

15th Annual HFMA Education Session

Medinah Country Club

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**“Never Events,” Payors Refusal to Pay
and
Industry Demand for Improved Quality**

Environmental Overview

- Identification of “Never Events”, i.e., unacceptable medical errors, resulting in reduced or denial of payments by CMS and private payors.
- Emphasis on Pay for Performance (“P4P”) by private and public payors regarding expected compliance with certain protocols, healthcare practices and quality outcomes.

Environmental Overview (cont'd)

- Transparency to the general public via hospital rankings, published costs and outcomes, accreditation status and mandatory reports to state and federal government.
- Greater demands being placed on Boards of Directors and hospital management to develop sufficient resources to ensure that quality of care standards and expectations are met through the hospital's quality improvement program that adopts metrics and benchmarks to measure progress in meeting targeted clinical quality standards as part of the hospital's corporate and governance policies.

Environmental Overview (cont'd)

- Good quality means good business.
- Adoption and enforcement by Joint Commission of focused and ongoing performance monitoring (“OPPE” and “FPPE”).
- More aggressive enforcement environment, especially by the OIG, which is beginning to hold hospital boards and management responsible for the provision of substandard or unnecessary care which lead to “Never Events” or adverse patient outcomes.

Environmental Overview (cont'd)

- Legal and accreditation expectations and requirements require that medical staff physicians are appropriately credentialed and privileged to exercise each and every one of the clinical privileges given to them at time of appointment and reappointment.
- Failure to abide by identified quality standards expectations will give rise to more malpractice and corporate negligence liability claims.

Environmental Overview (cont'd)

- Patient Safety Act
 - Implementation of Patient Safety Organizations (“PSOs”) as a means of collectively improving quality.
- Federal funding for electronic health record initiatives.
- Healthcare reform?

Never or Adverse Events

- In 1999, the Institute of Medicine created a report titled “To Error is Human: Building a Safer Health System” which estimated that between 44,000 and 100,000 patients die each year due to medical errors.
- In 2002, the National Quality Forum created a list of 27 Never Events which was expanded to 28 in 2006. These events were defined as “adverse events that are serious, largely preventable, and of concern to both the public and healthcare providers for the purpose of public accountability”.

Never or Adverse Events (cont'd)

- Examples include:
 - Surgery performed on the wrong body part
 - Surgery performed on the wrong patient
 - Infant discharged to the wrong person
 - Patient suicide or attempted suicide resulting in serious disability while being cared for in healthcare facility
 - Unintended retention of foreign object and the patient after surgery or other procedure

Never or Adverse Events (cont'd)

- The Leap Frog Group recommends that when a never event occurs a provider should consider the following actions:
 - Apologize to the patient
 - Report the event
 - Perform a root cause analysis
 - Waive cost directly related to the event

Never or Adverse Events (cont'd)

- CMS also has taken a number of steps to address never events.
 - Hospitals required to report on their Medicare claims as to whether selected conditions were present at the time the patient was admitted. If at discharge a selected condition is present that it was not identified by the hospital on admission, is considered “hospital-acquired condition”.

Never or Adverse Events (cont'd)

- Embolism
- Transfusion with wrong type of blood
- Severe pressure ulcers
- Falls and trauma
- Surgical site infection (October 1, 2008)
- Medicare will no longer pay hospitals at a higher rate for the increase cost of care that results when a patient is harmed by one of the listed conditions if it was hospital-acquired.

Never or Adverse Events (cont'd)

- Medicare prohibits the hospital from billing the beneficiary for the difference between a lower and higher payment rates. (October 1, 2008).
- Medicare has announced its plan to not pay doctors and hospitals for erroneous surgery.
 - Surgery on a wrong body part
 - Surgery on a wrong patient
 - Wrong surgery on a patient

Never or Adverse Events (cont'd)

- These three national coverage determinations (NCDs) were developed to establish a national policy that will prevent Medicare from paying for certain serious preventable errors and medical care. Unlike the HAC provisions, which only affect payments to hospitals where in-patient stays, the final NCDs could affect payment to hospitals, physicians and any other healthcare providers and suppliers involved in the erroneous surgeries.

Never or Adverse Events (cont'd)

- For fiscal year 2010, CMS is adding 13 new quality measures which it will calculate using Medicare claims data adding up to a total of 42 measures.
 - For example, CMS is tracking re-admissions for heart failure within thirty days of discharge. Re-admissions are said to cost the program \$15 billion annually with potentially \$12 billion of those costs being preventable.

The Patient Safety Act

- Creates independent Patient Safety Organizations (PSOs) that will receive protected data, analyze the data and share recommendations with healthcare providers for improvement.
- Provides Federal and State legal privilege and confidentiality protections to information that is assembled and reported by providers to a PSO or developed by a PSO to conduct patient safety activities.
- Limits the use of patient safety information in criminal, civil, and administrative proceedings and imposes monetary penalties for violations of confidentiality or privilege protections.

Who or What Does the Act Cover?

- Provides uniform protections for all healthcare workers.
- 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.

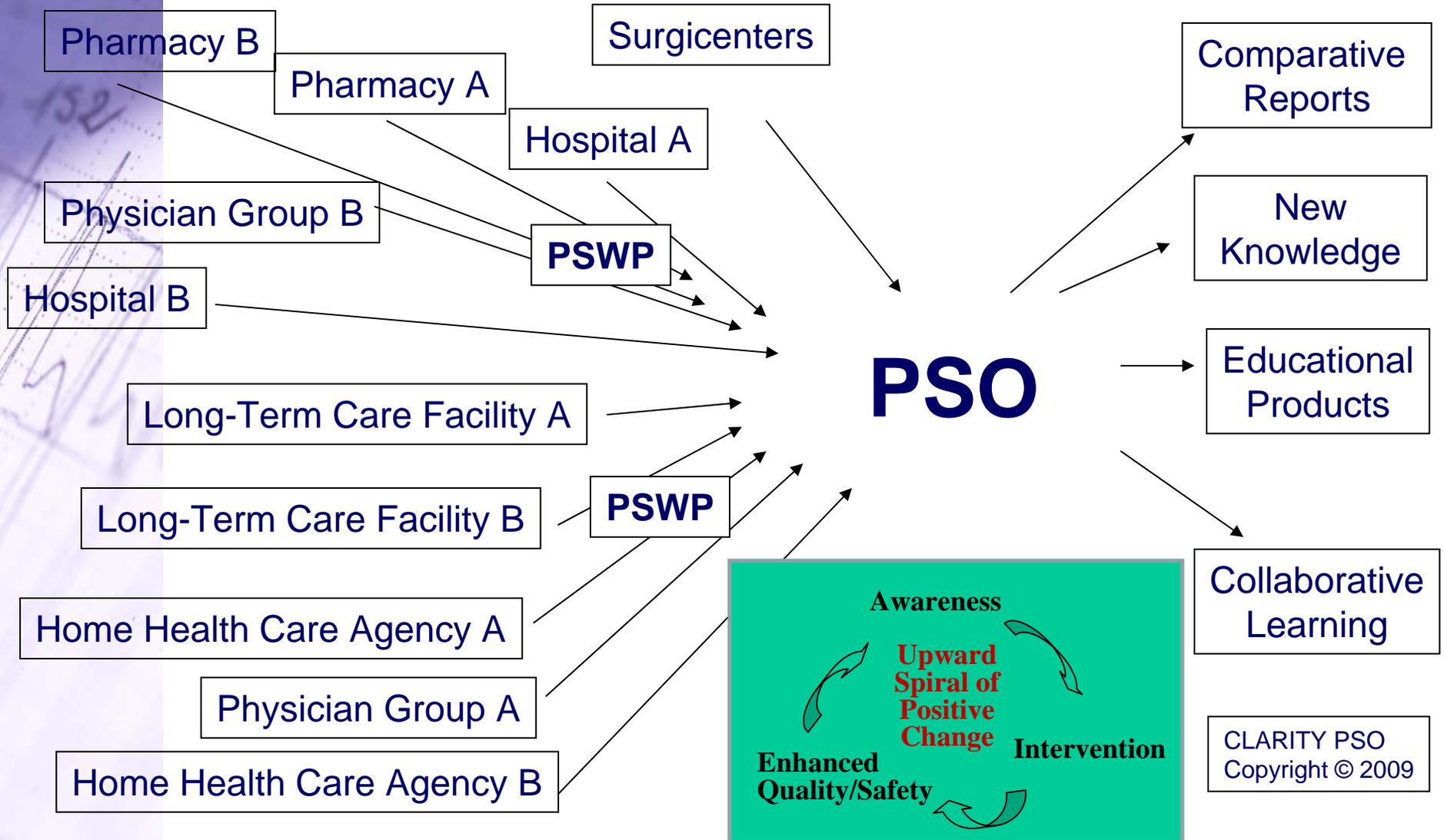
The Patient Safety Act Does Not

- Mandate provider participation in a PSO
- Does NOT make significant error reporting mandatory—defers to state
- Does not preempt stronger state protections
- Provide for any Federal funding of PSOs

Long-Term Goals of the PSA

- 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.

Expected Results



Adverse Events in Hospitals: Overview of Key Issues – OIG (12/08)

- In a report to Congress, the OIG identified several issues as critical to understanding the cause, effect and circumstances surrounding adverse events at hospitals based on interviews conducted with providers, trade associations, state agencies, public policy groups, payors, researchers and state and federal agencies, among others. The issues identified were as follows:

Adverse Events in Hospitals: Overview of Key Issues – OIG (12/08) (cont'd)

- Estimates of the incidents of adverse events in hospital vary widely and measurement is difficult
 - Estimate of frequency of adverse events and hospitals vary from 3% to 20% of hospital admissions because of no optimal method for measuring errors.
- Non-payment policies for adverse events are gaining in prominence and are viewed as a powerful incentive to reduce incidence but raise potential drawbacks.
 - Although seen as a way to prevent costly adverse events, drawbacks include resulting limited access to care, increased hospital cost and reduced hospital revenue.

Adverse Events in Hospitals: Overview of Key Issues – OIG (12/08) (cont'd)

- Hospitals rely on staff and managers to report adverse events internally, but barriers can inhibit reporting.
 - Although such reports can improve quality and accountability, reports are not always made because hospital personnel do not believe they will lead to improvement, do not have the time for completing, and sometimes fear punitive action for making such reports.
- Hospitals report adverse events to various oversight entities, although substantial underreporting is suspected.

Adverse Events in Hospitals: Overview of Key Issues – OIG (12/08) (cont'd)

- Public disclosure of adverse events can benefit patients but also raises legal concerns for patients and providers.
 - Public scrutiny pressures hospitals to improve practices but there is a general concern that such reporting can result in loss of legal protections which therefore can inhibit the full nature of any disclosure.
- Information to prevent adverse events is widely available but some hospitals and clinicians may be slow to adopt or routinely apply recommended practices.

OIG's FY 2008 Top Management and Performance Challenges

- In yet another report, the OIG assessed the performance of HHS and top management in various areas such as oversight of Medicare Part D, integrity of Medicare payments, appropriateness of Medicaid and SCHIP payments, as well as efforts relating to quality of care initiatives.
- In this report, the OIG identified a number of investigations and enforcement efforts relating to substandard care. One example involved use of the False Claims Act to address poor quality of care provided within a nursing facility chain, which included findings such as:

OIG's FY 2008 Top Management and Performance Challenges (cont'd)

- Staffing shortages
- Improper use of restraints
- Failure to implement medical orders or services identified on the care plan
- Failure to provide proper nutrition
- Failure to ensure that residents are protected from falls, physical abuse and medication errors
- Failure to prevent facility-acquired conditions, such as infections and pressure ulcers

OIG's FY 2008 Top Management and Performance Challenges (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.

OIG's FY 2008 Top Management and Performance Challenges (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.

OIG's FY 2008 Top Management and Performance Challenges (cont'd)

- The OIG 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.
- In this report, the OIG 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. . . .”

OIG's FY 2008 Top Management and Performance Challenges (cont'd)

- “As an educational resource to help the leaders of health care organizations improve the quality of care provided at their institutions and, ultimately, the overall quality of the nation’s health care system” the OIG cited to a collaborative publication with the American Health Lawyers Association entitled *Resource for Health Care Boards of Directors on Corporate Responsibility and Health Care Quality*.

Corporate Responsibility in Health Care Quality

- This “resource” was published in 2007 for the specific purpose of identifying the role and responsibility of corporate boards and management with respect to its fiduciary obligation to meet its charitable mission and legal responsibilities to provide health care quality services.
- Some key statistics motivating the Office of Inspector General relating to the US health care system included the following:

Corporate Responsibility in Health Care Quality (cont'd)

- The US does poorly at transition stages – hospital readmission rates from nursing homes are high; our reimbursement system encourages “churning”.
- Improving performance in key areas would save 100,000 to 150,000 lives and \$50,000,000,000 to \$100,000,000,000 annually.
- Resource identifies 10 key questions reflective of standards against which hospital boards will be measured relating to the delivery of quality health care services.
 - What are the goals of the organization’s quality improvement program?

Corporate Responsibility in Health Care Quality (cont'd)

- 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)

- 37 key indicators for 5 health care system dimensions (quality, access, equity, outcomes and efficiencies), the overall US score was 66 out of a possible 100.
- Efficiency was the single worst score among the 5 dimensions. For example, in 2000-2001, the US ranked 16th out of 20 countries in the use of electronic records.
- The US is the world leader in cost.
- The US scored 15th out of 19 countries in mortality attributable to health care services.
- Basic tools (i.e., health IT) are missing to track patients through their lives.

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?

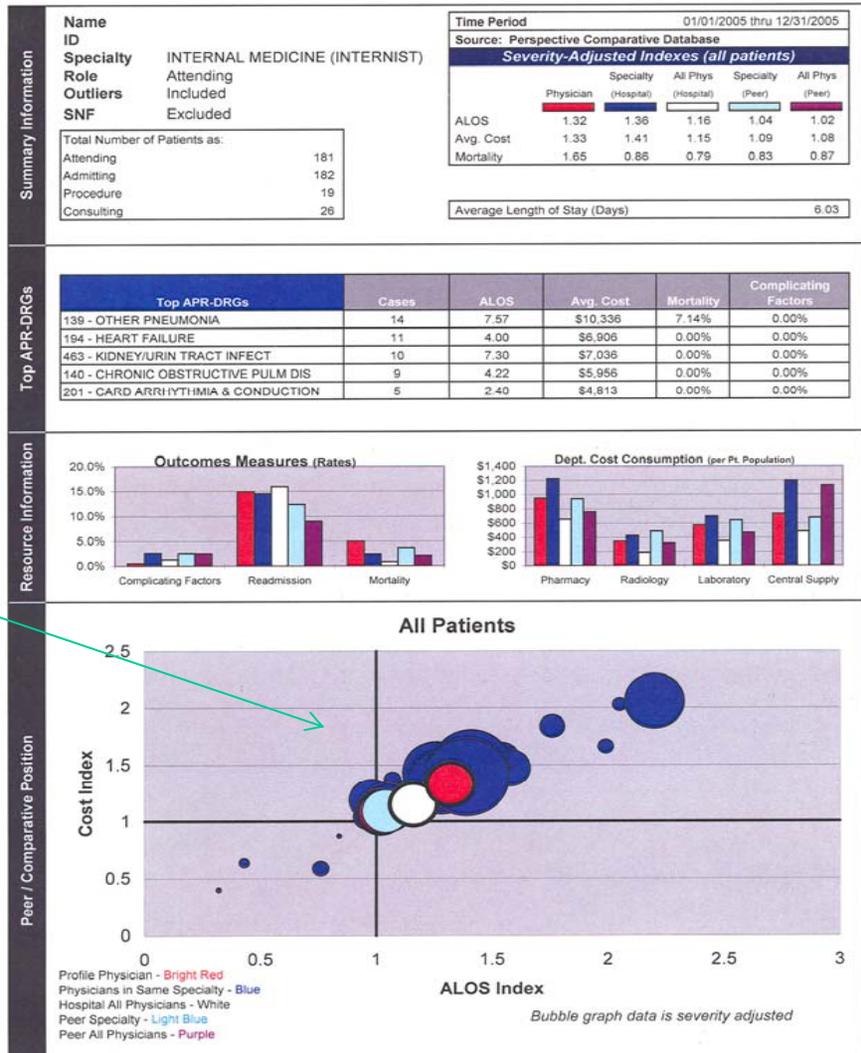
Variance Between Medicare Geo. Mean and Actual ALOS by Top 20 DRG's at Example Hospital

MEDICARE ONLY					
DRG #	DRG DESCRIPTION	ADMITS	ALOS	MEDICARE GEO. MEAN	VARIANCE
127	HEART FAILURE & SHOCK	294	6.6	4.1	2.5
88	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	152	5.9	4.0	1.9
89	SIMPLE PNEUMONIA & PLEURISY AGE>17 W CC	129	6.6	4.7	1.9
182	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE>17 W CC	117	4.7	3.4	1.3
143	CHEST PAIN	106	2.8	1.7	1.1
521	ALCOHOL/DRUG ABUSE OR DEPENDENCE W CC	104	3.9	4.2	-0.3
296	NUTRITIONAL & MISC METABOLIC DISORDERS AGE>17 W CC	85	5.5	3.7	1.8
416	SEPTICEMIA AGE>17	78	10.4	5.6	4.8
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG	77	4.9	3.3	1.6
174	G.I. HEMORRHAGE W CC	76	6.5	3.8	2.7
132	ARTHEROSCLEROSIS W CC	73	3.9	2.2	1.7
320	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W CC	73	6.0	4.2	1.8
138	CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS W CC	71	5.2	3.0	2.2
14	INTRACRANIAL HEMORRHAGE OR CEREBRAL INFARCTION	68	7.6	4.5	3.1
188	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE>17 W CC	68	5.7	4.2	1.5
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG	64	3.7	2.1	1.6
395	RED BLOOD CELL DISORDERS AGE>17	60	4.4	3.2	1.2
130	PERIPHERAL VASCULAR DISORDERS W CC	59	7.2	4.4	2.8
204	DISORDERS OF PANCREAS EXCEPT MALIGNANCY	58	5.5	4.2	1.3
294	DIABETES AGE >35	52	5.2	3.3	1.9

Example by Major Dx

- Heart Failure
- Card. Arrhythmia
- Percut Cardiovasc w/o AMI
- Angina

This physician's overall performance is in line w/the peer group

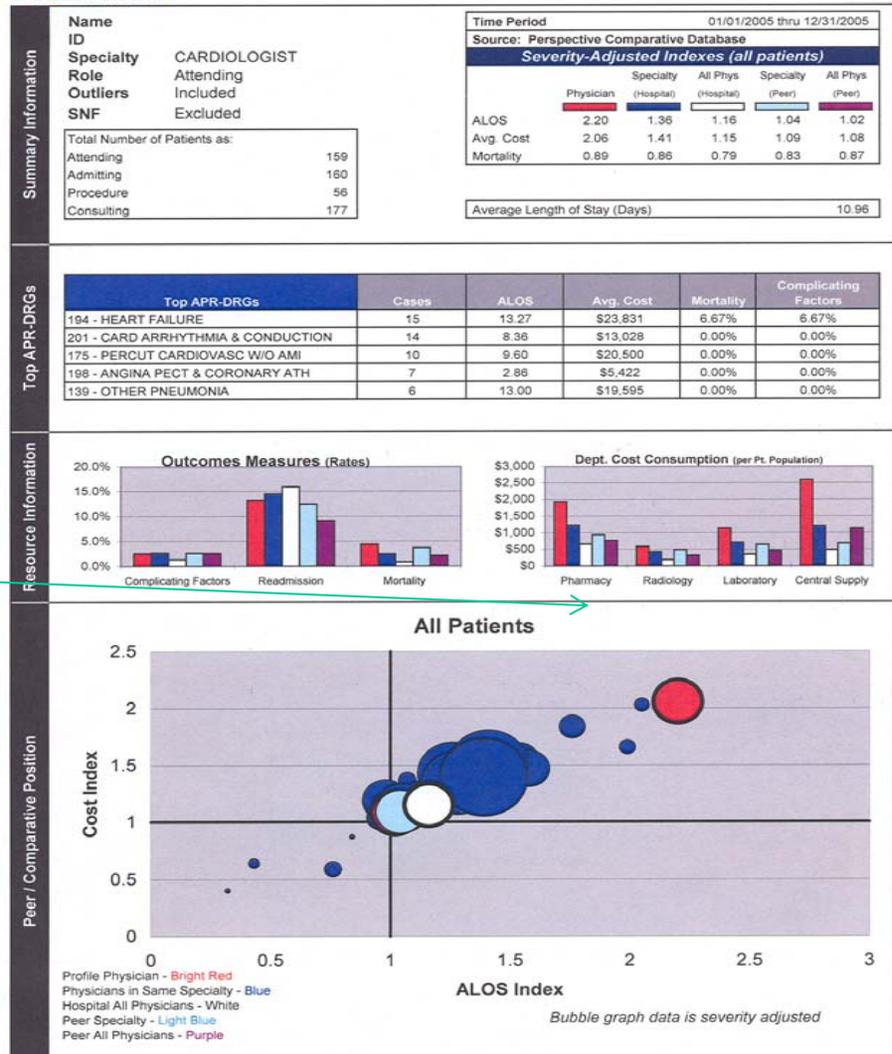


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Example by Major Dx

- Heart Failure
- Card. Arrhythmia
- Percut Cardiovasc w/o AMI
- Angina

This physician's overall performance is significantly worse the peer group



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