



2012 Update: Impact of Accountable Care Organizations (ACOs) and Health Care Reform on Credentialing, Privileging, and Peer Review

May 18, 2012

**Massachusetts Association of
Medical Staff Services
29th Annual Education Conference**

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Overview of Different Provider Arrangements and Role of Board of Directors

May 10, 2012



That's more than healthcare. That's smartcare.

- **Overview of New Alignment Initiatives**
- **Board of Directors oversight of new Performance Standards**
- **Review Methods for Credentialing/Privileging Providers using New Metrics**
- **Review OIG/DOJ Quality Enforcement Initiatives**
- **Utilization of PSOs in era of Quality Data Collection**

"The Moment It All Changed"



Modern Healthcare
THE ONLY HEALTHCARE BUSINESS NEWS WEEKLY MARCH 29, 2010 \$5.50

OBAMA SIGNS SWEEPING HEALTHCARE REFORM BILL AFTER PASSAGE BY THE HOUSE

THE MOMENT IT ALL CHANGED

Every sector of the industry starts sifting through hundreds of pages of legislation to assess the law's financial and regulatory impact / Page 6



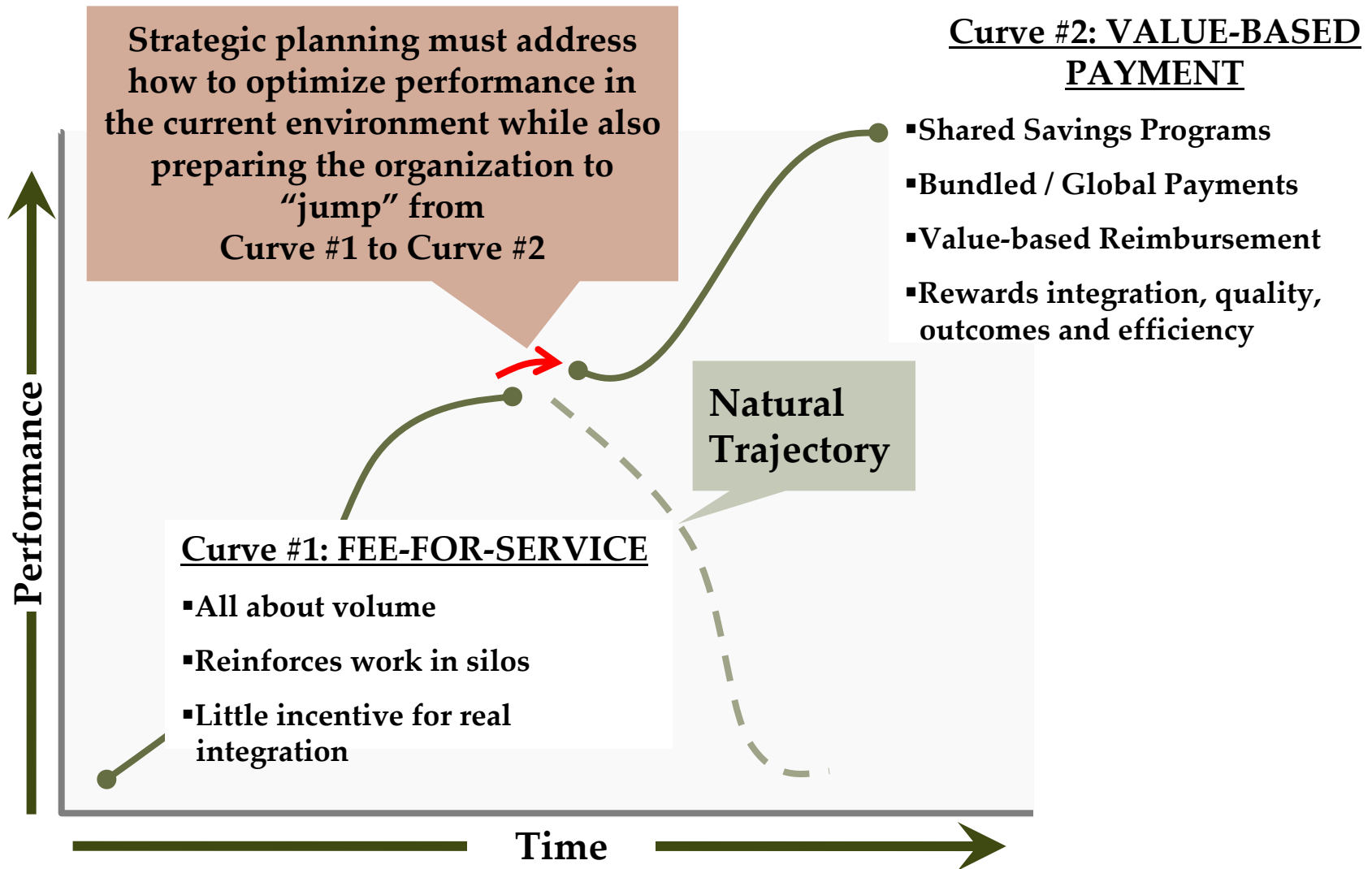
U.S. HOUSE - HEALTH CARE		LIVE	
HOUSE PASSES SENATE BILL			
AHEAD - Vote on Reconciliation Bill			
10:47 pm ET			
H R 3590			
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DEMOCRATIC	219	34	
REPUBLICAN	176		2
INDEPENDENT			
TOTALS	219	210	2
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Source: *Modern Healthcare*; Vol. 40 No. 13; March 29, 2010

Not Just Live in Fee-for-Service World, But Live in World of:

- **Health Reform**
- **Accountable Care Organizations**
- **CMS Bundled/Episodic Payment Program**
- **Hospital Value-Based Payment Program**
- **Patient Centered Medical Homes**
- **Deployment of Co-Management of Service Lines/Institutes**
- **Pay-For-Performance Models**
- **Evolving Physician Compensation Models**

Living in Two Worlds: *Jumping to "Curve 2"*

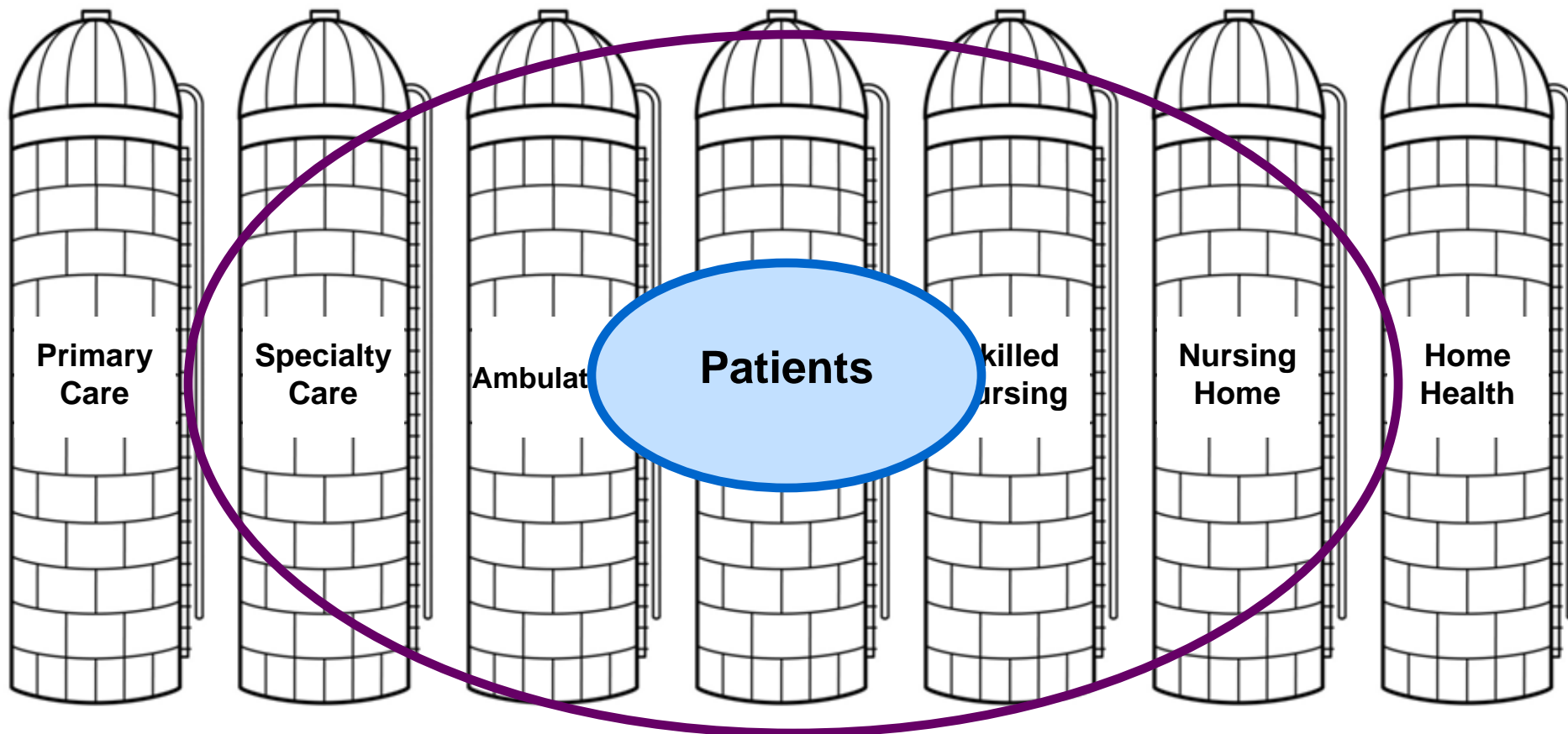


Berwick “Triple Aim”: Basis for Accountable Care

- **Better Care**
- **Better Outcomes**
- **Lower Health Care Costs**



Delivery of Accountable Care



Conditions of Participation

- **Operational Requirements:**
 - Participation in educational initiatives
 - Practice open to all new enrollees
 - Quality Assurance Program to hold providers accountable for outcomes improvement
- **Quality of Care Requirements:**
 - Adherence to ACO Care Models
 - Meet defined objective metrics including HEDIS, SCIP and CORE measures
- **Clinical Information Exchange Requirements:**
 - Utilization of ACO approved EMR
 - Exchange of clinical and demographic information necessary for ACO operations

ACO Surplus Payment Criteria: PCP

Incentive	Performance Measure	Benchmarks
50% PCP	Number of Enrollees	10 Enrollees per PCP
12.5% PCP	Patient Outcomes evidenced by HEDIS measures (e.g., Diabetes A1c control >9), Blood Pressure Control >140/90, Diabetes Cholesterol Control (LDL <100)	Improve on existing % by 10% or exceed 75% of HEDIS regional threshold
12.5%	Advance Care Model development by integration of Care Model templates into practice and timely completion of Health Risk Assessments (“HRA”)	Complete 50% of HRAs by end of year
12.5%	Attend 1 education session on patient care process improvement	Documented Attendance
12.5%	CG CAHPS Survey (e.g., getting appts, Dr. communication, helpful office staff, Dr. rating, f/u test results)	Exceed benchmark in 3 of 5 categories

ACO Surplus Payment Criteria: Specialist



Incentive	Performance Measure	Benchmarks
50% Specialist	Number of Enrollees	5 Enrollees per Specialist
12.5% Specialist	Patient Outcomes evidenced by Timely Consultation to PCP, and Standard Consult Report	20% of consultation reports received by PCP within 7 days
12.5% Specialist	Advance Care Model development by integration of Care Model templates into EMR	Introduction of charting templates into EMR
12.5% Specialist	Attend 1 education session on patient care process improvement	Documented Attendance
12.5%	CG CAHPS Survey (e.g., getting appts, Dr. communication, helpful office staff, Dr. rating, f/u test results)	Exceed benchmark in 3 of 5 categories

- **Patient/Caregiver Experience (7 measures)**
 - CAHPS Patient Satisfaction Surveys
- **Care Coordination/Patient Safety (6 measures)**
 - Readmission Rates
 - Management of Ambulatory Sensitive Conditions
 - Electronic Health Records Implementation
- **Preventive Health (8 measures)**
 - Preventive Screenings
- **At-Risk Populations (12 measures)**
 - Measures impacting care of Diabetes, Hypertension, IVD, Heart Failure and Coronary Artery Disease

CMS Bundled Payment Program



	Model 1: Inpatient Hospital Stay	Model 2: Inpatient Stay + Post discharge Services	Model 3: Post discharge Services Only	Model 4: Inpatient Stay Only
SERVICE	Inpatient hospital services	Inpatient hospital + Physician Services and related post-acute care services	Post-acute care services and related readmissions	Inpatient hospital and physician services and related readmissions
CONDITION	All MS-DRGs	Applicant to propose based on MS-DRGs for inpatient hospital stay		
Payment/Expected Discount	Discounted IPPS payment; 0% for first 6 months, increasing to 2% in year 3	Retrospective Comparison of Target Price/Actual FFS Payments; Minimum of 3% for 30-89 days post discharge; minimum 2% for > 90 days post discharge	To be proposed by applicant	To be proposed by application, subject to minimum 3% discount

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- **Beginning in October 2012, Hospitals will begin to receive payment based on quality of inpatient care delivered to patients**
- **CMS will pay for meeting minimum performance standards around various quality metrics over a defined time period**
- **Metrics for FY 2013 payments**
 - 12 clinical process of care measures on heart failure, AMI, pneumonia and surgical care and 8 HCAHPS dimensions
- **Metrics for FY 2014 payments**
 - 13 clinical process measures; 8 Hospital Acquired Conditions measures; 3 outcomes measures – 30-day mortality

- **Agreements to reward Physicians for managing and improving Hospital Service lines. Payment metrics typically include the following:**
 - Supply Chain Standardization (e.g. product standardization)
 - Quality Improvement through meeting benchmarks including clinical care guidelines
 - Cost Containment (e.g. OR efficiency, staffing efficiency)
 - Patient/Staff Satisfaction
 - Disease Management/Population Health Programs

- **Networks of physicians who become Clinically and Financially integrated to deliver care**
- **Meet FTC/DOJ guidelines in order to collectively negotiate with Payers**
- **Develop care models/pathways which all Physicians must follow as target certain disease states**
- **Define quality benchmarks based on (i) policies/procedures developed by entity, (ii) industry related benchmarks, (iii) evidenced based pathways, or (iv) specific payor requirements**

Employed Physician Compensation Models



- **Rapid Increase of Number of Employed Physicians beginning in Mid-2000s**
- **Initially, pay strictly for production or RVUs**
- **Current transformation of compensation model includes metrics around Quality, Citizenship, Patient Satisfaction, Financial and other goals**
- **For Physicians that do not meet Quality standards, common responses include (i) compensation adjustment either through withhold of payment or failure to pay bonus, (ii) mentoring, or (iii) termination with or without cause**

METRIC

Patient Access (e.g., time to get appointment)

Panel Size (e.g., # of unique patients)

Mid-Level Provider Supervision

Care Coordination Fee (e.g., PMPM)

Medical Home Development

**Chronic Disease/Ambulatory Condition Management
(e.g., Diabetes)**

New Metrics: Specialists

METRIC

Timely Consults (measured by PCP survey or set timeframe)

Clinical Co-Management Services (e.g., OR, staffing efficiency)

Care Coordination

Post-Discharge Telemonitoring/Summary to PCP

Readmissions Reduction Program

Medication Reconciliation

On-Time Surgical Starts

Discharge Planning

Patient Access to Specialist Appointment

METRIC

Inpatient SCIP & Core Measures

NCQA/HEDIS/NQF Standards

Care Model Development/Adoption

Patient Outcomes around Identified Conditions

Completed Health Risk Assessments/Screening Exams

33 ACO Quality Metrics

Use of Disease Registries

PREVENTIVE MEASURES

Mammogram Screening

Colon Cancer Screening

Cervical Screening

Osteoporosis Screening

Influenza Vaccination

Pneumonia Vaccination

Blood Pressure Screening

Eye/Foot Exams

Cholesterol Screening

Patient Satisfaction Metrics



METRICS

CG CAHPS

Press Ganey/Studer/Southwind

Peer-Peer Reviews

Staff-Peer Reviews

Patient Phone Surveys

360 Surveys

METRICS

Timely Medical Record Completion

Successful Coding Audits

Call Coverage (e.g., OPPS)

Follow System Standards of Behavior

IT Adoption

Meeting Attendance

Risk Management/Compliance Education

- **PCMH puts patients at the center of the health care system, and provides comprehensive primary care**
- **Key Components of PCHM include:**
 - Personal Physician who coordinates all care for patient and serves as leader of Care Team
 - Care Team to coordinate care for patient across entire spectrum of care
 - Holistic approach to patient to provide comprehensive care
 - Open-Access scheduling/virtual visits/emails
 - Focus on Patient Safety/Quality Improvement
 - Reimbursement driven by value of Coordinated Care

Features of PCMH

Enhanced Access

- Extended Hours, Open Schedule
- Internet, e-mail

Increased same day access avoids ER and increase continuity

Quality and Safety

- Evidence Based Medical care
- QI projects at the practice level

Coordinated/Integrated Care

- Registries
- Proactive care
- Information Technology
- Health Information Exchange
- Chronic care coordination
 - ✓ Internal/external care coordination
 - ✓ Part of a patient's health plan

Reduced duplication and improved coordination across the spectrum of care

Physician Directed Medical Practice Team

- Team approach
 - ✓ Low complexity tasks handled by other members of the team
 - ✓ Team members can be internal/external
- Collaborative relationship between physician and non-physician practitioners

Personal Physician & Whole Person Orientation

- First contact, continuous and comprehensive care
- Contextual Care

Having a usual source of care is associated with a greater likelihood that people receive appropriate care, preventive care, better outcomes, lower cost

MEASURE	DOMAIN
Breast Cancer Screening	Preventive Care
Colorectal Cancer Screening	
Childhood Immunization	
Diabetes-HbA1c Testing	Chronic Care
Diabetes-HbA1c Level	
Diabetes-BP Level	
Diabetes-LDL Level	
Diabetes-Kidney Disease Screening	
Diabetes-Eye Exam	
Diabetes-Foot Exam	Chronic Care
Hypertension-BP Level	

PCMH Metrics (Cont.)



MEASURE	DOMAIN
CAD-BP Level	Chronic Care
CAD-Lipid Level	
CAD-Documented Care Plan	
CAD-Antiplatelet Rx	
CAD-Beta-Blocker Rx Prior Myocardial Infarction (MI) or LVEF <40%	
CAD-ACE/ARB Rx for Diabetes or LVSD	
CAD-BP Level	
CAD-Lipid Level	
CAD-Documented Care Plan	
CAD-Antiplatelet Rx	
CAD-Beta-Blocker Rx Prior Myocardial Infarction (MI) or LVEF <40%	

MEASURE	DOMAIN
Heart Failure-BP Level	Chronic Care
Heart Failure-Lipid Level	
Heart Failure-Measure of LV function	
Heart Failure-Beta-Blocker Rx with LVSD	
Heart Failure-ACE/ARB Rx with LVSD	
Heart Failure-Warfarin Rx with Atrial Fibrillation	
ED Visit-PCP Visit after Discharge-Hospitalization	Cost
CAHPS Survey-primary care focus	Patient/ Provider Satisfaction
Provider Survey-assess provider's PCMH experience	
Referral Tracking	Care Coordination

NCQA PCMH Recognition Program



NCQA certification consists of six (6) standards with 100 points to achieve Level 3 certification, 85-100 points and 6 of 6 must-pass elements.

** Indicates a must-pass element

NCQA Standard	Points	NCQA Standard	Points
PCMH 1: Enhance Access and Continuity		PCMH 4: Provide Self-care Support and Community Resources	
A. Access during office hours**	4	A. Support self-care process**	6
B. After-hours access	4	B. Provide referrals to community resources	3
C. Electronic access	2	Total Points	9
D. Continuity	2	PCMH 5: Track and Coordinate Care	
E. Medical home responsibilities	2	A. Test tracking and follow up	6
F. Culturally and linguistically appropriate services	2	B. Referral tracking and follow up**	6
G. Practice team	2	C. Coordinate with facilities/care transitions	6
Total Points	20	Total Points	18
PCMH 2: Identify and Manage Patient Populations		PCMH 6: Measure and Improve Performance	
A. Patient information	3	A. Measure performance	4
B. Clinical data	4	B. Measure patient/family experience	4
C. Comprehensive health assessment	4	C. Implement continuous quality improvement**	4
D. Use data for population management**	5	D. Demonstrate continuous quality improvement	4
Total Points	16	E. Report performance	3
PCMH 3: Plan and Manage Care		F. Report data externally	3
A. Implement evidence-based guidelines	4	Total Points	3
B. Identify high-risk patients	3		2
C. Care management**	4		20
D. Manage medications	3		
E. Use electronic prescribing	3		
Total Points	17		

- **Accountable Care Organizations**
 - Medicare Shared Savings Program (MSSP)
 - 27 ACOs—April 1 Start Date
 - 150 ACOs—Applied for July 1 Start Date
 - 32 organizations—CMS Innovative Center Pioneer Program
 - 6 organizations—Physician Group Practice Transition Demonstration ACOs
- **Bundled Payment Program**

- **Center for Medicare Innovations (“CMII”)**
 - Variety of Demonstration Projects around Care Coordination and Innovative Models of Care Delivery
- **Commercial Payers**
 - United Health Group seeks to replace its current fee-for-service payment model with plan that will compensate Physicians and Hospitals for meeting quality benchmarks—*Wall Street Journal, February 9, 2012*
 - By 2015, 50%-70% of United Health’s 26 million members will be covered by value-based contracts

TRANSITION TO NEW FORMS OF CREDENTIALING/PRIVILEGING

Transition of Credentialing Providers in New Initiatives



Board/Medical Staff Actions Around Quality Metrics



- **Historically, the Board of Directors of the Hospital delegated credentialing/privileging decisions to the Medical Staff to govern inpatient/outpatient privileges based on a threshold level of competency**
- **The Medical Staff policed its members through creating disciplinary process to investigate and act upon complaint filed against its members. However, the Medical Staff did not create specific quality benchmarks to evaluate its Physicians performance**

Evolution of Health Care and Impact on Credentialing

- **New entities seek to assess initial and ongoing qualifications of providers**
- **Organization must define new levels of baseline competency and create infrastructure to measure quality of care delivered**
- **Challenges include creating the IT infrastructure necessary to mine the data to properly evaluate quality of care**
- **Need to Develop effective means for reporting and addressing quality concerns and protecting the privacy of the data**
- **Create mechanism to track and report individual performances against defined benchmarks**

- **Accountable Care Organizations**
 - Delivery Network or Physician Panel typically created through invitation process to like-minded Physicians
- **Clinical Value or Other Committee delegated by ACO Board authority to define and address performance around quality standards**
- **CMS MSSP Performance Metrics (33 metrics)**
 - 1st Year: Report Only
 - 2nd, 3rd Year: Report and Perform
- **CMS program requires ACOs to institute a Corrective Action/Performance Improvement Plan**
 - Remedial Process to ensure that Physicians meet the performance criteria necessary for (i) Shared Savings Distribution, or (ii) continued participation in the ACO

- **In contrast to due process rights of Medical Staff members, Employed Physicians have contractually designated process to address lack of performance which typically includes (i) mentoring, (ii) notice and right to cure, or (iii) termination with or without cause**
- **To ensure Group performance, mechanisms include:**
 - Front-End Due Diligence
 - Physician Advisory Council (e.g. Mentoring, Proctoring)
 - Compensation Committee/Comp Model create financial incentive to perform against benchmarks
 - Sharing Information with Medical Staff

- **Bundled Payment:**

- The Hospital will perform front-end due diligence to ensure highest quality providers participate in program in choosing the conditions it will discount to CMS.
- Based upon Hospital participation in the program, Medical Staff and Hospital administration will need to be proactive in ensuring all physicians on its staff meet program criteria
- Gainsharing will serve as a financial inducement to behavior modification but will need right to remove physicians who refuse to modify behavior

- **Medical Homes:**
 - In light of certification requirements, Medical Homes utilize enhanced peer review in order to ensure compliance with certification standards
- **Co-Management**
 - Contractual right to terminate agreement or to reduce payment based upon failure to meet pre-defined metrics
- **Value-Based Purchasing Program**
 - Meet Quality metrics to avoid payment reduction
- **Clinical Integrated Networks**
 - Define clinical care benchmarks for members based upon organizations own standards and those of payers

- **The traditional Medical Staff continues to address behavioral, competency and other complaints brought against Medical Staff Members**
- **The Medical Staff has the authority to address issues with both employed and independent physicians without regard to their participation in any new initiatives**
- **In light of Hospital Value-Based Purchasing Standards, Medical Staff will need to develop new competency standards to ensure Hospital does not experience declining reimbursement**
- **Standards no longer defined in Bylaws, but in Membership, Employment or in other Contracts**



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Introduction

Kate Conklin has over twenty five years experience in the healthcare field that relates to the self-governed Medical Staff Organization. Kate's expertise is creating and sustaining a collaborative working relationship with hospital administrators and physicians and educating on the importance of understanding the value of that partnership in providing high quality healthcare. Kate has worked extensively with physician leaders within Medical Staff organizations in carrying out their roles and responsibilities in quality initiatives for professional credentialing, clinical privileging, and peer review. In her current role as a hospital Vice President of Quality & Medical Staff Services, Kate provides leadership for the hospital's Medical Staff Services Department, Risk Management, and Quality Management and oversight of the organization's patient safety program and regulatory and accreditation surveys.

Kate has served in various leadership positions on State and National Associations and is the immediate Past President of the National Association Medical Staff Services (NAMSS).

Quality Metrics in Credentialing

A look back

- Cost-Based Reimbursement
- HMO's, PPO's
- IPPS (DRGs)
- Managed Care
- Stark I and Stark II
- Medicare Fraud and Abuse Reporting

Competency based solely on patient outcomes during this time.

Quality Metrics in Credentialing

The “Accountable” Care Era

The healthcare “team” is redefined.

- Physicians (employed and non-employed,
- All healthcare providers
- Administrators
- Board of Trustees

Quality Metrics in Credentialing

Hospitals Have been Challenged for years in the collection of meaningful clinical performance data.

Some examples:

- Traditional Peer Review

- Tissue Review / Surgical Appropriateness

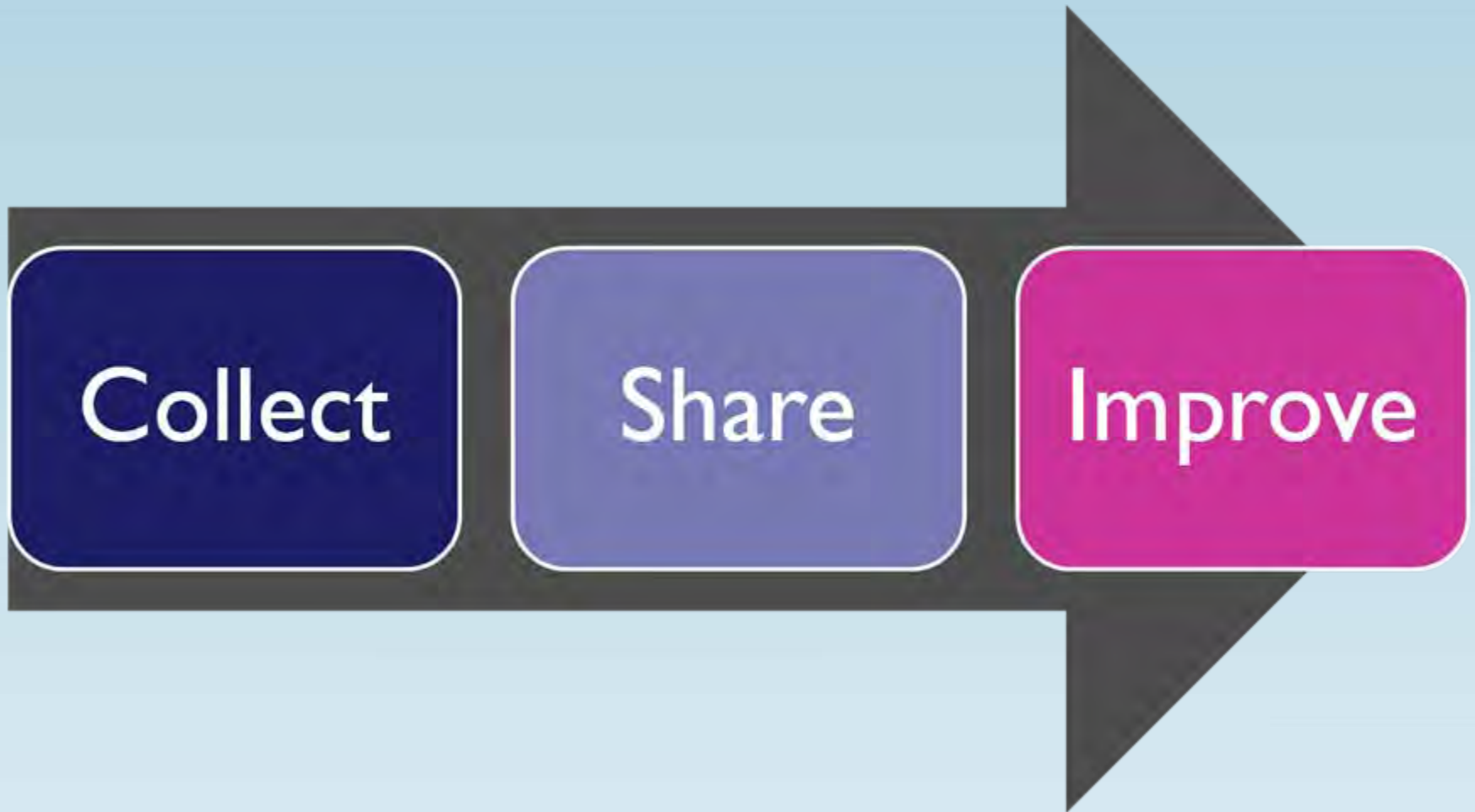
- Utilization Review (ALOS)

- Mortality and Complication Rates

- Medical Record Completion

Data collection not always from a “source of truth.”

Quality Metrics in Credentialing



Quality Metrics in Credentialing

Joint Commission Standards Related to Ongoing Professional Practice Evaluation (2008)

Key Components of Standard:

Ongoing (more frequent than every two years)

Specialty-specific indicators

Integrated with performance improvement

Quality Metrics in Credentialing

ACO and VBP Metrics:

Provides sharper focus on “what” to measure. The era of Pay for Performance and the financial impact of physician performance has grabbed the attention of every healthcare organization across the country.

Quality Metrics in Credentialing

Clinical Performance Areas that are now tied to reimbursement:

- Evidence Based Medicine (Clinical Process Measures)
- Patient Perception (HCAHPS)
- Hospital Readmissions
- Hospital Acquired Conditions
- Never Events

Quality Metrics in Credentialing

Evidence Based Medicine: Clinical Process of Care Measures

- Acute Myocardial Infarction
- Heart Failure
- Pneumonia
- Surgical Care Improvement and healthcare associated infections.

Quality Metrics in Credentialing

Patient Perception of Care (HCAHPS)

(Hospital Consumer Assessment of Healthcare Providers and Systems)

- Communication with Nurses
- **Communication with Doctors**
- Responsiveness of Hospital Staff
- **Pain Management**
- **Communication about Medications**
- Cleanliness of Hospital Environment
- **Discharge Information (instructions)**
- Overall Rating of Hospital

Quality Metrics in Credentialing

Hospital Readmission (within 30 days)

- All-cause readmission for acute MI, congestive heart failure, and pneumonia.

Quality Metrics in Credentialing

Hospital Acquired Conditions

- Never Events (Completely avoidable)
- Harm Events (pressure ulcers, poor glycemic control)
- Infections: CLABSI, CAUTI

Quality Metrics in Credentialing

Challenges

- Finding the Source of Truth (coding, chart review)
- Physician Engagement and Education
- Consistent Data Reporting
- Office-Based Physicians – what is their role and how is performance assessed?
- Employed and Non-employed physicians

Quality Metrics in Credentialing

Solutions

- “Focus” the data collection.
- Allocate the resources.
- Foster a culture of transparency in your organization.
- Create a physician report card!
- Physician report cards will become part of the data-sharing between healthcare organizations and used during routine credentialing.

Physician Profile for Value Based Purchasing

Core measures

- Acute myocardial infarction (AMI), heart failure, pneumonia

HCAHPS

- Communication with physician; courtesy and respect, listens carefully, explains things, pain management.

Hospital acquired conditions

- Central line blood stream infections (CLABSI)
- Catheter associated urinary tract infection (CAUTI)

Outcomes

- Readmission rate
- Complication rate
- Mortality rate

Terms

Achievement: Average score

Benchmark: 90th %ile

Total is the higher of achievement or improvement score

Total VBP score is the sum of the total/possible points (83/130=63.8%)

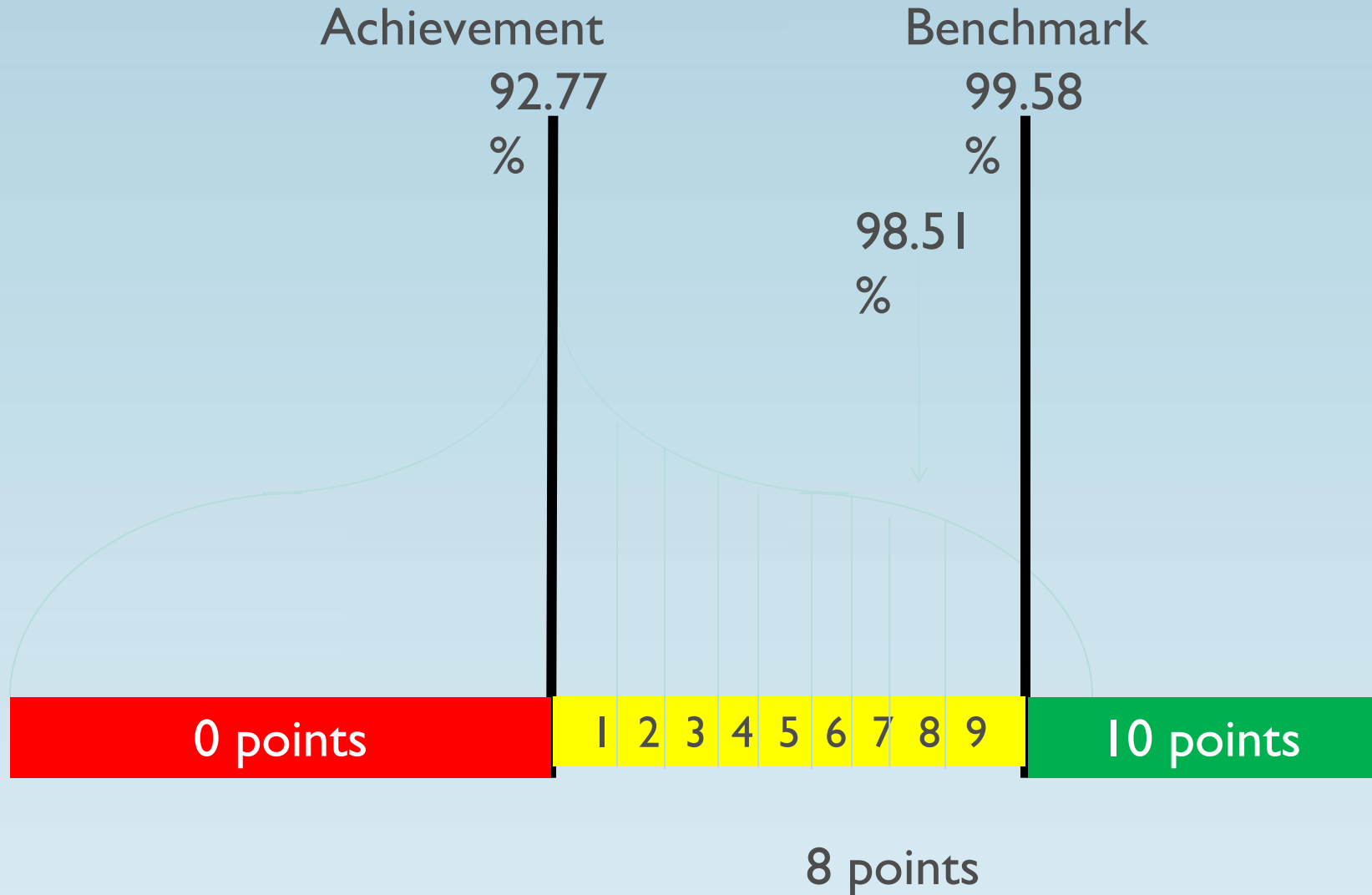
Green is > benchmark

Yellow is between achievement and benchmark

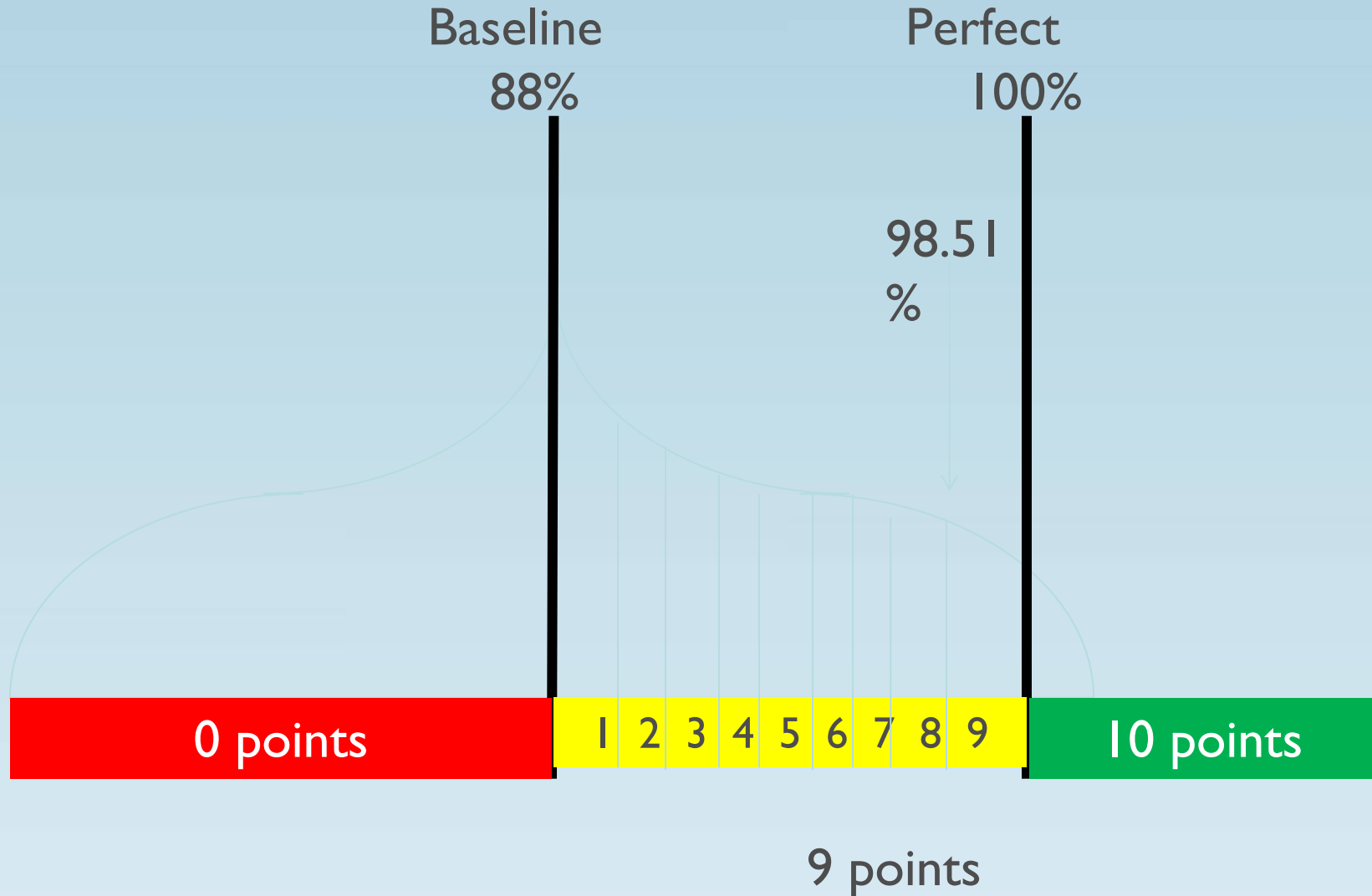
Red is below achievement

Outcomes are compared to expected using Case Mix (Achievement is 1.0, .8 is 20% below expected)

How are Achievement points calculated?



How are improvement points calculated?





Enforcement Initiatives Focusing on Quality of Care

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Corporate Responsibility in Health Care Quality

- In 2007 the OIG and AHCA collaborated on a publication titled “Resource for Health Care Boards of Directors on Corporate Responsibility and Health Care Quality”
- Was published “for the specific purpose of identifying the role and responsibility of corporate boards and management with respect to its fiduciary obligations to meet its charitable mission and legal responsibilities to provide health care quality services”
- Cites ten key questions reflective of standards against which hospital boards will be measured

Corporate Responsibility in Health Care Quality (cont'd)

- What are the goals of the organization's quality improvement program?
 - What metrics and benchmarks are used to measure progress towards each of the performance goals? How is each goal specifically linked to management accountability?
 - How does the organization measure and improve the quality of patient/resident care? Who are the key management and clinical leaders responsible for these quality and safety programs?
 - How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?

Corporate Responsibility in Health Care Quality (cont'd)

- Does the board have a formal orientation and continuing education process that helps members appreciate external quality of patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?
- What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board receive reports about the quality improvement effort?

Corporate Responsibility in Health Care Quality (cont'd)

- Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?
- Do the organization's competency assessment and training, credentialing and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?
- How are these "adverse patient events" and other medical errors identified, analyzed, reported and incorporated into the organization's performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization's liability exposure?

Corporate Responsibility in Health Care Quality (cont'd)

- How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization's risk management and corrective action plans?
- What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report programs? What guidelines exist for reporting quality and patient safety concerns to the board?

Examples of Quality Enforcement Efforts

- The OIG has identified that its principal enforcement tools include allegations of violations of the False Claims Act, use of corporate integrity agreements, including the use of external quality of care monitors, as well as civil fines and, in extreme circumstances, exclusion from the Medicare program
- The OIG has made the following statements:

“To hold responsible individuals accountable and to protect additional beneficiaries from harm, the OIG excludes from participation in federal health care programs individuals and entities whose conduct results in poor care. In enforcement actions against corporate entities, . . . OIG places particular emphasis on high level officials, such as owners and chief executive officers. . . .”

Examples of Quality Enforcement Efforts (cont'd)

- Grand Jury indicted a Michigan hospital based on its failure to properly investigate medically unnecessary pain management procedures performed by a physician on the medical staff.
- A California hospital paid \$59.5 million to settle a civil False Claims Act allegation that the hospital inadequately performed credentialing and peer review of cardiologists on its staff who perform medically unnecessary invasive cardiac procedures.

Examples of Quality Enforcement Efforts (cont'd)

- In a settlement with Tenet Health Care Corporation and pursuant to a Corporate Integrity Agreement, a hospital board was required to:
 - Review and oversee the performance of the compliance staff.
 - Annually review the effectiveness of the compliance program.
 - Engage an independent compliance consultant to assist the board and review an oversight of tenant's compliance activities.
 - Submit a resolution summarizing its compliance efforts with the CIA and federal health care program requirements, particularly those relating to delivery of quality care.
- A Pennsylvania hospital recently entered into a \$200,000 civil False Claims Act settlement to resolve substandard care allegations related to the improper use of restraints.

Examples of Quality Enforcement Efforts (cont'd)

- Rogers v. Azmat (2010)
 - DOJ interviewed in a False Claims Act lawsuit alleging that Satilla Regional Medical Center and Dr. Najam Azmat submitted claims for medical substandard and unnecessary services to Medicare and Medicaid . The complaint alleges, among other things, that the defendants submitted claims for medical procedures performed by Dr. Azmat in Satilla's Heart Center that the physician was neither qualified nor properly credentialed to perform. As a result, at least one patient died and others were seriously injured.

Examples of Quality Enforcement Efforts (cont'd)

- The complaint states that Satilla placed Dr. Azmat on staff even after learning that the hospital where he previously worked had restricted his privileges as a result of a high complication rate on his surgical procedures. The complaint also states that after Dr. Azmat joined the Satilla staff, the hospital management allowed him to perform endovascular procedures in the hospital's Heart Center even though he lacked experience in performing such procedures and did not have privileges to perform them.

Examples of Quality Enforcement Efforts (cont'd)

- The complaint further states that the nurses in Satilla's Heart Center recognized that Dr. Azmat was incompetent to perform endovascular procedures and repeatedly raised concerns with hospital management. Despite the nurse's complaints and Dr. Azmat's high complication rate, Satilla's management continued to allow him to perform endovascular procedures and to bill federal health care programs for these services.

The Changing Healthcare Landscape

(cont'd)

- Increased enforcement
 - 2012 OIG Work Plan
 - Reliability of hospital-reported quality measures data
 - Hospital admissions with conditions coded as “present-on-admission” and accuracy of “present on admissions” indicators
 - Review of Medicaid payments for HACs and never events
 - Acute-care inpatient transfers to inpatient hospice care
 - Safety and quality of surgeries and procedures in surgicenters and hospital outpatient departments

The Changing Healthcare Landscape

(cont'd)

- Quality of care and safety of residents and quality of post-acute care for nursing homes
- Hospital reporting of adverse events
- Hospital same-day readmissions
- Hospitalizations and re-hospitalization of nursing home residents
- Review effectiveness of PSO programs

The Changing Healthcare Landscape

(cont'd)

- January, 2012 OIG Report: “Hospital Incident Reporting Systems Do Not Capture Most Patient Harm”
 - All hospitals have incident reporting systems to capture events and are heavily relied on to identify problems
 - These systems provide incomplete information about how events occur
 - Of the events experienced by Medicare beneficiaries, hospital incident reporting systems only captured an estimated 14% due to events that staff did not perceive as reportable or were simply not reported
 - Accrediting bodies only review incident reports and outcomes but not the methods used to track errors and adverse events

So Now What?

- 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
- 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

So Now What? (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 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)

So Now What? (cont'd)

- Providers therefore need to incorporate these quality metrics and standards into their policies and procedures
- Standards need to be developed that track performance 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

So Now What? (cont'd)

- Remedial action plans need to be developed that are designed to assist providers in meeting standards but can include the ability to suspend or terminate participation
- 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

So Now What? (cont'd)

- It is important that provider evaluate its processes and procedures, reports, analyses, etc., so as to maximize available confidentiality and immunity protections under state and federal law (e.g., participation in a Patient Safety Organization under Patient Safety and Quality Improvement Act of 2005).

So Now What? (cont'd)

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

So Now What? (cont'd)

5. Can an ACO be held liable under negligent credentialing/corporate negligence/apparent agency or related liability principles?
6. 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?
7. 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

So Now What? (cont'd)

- in order to maximize confidentiality protections?
- 8. 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?
- 9. 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?

So Now What? (cont'd)

10. 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?
11. 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?



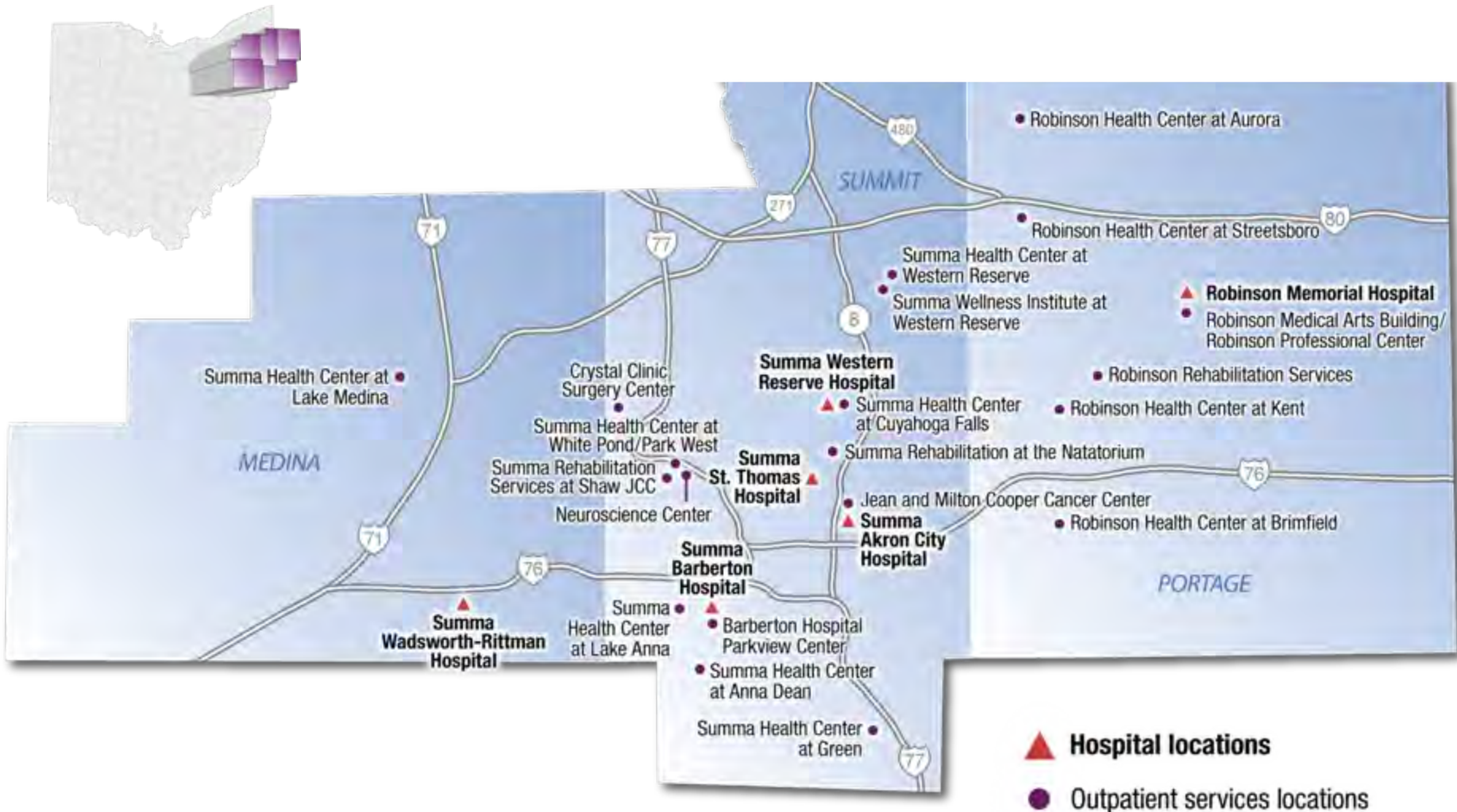


Utilizing PSO's to Maximize Confidentiality and Privilege Protections

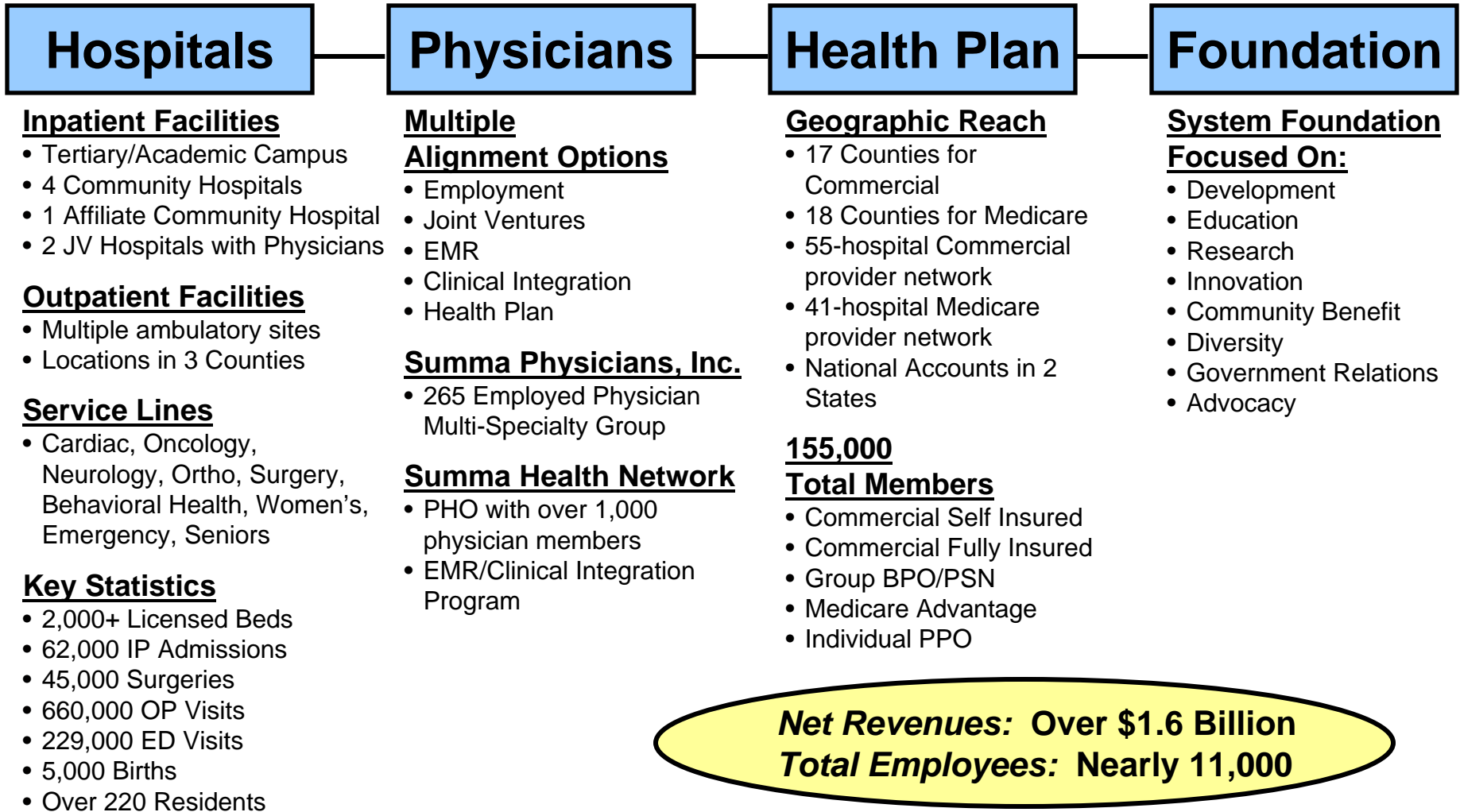
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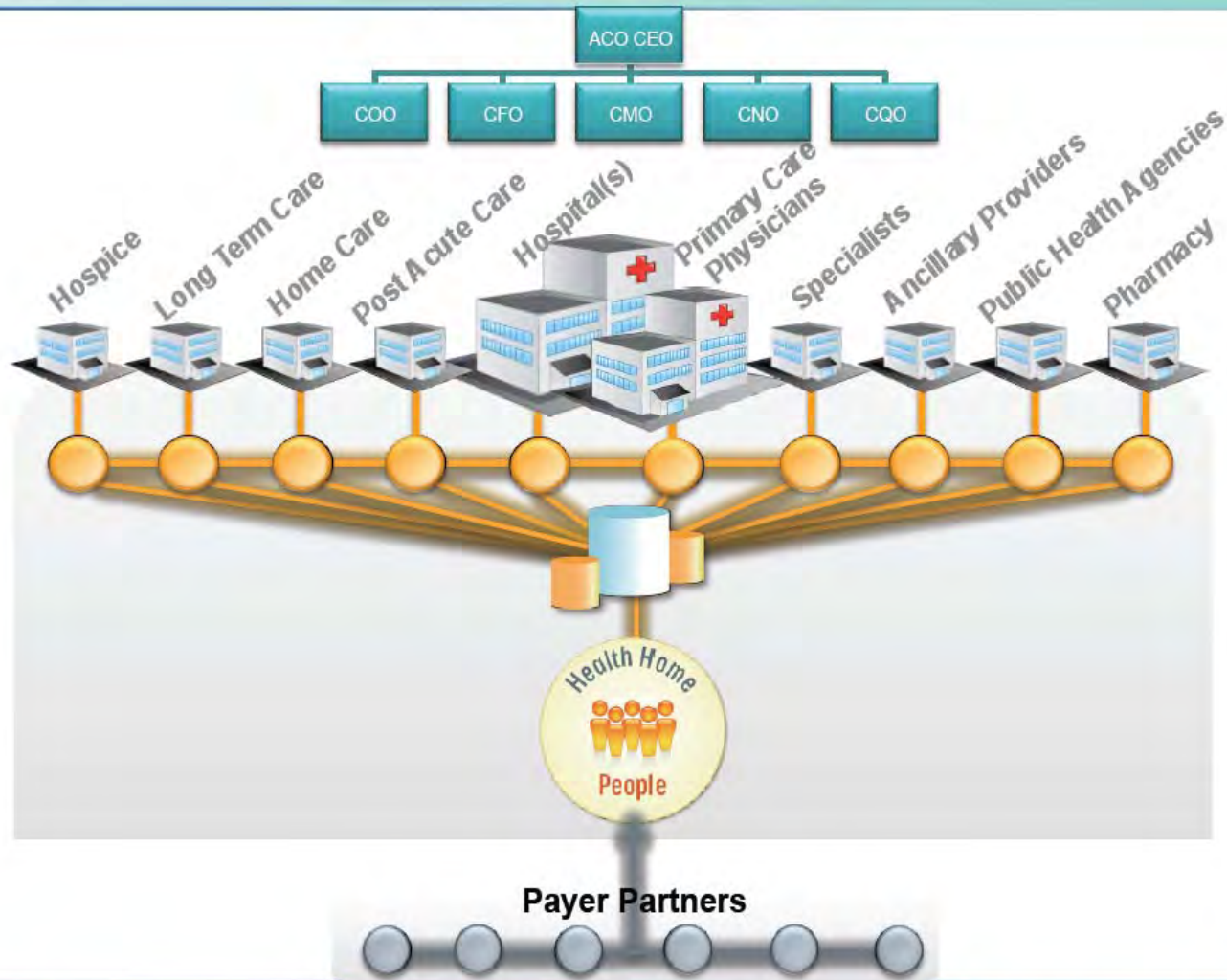


The Integrated Delivery System



That's more than healthcare. That's smartcare.

Complete view of an operational ACO



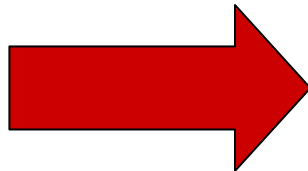
Patient Safety and Quality Improvement Act (PSQIA) Purpose

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

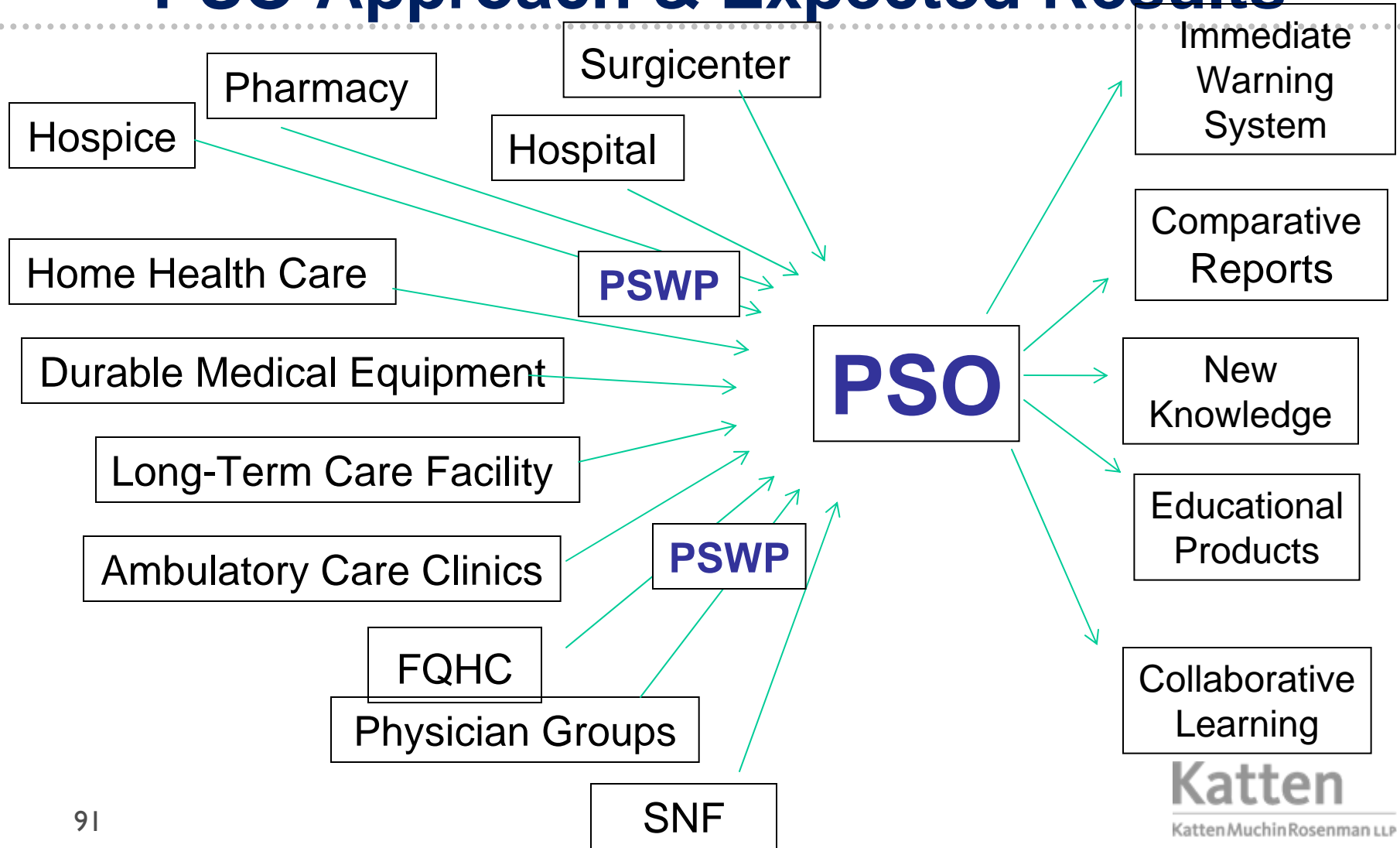


Further accelerating the speed with which solutions can be identified for the risks and hazards associated with patient care through the magnifying effect of data aggregation

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



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?

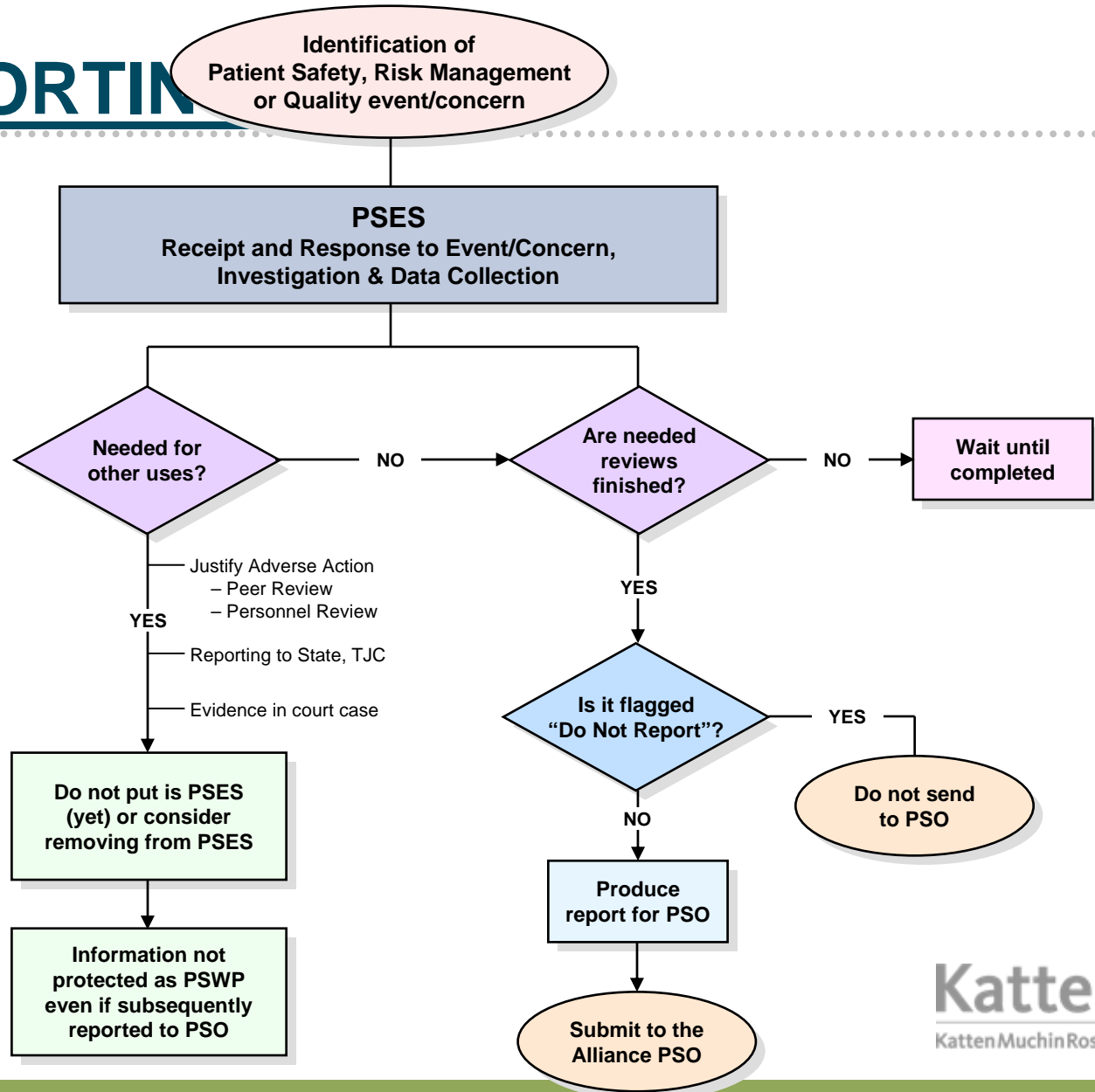
- Patient's medical record, billing and discharge information, or any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES. *Such separate information or a copy thereof reported to a PSO shall not by reason 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(s)**

PSO REPORTING



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



Event/Incident Reporting Policy

- **Modify existing policies as needed to reflect the purpose of internal event reporting is to ...**
 - **Improve patient safety, healthcare quality and patient outcomes**
 - **Provide learning opportunity through reporting to a PSO**
- **Include a process (through the PSES) for the removal of incidents from PSES or separate system for ...**
 - **Disciplinary action**
 - **Just culture**
 - **Mandatory state reporting**
 - **Independent/separate peer review**

Questions To Answer When Developing PSES Policy

Who or What Committee(s)

- **Collects data that will be reported to a PSO?**
 - **Single source or multiple sites?**
 - **Single department or organization wide event reporting?**
- **Analyzes data that will be reported to a PSO?**
- **Removes data from PSES prior to reporting to a PSO?**
- **Submits the data from the PSES to the PSO(s)?**
 - **Committee or individual authorized submission?**

Questions To Answer When Developing PSES Policy

What data should be ...

- Collected to report to a PSO?
 - Patient safety data, healthcare quality and outcomes data
 - * **Data cannot be used for adverse disciplinary, versus remedial, employment action, mandated state reporting**
- Removed from PSES prior to reporting to a PSO?
 - Criteria based or subjective case-by-case decision making
 - Peer review information that could lead to disciplinary action
- When is data ...
 - Reported to PSES?
 - Removed from PSES?
 - Reported to PSO?
 - * **Each date must be documented**

How Does a Provider Determine Which Data Should Be Reported To A PSO?

Criteria-based Prioritization

Suggested criteria

- Promotes culture of safety/improves care
- Impressions/subjective data that is not available in the medical record
- Information that could be damaging during litigation
- Not required to report elsewhere
- Required to report elsewhere, but data for reporting could be obtained from medical record
- Data will not be used to make adverse employment decisions

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**

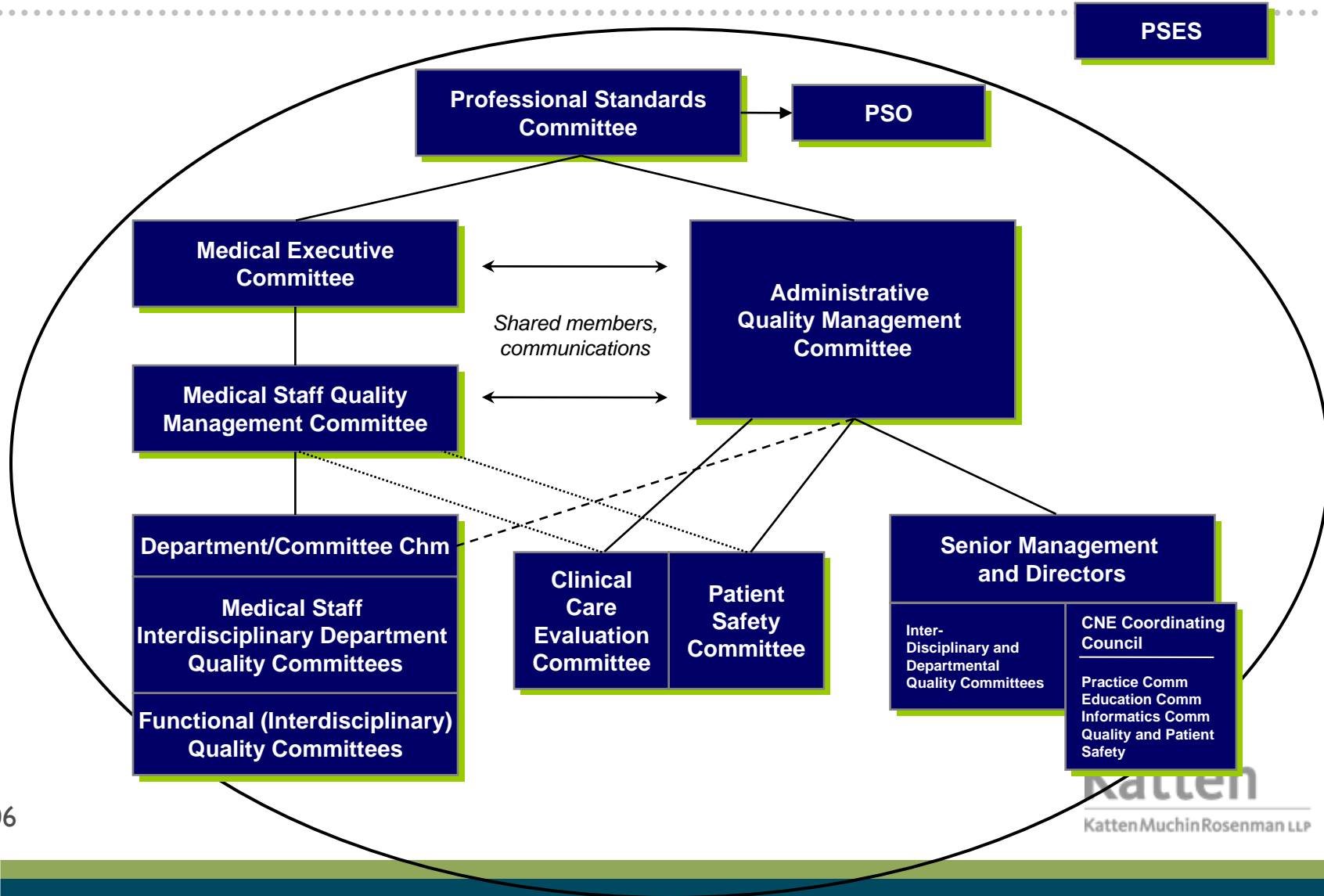
PA Patient Safety Authority: Reports Identify Trends

- Hidden sources of Latex in Healthcare Products
- Use of X-Rays for Incorrect Needle Counts
- Patient Identification Issues
- Falls Associated with Wheelchairs
- Electrosurgical Units and the Risk of Surgical Fires
- A Rare but Potentially Fatal Complication of Colonoscopy
- Fetal Lacerations Associated with Cesarean Section
- Medication Errors Linked to Name Confusion
- When Patients Speak- Collaboration in Patient Safety
- Anesthesia Awareness
- Problems Related to Informed Consent
- Dangerous Abbreviations in Surgery
- Focus on High Alert Medications
- Bed Exit Alarms to Reduce Falls
- Confusion between Insulin and Tuberculin Syringes (Supplementary)
- The Role of Empowerment in Patient Safety
- Risk of Unnecessary Gallbladder Surgery
- Changing Catheters Over a Wire (Supplementary)
- Abbreviations: A Shortcut to Medication Errors
- Lost Surgical Specimens

Steps to PSO Reporting

- **Inventory Data Currently Collected**
 - Patient safety, quality of care, healthcare outcomes
- **Prioritize Data that will be submitted to a PSO and become PSWP; what data will do the most to support improving the culture of safety**
- **Establish a system for data collection and review**
 - Standardized data collection will both enhance benchmarking comparisons and ultimately comply with AHRQ's mandate for PSOs to collect standardized data; AHRQ's "Common Formats" or another common format
 - Agree to the processes that the PSES will follow to determine PSWP
- **Create appropriate policies: Event Reporting; PSES, PSO Reporting**

PSO Reporting Process



Confidentiality and Privilege Protections

Patient Safety Work Product

In order to optimize protection under the Act:

- **Understand the protections afforded by the Act**
- **Inventory data from all sources to determine what can be protected**
- **Internally define your PSES**
- **Complete appropriate policies on collection, analysis and reporting**
- **Develop component PSO and/or select listed PSO**

Patient Safety Work Product Privilege

PSWP is privileged and shall not be:

- **Subject to a federal, state, local, Tribal, civil, criminal, or administrative subpoena or order, including a civil or administrative proceeding against a provider**
- **Subject to discovery**
- **Subject to FOIA or other similar law**
- **Admitted as evidence in any federal, state, local or Tribal governmental civil or criminal proceeding, administrative adjudicatory proceeding, including a proceeding against a provider**
- **Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law**

Patient Safety Work Product

Exceptions:

- **Disclosure of relevant PSWP for use in a criminal proceeding if a court determines, after an in camera inspection, that PSWP**
 - **Contains evidence of a criminal act**
 - **Is material to the proceeding**
 - **Not reasonably available from any other source**
- **Disclosure through a valid authorization if obtained from each provider prior to disclosure in writing, sufficiently in detail to fairly inform provider of nature and scope of disclosure**

Patient Safety Work Product Confidentiality

Confidentiality:

PSWP is confidential and not subject to disclosure

Exceptions:

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 - **Contains evidence of a criminal act**
 - **Is material to the proceeding**
 - **Not reasonably available from any other source**
- **Disclosure through a valid authorization if obtained from each provider prior to disclosure in writing, sufficiently in detail to fairly inform provider of nature and scope of disclosure**

Patient Safety Work Product Confidentiality

Exceptions (cont'd):

- Disclosure to a PSO for patent safety activities
- Disclosure to a contractor of a PSO or provider
- Disclosure among affiliated providers
- Disclosure to another PSO or provider if certain direct identifiers are removed
- Disclosure of non-identifiable PSWP
- Disclosure for research if by a HIPAA covered entity and contains PHI under some HIPAA exceptions
- Disclosure to FDA by provider or entity required to report to the FDA regarding quality, safety or effectiveness of a FDA-regulated product or activity or contractor acting on behalf of FDA

Patient Safety Work Product Confidentiality

Exceptions (cont'd):

- **Voluntary disclosure to accrediting body by a provider of PSWP but if about a provider who is not making the disclosure provider agrees identifiers are removed**
 - **Accrediting body may not further disclose**
 - **May not take any accrediting action against provider nor can it require provider to reveal PSO communications**
- **Disclosure for business operations to attorney, accountants and other professionals who cannot re-disclose**
- **Disclosure to law enforcement relating to an event that constitutes the commission of a crime or if disclosing person reasonably suspects constitutes commission of a crime and is necessary for criminal enforcement purposes**

Enforcement

- **Confidentiality**
 - **Office of Civil Rights**
 - **Compliance reviews will occur and penalties of up to \$10,000 per incident may apply**
- **Privilege**
 - **Adjudicated in the courts**