According to a New Study by the national Research Council and the Institute of Medicine

- U.S. men rank last among 17 high-income countries in life expectancy (75.64 years).
- U.S. women rank next-to-last (80.78 years).
- “Even highly advantages Americans may be in worse health than their counterparts.”
- This gap in life expectancy has been growing over the past three decades, especially among women.

Did you Know?

**According to the Institute of Medicine:**

- We waste **$750B** a year annually through:
  - Unnecessary services ($210 billion)
  - Inefficient delivery of care ($130 billion)
  - Excess administrative costs ($190 billion)
  - Inflated prices ($105 billion)
  - Prevention failures ($55 billion)
  - Fraud ($75 billion)
Overtreatment is Taking a Harmful Toll


“...[A]n epidemic of overtreatment – too many scans, too many blood tests, too many procedures – is costing the nation’s health care system at least $210 billion a year, according to the Institute of Medicine, and taking a human toll in pain, emotional suffering, severe complications and even death.”

Did you Know?

- Just one year’s waste = 10 years of Medicare cuts & enough to care for all the uninsured.
- Recommendations to fix the system:
  - Better use of clinical & financial data;
  - Reimbursement that rewards quality and value;
  - EHRs and mobile technologies; and
  - Transparency about costs and outcomes of care

The Changing Healthcare Landscape

- Consolidation of market.
- Provider margins are under attack
- New models of provider integration are emerging
- Increased fraud enforcement
- Shift from “Volume to Value” as a basis of reimbursement
Why are New Models Emerging

- Hospitals are seeking ways to build relationships with providers.
- Pressure on future reimbursement increases/focus on decreasing overall cost structure to maintain margins will require organizational redesign and implementation.
- CMS, employers, and payers are demanding delivery of high quality healthcare at lower costs. . . value based purchasing of healthcare

Cornerstones of New Model

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Cornerstones of the New Model – Delivery Model

- Right hospitals
- Right clinicians
- Defined clinical pathways and protocols, including alert monitoring systems
- Right site of care
Cornerstones of the New Model –
Aligned Incentives
- Identify opportunities to mutually benefit from improved performance.
  - Bundling readmissions into base rate to maintain current episode payment.
  - Share savings from reducing supply unit cost.
- Requires aligning external payment model (payer to provider) with internal funds flow (hospital to physician).
- Line of site into episode view for tracking performance requires ability to track hospital, physician, post acute claims.
- Requires investment of HIE/Analytics/Reporting.

Cornerstones of the New Model –
Legal Structures/Governance
- Choice of legal entity.
- Equity participation and associate rights.
- Board composition.
- Committee infrastructure.
- Contractual relationships.
- **Key to success:** Involving and empowering physician champions in decision making to achieve physician buy-in and participation in quality and cost-saving initiatives.

Moving from Volume to Value

**20th Century ("Cost and Volume")**
- Vertical integration
- Steerage
- Eliminate “middle man”
- Medical Management
- Transfer Pricing
- Target small and/or local employers
- Medical cost analysis
- Fully insured
- Preferred providers/exclusive networks
- Gatekeepers
- Site specific medical records
- Physicians as passive participants

**21st Century ("Value")**
- Clinical Integration
- Collaboration
- New value proposition
- Evidence Based Approaches
- Value Based Pricing
- Target all purchasers
- Patient outcome analysis
- Evolving economic structure
- Rational delivery system
- Empowered consumers/patients
- Integrated electronic health record
- Physicians economically integrated
Payment, Incentive, & Delivery Alignment Framework

Emerging Shared Savings Models
- The models that most payers and providers are implementing including a version of:
  - Shared Savings
  - Patient Centered Medical Home
  - Bundled/Episodic Payment
- Key Decision Points
  - What shared savings model will create the greatest value for both payer and providers?
  - What population will shared savings be measured?
  - What mechanism will the payer/provider implement to share savings?
  - What risks will providers need to manage?
  - What are the specific steps/investments the payer and provider need to undertake to be able to operationalize the shared savings model?

The Approach To Each Model
- Step 1: Assess the Opportunities
  - Identify and quantify reductions opportunities - avoidable days, readmissions, length of stay, avoidable emergency room visits, etc.
  - Calculate the cost savings reduction opportunity through improved process, utilization management, discharge planning, etc.
- Step 2: Design the solutions
  - Design changes to the delivery model required to achieve cost savings.
  - Design changes to the payment model required to support and incentivize change.
- Step 3: Implement the program
  - Implement the operational model for achieving results.
  - Establish metrics/analytics and reporting to support corrective action.
Shared Savings

- Shared savings is a payment strategy that offers incentives for providers to reduce health care spending for a defined patient population by offering them a percentage of net savings realized as a result of their efforts.
- Shared savings can be applied to some or all of the services that are expected to be used by a patient population.

Requirements of Shared Savings

- Payers and Providers must agree on savings opportunities that can be achieved and also provide a meaningful incentive for the providers.
- The financial model will need to provide reasonable protection that calculated savings do not reflect random variation in health care costs.
- Providers need tools to succeed if they are to transform care delivery, including timely, trended performance data with targets and benchmarks, and giving practices the ability to manipulate such data.
- To be successful performance measures which focus on both cost and quality, must be aligned across all payers, governmental and commercial. A common framework will be required.
- Models will need to be evaluated for effectiveness and providers/payer must refine the shared-savings payment model over time to maximize effectiveness.

The Shared Savings Model – Gives & Gets

Think of the financial model as a series of “gives & gets,” with clear revenue and expense tradeoffs between hospitals, physicians and payers.
How will Savings Be Achieved?

- Care Management Programs
  - Personalized care coaches
  - Standardized care workflows
  - Chronic and acute care management programs
  - Referral management program
- Member Engagement
  - Customized benefit designs
  - Higher cost sharing on discretionary, elective services

How will Savings Be Achieved? (cont’d)

- Transparency tools to encourage members to use high quality, low cost providers (labs, imaging, hospitals, etc.)
- Personalized patient care plans
- Nurse hotline
- Provider Portal/Reporting
  - Gold care authorization process (reduces administrative costs)
  - Secure messaging
  - Payer-data driven analytics and reporting (to track shared savings progress to plan)

How will Savings be Achieved?

- Savings opportunities can only be as robust as the clinical process mapping activities that will ultimately identify savings opportunities

Stage A
- High Risk, but no Heart Disease or symptoms of HF
  - Hypertension
  - CAD
  - Diabetes
- Treat hypertension
- Smoking cessation
- Treat lipid disorders
- Regular exercise

Stage B
- Heart Disease, but no symptoms of HF
  - All measures under Stage A
  - ACE inhibitors as appropriate
  - Beta blockers as appropriate

Stage C
- Heart Disease with prior or current symptoms of HF
  - Known structural heart disease
  - Shortness of breath and fatigue
  - Reduced exercise tolerance
  - All measures under Stage A
  - Diuretics, ACE inhibitors, Beta blockers
  - Dietary restrictions

Stage D
- Refractory HR requiring intervention
  - All measures under Stages A, B, C
  - Mechanical assist devices
  - Continuous IV infusions
  - Hospice care

High symptoms at rest despite maximal therapy
- Recurrent hospitalizations
- Previous MI
- LV systolic dysfunction
- Asymptomatic valvular disease
- All measures under Stages A, B, C, D
Measuring and Distributing Shared Savings

- How will savings be determined?
  - Comparison to budget
    - Payer considers the past health care costs associated with an attributed population, projected forward for future costs.
  - Comparison to a control/benchmark group
    - Payer compares the rate of change in PMPM cost of the attributed population to a comparison group or the full regional network of providers.
    - If the trend rate falls below the control group, the difference in trend rates is used to calculate the amount of savings.

Measuring and Distributing Shared Savings (cont’d)

- How will savings be distributed?
  - Withhold requirements?
  - Quality and/or cost savings requirements?
  - Frequency of distribution?

How Might the Model Evolve Over Time?

- Year 1: Attributed Member Pilots
  - FFS
  - Quality Performance Incentive
  - Shared Savings Funding (spend based)
  - Medical Care Management Fees
  - Disease Specific Centers of Excellence
  - Bundled Payment

- Year 2: Narrow Network / Co-Branded Products
  - Global Budget Incentive
  - % of Premium with Reinsurance
  - Own Health Plan / Joint Venture
  - Direct Contracting
  - Insurance Exchange
  - Rationalization

- Year 3: Narrow Network / Co-Branded Products
  - Global Budget Incentive
  - % of Premium with Reinsurance
  - Own Health Plan / Joint Venture
  - Direct Contracting
  - Insurance Exchange
  - Rationalization

- Court upheld individual mandate by 5-4 majority.
- Found case ripe for decision – thus struck down challenge under Anti-Injunction Act.
- Upheld the Act’s Medicaid expansion *BUT* (by 7-2 majority) left decision-making to the states – Congress cannot cut off a state’s entire Medicaid funding if the state decides against the expansion.

> “Congress’s use of the Taxing Clause to encourage buying something is, by contrast, not new. Tax incentives already promote, for example, purchasing homes and professional educations. … Sustaining the mandate as a tax depends only on whether Congress has properly exercised its taxing power to encourage purchasing health insurance, not whether it can. Upholding the individual mandate under the Taxing Clause thus does not recognize any new federal power. It determines that Congress has used an existing one.”

The Affordable Care Act Three Years Later

**Kaiser Family Foundation Publication #8429 (March 2013)**

1) Private Insurance and Exchanges:
- Young adults on parents’ policies to age 26.
- 17 states and DC are establishing exchanges.
- No coverage exclusions for children with pre-existing conditions.
- Medical loss ratio and rate review in place/premiums lower.
- Health plans must provide Summary of Benefits and Coverage.

2) Medicaid
- Medicaid expansion supported in 27 states.
- Medicaid expanded to adults in 7 states.
- Low-income children/pregnant women still primarily covered by Medicaid and CHIP.
- Most states have modernized/streamlined Medicaid enrollment.
- Health home option adopted by 10 states.
- Many states have expanded home/community-based long-term services.
The Affordable Care Act Three Years Later (cont’d)

3) Access to Primary Care
- Increased M/M payments to primary care providers.
- Increased state health center patient capacity.
- National Health Service Corps ranks have tripled since 2008, in medically underserved communities.
- Expansion efforts underway for primary care workforce.

4) Access to Preventive Care
- Medicare and most private insurance now provide preventive benefits with no cost-sharing.
- New Prevention and Public Health Fund.

The Affordable Care Act Three Years Later (cont’d)

5) Medicare
- 52.5% discount on brand name Part D drugs in doughnut hole.
- New delivery system/payment initiatives, including ACOs and bundled payments.
- Miscellaneous savings measure.

6) Dual Eligibles
- Some states developing/testing models that align Medicare/Medicaid financing.

Reform Implementation Timeline - 2013

- State notification regarding exchanges.
- Medicare bundled payment pilot program.
- Medicaid coverage of preventive services.
- Medicaid payments for primary care.
- Itemized deductions for medical expenses.
- Flexible spending account limits.
- Medicare tax increase.
Reform Implementation Timeline – 2013 (cont’d)

- Employer retiree coverage subsidy.
- Tax on medical devices.
- Financial disclosure.
- Co-op health insurance plans.
- Extension of CHIP.
- Medicare disproportionate share hospital payments.
- Medicaid disproportionate share hospital payments.

Reform Implementation Timeline - 2014

- Expanded Medicaid coverage.
- Presumptive eligibility for Medicaid.
- Individual requirement to have insurance.
- Health insurance exchanges.
- Health insurance premium and cost sharing subsidies.
- Guaranteed availability of insurance.
- No annual limits on coverage.
- Essential health benefits.

Reform Implementation Timeline – 2014 (cont’d)

- Multi-state health plans.
- Temporary reinsurance program for health plans.
- Basic health plan.
- Employer requirements.
- Medicare advantage plan loss ratios.
- Wellness programs in insurance.
- Fees on health insurance sector.
- Medicare payments for hospital-acquired infections.
Post-Election Rules

- Proposed rule on ACA provisions re: fair health insurance premiums, guaranteed insurance availability and renewability, statewide insurance risk pools, enrollment in catastrophic plans, and insurance rate reviews. 77 Fed. Reg. 70584 (Nov. 25, 2012).

Post-Election Rules (cont’d)

- OPM proposed rule on ACA multi-state plan program to promote competition on exchanges. 77 Fed. Reg. 72582 (Dec. 5, 2012).
- OSHA interim final rule to protect employees against retaliation by an employer for reporting alleged violations of various insurance provisions. 78 Fed. Reg. 13222 (Feb. 27, 2013).

Post-Election Rules (cont’d)

- IRS proposed rule re: ACA’s annual fee on covered entities engaged in the business of providing health insurance. 78 Fed. Reg. 14034 (March 4, 2013).
- OPM final rule re: multistate insurance plans that will be offered on state health insurance exchanges beginning in January 2014. 78 Fed. Reg. 15559 (March 11, 2013).
**Post-Election Rules** (cont’d)


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**What is an Accountable Care Organization (ACO)?**

- ACOs are groups of doctors, hospitals, and other health care providers who come together voluntarily to give coordinated high quality care to their patients.
- The goal of coordinated care is to ensure that patients, especially the chronically ill, can get the right care at the right time while avoiding unnecessary duplication of services and preventing medical errors.
- When an ACO succeeds in both delivering high quality care and spending health care dollars wisely, it will share in the savings it achieves for the Medicare program.

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**Who Can Participate?**

- All licensed providers who form and/or have a participating provider agreement with a CMS certified ACO and is listed by the ACO and identified by its Medicare-enrolled tax ID number (TIN).
  - Group practice
  - Active care hospital
  - Pharmacy
  - Solo Practice
  - Critical access hospital
  - APN
What Requirements Must be Met?

• Legal Structure
  • Recognized by state with legal authority through a governing body to implement and enforce all required ACO functions.
  • An ACO must be able to receive and distribute shared savings.
  • An ACO can be an existing legal entity and the same Governing body.

What Requirements Must be Met? (cont'd)

Shared Governance
• The governing body must be composed of ACO participants or their designated representatives, each of whom owes a fiduciary duty to the ACO.
• The governing body must include at least one Medicare beneficiary representative who is served by the ACO.
• At least 75% control of an ACO’s board of directors must be held by ACO participants.
• ACO participants must have meaningful participation with respect to the composition and control of the ACO’s governing body.

What Requirements Must be Met? (cont'd)

Management
• An ACO must be managed by an executive, officer, manager or general partner under the control of the ACO’s governing body.
• Clinical management must be through a senior-level medical director who is present on a regular basis and is a board-certified physician licensed in the state in which the ACO operates.
What Requirements Must be Met? (cont’d)

Sufficient Number of ACO Professionals and Beneficiaries

- An ACO must have a sufficient number of primary care ACO professionals to treat at least 5,000 Medicare patients assigned to it and must maintain an assigned beneficiary population of at least 5,000 such patients.

What Requirements Must be Met? (cont’d)

Quality Assurance and Process Improvement

- Internal performance standards for quality of care and services, cost-effectiveness and other standards must be adopted and implemented.
- ACO participants must make a meaningful commitment either through financial investment or meaningful investment of time and effort.
- An ACO must have data collection and evaluation infrastructure, such as information technology.
- An ACO must provide to CMS a description and example of an individualized care plan.

What Requirements Must be Met? (cont’d)

Compliance Plan

- An ACO must have a compliance plan that meets specific requirements which are standard within the health care industry, including a compliance official who is not the in-house general counsel.

Required Processes and Patient-Centeredness Criteria

- An ACO must meet patient-centeredness criteria specified by CMS, including evidence-based medicine, patient engagement, coordination of care across the ACO continuum, and processes to report on quality and cost metrics.
What Requirements Must be Met? (cont’d)

Assignment of Medicare Beneficiaries to ACOs

- Medicare fee-for-service beneficiaries are assigned to an ACO based on their utilization of primary care services by a primary care physician who is an ACO provider/supplier during the performance year for which savings are determined.
- Beneficiary assignment does not in any way diminish or restrict the rights of beneficiaries to exercise free choice in determining where to receive health care services, including a provider, who is not a participant in the assigned ACO.

What Requirements Must be Met? (cont’d)

Distribution of Savings

- ACOs will be required to provide in their application a description of the criteria to be employed for distribution of shared savings among ACO participants and how such savings will be used to align with the aims of better care for individuals, better health for patient populations, and lower growth of expenditures.

What Requirements Must be Met? (cont’d)

Three-Year Agreement with CMS

- ACOs will be required to enter into a three-year agreement with CMS with revised start dates of April 1, 2012, or July 1, 2012, and then January 1 for every start year thereafter.
What Requirements Must be Met? (cont'd)

Quality and Other Reporting Requirements

• The Final Rule identifies 33 quality measures, which was a reduction from the proposed 65. The required benchmarks for each measure have not yet been identified by CMS.

• Measures are divided into four domains:
  − Patient/caregiver experience (7 measures)
  − Care coordination/patient safety (6 measures)
  − Preventative health (9 measures)
  − At-risk population
    ▶ Diabetes (5 measures)
    ▶ Hypertension (1 measure)
    ▶ Ischemic vascular disease (2 measures)
    ▶ Heart failure (1 measure)
    ▶ Coronary artery disease (2 measures)

• Where an ACO fails to meet minimum attainment levels for one or more domains, fails to report all required measures or provides inaccurate or incomplete recording, the ACO agreement may be terminated under certain conditions.

• An ACO must submit quality measures data to CMS in order to monitor and determine whether it has achieved minimal compliance with required benchmarks.

  • The level of compliance with these benchmarks will affect the percentage of savings that the ACO will be entitled to receive and distribute to its participants.
## Greater Legal Flexibility

- Certified ACO presumed to be “clinically integrated” for antitrust purposes as so to permit single signature managed care contracting and will review under rule of reason standard.
- Safety zone for market share in primary service area for each common service that is less than or equal to 30% in a geographic market defined as lowest number of postal zip codes where ACO participant draws at least 75% of its patients for that service.

## Greater Legal Flexibility (cont’d)

**Fraud and abuse waivers of Stark, Anti-Kickback and Civil Monetary Penalty Laws**

- **Pre-Participation Waiver:** Permits potential ACOs and ACO participants to share resources to start ACOs if the arrangement meets certain conditions.
- **Participation Waiver:** Allows arrangements between the ACO, one or more ACO participants and/or ACO providers/suppliers if the arrangement meets certain conditions.
- **Shared Savings Waiver:** Allows for distributions under the Shared Savings Program, subject to specified conditions, and for financial relationships among the ACO, ACO participants and ACO providers/suppliers directly related to participation in the Shared Savings Program.

## Greater Legal Flexibility (cont’d)

- **Compliance with the Stark Law Waiver:** Distribution of shared savings received by an ACO from CMS under the Shared Savings Program to or among ACO participants and ACO providers/suppliers, and activities necessary for and directly related to an ACO’s participation in the Shared Savings Program are waived from the Anti-Kickback Statute and the gain sharing portion of the CMP laws if such financial relationships fully comply with an applicable Stark Law exception.
- **Patient Incentives Waiver:** Waives the application of the CMP provisions prohibiting inducement of beneficiaries and the Anti-Kickback Statute for items or services provided by an ACO, ACO participants or ACO providers/suppliers to beneficiaries for free or below fair market value if certain requirements are satisfied.
The Integrated Delivery System

The Integrated Delivery System

- Hospitals
  - System Facilities
  - Specialty Facilities
  - 17 Community Hospitals
  - 15 Affiliate Community Hospitals
  - 24 Hospitals with Physicians
- Outpatient Facilities
  - Multiple ambulatory sites
  - Locations in 3 Counties

The Integrated Delivery System

- Physicians
  - Multi-Specialty Group
  - Multi-Specialty Group

The Integrated Delivery System

- Health Plan
  - Multi-Specialty Group
  - Multi-Specialty Group

The Integrated Delivery System

- Foundation
  - Multi-Specialty Group
  - Multi-Specialty Group
Summa’s Service Area

CI/ACO Business Model Process

Phase 1: Structure Development
- Craft action plan
- Milestones
- Interim strategies
- Potential structures
- Governance models
- Identify required resources
- Create organizational structure
- Set-up governance
- Define participation criteria
- Design care management structure
- Establish clinical protocol priorities

Phase 2: Population Management
- Identify IT interconnection plan
- Establish clinical automation
- IT resources
- Physician leadership
- Care management
- Create roadmap that identifies paper contracting opportunities
- Draft definitive business plan
- Identify plans for interim as well as long-term strategy
- Establish entity
- Develop protocols/measures
- Implement IT
- To be determined by organization
- Establish payer relationship(s)

Phase 3: Market Value to Payers
- Establish entity
- Develop protocols/measures
- Implement IT
- Propose for collecting and monitoring clinical results
- Begin data collection
- Implement related strategies
- To be determined by organization
- Establish payer relationships

Clinical Integration Building Blocks

Improved Quality and Access
- Medical Home Models
- Population Management
- Care Management
- Value-Based Payment Models

Reduce Costs and Waste
- Care Model
- Information Technology
- Organizational Structure
- Finance
- Managed Care
- Delivery Network

Improved Quality and Access
- Evidence-based care
- Patient/family engagement
- Health information technology
- Care coordination
- Population health

Reduce Costs and Waste
- Clinical variability
- Diagnostic and treatment interventions
- Preventive care
- Cost containment
- Community health

2013 Morrisey Technology and Educational Conference
Care Management Process

- Patient identification through:
  - Population stratification
  - Clinical qualifiers
  - Disease states
  - Frailty
  - Coordination needs

- Patient engagement at:
  - Home
  - Hospital, SNF
  - Care transitions
  - Telephonic

- Patient outreach when:
  - New patient
  - After PCP visit
  - 30 days post-acute
  - New diagnosis
  - New prescription

Impact on ACOs

- First Year Results – Pioneer ACOs.
  - Designed specifically for organizations experienced in offering coordinated, patient-centered care and operating in ACO-like arrangements.
  - Pioneer ACOs included:
    - Allina Health
    - Banner Health Network
    - Beth Israel Deaconess Physician Organization
    - Dartmouth – Hitchcock ACO
    - OSF Healthcare System
    - Sharp Healthcare System
    - University of Michigan

Impact on ACOs (cont’d)

- Beginning on January 2, 2012, for a period of two years there is a shared savings and shared losses payment arrangement with higher levels of rewards and risks than in the Shared Savings Program.
- By end of 2012, Pioneer ACOs must attest and CMS must confirm that at least 50% of ACO’s primary care providers have met meaningful use EHR requirements.
- Must meet quality reporting and cost targets.
Impact on ACOs (cont’d)

• Results
  • Savings/Costs
    - Costs for 669,000 beneficiaries grew by only .3% compared to .8% for a comparable patient population.
    - 13 out of 32 produced shared savings for a gross savings of $87.6 million and a net of $33 million for the Medicare Trust.
    - ACOs earned a share of $76 million.
    - 2 ACOs had shared losses totaling $4 million. Another 12 did not meet cost targets.

Impact on ACOs (cont’d)

• Quality
  - All successfully reported quality measures and earned incentive payments.
  - Most ACOs performed better for all clinical quality measures than published rates.
    - 25 of 32 had lower readmission rates.
    - All performed better on blood pressure controls.
    - Higher ratings on patient experience measures.
  - 70,000 hospital readmissions avoided.

Impact on ACOs (cont’d)

• Continued Participation?
  - Five ACOs with losses will remain in Pioneer program.
  - Seven with losses are moving to the Medicare Shared Savings Program – less risk.
  - Presbyterian Health Services and Plus ACO dropping out altogether in addition to seven physician run ACOs.
What is a PSO?

- PSOs are a creature of the Patient Safety and Quality Improvement Act of 2005 ("PSQIA") and not the Patient Protection and Affordable Care Act ("ACA").

Patient Safety and Quality Improvement Act (PSQIA) Purpose

To encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of health care; to promote rapid learning about the underlying causes of risks and harms in the delivery of health care; and to share those findings widely, thus speeding the pace of improvement.

- Strategy to Accomplish its Purpose
  - Encourage the development of PSOs
  - Establish strong Federal and greater confidentiality and privilege protections
  - Facilitate the aggregation of a sufficient number of events in a protected legal environment.
Long-Term Goals of the PSQIA

- Encourage the development of PSOs
- Foster a culture of safety through strong Federal and State confidentiality and privilege protections
- Create the Network of Patient Safety Databases (NPSD) to provide an interactive, evidence-based management resource for providers that will receive, analyze, and report on de-identified and aggregated patient safety event information

Further accelerating the speed with which solutions can be identified for the risks and hazards associated with patient care through the magnifying effect of data aggregation

Who or What Does the Act Cover?

- Provides uniform protections against certain disciplinary actions for all healthcare workers and medical staff members
- Protects Patient Safety Work Product (PSWP) submitted by Providers either directly or through their Patient Safety Evaluation System (PSES) to Patient Safety Organizations (PSOs)
- Protects PSWP collected on behalf of providers by PSOs, e.g., Root Cause Analysis, Proactive Risk Assessment

PSO Approach & Expected Results

Immediate Warning System
Comparative Reports
New Knowledge
Educational Products
Collaborative Learning
Essential Terms of the Patient Safety Act

- Patient Safety Evaluation System (PSES)
- Patient Safety Work Product (PSWP)
- Patient Safety Organization (PSO)

Patient Safety Evaluation System (PSES)

PSES Definition
- Body that manages the collection, management, or analysis of information for reporting to or by a PSO (CFR Part 3.20 (b)(2))
  - Determines which data collected for the PSO is actually sent to the PSO and becomes Patient Safety Work Product (PSWP)
  - PSES analysis to determine which data is sent to the PSO is protected from discovery as PSWP

Patient Safety Work Product (PSWP)

PSWP Definition
Any data, reports, records, memoranda, analyses (such as Root Cause Analyses (RCA)), or written or oral statements (or copies of any of this material) which could improve patient safety, health care quality, or health care outcomes;

And that:
- Are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a PSES for reporting to a PSO, and such documentation includes the date the information entered the PSES; or
- Are developed by a PSO for the conduct of patient safety activities; or
- Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES
What is NOT PSWP?

- Patient’s medical record, billing and discharge information, or any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP
- PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES and no longer considered PSWP if:
  - Information has not yet been reported to a PSO; and
  - Provider documents the act and date of removal of such information from the PSES

What is Required?

Establish and Implement a Patient Safety Evaluation System (PSES), that:

- Collects data to improve patient safety, healthcare quality and healthcare outcomes
- Reviews data and takes action when needed to mitigate harm or improve care
- Analyzes data and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
- Conducts RCAs, Proactive Risk Assessments, in-depth reviews, and aggregate RCAs
- Determines which data will/will not be reported to the PSO
- Reports to PSO(x)

PSO REPORTING

Identifiers of Patient Safety, Risk Management, Investigation & Data Collection

PSOS

Receipt and Response to Event/Concern, Investigation & Data Collection

Please, refer to the slide for the flowchart process.
Designing Your PSES

- Events or Processes to be Reported
  - Adverse events, sentinel events, never events, near misses, HAC, unsafe conditions, RCA, etc.
- Committee Reports/Minutes Regarding Events
  - PI/Quality committee, Patient safety committee, Risk Management committee, MEC, BOD
- Structures to Support PSES
  - PI plan, safety plan, RM plan, event reporting and investigation policies, procedures and practices, grievance policies and procedures

Types of Data PSES May Collect and Report To The PSO

- Medical Error, FMEA or Proactive Risk Assessments, Root Cause Analysis
- Risk Management – incident reports, investigation notes, interview notes, RCA notes, notes rec’d phone calls or hallway conversations, notes from PS rounds
- Outcome/Quality—may be practitioner specific, sedation, complications, blood utilization etc.
- Peer Review
- Committee minutes—Safety, Quality, Quality and Safety Committee of the Board, Medication, Blood, Physician Peer Review

Risk Management & Patient Safety Events Flow
Impact on PSOs

- ACA includes section 1311(h) titled “Quality Improvement” under “Part 2 – Consumer Choices and Insurance Competition Through Health Benefit Exchanges”.

- This section states as follows:
  - (1) ENHANCING PATIENT SAFETY—Beginning on January 1, 2015, a qualified health plan may contract with
    - (A) A hospital with greater than 50 beds only if such hospital—
      - Utilizes a patient safety evaluation system as described in part C of title IX of the Public Health Service Act; and
      - Implements a mechanism to ensure that each patient receives a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional; or
    - (B) a health care provider only if such provider implements such mechanisms to improve health care quality as the Secretary may by regulation require.
  - (2) EXCEPTIONS—The Secretary may establish reasonable exceptions to the requirements described in paragraph (1).
  - (3) ADJUSTMENT—The Secretary may by regulation adjust the number of beds described in paragraph (1)(A).
Impact on PSOs (cont’d)

- A PSES is defined under the PSQIA as information collected, managed or analyzed for reporting to an AHRQ approved PSO.
- Therefore, many PSOs and others have interpreted the provision and cross reference to the PSQIA as requiring hospitals to contract with a listed PSO in order to contract with a qualified health plan offered through a state insurance exchange even though Congress did not clearly express this intention in the ACA.
- Various questions remain.
  - Many of the 79 AHRQ approved PSOs have a specialty focus, i.e., breast cancer, pediatric anesthesia. It is not clear whether a hospital participating in a specialty PSO will satisfy this ACA provision.

Impact on PSOs (cont’d)

- Provision allows for exceptions to the requirements in Part (1) such as the number of beds or an alternative mechanism to contracting with a PSO.
- Some states require hospitals to contract with a PSO agency and under state law. There are differences in the state and federal provisions. If ACA requires a hospital to contract with an AHRQ listed PSO, then hospital may be required to contact with both.
- Is contracting with a PSO sufficient? How is the term “utilize” to be interpreted?
- AHA has been working with the Center for Consumer Information and Insurance Oversight (“CCIIO”) within HHS which is responsible for promulgating regulations related to health insurance marketplaces.
- Regulations are expected but date of issuance not yet know.

Impact on Health Care Professionals and Boards

- Compliance with ACO quality performance standards will be mandated in order to remain eligible for the Shared Savings Program and will affect the percentage of savings that can be shared among ACO participants.
- Physicians will likely be required to produce their own quality/utilization report card at time of appointment/reappointment.
- Hospitals not yet aligned with a system or an ACO will be expected to produce their own report card.
- Physicians/AHPs likely will be denied membership if not performing up to standard.
Impact on Health Care Professionals and Boards (cont’d)

- Standards need to be developed that track ACO measures, VBP measures, and P4P measures, and ensure that they are communicated to providers and then monitored for compliance.
- Providers need to receive periodic reports regarding their individual and comparative performances—need to maximize confidentiality protections.
- Performance results should be taken into consideration at the time of appointment, reappointment, and contract renewal, and some internal administrative process/fair hearing for participants who are excluded should be provided.

Impact on Health Care Professionals and Boards (cont’d)

- Compliance plans need to be updated or prepared which reflect the provider’s commitment to improving quality as per the areas identified by the OIG—Boards and senior management will be held accountable.
- Even if not seeking ACO certification at this time, hospital should review the ACO final rules as a future standard on which private and public reimbursement and standards of care will be based.

Impact on Health Care Professionals and Boards (cont’d)

- A failure to comply with ACO, VBP, and other developing standards, including a pattern of HACs and Never Events, may also have a direct or indirect impact on provider responsibilities:
  - Accreditation and license standards
  - Doctrine of corporate negligence and related civil liability theories
  - DOJ/OIG expectations on board responsibility for delivering quality health care services which could trigger False Claims Act exposure (Azmat case)
  - ACO’s, hospitals, providers need to design their quality, peer review, and risk management procedures in a way so as to maximize confidentiality, privilege and community protections.
Remaining Questions

- Is or can an ACO be a health care entity for HCQIA query, reporting and immunity purposes?
- Under what circumstances can an ACO be considered a “provider” under the Patient Safety Act for purposes of participating in a patient safety organization?
- Is an ACO eligible for or what criteria must be met in order to qualify for state confidentiality/immunity protections?
- Can an ACO attempt to qualify as a Patients Safety Organization (“PSO”)?
- What risks, if any, are there if different credentialing/privileging/peer review standards are developed for ACOs versus hospitals?

Remaining Questions (cont’d)

- Can an ACO be held liable under negligent credentialing/corporate negligence/apparent agency or related liability principles?
- How does an ACO best incorporate/implement ACO quality metrics, value based purchasing and similar quality standards as part of its credentialing/privileging/ peer review procedures?
- Does the sharing of peer review, credentialing or otherwise protected information by and between a hospital/ACO and other providers in the ACO adversely affect confidentiality protections? What are ways to structure information sharing arrangements in order to maximize confidentiality protections?

Remaining Questions (cont’d)

- How will an ACO balance the requirement to provide quality and utilization data to payers against the need or preference to keep certain information confidential?
- Should hearing procedures be the same for ACOs and hospitals or should and can they be more streamlined? Can they be modified and still maintain HCQIA and other immunity protections?
Remaining Questions (cont’d)

- Will or should the standards for remedial/corrective action be different, i.e., should overutilization or failure to satisfy quality metric standards, which in turn can reduce shared savings or other forms of reimbursement, serve as a basis for action, including termination?

- What should be the inter-relationship between ACO and medical staff/AHP membership and ACO membership? Should removal from one result in removal from the other?