticipating Antitrust, Fraud, Patient Privacy and Stark Law Pitfalls

WEDNESDAY, APRIL 27, 2011

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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McDermott Will & Emery

Accountable Care Organizations: Proposed Regulations Finally Released

Sponsored by the Legal Publishing Group of Strafford Publications
April 27, 2011

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Accountable Care Organizations: Proposed ACO Regulations

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- Summary of Proposed ACO Regulations
- Key State Law Issues

Medicare ACO Regulations

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- Medicare Shared Savings Program proposed regulations finally released March 31, 2011 by:
  - Centers for Medicare & Medicaid Services (CMS),
  - CMS/Office of the Inspector General (OIG),
  - Federal Trade Commission (FTC)/Department of Justice (DOJ),
  - Internal Revenue Service (IRS)
- Official proposed regulations in April 7 *Federal Register*.
- Comments to CMS/OIG due June 6; comments to DOJ/FTC and IRS due May 31.
- Program still set to begin January 1, 2012 (maybe).

Opportunity to Comment

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- CMS proposed rule for the Medicare Shared Savings Program/ACOs
  - Comments due 60 days from the date of publication (June 6, 2011)
    1. Go to http://www.regulations.gov
    2. Select “Submit a comment”
    3. Select “Proposed rule” in “Select Document Type”
    4. Type “**CMS-1345-P**” into the “Keyword or ID” box
    5. Find “**Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations**” (should be first selection)
    6. Click on “Submit a Comment” under “Actions”

Eligibility

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- Providers eligible to form ACOs:
  - Hospitals employing ACO professionals,
  - ACO professionals in group practice arrangements,
  - Networks of individual practices of ACO professionals,
  - Partnerships or joint venture arrangements between hospitals and ACO professionals, and
  - Critical Access Hospitals under Method II billing.
- Other providers and suppliers may participate in ACOs.

Eligibility (cont'd)

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- ACO must have 5k lives attributed in base period, then CMS will assume sufficient pool during agreement.

- If ACO's lives drop below 5k, CMS will establish Corrective Action Plan and ACO must exceed 5k in next year or will be ineligible.

Legal and Organizational Structure

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- Must have a legal entity (e.g., corporation, partnership, LLC) that is recognized by the state, has a Tax Identification Number (TIN), and is capable of:
  - Receiving and distributing funds;
  - Repaying shared losses;
  - Establishing, reporting, and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including quality performance standards; and
  - Performing other functions as identified in statute.
- Must have mechanism for shared governance that provides all participants with an appropriate proportionate control over ACO decision-making process.

Governance

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- Governing body with adequate authority:
  - Representatives from each provider/supplier participant
  - Medicare beneficiary representatives
  - At least 75% of body must be ACO participants
  - May include non-providers (e.g. health plan management companies)
  - May include community representatives
- ACA requires a “leadership and management structure that includes clinical and administrative systems.”

ACO Application Requirements

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- Documents that describe the participants' **rights and obligations** in the ACO, the shared savings that will encourage participants to adhere to the quality assurance and improvement program and the evidenced-based clinical guidelines;
- Documents that describe the scope and scale of the **quality assurance and clinical integration** program, including all relevant systems and processes;
- Materials documenting the **organizational and management structure**, including an organizational chart, a list of committees and their structures, and job descriptions for senior administrative and clinical leaders;

ACO Application Requirements (cont'd)

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- Evidence that a board-certified physician serves as its **medical director** who is licensed in the ACO's state and that a principal CMS liaison is identified in its leadership structure.
- Evidence that the **governing body** includes persons who represent the ACO participants, and that these ACO participants hold at least 75 percent control of the governing body.
- Upon request, the ACO would also be required to provide copies of the following documents:
  - **Formation and operation**, including charters, by-laws, articles of incorporation, and partnership, joint venture, management, or asset purchase agreements.
  - **Remedial processes** that will apply when ACO participants and ACO providers/suppliers fail to comply with the ACO's internal procedures and performance standards.

Medicare Beneficiary Assignment and Participating Providers

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- ACOs identified operationally as collection of Medicare-enrolled tax ID numbers (TINs) practicing as group practice arrangement or network.
- Retrospective attribution based on claims review (allowed charges) of plurality of primary care services provided by primary care physicians who are all exclusive to one ACO:
  - General practice,
  - Family practice,
  - Internal medicine, and
  - Geriatrics medicine.
- Other ACO participants (e.g., hospitals, specialists) could participate in multiple ACOs.

Contract

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- Three year contract, with calendar year annual performance period.
- CMS considering new possible start date of July 1, 2012 in addition to January 1, 2012 (but then would be 3.5 year agreement).
- 60-day Termination (forfeit 25% shared savings withhold)
- CMS will approve/deny applications prior to the end of the calendar year in which the applications are submitted.
- Subject to regulatory modifications except:
  - Eligibility requirements,
  - Calculation of sharing rate, and
  - Beneficiary assignment

Benchmarks

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- Estimates benchmark for each agreement period using most recent 3 years of per-capita Medicare Parts A and B FFS expenditures for attributed beneficiaries during that period.
- 6-month claims “run-out” period to calculate the benchmark.
- Beneficiary risk and growth trend adjusted across 3 base years.
- Excludes expenditures for incentive payments and penalties for Section 1848 value-based purchasing initiatives (e.g., Physician Quality Reporting System, eRx, EHR incentives).
- Does NOT exclude special payment add-ons like teaching and disproportionate share adjustments or geographic adjustments.
- Updates the benchmark by absolute annual dollar growth in national per capita FFS spending under Medicare Parts A and B.

Earlier Medicare Payment Advisory Commission ("MedPAC") Comments Result in "Two-sided Risk"

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- MedPAC letter to CMS on November 22, 2010 critiqued FFS Shared Savings ACO Payment Model
- Argued for "Two-Sided Risk Model" (e.g., various forms of capitated or quasi-capitated risk-sharing payment models)
- Medicare Beneficiaries need to receive disclosure and "opt-out" right; suggested possible ways to get beneficiaries "on board" with their ACO
- Suggested quality metrics

MedPAC's View on Two-Sided Risk Model

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- Solving the "random variation" problem (which otherwise can result in wasteful spending by CMS) requires the "Two-Sided Risk Model"

- If PPACA § 3022 ACO provisions do not allow for "Two-Sided Risk Model," MedPAC said CMS should use CMMI (not yet organized) to introduce the concept

- But CMS has determined that ACO two-sided risk model within scope of statutory authority

Two Alternative Payment Tracks

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- **Track 1: Shared Savings Only in Years 1 and 2: Two-sided Risk Model Starts in Third Year**
  - Continue to get paid FFS during the performance period
  - One-side risk model in years 1 and 2, reconciled annually
  - Must first meet minimum savings rate between 2% and 3.9% (depending on size of population)
  - Share up to 50% of savings depending on quality scores after 2% threshold,
  - ACOs in rural areas or physician-led that have fewer than 10k beneficiaries exempt from threshold,

Two Alternative Payment Tracks (cont'd)

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- **Track 1: Shared Savings Only in Years 1 and 2: Two-sided Risk Model Starts in Third Year**
  - ACOs including FQHC/RHCs share up to 2.5% more in first 2 years
  - Caps savings at 7.5% of benchmark in years 1 & 2 and 10% in year 3
  - **Two-sided risk model in year 3 following track 2 parameters**
  - Caps loss in year 3 to 5% of benchmark
  - Applies 25% withhold on savings each year to ensure ACO can repay losses; returned at the end of the agreement period if not depleted.

Two Alternative Payment Tracks (cont'd)

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- **Track 2: Two-sided Risk Model For Three Years**
  - Share up to 60% of savings/losses depending on quality scores
  - First dollar savings/loss after 2% minimum surpassed
  - ACOs including FQHC/RHCs share up to 5% more
  - Caps savings at 10% of benchmark
  - Caps losses at:
    - 5% of benchmark in year 1
    - 7.5% in year 2
    - 10% in year 3
  - Applies 25% withhold on savings to ensure ACO can repay losses
  - Must make payment in full within 30 days of notice and need to submit a certification of compliance and accuracy of information.

Savings

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- Calculate Medicare Part A/B per capita expenditures and compare to benchmarks:
  - Same methodology as benchmarks using performance period data.
- ACO must describe in application how it will distribute savings to ACO participants:
  - Criteria it plans to employ for distributing shared savings among its participants;
  - How the proposed plan will achieve the specific goals of the program; and
  - How the proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.

Medicare Beneficiaries

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- CMS will educate beneficiaries on ACOs, their utilization of services by an ACO and the possibility of assignment.
- Providers will have to inform beneficiaries of ACO participation/withdrawal and offer an ability to opt-out of CMS sharing data with the ACO on their care.
- Beneficiaries can visit whichever doctors they choose regardless of whether some of care is furnished by ACO.
- Program Integrity reviews to ensure no unintended consequences on beneficiaries such as:
  - Conduct claims and quality measure analyses,
  - On-site visits to some ACOs,
  - Beneficiary surveys, and
  - Medical record audits.

ACO Marketing Rules

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- Marketing Materials:
  - Requires CMS approval for ACO marketing materials or activities (written materials, calls, ads, web pages, community events), or changes to approved items, used to educate, solicit, notify or contact beneficiaries or providers/suppliers regarding the ACO.
- Non-covered communications include:
  - Customized informational materials,
  - Materials limited to a subset of beneficiaries,
  - Materials that do not contain ACO/provider information,
  - Billing/claims communications,
  - Specific health related issues,
  - Education on specific medical conditions, or
  - Referrals.

Eight Patient Centered Criteria

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- 1. Ongoing patient experience evaluation
- 2. Patient involvement with governance
- 3. Evaluating population needs and diversity
- 4. Identifying high risk individuals
  - Use of individualized care plans
  - Use of community resources
- 5. Coordination of care
  - Use of EHRs and exchange of e-information between sites of care
- 6. Communicating clinical knowledge
  - Use of shared decision making
- 7. Beneficiary access to medical records
  - Written standards that describe related policies and procedures
- 8. Internal Process to measure clinical service by physicians
  - as part of the quality assurance program requirements

Individualized Care Plans

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- ACO must demonstrate use of individualized care plans for targeted beneficiary populations to be eligible for the Shared Savings Program.
- As part of application, an ACO must submit description of individualized care program with:
  - A sample care plan,
  - Explanation of how program used to promote improved outcomes for, at a minimum, their high-risk and multiple chronic condition patients,
  - Identification of additional target populations that would benefit from individualized care plans, and
  - Description of how the ACO will partner with community stakeholders; ACOs that have stakeholder organization serving on their governing body would be deemed to have satisfied this requirement.

ACO Criteria: Clinical & Administrative Systems

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- Operations would be managed by an executive, officer, or general partner appointed by the organization's governing body.
- Clinical oversight would be managed by a senior-level board-certified medical director who is physically present in that state.
- ACO participants and providers/suppliers would have a meaningful commitment to the ACO's clinical integration program to ensure its likely success

ACO Criteria: Clinical & Administrative Systems (cont'd)

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- ACO would have a physician-directed quality assurance and process improvement committee as an oversight measure. It must also have processes and procedures in place to identify and correct poor compliance and promote continuous quality improvement.
- Must develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, and lower growth in expenditures. This could be accomplished through integrated EHR with clinical decision support.
- The ACO must have an infrastructure, such as HIT, that enables it to collect and evaluate data and provide feedback

Quality Performance Measures

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- **ACOs that do not meet the Quality Performance Standard (reporting, accuracy and performance) will not be eligible for shared savings.**
- For Year 1 of an ACO contract, an ACO will be considered to meet the ACO Quality Performance Standard if it has **reported** completely and accurately on all quality measures; there will be an audit process.
- For Years 2 and 3, an ACO will have to both completely and accurately **report** quality measures and **achieve** performance minimums.

Quality Performance Measures (cont'd)

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- CMS proposes an initial 65 measures to evaluate quality performance
- While one of the 65 measures, CMS also expects that at a minimum, at least 50% of an ACO's primary care physicians must attain Stage 1 HITECH meaningful use requirements.
- Measures may be expanded to address highly prevalent conditions of interest and may add measures of hospital-based care and measures for care furnished in other settings as well as HITECH requirements.

About the Measures

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- 65 Measures across two dimensions: improving care, improving health
- The measures are further divided by five domains:
  1) Patient/Caregiver Experience (7 measures)
  2) Care Coordination (16 measures, including transitions of care and HIT)
  3) Patient Safety (2 measures)
  4) Preventive Health (9 measures)
  5) At-Risk Population/Frail Elderly Health (31 measures) on the following:
     - Diabetes, Heart Failure, Coronary Artery Disease, Hypertension, Chronic Obstructive Pulmonary Disease, Frail Elderly

Implications for Measurement

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- To demonstrate the ability to effectively improve the quality of care and health, ACO:
  - May need to independently conduct measurement, much more frequently than the annual measurement enabled largely by CMS,
  - May need to conduct measurement at practice level, not just ACO at the ACO level to support actionable change by providers, and
  - May need informatics capacity to understand the ACO population's needs and to identify beneficiaries at the greatest risk.
- Important to evaluate not only to ACO's ability to submit to CMS accurate and complete quality measures annually but also its ability to routinely support internal analysis of quality improvement and utilization trends.

Monitoring Compliance with Quality Reporting Standards

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- ACO contract can be terminated by CMS if ACO does not meet the established quality performance, as determined by:
  - Reviewing the ACO's submission of quality measurement data.
  - Requesting additional documentation from an ACO or its ACO participants or ACO providers/supplier, as appropriate.
- In those instances where an ACO fails to meet the minimum attainment level for one or more domains, CMS proposes to give the ACO a warning and to re-evaluate the following year.
- If the ACO continues to underperform on the quality performance standards in the following year, the agreement will be terminated by CMS.

Public Reporting

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- Timing:
  - By January 1, 2013, the Secretary must implement a plan for making publicly available information on ACO quality and patient experience measures.
- Proposed content (within existing legal frameworks):
  - Name and location, primary contact, and organizational information:
    - ACO participants,
    - Identification of ACO participants in joint ventures between ACO professionals and hospitals, and
    - Identification of the ACO participant representatives on its governing body and associated committees and committee leadership.

Public Reporting (cont'd)

McDermott Will & Emery

- Shared savings information:
  - Shared savings performance payment received by ACOs or shared losses payable to CMS
  - Total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim goals of better health for populations, and better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants.
- Quality performance standard scores.

Data Sharing

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- Aggregate data reports on quality and utilization at the start of the agreement period based on the historical beneficiaries used to calculate the benchmark, *and quarterly* thereafter (most recent 12-mo).
- ACO can request a list of attributed beneficiaries included in the benchmark and at the end of each performance period:
  - Name,
  - Date of Birth,
  - Sex, and
  - Health Insurance Claim Number (HIC).

Representative State Law Issues

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- Corporate Practice of Medicine/Fee-Splitting

- HMO/Insurance/Managed Care Contracting Laws

Representative State Law Issues: Corporate Practice of Medicine

McDermott Will & Emery

- Most states still have laws that prohibit, to varying degrees, the “corporate practice of medicine” (“CPOM”), which generally prevent unlicensed lay entities from employing physicians or otherwise contracting with physicians to furnish medical care, and “fee-splitting” (unearned division of professional medical fee with layperson/lay entity).

- CPOM laws may limit the flexibility of physicians and non-physicians to structure ownership and employment arrangements of an ACO unless licensed as a managed care organization or hospital may employ physicians under state CPOM law.

Representative State Law Issues: Corporate Practice of Medicine (cont'd)

McDermott Will & Emery

- Some states with strong CPOM laws (e.g., California, Nevada, and Texas) even prohibit hospitals from employing physicians, but have laws permitting nonprofit "medical foundations" to engage physicians (e.g., in medical group) indirectly to provide medical care

- "Friendly Physician" or "Management" models in CPOM states will require careful regulatory analysis to minimize regulatory risk

HMO/Insurance/Managed Care Licensing Laws

McDermott Will & Emery

- National Association of Insurance Commissioners ("NAIC") determined in 1990s that a health care provider receiving capitated-type payments assumes insurance-type financial risk

- In most states, capitation is permissible under state insurance/HMO law for state-licensed HMO's "downstream" providers, within the scope of their medical/health licensure, for services provided to that HMO's members

HMO/Insurance/Managed Care Licensing Laws

McDermott Will & Emery

- Capitated or Other "Downside Risk" Payments?
  - In a number of states (e.g., California, Colorado, Illinois, New Jersey, New York, Ohio and Pennsylvania) an ACO is prohibited from assuming capitated or other substantial financial risk, unless the ACO is licensed by the state to assume such financial risk or falls within an exception.
- ACO that direct contracts with self-funded ERISA plan is not shielded from state insurance/HMO licensure and regulation by ERISA preemption, which applies only to plan itself. [See Hewlett-Packard Co. v. Barnes, 571 F. 2d 502 (9th Cir 1978)]
  - Congress could preempt state insurance/HMO laws for Medicare capitation, but PPACA does not appear to do so.

HMO/Insurance/Managed Care Licensing Laws (cont'd)

McDermott Will & Emery

- Examples of State Managed Care Laws that May Apply to ACOs include:
  - California Department of Managed Health Care: ACO requires "restricted" Knox-Keene license before assumes downside risk for inpatient hospital services
  - Colorado's Division of Insurance Regulations
  - Florida's Definition of Fiscal Intermediary Service Organization
  - Illinois' PPO Regulations under the Health Care Reimbursement Reform Act of 1985
  - New Jersey's N.J. Stat. §§ 17:48H-1 et. seq.
  - Ohio's Rev. Stat. Chapter 1751
  - Pennsylvania's Department of Insurance Regulations

HMO/Insurance/Managed Care Licensing Laws (cont'd)

McDermott Will & Emery

- Applicability of state insurance/HMO/managed care laws will depend on precise payment structure
  - Global capitation/percentage of premium
  - Capitation only for services that capitating provider is licensed to provide (e.g., California)
  - Risk corridors (10-15% or 50%?)
  - FFS combined with withholds (10-15% or 50%+)
  - FFS with upside shared savings bonus (not regulated)
  - ACO contracts with private payor or Medicare Advantage Plan vs. self-funded employer

HMO/Insurance/Managed Care Licensing Laws (cont'd)

McDermott Will & Emery

- In some states (such as California, Ohio, and New Jersey), providers that lack state health plan license generally may not capitate or assume substantial financial risk other than under contract with a licensed HMO, and then only for services within scope of provider's licensure.

- In those states, ACO may still engage in direct employer fee-for-service contracting as permitted by CPOM (including case rates and other bundled pricing) but prohibited from being paid on a capitated basis or otherwise assuming downside financial risk unless ACO holds the required state HMO, PPO or insurance license or subcontracts for its own licensed health care with an HMO services with an HMO.

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LEGAL ISSUES

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MAIN POINTS

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- Broad waivers of Stark, Anti-kickback and CMP Laws to facilitate ACO financial arrangements
- CMS-approved ACOs are clinically integrated for antitrust purposes
- New antitrust safety zone addresses ACO market power concerns
- Expedited FTC/DOJ review of ACOs that don't meet the safety zone
- Participation in a CMS-approved ACO will not jeopardize tax exempt status or result in unrelated business income

CMS/OIG PROPOSED WAIVERS

McDermott Will & Emery

- Would apply only to Medicare Shared Savings Program
- Would cover the following statutes:
  - Stark Law
  - Anti-kickback Statute
  - CMP Law
- Must be in compliance with Program conditions

CMS/OIG PROPOSED WAIVERS

McDermott Will & Emery

- Distributions of shared savings among ACO participants and ACO provider/suppliers:
  - Stark Law and AKS waived
  - CMP Law waived except for payments by a hospital to a physician that are made knowingly to induce the physician to reduce *medically necessary* items or services

CMS/OIG PROPOSED WAIVERS

McDermott Will & Emery

- Distributions of shared savings to outsiders for activities necessary for and directly related to the ACO's participation in and operations under the Program:
  - Stark Law and AKS waived
  - CMP Law doesn't apply
  - What activities are "necessary for and directly related"?

CMS/OIG PROPOSED WAIVERS

McDermott Will & Emery

- Other financial relationships among the ACO, ACO participants and ACO provider/suppliers necessary for and directly related to the ACO's participation in and operations under the Program:
  - No Stark Law waiver
  - AKS and CMP Laws waived for any arrangements that implicates the Stark Law, as long as arrangement meets a Stark exception

CMS/OIG PROPOSED WAIVERS

McDermott Will & Emery

- Waivers related to distribution of shared savings would apply regardless of whether distribution is made during or after the term of the CMS agreement
- Waivers related to other financial relationships would apply only during the term of the CMS agreement

CMS/OIG PROPOSED WAIVERS

McDermott Will & Emery

- Soliciting comments regarding waivers related to:
  - Forming the ACO
  - Implementing the governance and administrative requirements
  - Building technological and administrative capacity
  - Payments necessary for and directly related to achieving the integrated care, cost savings and quality goals of the Program
  - Payments to outsiders (e.g., health plans, management companies, etc.)
  - Commercial ACO payments (can create Stark exposure)
  - Beneficiary inducements
  - EHR (after 2013)

CMS/OIG PROPOSED WAIVERS

McDermott Will & Emery

- Questions:
  - Scope of proposed waivers?
  - No AKS or CMP Law waiver for arrangements that fall outside of Stark Law (e.g., indirect compensation arrangements)?
  - If payment to a physician is tied to implementation of evidence-based protocols, is that an inducement to limit medically necessary items or services?
  - What about performance-based compensation for the final period prior to expiration of the CMS agreement?

FTC/DOJ PROPOSED POLICY STATEMENT

McDermott Will & Emery

- Would apply to collaborations of independent providers formed after March 23, 2010
- Would also apply to ACO initiatives under the Innovation Center that are substantially clinically or financially integrated

FTC/DOJ PROPOSED POLICY STATEMENT

McDermott Will & Emery

- ACOs approved for participation in the Program are clinically integrated for antitrust purposes
- CMS-approved ACOs will be subject to rule of reason treatment with respect to commercial market activity, as long as the same governance and leadership structures and clinical and administrative processes are used

FTC/DOJ PROPOSED POLICY STATEMENT

McDermott Will & Emery

- Safety Zone
  - Independent ACO participants that provide the same type of service in the same Primary Service Area ("PSA") must not have more than 30% combined market share in that PSA
  - PSA is the lowest number of contiguous postal zip codes from which the ACO participant draws at least 75% of its patients

FTC/DOJ PROPOSED POLICY STATEMENT

McDermott Will & Emery

- All hospitals and ASCs must be non-exclusive to the ACO, regardless of market share
  - Must be able to contract individually or to affiliate with other ACOs or commercial payors
  - No-exclusivity must be in fact, not just in name

FTC/DOJ PROPOSED POLICY STATEMENT

McDermott Will & Emery

- Rural Exception:
  - May include one physician per specialty from each rural county on a non-exclusive basis even if 30% PSA market share limitation is exceeded
  - May include rural Sole Community Hospitals or CAHs on a non-exclusive basis even if 30% PSA market share for any common service is exceeded

FTC/DOJ PROPOSED POLICY STATEMENT

McDermott Will & Emery

- Dominant Provider Exception
  - ACO participant with more than 50% market share in its PSA must be non-exclusive
  - ACOs with Dominant Providers cannot require commercial payors to contract exclusively with the ACO or otherwise restrict the payor's ability to deal with other ACOs or provider networks

FTC/DOJ PROPOSED POLICY STATEMENT

McDermott Will & Emery

- Safety zone protection continues while CMS agreement is in effect, unless there are significant changes in provider composition
- ACOs (other than those in the rural exception) will not lose safety zone protection solely because they attract more patients

FTC/DOJ PROPOSED POLICY STATEMENT

McDermott Will & Emery

- Expedited Review (90 days)
  - Mandatory review for ACOs with two or more providers of a common service within a given PSA, where those providers have more than 50% market share in that PSA (no objection letter required to participate in the program)
  - Optional review available for ACOs below the 50% market share threshold that do not meet the safety zone

FTC/DOJ PROPOSED POLICY STATEMENTS

McDermott Will & Emery

- Guidance to ACOs outside of safety zone:
  - Avoid preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through "anti-steering," "guaranteed inclusion," "product participation," "price parity," or similar contractual clauses or provisions
  - Avoid tying sales (either explicitly or implicitly through pricing policies) of the ACO's services to the commercial payer's purchase of other services from providers outside the ACO (and vice versa), including providers affiliated with an ACO participant (e.g., an ACO may not require a purchaser to contract with *all* the hospitals in the same network as the hospital that belongs to the ACO)

FTC/DOJ PROPOSED POLICY STATEMENTS (cont.)

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- With an exception for primary care physicians, avoid contracting with other ACO physician specialists, hospitals, ASCs, or other providers on an exclusive basis, thus preventing or discouraging them from contracting outside the ACO, either individually or through other ACOs or provider networks
- Avoid restricting a commercial payer's ability to make available to its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers in the health plan, if that information is similar to the cost, quality, efficiency, and performance measures used in the Shared Savings Program
- Avoid sharing among the ACO's provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO

FTC/DOJ PROPOSED POLICY STATEMENTS

McDermott Will & Emery

- Why exclude organizations formed prior to 3/23/10?
- Why must hospitals and ACOs with less than 30% market share of any common service in their PSA be non-exclusive?
- Will hospitals and ASCs be required to participate in multiple ACOs in order to qualify for safety zone?
- Is the rural exception too burdensome on specialists (e.g., call responsibility)?

IRS NOTICE 2011-20

McDermott Will & Emery

- Solicits comments as to whether existing IRS guidance is sufficient for tax-exempt organization participating in ACOs
- CMS-approved ACOs generally will not result in inurement or excessive private benefit
- Activities that generate shared savings payments generally will not be subject to unrelated business income tax (UBIT)
- Comments solicited regarding participation in commercial ACO arrangements

HMO/Insurance/Managed Care Licensing Laws (cont'd)

McDermott Will & Emery

- Must review state insurance/HMO managed care law carefully before structuring ACO

- Note: If ACO is not a licensed health plan and is delegated TPA functions (e.g., claims adjudication), ACO may be required to obtain a state third party administrator ("TPA") license

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DELIVERING ON HEALTHCARE REFORM

Accountable Care Organizations:
Proposed Regulations Finally Released
A Webcast Series

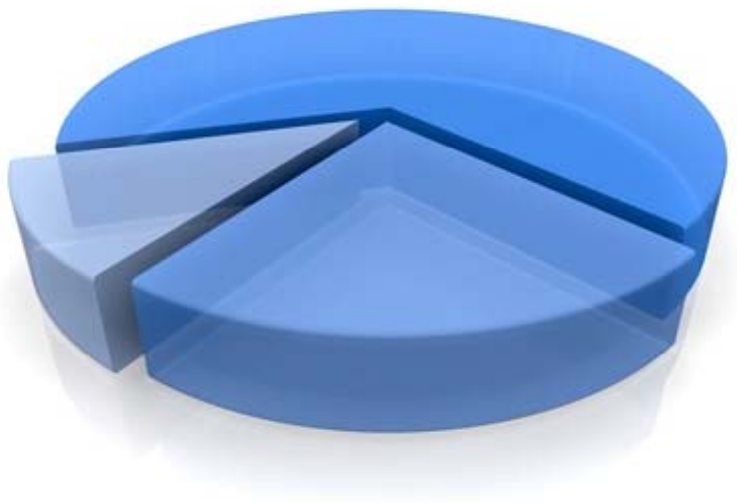
Accountable Care Provider Reimbursement Strategies

Peter Boland, PhD
Managing Partner
Polakoff Boland

April 27, 2011

Common Sense Questions

1. How will the pie be divided?
2. Who will divide up the pie?
3. How big is the pie?
4. How much does the pie cost?
5. Who is paying for the pie?
6. How much are customers willing to pay?



Common Sense Answers

1	How will the pie be divided?	Distribution formula based on capital investment, risk assumption, risk/cost management capability, performance bonus
2	Who will divide up the pie?	ACO leadership
3	How big is the pie?	Year 1 – less than the year before Year 2 – less than the year before Year 3 – less than the year before
4	How much does the pie cost?	Whatever providers can negotiate with payers based on purchaser price points
5	Who is paying for the pie?	Government, commercial insurers, employers and individuals
6	How much are customers willing to pay?	Medicare and Medicaid: less each year; Insurers: trend + 4%; Employers: CPI + 1%

Simple Math

1. Revenue minus costs
2. Less payment for same services
3. Same services must be provided differently

Simple Math Conclusions

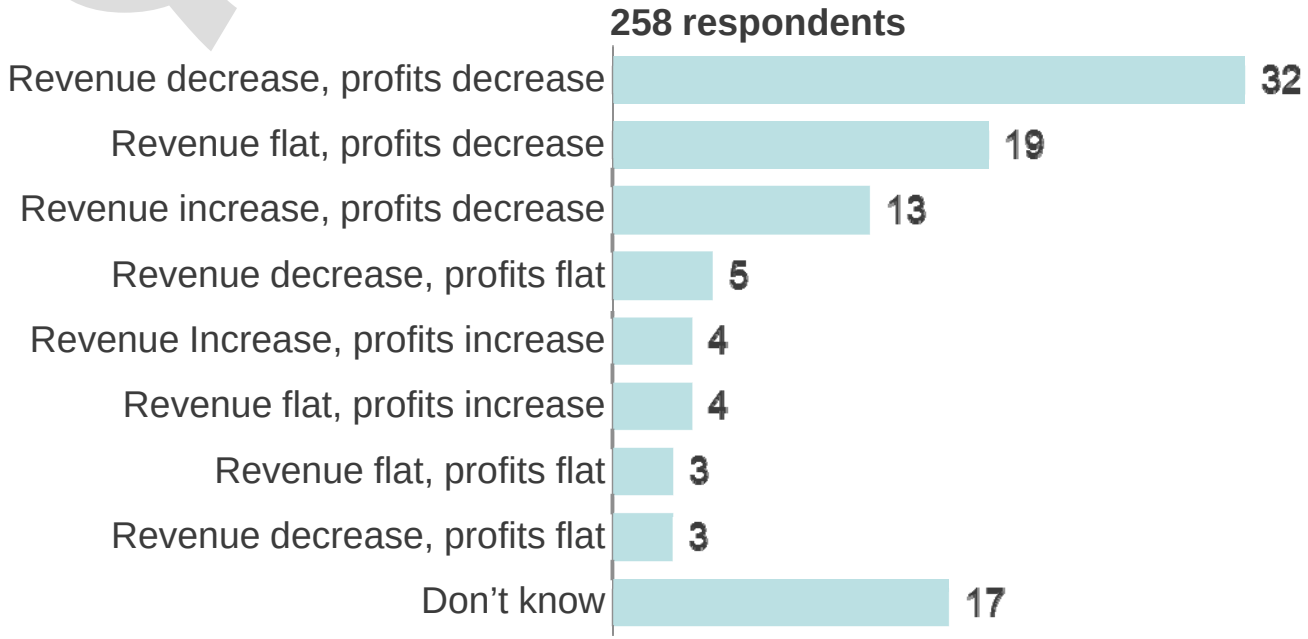
1. Revenue minus costs
2. Less payment for same services
3. Same services must be provided differently

- Healthcare reform reimbursement will not grow with provider costs
- Spread between Medicare and commercial payment will narrow
- Providers cannot make up revenue loss on volume under current or expected rates
- Providers can make it up on: (1) quality bonuses, (2) higher per capita rates linked to better outcomes, (3) superior patient management skills, and (4) total cost reduction with capitated or global risk payments
- Providers must learn to break even on Medicare rates

Hospital Perceptions of ACOs

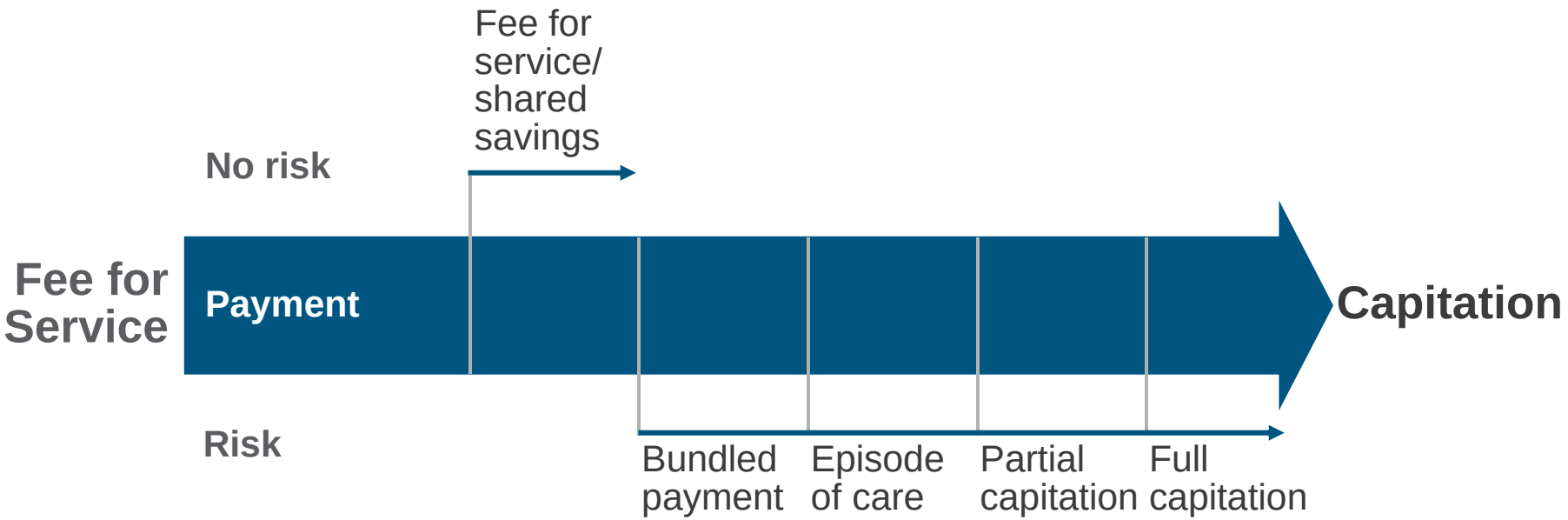
Q

Which phrase best describes the financial impact to hospitals you expect from medical home and ACO strategies in the future?

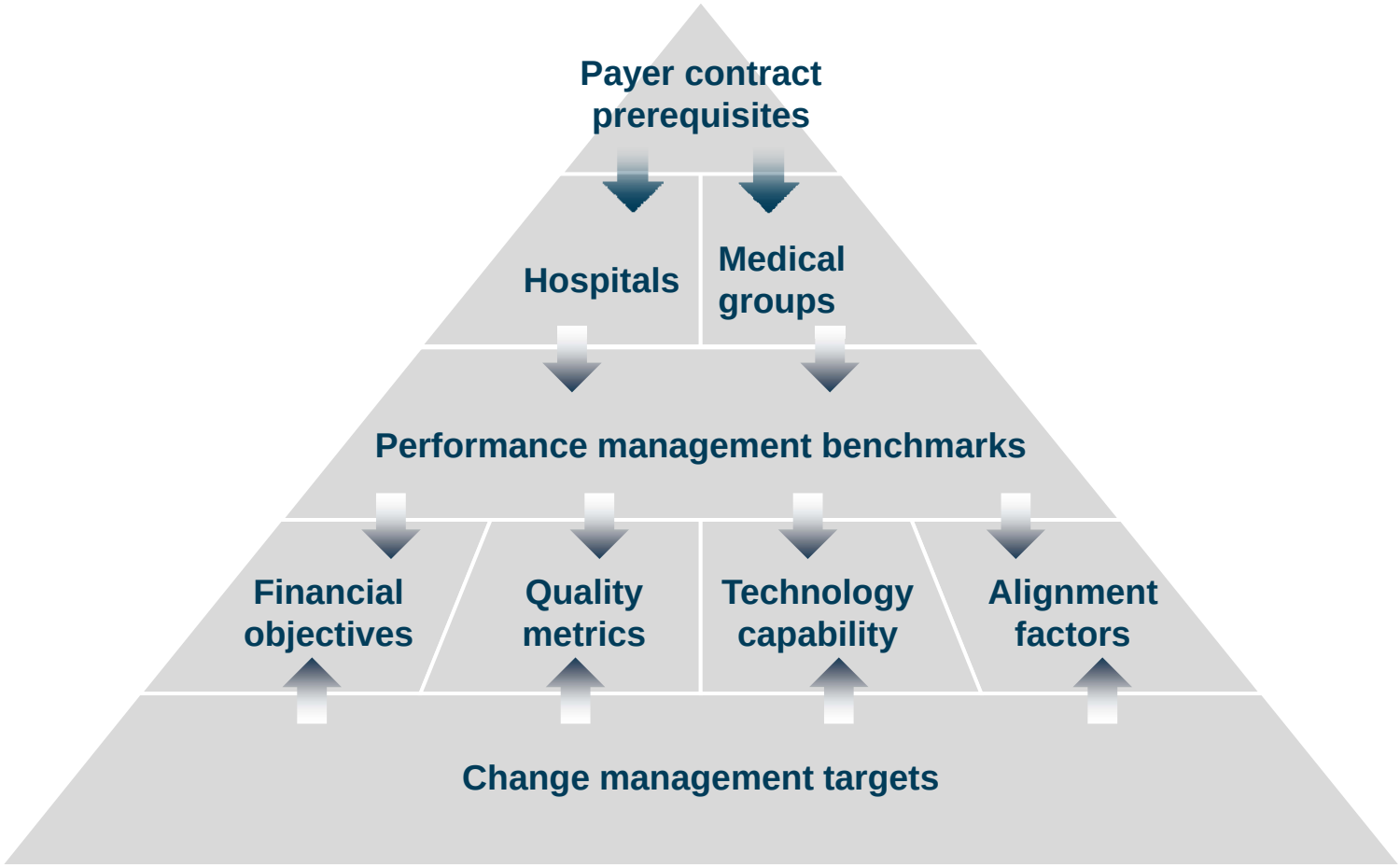


Source: 2011 National Payor Survey, Revive Public Relations, 2011

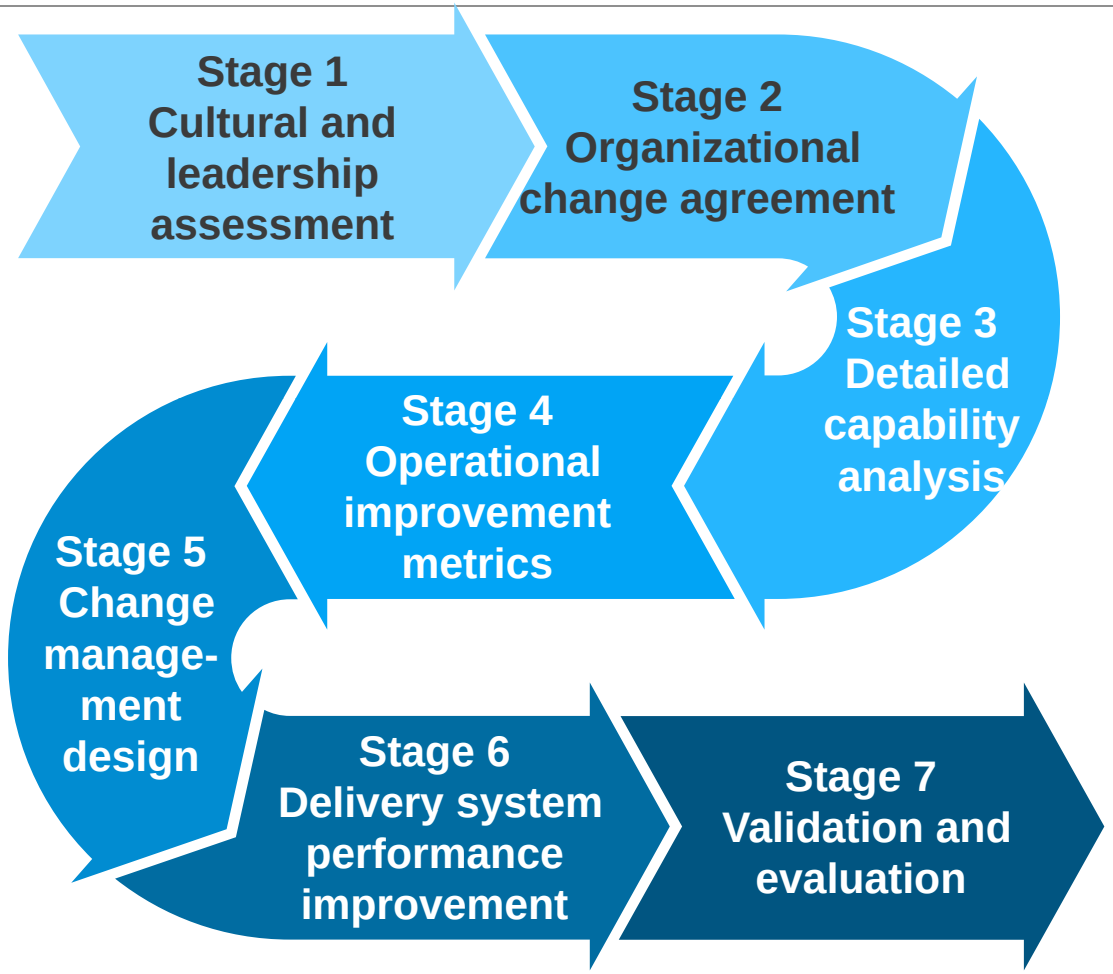
Reimbursement Risk Continuum



Accountable Care: Change Management Model



Accountable Care Competency Stages



Alignment Factors: Sequence

Activity focus	Stage 1 Executive education	Stage 2 Leadership skills	Stage 3 Communication/ coaching	Stage 4 Performance management	Stage 5 Evaluation
Work content	Market analysis	Strategic thinking	Organizational change	Operational redesign	Contract requirements validation
Management objective	Develop common frame of reference and language	Redefine mission, objectives and service benchmarks	Establish process to change culture, and communication patterns	Increase work efficiency, clinical efficacy, care integration and coordination	Implement tracking tools to assess progress and implement corrections
Intended result	Incorporate new market intelligence in business planning	Modify business strategy and financial model	Enhance ability to coordinate across silos	Improve capacity to reduce cost and improve quality	Match internal resources to cost/quality targets and benchmarks

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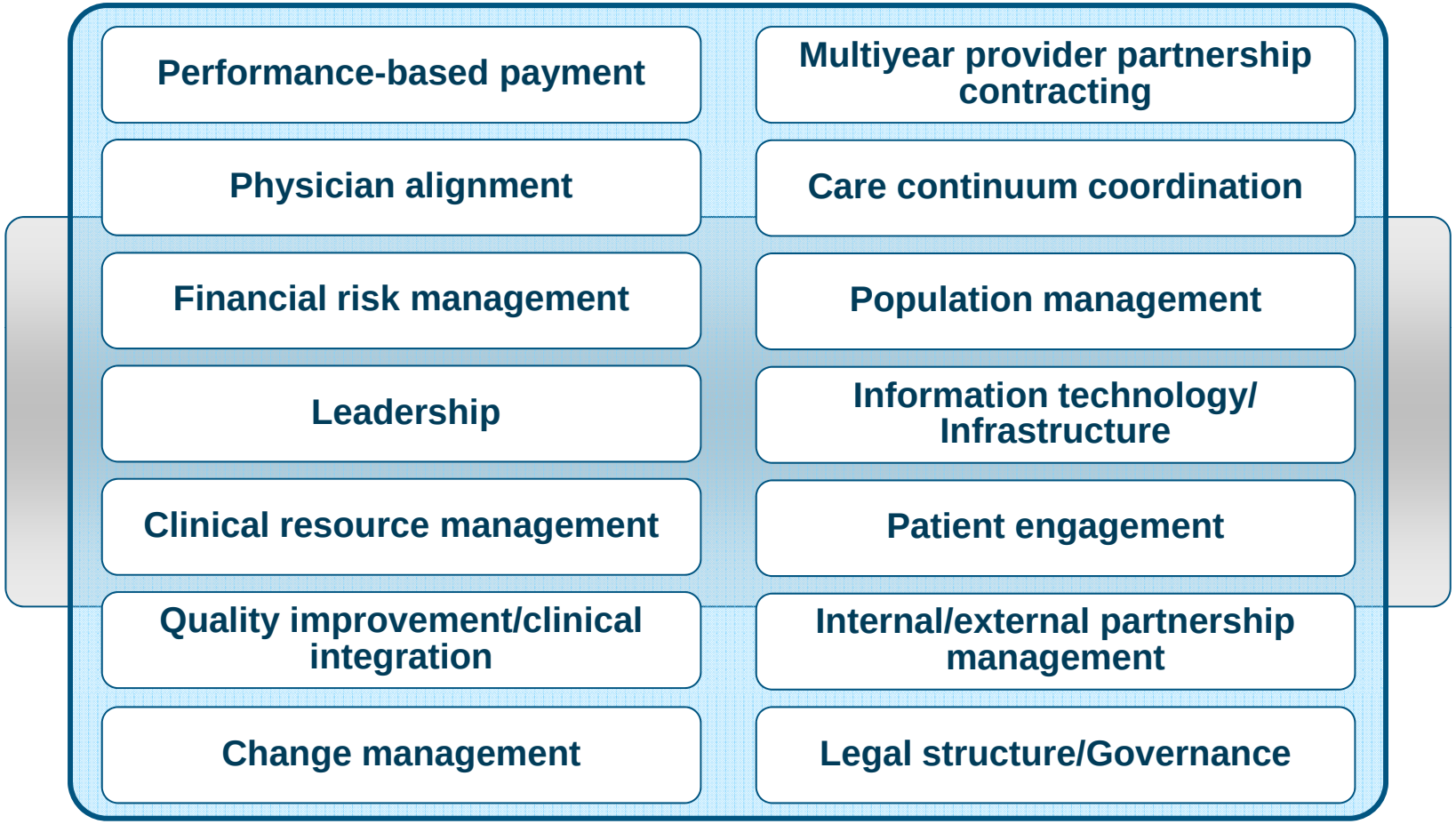
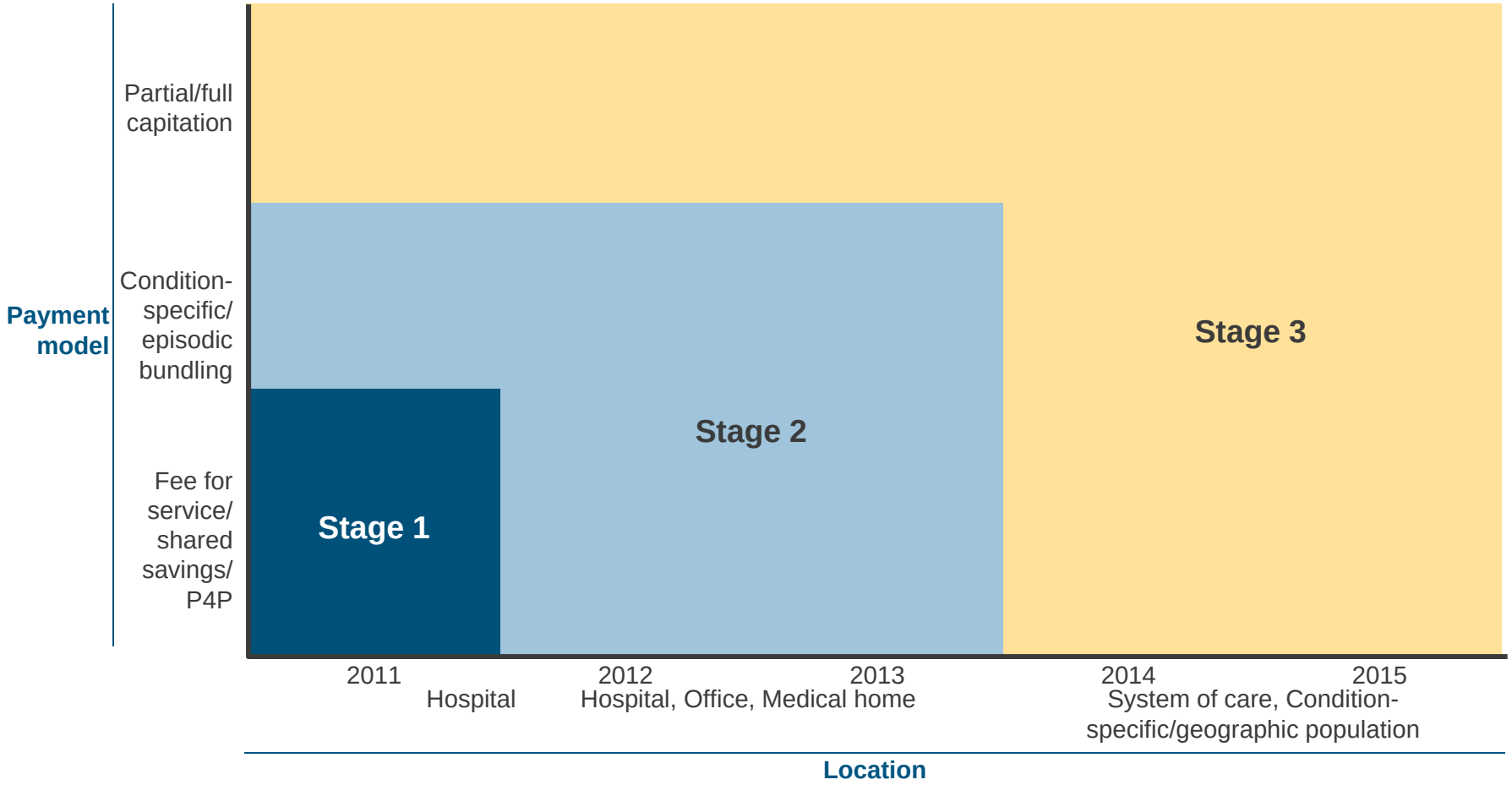
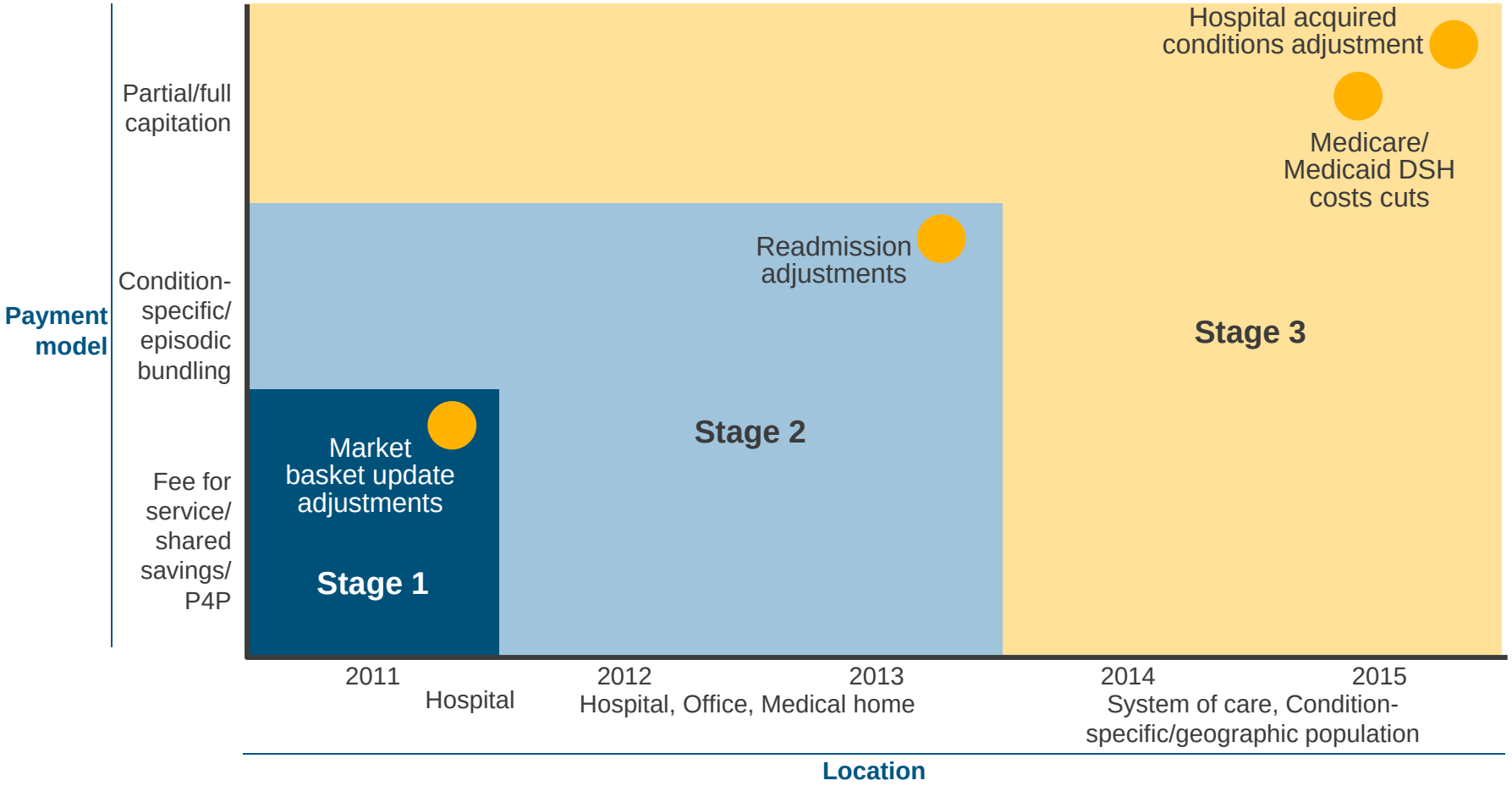
Accountable Care Developmental Competencies



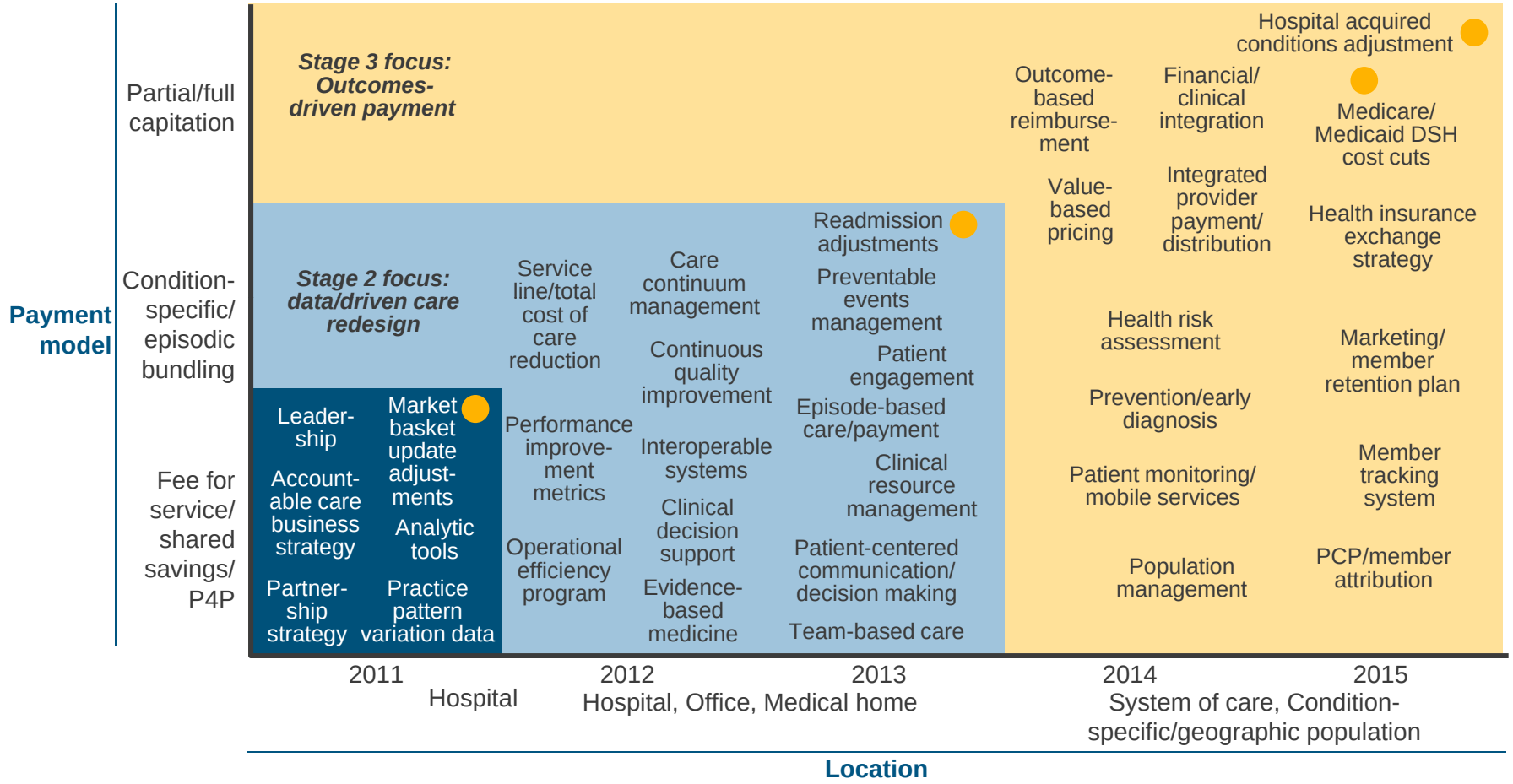
Payment Models and Developmental Capabilities



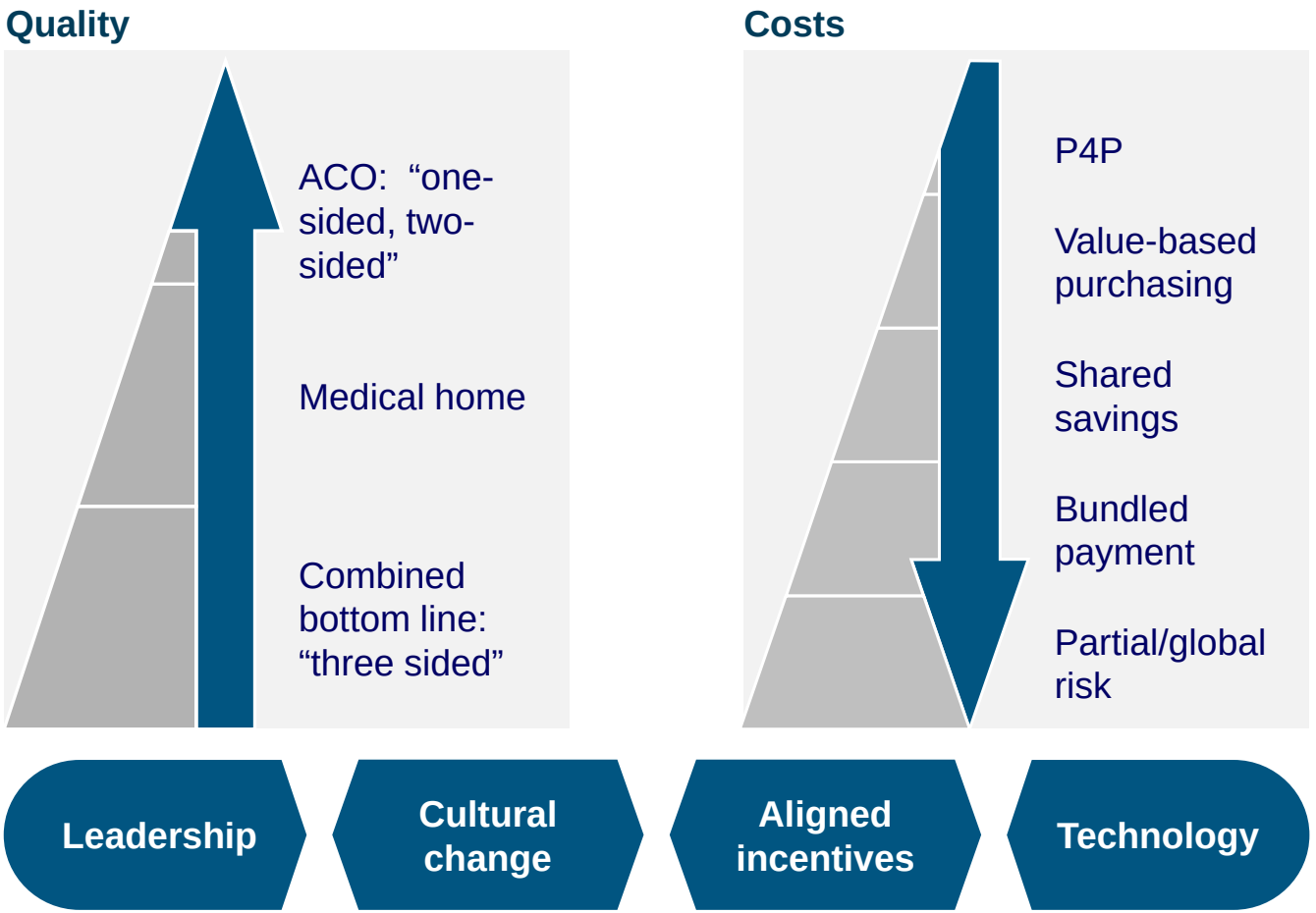
Payment Models and Developmental Capabilities



Payment Models and Developmental Capabilities



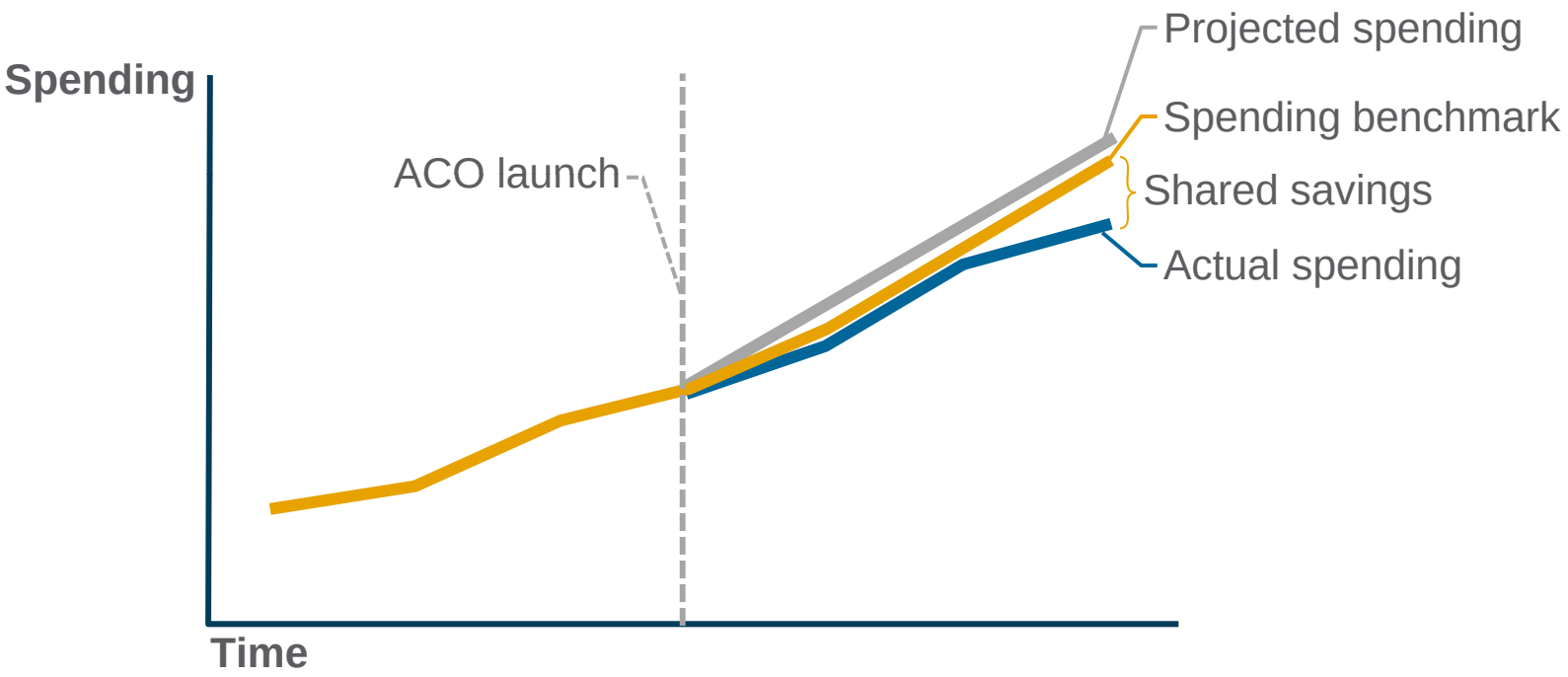
Realignment Challenges



Shared Savings Model

How do "shared savings" models work?

Initial shared savings derived from spending below benchmarks



Source: The Dartmouth Institute for Health Policy & Clinical Practice, 2010

Options For Payment Reform

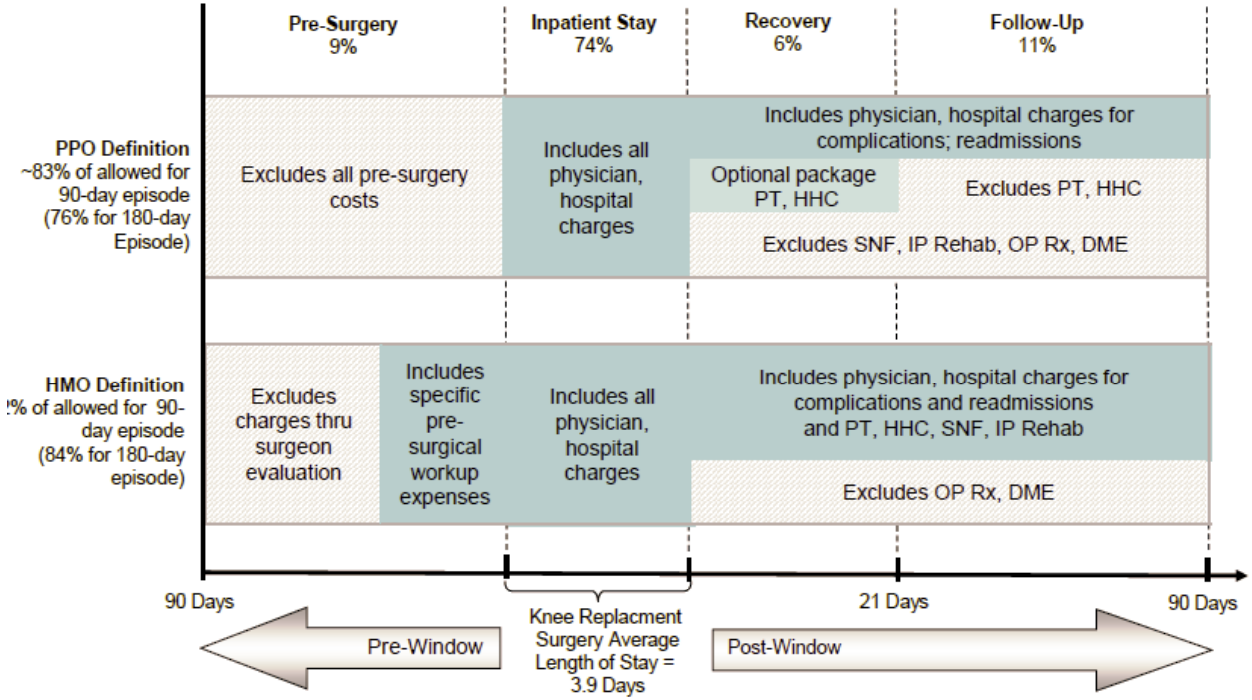
Shared savings + symmetrical risk	• No risk for spending over the benchmark • 2% threshold before savings can be distributed • Shared savings split of 50/50
Simple shared savings	• Split of shared savings is 80/20, with symmetrical risk (withhold)
Shared savings + partial capitation	• 10-15% capitation on ACO patient expenditures • Shared savings split of remaining 50-90% based on risk relationship
Quality first	ACO providers must meet quality thresholds in order to qualify for shared savings

Source: The Dartmouth Institute for Health Policy & Clinical Practice, 2010

Attachment A

Episode Definition: Knee Replacement

Distribution of Contractual Allowed Amounts in Commercial Population[1]



[1]Source: Ingenix Claims Data – 7,632 complete episodes

Accountable Care Prerequisites: 4 Strategies

1	Change and align organizational culture	• Peer-to-peer feedback • Data driven quality improvement • Performance measurement • Patient-centered treatment modalities
2	Leverage IT resources and capability	• Clinical decision support • EHR and patient-centered portal • Data warehouse and marts • Interoperability across silos
3	Reframe care delivery with clinical metrics	• Clinical/financial integration • EBM guidelines • Team-based treatment • New staff roles and functions • Population-based services • Telehealth and online engagement
4	Implement cost-reduction strategies with financial objectives	• Unit cost reduction • LEAN • Lower cost treatments, settings and providers • Reduce clinical practice variation • Risk adjustment/case mix adjustment

Source: Adapted from "Best Practices, Evidence Base Care, and the Evolution of Clinical Care in the ACO Era," Richard Lopez, MD; March 1, 2011

Medical Group and Hospital Imperatives

	Challenge/opportunity	Resource focus
Manage risk and revenue *better*	Risk-based reimbursement	Risk analysis, distribution formulas
	Unit cost reduction	Care redesign/economic model redesign
Manage across care continuum *better*	Care coordination	IP, OP, ambulatory, home, LTC
	Pre/post-discharge planning	Patient monitoring
Manage clinical information exchange *better*	Real-time data availability	Multiple care settings, providers
	Point-of-care access	User requirements
Managed quality reporting *better*	Meaningful use	EHR stages 1-3
	PQRI measures	Dashboard, ad hoc reporting, bonus metrics
Manage patient engagement *better*	Personalized treatment/ decision support	Outreach, coaching
	Real-time lifestyle support	Online, mobile applications, social media

California Payer-Provider Medicare ACOs

		Lessons learned
HealthCare Partners Medical Group	HealthCare Partners Medical Group	• Care management at each organization must be integrated to focus on high-cost patients • Silos in each organization must be broken down
Anthem Decide to be healthy. WELLPOINT	Anthem/ Wellpoint	• Start with FFS, then partial capitation and full capitation • Delegate UM, CM and DM to medical groups with care management fee (transparent data)
Monarch HealthCare A Medical Group, Inc.	Monarch HealthCare Medical Group	• Amount of resources and commitment required over 5 years should not be underestimated • Providers must get over their bias about payer financing, profitability and compensation

Interdependent Wheel

Interdependent Wheel Elements

Cost reduction ● Quality improvement ● Performance-linked payment ● Patient engagement

Business strategy ● Utilization and clinical data ● Product pricing ● Gain/risk distribution

Mission and objectives ● Governance and structure ● Data integration ● Clinical integration ● Care coordination ● Population management ● Payment model ● Metrics and reporting ● Patient experience ● Physician alignment ● Communications

Delegated utilization and case management ● Float cycle ● Member channeling ● Common bottom line

Risk/Reward Sharing Distribution Models

1. Reimbursement Model – FFS

Physician	FFS
Hospital	FFS, case rate
Payer	Traditional

Service	Medical groups	Hospital	Health plan	Employer
Institutional			100%	
Professional			100%	
Prescription drug			100%	

Risk/Reward Sharing Distribution Models, continued

2. Reimbursement Model – Hybrid

Physician	Capitation
Hospital	FFS
Payer	Traditional

Service	Medical groups	Hospital	Health plan	Employer
Institutional	37.5%	25%	37.5%	
Professional	100%			
Prescription drug	100%			

Risk/Reward Sharing Distribution Models, continued

3. Reimbursement Model – Mixed Risk

Physician	Capitation
Hospital	Partial risk
Payer	Traditional

Service	Medical groups	Hospital	Health plan	Employer
Institutional	50%	50%		
Professional	50%		50%	
Prescription drug	50%		50%	

Risk/Reward Sharing Distribution Models, continued

4. Reimbursement Model – Shared Savings/Risk

Physician	Capitation/combined bottom line
Hospital	Partial risk/global risk/combined bottom line
Payer	Combined bottom line (conceptual)

Service	Medical groups	Hospital	Health plan	Employer
Institutional	33.3%	33.3%	33.3%	Negotiable
Professional	33.3%	33.3%	33.3%	Negotiable
Prescription drug	33.3%	33.3%	33.3%	Negotiable

Risk/Reward Sharing Distribution Models, continued

5. Reimbursement Model – Shared Savings/Risk*

Physician	Capitation/combined bottom line
Hospital	Partial risk/global risk/combined bottom line
Payer	Combined bottom line (actual)

Service	Medical groups	Hospital	Health plan	Employer
Institutional	Each partner mutually responsible for costs in each care category	Each partner mutually responsible for costs in each care category	Each partner mutually responsible for costs in each care category	Premium guarantee in Year 1; lower premium costs Year 2 and 3
Professional				
Prescription drug				

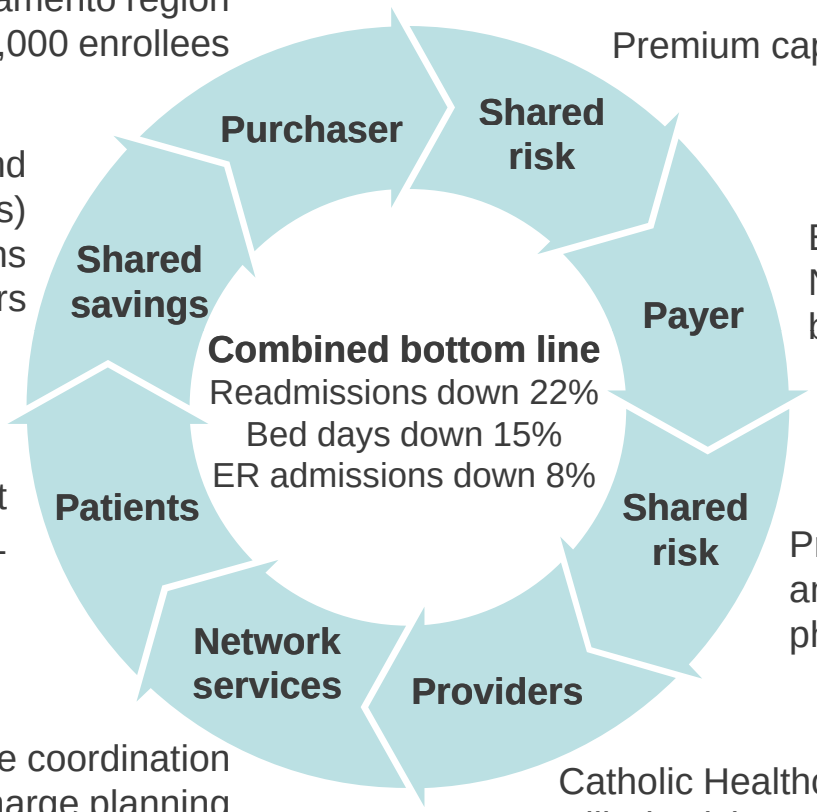
* Internal cell structure for a "combined bottom line" model will not be equally divided and will reflect multiple factors.

Distribution Elements

Distribution of risk/ reward will be a function of elements such as …

- Goals of an organization (shared vision and commitment to cost/quality targets)
- Geographic-specific market conditions
- Financial and business needs of each stakeholder (to be explicitly addressed)
- Relative financials of each organization
- Capabilities of each organization to impact and manage cost and quality issues for each line of business (the “heavy lifting”)
- Amount of stake in the deal (“skin in the game”) for each organization
- Other tangible and intangible assets represented by each party
- Allocation to be revisited periodically

Commercial Funds Flow: Combined Bottom Line



CalPERS Sacramento region
42,000 enrollees

Premium cap Year 1

Lower out-of-pocket costs and contributions (payroll deductions)
Lower costs/contributions for purchasers

Blue Shield of California Net Value Plan (no benefit changes)

$15.5 million cost reduction Year 1

Proportional distribution among hospitals, physician, health plan

Care coordination
Pre- and post-discharge planning
Population management

Catholic Healthcare West hospitals (4)
Hill Physicians Medical Group (520)

Multipartner ACO

		Lessons learned
	Catholic Healthcare West	▪ Medical groups, hospitals and payer must all work together – not two versus one ▪ Understand each party's issues, respect their vulnerabilities and solve them
	Blue Shield	▪ Health plans must be transparent about pricing to build trust with providers ▪ Clinical and financial integration is the crux of collaboration between payers and providers
	Hill Physicians	▪ Each partner has critical clinical and utilization data; transparency is key ▪ Four organization's divergent cultures must work hand-in-glove
	CalPERS	▪ Zero trend in 2010 (same benefit structure) ▪ Bed days down 15%; readmissions down 22%; ER admissions down 7.6%; ALOS down 0.72 days

Changing Payer-Provider Corporate Culture

"If staff had done this, they would have been fired"

"Everyone wants money off the top, but you need to wait to get the savings"

"At the end of the day, it comes down to people with feet on the ground – physicians, nurses, and techs"

"One person's savings is another's revenue"

Provider/Payer Care Coordination Management

Provider/payer focus

- Collaborate across patient conditions, services and care settings
- Share information across disciplines and systems
- Standardize process across care continuum
- Design performance incentives to reward coordination
- Engage physicians as active partners

Patient-centered focus

- Personalize information and education
- Design incentives for adherence to care plan
- Monitor and reinforce adherence through different media
- Incorporate patient values in decision-making process
- Reward self-management

The New Normal

- Reduce admissions
- Reduce inpatient fee for service
- Eliminate payment for preventable events
- Link payment to performance
- Pay for care coordination
- Pay for episodes of care vs. procedures or volume
- Pay for quality/value

Contact Information

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