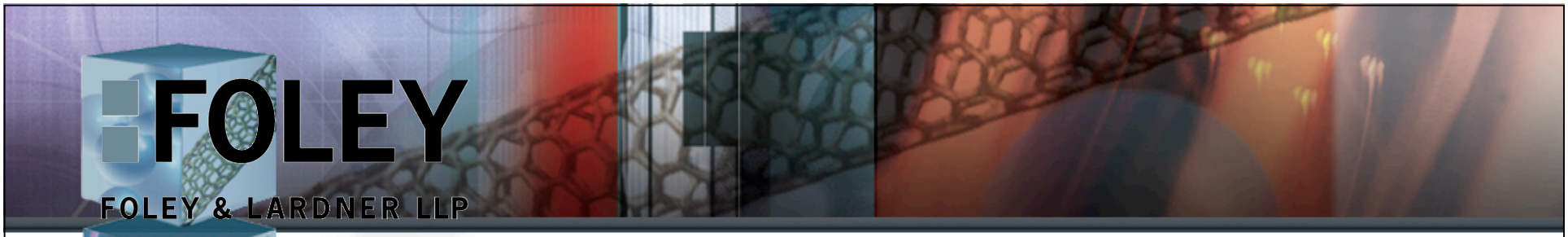

Improving Quality & Patient Safety Through Payment Reform, Public Reporting and Enforcement

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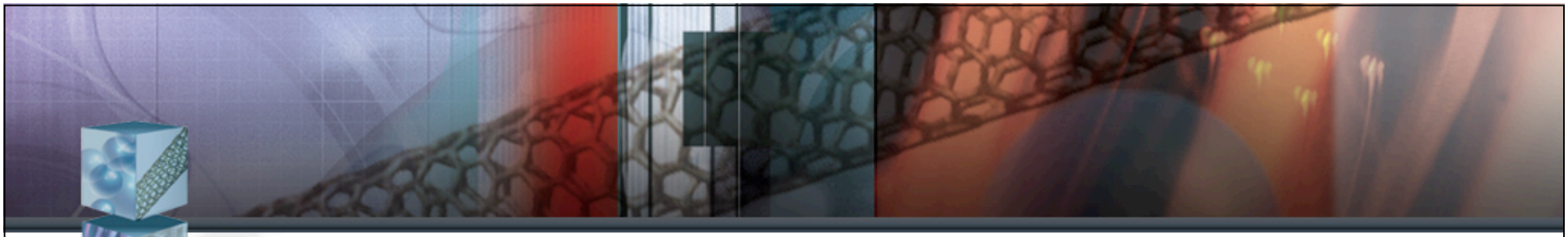
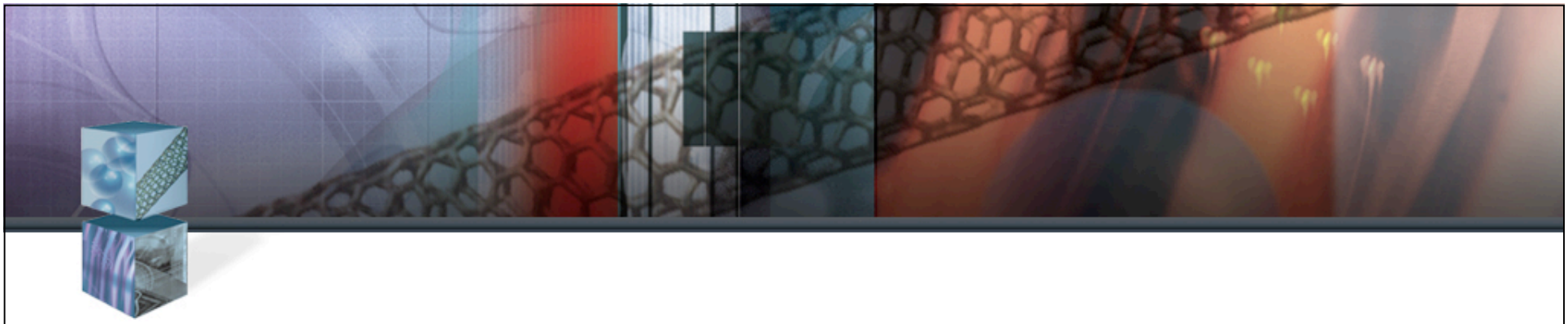
Patient Safety Audio Conference on Legal Issues in Quality of Care

January 26, 2009

FOLEY & LARDNER LLP



- Incentivizing quality care through payment reform
- Driving quality of care through public reporting
- Enforcing quality of care through the False Claims Act



UPDATE ON PAYMENT REFORM

- *"I strongly support linking provider payment to quality care as a way to make Medicare a better purchaser of health care services. Today, Medicare rewards poor quality care. That is just plain wrong and we need to address this problem."*

  Sen. Chuck Grassley,

  Budget Hearing with Michael Leavitt

  February 7, 2007

- The Hospital Quality Initiative was created in 2003 to improve quality of care through public reporting
- Hospitals are required to report on quality measures to receive their full annual payment update (RHQDAPU)
- It is the precurser to Medicare's Value Based Purchasing reimbursement system

For 2010, 42 inpatient measures to be reported are:

- Heart attack (MI) – 8 measures (removed one as of 4/09)
- Heart failure (HF) – 4 measures
- Pneumonia (PN) – 6 measures
- Surgical Care Improvement Project (SCIP) - 8 measures
- Mortality – 3 measures
- Experience of Care (HCAHPs survey)

- Heart failure re-admission rate
- Nursing – failure to rescue
- AHRQ – Patient Safety & Quality Indicators – 9 measures
- Participate in cardiac surgery database

- 2009 OPPS Final Rule expanded outpatient reporting requirements from the initial 7 measures to a total of 11 measures
  - Emergency Department – 5 measures
  - Surgery – 2 measures
  - Imaging – 4 measures (new)
- CMS will apply a 2% reduction in OPPS payment rates for failing to report by reducing the conversion factor used to calculate the rate

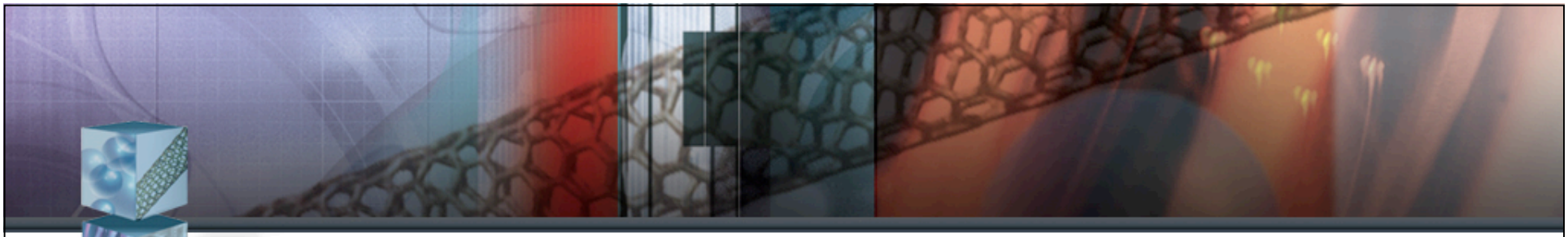
- The Deficit Reduction Act mandated CMS to develop a "Value Based Purchasing Plan" for hospitals, and CMS issued its final report to Congress on Hospital VBP November 21, 2007
- The VBP will build on the RHQDAPU program

- Introduced in the House Sept 25, 2008. The first and most substantive VBP proposal to date. Although the bill expired, if re-introduced, it may be a starting point to advance VBP legislation in 2009
- The Quality FIRST Act would reward hospitals for their performance on process measures for the four specified conditions currently reported to CMS
  - acute myocardial infarction
  - heart failure
  - pneumonia
  - surgical care improvement/surgical infection prevention

- Under the Quality FIRST Act, the VBP program would begin FY 2011 with the benchmark levels announced in FY 2009 using hospital performance data from FY 2008. Hospitals' payments would be adjusted in FY 2011 based on performance on quality measures in FY 2010

- A four-year, phased-in transition of Medicare payment bonuses would start with 0.5% for FY 2011, 1% for FY 2012, 1.5% for FY 2013, and 2% for FY 2014

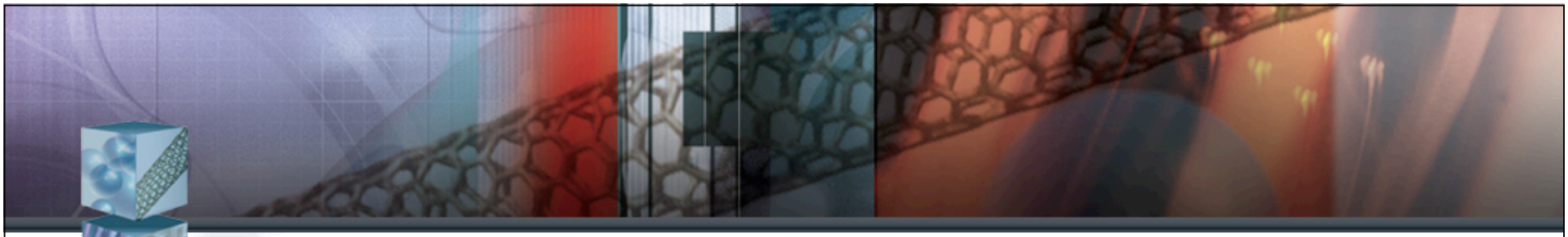
- Hospitals would have the opportunity to earn up to 2% of their reimbursement payments by meeting certain performance quality benchmarks. Bonus payments would be made to high-performing hospitals from the pool of funds made available by payment reductions to hospitals that do not meet the full-incentive benchmark level



- On November 12, 2008, Senators Grassley and Baucus released a discussion draft of Medicare Hospital Quality Improvement Act of 2008 to implement VBP plan for hospitals
- Phased transition commencing in 2012 (1%) and be fully implemented by 2016 (2%)
- Same 4 conditions as Quality First

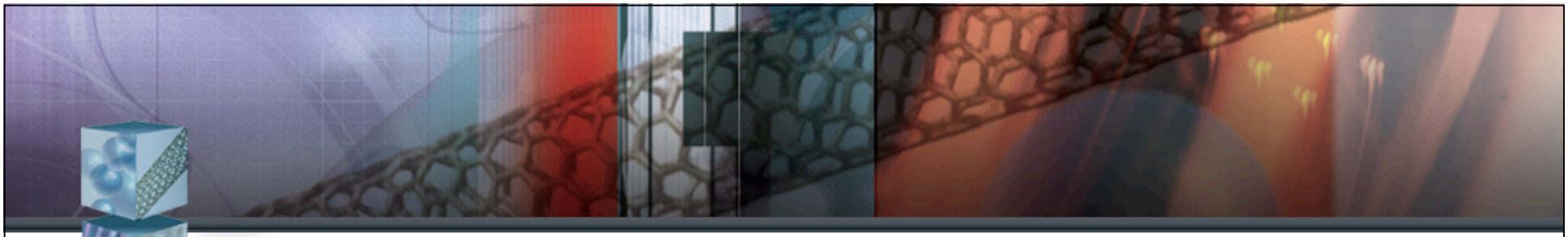
No Payment for Poor Quality

- Effective October 1,2008, hospitals will not be paid for certain “hospital acquired conditions” unless present on admission
  - Object left in during surgery
  - Air embolism
  - Blood incompatibility
  - Catheter associated UTI
  - Pressure ulcers (Stage III and IV)
  - Vascular catheter associated infection
  - Surgical site infection following CABG, Bariatric Surgery and certain orthopedic surgery
  - Falls and trauma
  - Certain manifestations of poor Glycemic control
  - DVT/PE following knee or hip replacement



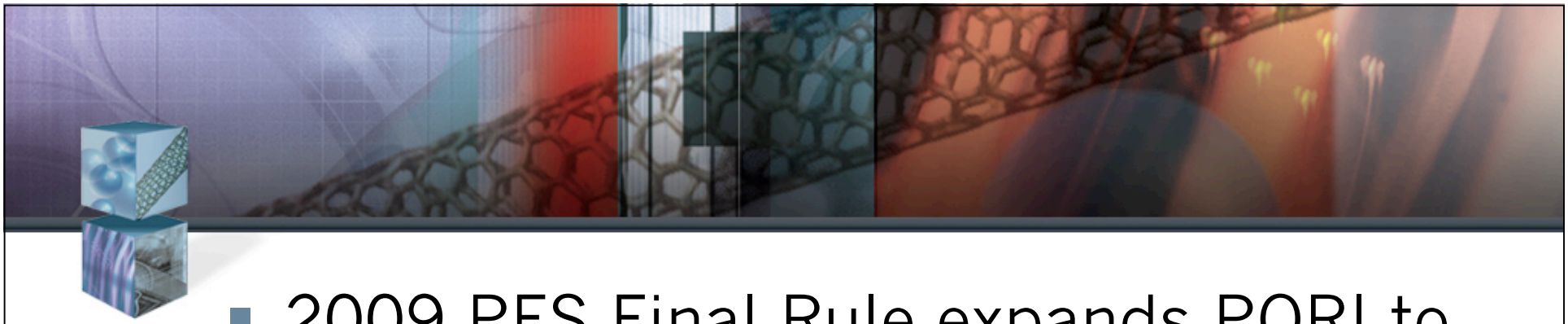
- HAC will continue to evolve and expand
- CMS is considering ways to make HAC more precise, including risk-adjusting for a condition's prevalence and assessing rates of a condition's occurrence over time
- CMS is also looking into expanding the policy to “Healthcare Associated Conditions” other payment settings, including outpatient hospitals, ambulatory surgery centers, physicians' offices, home health agencies, and skilled nursing facilities
- Listening session held December 18, 2008

- On January 15, 2009, CMS issued 3 NCDs to establish uniform national policies that will prevent Medicare from paying for certain serious, preventable errors in medical care
  - Wrong surgical or other invasive procedures performed on a patient
  - Surgical or other invasive procedures performed on the wrong body part
  - Surgical or other invasive procedures performed on the wrong patient

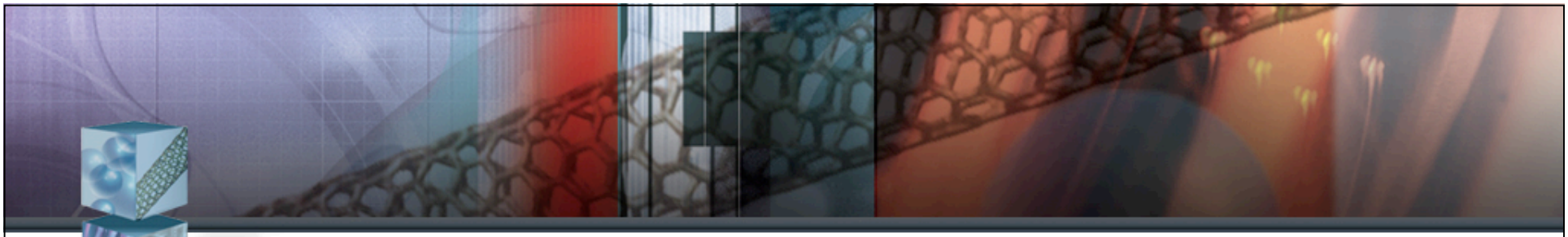


- PQRI is a voluntary program to provide financial incentives to physicians who successfully report quality data to CMS
- For 2008, eligible professionals who meet the criteria for satisfactory submission of quality measures data for services furnished during the reporting period (January 1, 2008 - December 31, 2008) will earn an incentive payment of 1.5% of their total allowed charges for Physician Fee Schedule (PFS) covered professional services furnished during that same period (the 2008 calendar year)

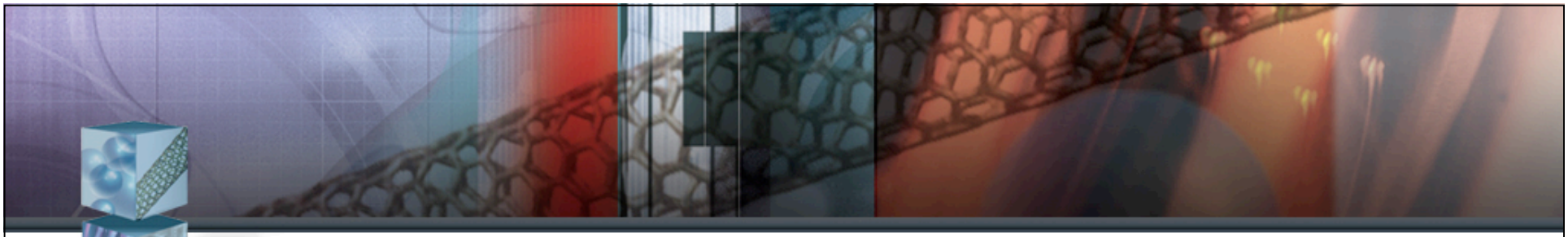
- Reporting only applies to measures applicable to the services rendered to Medicare beneficiaries
- Reporting non-compliance also encouraged
- No public reporting at this time, but some information regarding participation, reporting and performance rates may be made public
- In addition to submitting PQRI measure data as part of their Medicare claims submissions, eligible professionals may report data on quality measures to a medical registry, and these registries will then report that data to CMS



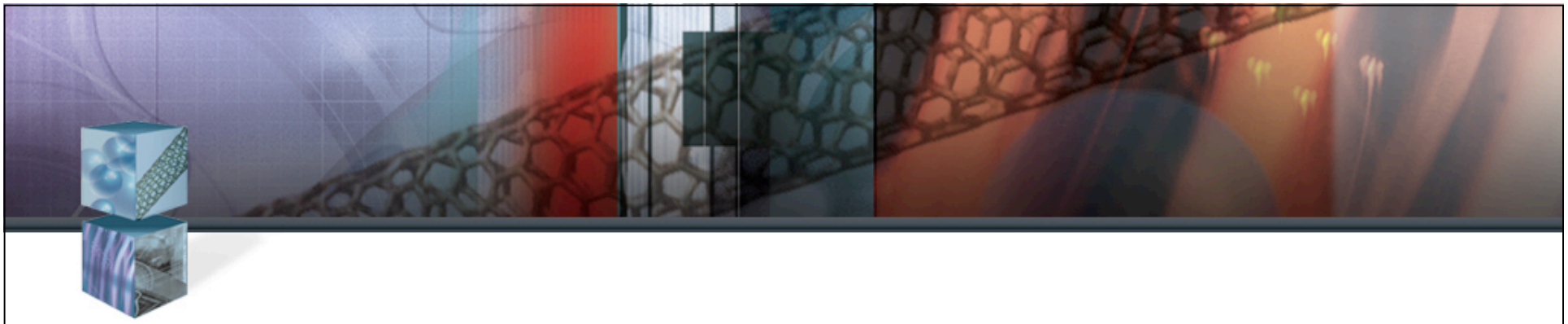
- 2009 PFS Final Rule expands PQRI to include 153 measures with 7 measure groups
- Applies to all "eligible professionals" (physicians, mid-level practitioners, occupational therapists, speech-language therapists and audiologists)
- Bonus equals 2% of allowed Medicare charges for services during reporting period



- Combination of financial incentives and payment reductions to encourage "eligible professionals to use e-prescribing
  - 2009-2013 successful e-prescribing can earn up to 2% of allowed Medicare charges for 2009; bonus declines in subsequent years until it is eliminated in 2013
  - 2012 payment reduction of 1% imposed for failure to use e-prescribing, increasing to 2% reduction by 2014



- The transition to a VBP program for physicians and other professionals is required by MIPPA
- By May 1, 2010, CMS is required to submit a report to Congress with recommendations for legislation and administrative action
- "One possible approach would be to have multiple parallel tracks: a track appropriate for participation by virtually all physicians and other professionals, a track focused particularly on primary care for the management of beneficiaries with multiple chronic diseases, and a track focused on medical groups and entities that link professionals and institutional providers with the scope of practice broad enough to achieve cost savings," according to a November 26, 2008 issue paper from CMS
- Final PFS Rule expanded PQRI and signaled CMS intent to use PQRI as basis for professional VBP



PUBLIC REPORTING

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Hospital Compare

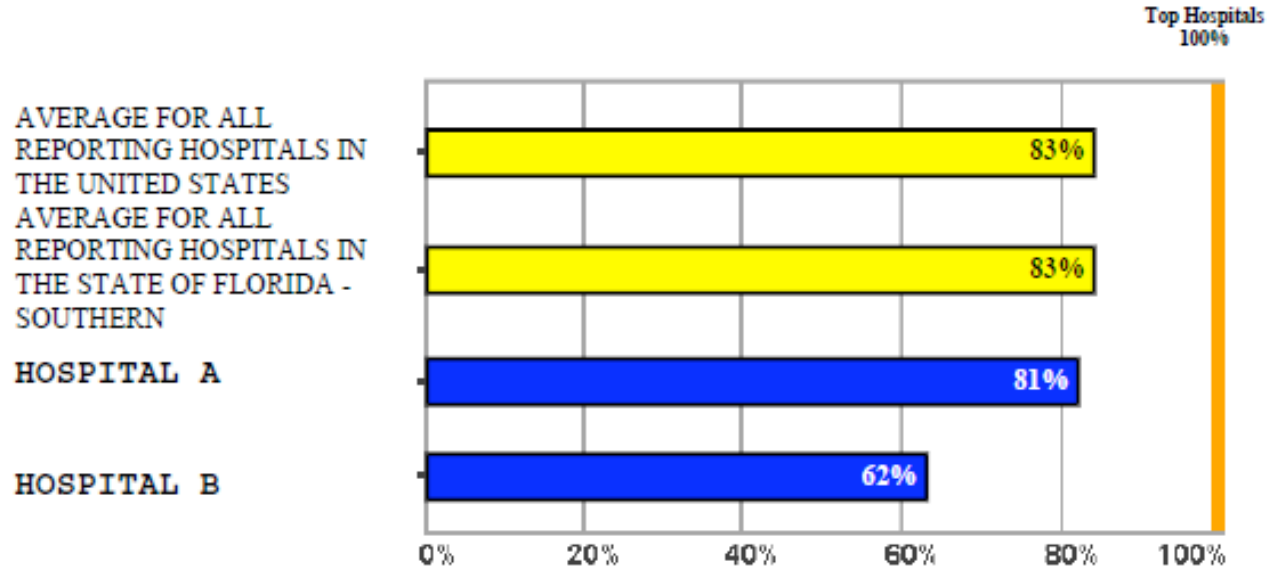
- Consumer-oriented website to allow viewing of hospital performance on quality measures
- Contains process of care and outcome measures
- HCAHPS measures added in Spring, 2008
- Volume and price data added in Spring, 2008
- HOPQDRP data to be added by 2010

HHS - Hospital Compare - Process of Care Measure Graphs

Graph 1 of 4

Percent of Heart Failure Patients Given ACE Inhibitor or ARB for Left Ventricular Systolic Dysfunction (LVSD)

The rates displayed in this graph are from data reported for discharges April 2006 through March 2007.



Top Hospitals represents the top 10% of hospitals nationwide. Top hospitals achieved a 100% rate or better.

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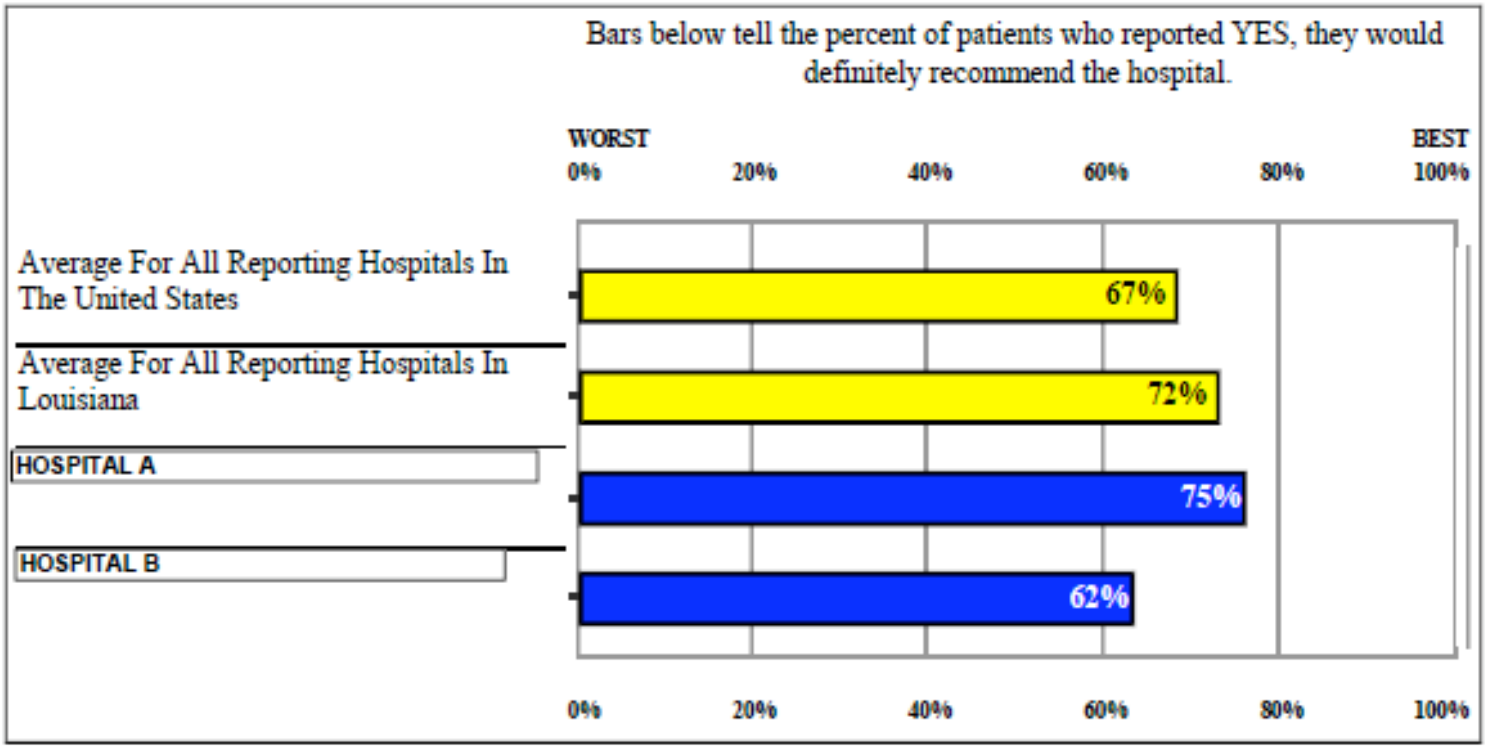
Hide

Would patients recommend the hospital to friends and family?

These results are from patients who had overnight hospital stays from October 2006 through June 2007.

The survey asked patients **whether they would recommend the hospital** to their friends and family.



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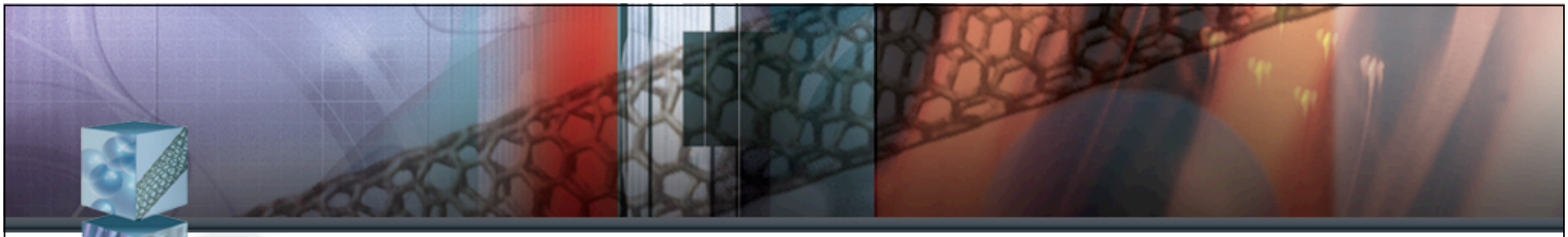
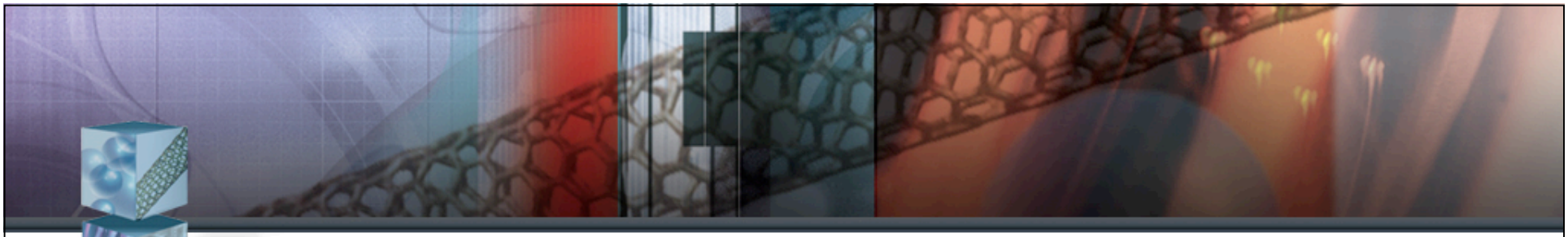


Hospital Information Name, Address, Telephone, Type of Hospital and Distance	Accredited	Provides Emergency Services	Hospital Quality Information			Pneumonia and Pleurisy in Adults With Complications or Preexisting Conditions (DRG 089)	
			Hospital Process of Care Measures	Hospital Outcome of Care Measures	Survey of Patients' Hospital Experiences[a]	Average Medicare Payment to Hospital	Number of Medicare Patients Treated[c]
Medicare Payment Range for Hospitals in the United States for this Diagnosis Related Group $5,241 - $6,415 Total Number of Medicare Patients Treated in the United States for this Diagnosis Related Group 470,498							
Medicare Payment Range for Hospitals in Louisiana for this Diagnosis Related Group $4,955 - $5,639 Total Number of Medicare Patients Treated in Louisiana for this Diagnosis Related Group 7,953							
HOSPITAL A	Yes	Yes	Available	Not Available	Available	**$6,744**	135 Medicare Patients
HOSPITAL B	Yes	Yes	Available	Not Available	Available	**$6,602**	60 Medicare Patients
HOSPITAL C	Yes	Yes	Available	Not Available	Available	**$8,264**	16 Medicare Patients

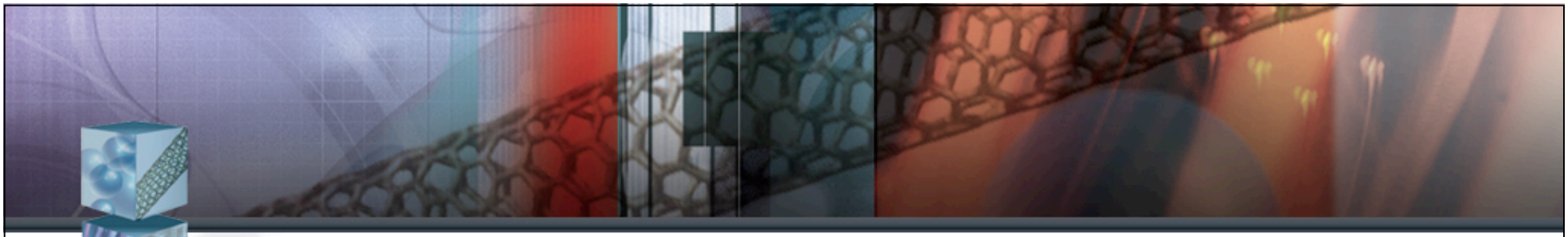
- 2009 PQRI will be reported publicly on "Physician and Other Health Care Professional Compare" website in 2010
- Successful e-prescribers to be included

- **Three New Reports Issued by OIG in December, 2008 Regarding Research into "Adverse Events" in Hospitals**
  - Overview of Key Issues
  - State Reporting Systems
  - Case Study of Incidence Among Medicare Beneficiaries in Two Selected Counties
- **Reports Required by Tax Relief and Health Care Act of 2006**



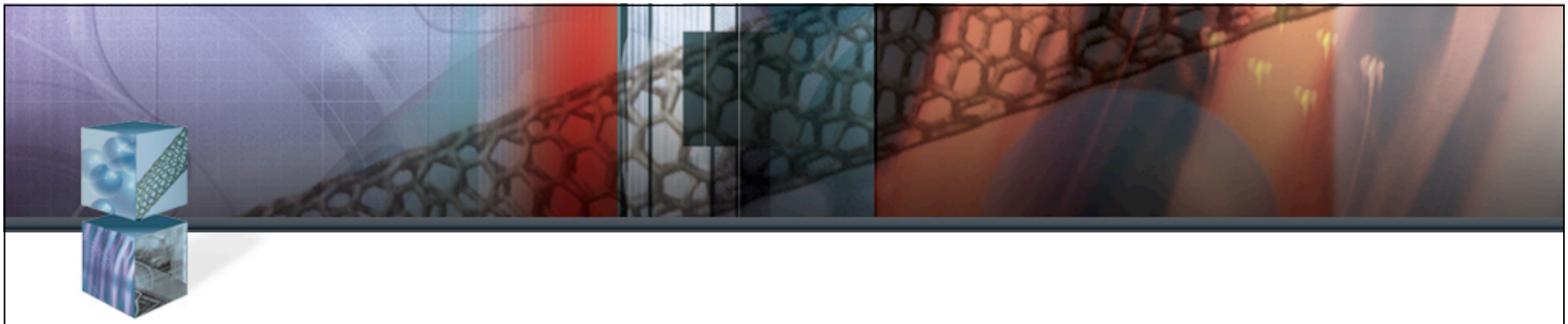
- Key Issues Report
  - Identifies seven issues regarding adverse events deemed “most critical”
- The OIG Recommendations
  - Create national body to lead patient safety efforts
  - Focus on structures to encourage hospital use of evidenced based practices
  - Establish consistent method to measure incidence of adverse events
  - EHR
  - Monitor effect of policies to deny payment for adverse events
  - Improve and streamline adverse event reporting

- State Reporting
  - 26 states have an adverse event reporting system and are actively receiving reports as of January 1, 2008
  - Reporting systems are disparate in list of reportable events, criteria to determine adverse events; information that must be reported and strategies to obtain reports and maintain confidentiality
    - Hospital underreporting is common problem
  - OIG Conclusion: state adverse event reporting systems are unsuitable for use in national initiatives

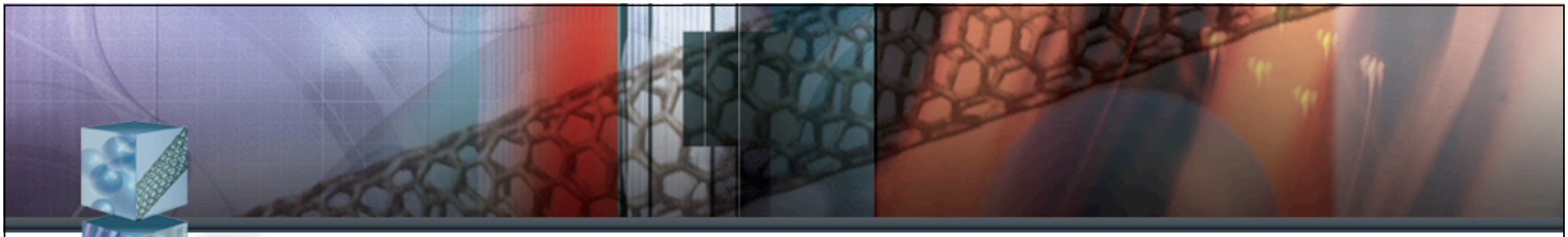


- County Incidence Report
  - Measuring the incidence of adverse events is common problem
  - Review included events on NQF list; CMS HAC list; and those resulting in serious harm to patient (prolonged hospital stay, permanent harm, life-sustaining intervention, or death)
  - 15% experienced adverse event; another 15% experienced adverse event classified as "temporary harm". THIS MEANS OVERALL INCIDENCE WAS 30%
  - Most "adverse events" found were not on NQF or CMS list and only 2 resulted in higher reimbursement
  - Some hospitals omitted the HAC diagnosis codes (of concern to OIG)

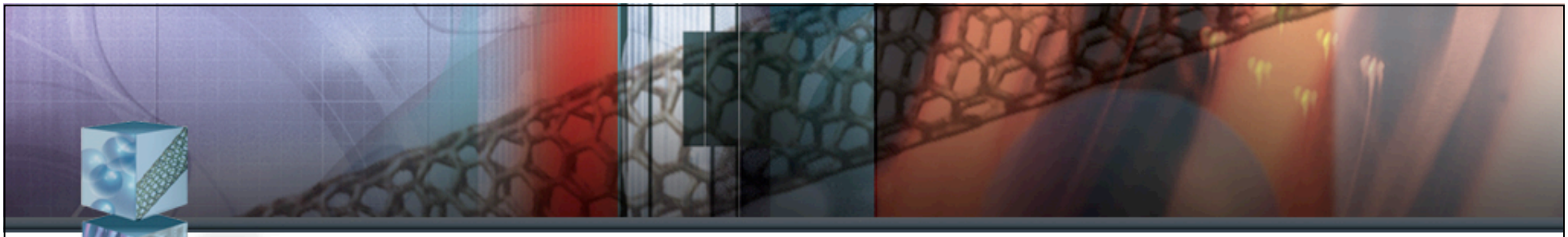
- Significant Findings From OIG Adverse Event Reports
  - County Report suggests adverse event incidence rate much higher than previously thought
  - Reducing adverse events is a high priority for the government
  - Measuring incidence rate of adverse events is difficult and needs to be defined
  - **Overall positive view of policy to deny payment of adverse events as a means to prevent them**



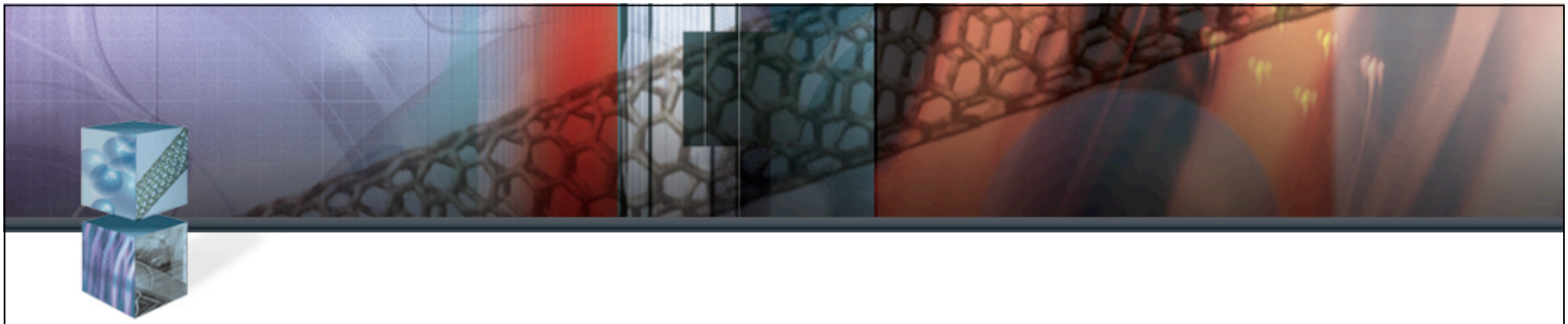
- Current structures not conducive to implementation of recommended practices
- Need a national reporting system and CMS may propose modification to PSO legislation to provide for mandatory national reporting
- OIG committed to undertake further analysis



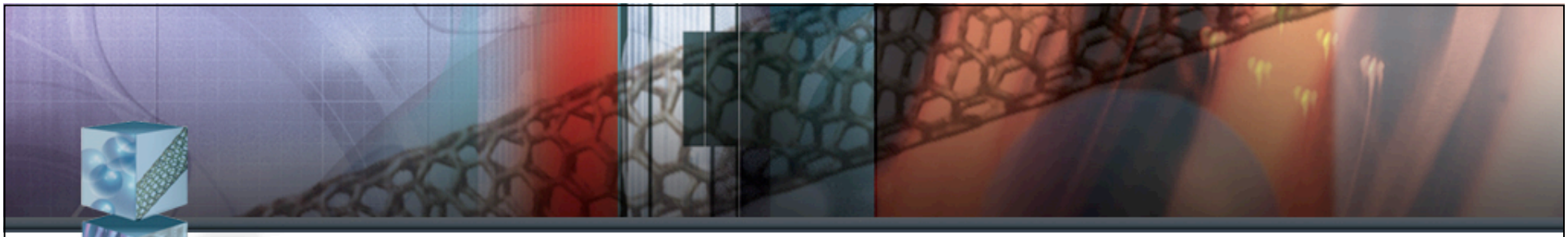
- November 21, 2008 HHS final rule (effective January 19, 2009) created a system of voluntary reporting to Patient Safety Organizations (PSOs)
- Designed to complement the 2005 PSQIA (Pub. L. No. 109-41; S. 544)
- Final Rule has 4 Sections
  - General Provisions
  - PSO Requirements and Agency Procedure
  - Confidentiality and Privilege
  - Enforcement



- PSOs would develop and maintain databases of information for healthcare organizations
- A PSO can be a public or private entity or component thereof but must have primary activity to improve patient safety
- Simple attestation process to be certified
- Incentive = Confidentiality for Patient Safety Work Product (PSWP), which is broadly defined to include all information collected for purpose of reporting to a PSO
- Requires the development of Patient Safety Evaluation System. Documentation is key to achieve privilege/confidentiality protections



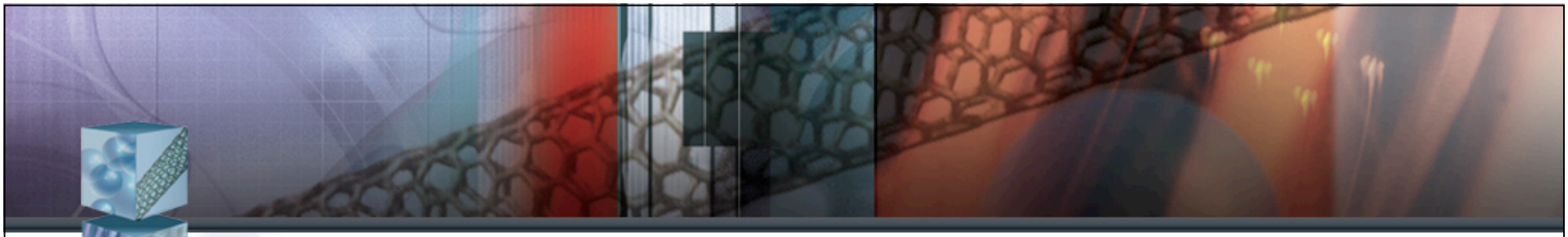
ENFORCEMENT



- The government uses a variety of legal theories under the FCA to attack quality failures, but all follow the same principle: **the government will not pay for medically unnecessary or substandard care**
- Physicians, executives, and board members face *real risks* for poor quality of care

- *"You will see more and more physicians going to jail."*
  - Kirk Ogrosky, Deputy Chief for Health Care Fraud, Department of Justice, Criminal Division (Dec. 4, 2007)

- *"We're holding those individuals accountable." "You may not go to jail ... but we will take your money."*
  - Lewis Morris, Chief Counsel to the Office of Inspector General, U.S. Department of Health and Human Services (Dec. 4, 2007)



Traditional Theories

- Claims for services not rendered
- Unbundling
- Claims for services not covered
- Duplicate payments

Quality of Care Theories

- Express False Certification
- Implied False Certification
- Worthless Services
- Criminal Statutes

- 2 Initiatives focused on quality of care
  - Reliability of quality reporting
  - Serious medical error
- Commitment to investigate health care fraud related to quality of care, i.e. billing for unnecessary services or for substandard care ("failure of care")
- ROI – for 2008, recovered $17 for each $1 invested