Healthcare Reform: The Road Ahead

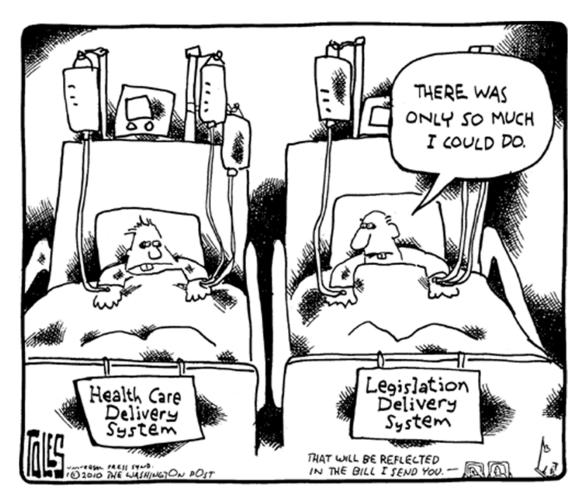
Kevin Lyles, Esq.
Partner, Jones Day
kdlyles@jonesday.com
(614) 281-3821

Diane Meyer
Chief Compliance and Privacy Officer
Stanford University Medical Center
DMeyer@stanfordmed.org
(650) 724-2572

Frank E. Sheeder, Esq.
Partner, DLA Piper
frank.sheeder@dlapiper.com
(214) 743-4560







The Real Healthcare Reform = Payment Reform

HISTORICAL HEALTH POLICY DISCUSSIONS

- Underlying concerns focused on three general areas:
 - Quality
 - Cost
 - Access
- A careful review of the new framework established by the Patient Protection and Affordable Care Act of 2010 ("PPACA") reveals a slight variation to the traditional tripartite presentation of policy concerns.

THE REFORMED HEALTH POLICY FOCUS

- Health Reform framework highlights:
 - Quality
 - Cost
 - Population Health/Prevention
- This new focus on population health and prevention to promote healthier communities is part of a larger movement promoting systems-based medicine that will continue despite the many legal and legislative challenges threatening to repeal PPACA.

WHY POPULATION HEALTH AND PREVENTION?

- Rising rates of costly chronic conditions
 - -Chronic illness accounts for an estimated 84% of U.S. health care expenditures*
 - –Over the past 20 years, nearly half of inflation-adjusted rise in Medicare spending is due to 10 chronic conditions**

^{*}Chronic care: making the case for ongoing care: Feb 2010 update. Available from: www.rwjf.org/pr/product.jsp?id=50968

^{**} Thorpe KE, Ogden LL, Galactinoova K. Chronic conditions account for rise in Medicare spending from 1987 to 2006. Health Aff (Millwood). 2010; 29(4): 718-24.

MANAGING CHRONIC CONDITION COSTS

- To advance strategies for maintaining quality and containing costs associated with such conditions, the new framework advanced under PPACA aims to
 - Better manage existing illness
 - Prevent additional disease and disability

CMS INNOVATION CENTER

- Mission: better care and better health at reduced costs through improvement
 - Better health care: by <u>improving all aspects of patient care</u>, including Safety, Effectiveness, Patient-Centeredness, Timeliness, Efficiency, and Equity (the domains of quality in patient care as defined by the Institute of Medicine)
 - Better health: by <u>encouraging healthier lifestyles</u> in the entire population, including increased physical activity, better nutrition, avoidance of behavioral risks, and <u>wider use of preventative care</u>
 - Reduced costs: by <u>promoting preventative medicine</u>, better record keeping, and <u>improved coordination of health care services</u>, as well as by <u>reducing waste</u>, <u>inefficiency</u>, <u>and miscommunication</u>. These efforts will reduce the national cost of health care and lower out-ofpocket expenses for all Medicare, Medicaid, and CHIP beneficiaries

KEY ELEMENTS OF PAYMENT REFORM HERE TO STAY

- Transitioning From Fee For Service (FFS)
 Payment
- Building Integrated Care Delivery Models
- Promoting Prevention and Healthier Communities

THE NEED TO TRANSITION FROM FFS PAYMENTS

- •Permits and promotes fragmentation among providers (e.g., very small medical practices, "silos" of specialty care) often with lack of coordination and a duplication of services
- •Generally accepted that it is impossible to "bend the cost curve" when FFS payment model is dominant

COSTLIER CARE IS OFTEN WORSE CARE

Atul Gawande's New Yorker article, "The Cost Conundrum: What a Texas town can teach us about health care," compares healthcare costs (using 2006 Medicare data) in McAllen vs. El Paso, two Texas cities with similar demographics.

| Market | Medicare Spending per Enrollee | Utilization | Quality | | |
|---------|--------------------------------------|---|--|--|--|
| El Paso | ~ \$7,500 | See below | Hospitals on average performed better on 23 of 25 Medicare quality metrics (than McAllen average) | | |
| McAllen | ~ \$15,000 | Significantly higher per capita rates (than El Paso) of: specialist visits, diagnostic studies, surgeries, implantable devices, home health visits, etc. | Hospitals on average performed better on 2 of 25 quality metrics (than El Paso average) | | |

Source: *The Cost Conundrum*, The New Yorker, June 1, 2009; *Atul Gawande: The Cost Conundrum Redux;* The New Yorker; June 23, 2009

KEY TRANSITIONS FROM FFS MEASURES

- Hospital Readmission Penalties
- Bundled Payments
- Value-Based Purchasing

HOSPITAL READMISSION PENALTIES

- Effective October 1, 2012, Medicare will reduce payments to hospitals with high readmission rates.
- 1/5 of Medicare acute care hospital stays result in readmission within 30 days, and nearly a 1/3 result in readmission within 60 days
- Potential annual savings of \$15 billion by eliminating avoidable readmissions; potential \$188 billion Medicare savings from 2013 to 2019 by preventing avoidable readmissions within 30 days

POTENTIAL IMPACT TO HOSPITALS

- 18% of 30-day Readmissions:
 - Heart Attack
 - Heart Failure
 - Pneumonia
- Hospitals will likely face lower payments for such high-volume and high-cost conditions unless systemic measures are implemented to limit avoidable readmissions.

BUNDLED PAYMENTS

- "From a patient perspective, bundled payments make sense. You want your doctors to collaborate more closely with your physical therapist, your pharmacist and your family caregivers. But that sort of common sense practice is hard to achieve without a payment system that supports coordination over fragmentation and fosters the kinds of relationships we expect our health care providers to have."
 - Donald M. Berwick, M.D., M.P.P., Administrator for CMS

BUNDLED PAYMENT PROGRAM

- 4 Proposed Models
- Providers may elect which episodes of care and which services will be bundled together
- Providers will determine which bundled payment model works best for their organizational structure
- Permits providers of different sizes and readiness to participate in the bundled payment initiative

BUNDLED PAYMENT MODELS

- Retrospective Payment Bundling
 - Model 1 Inpatient Stay Only
 - Model 2 Inpatient Stay and Post-Acute Care Services
 - Minimum 30 days post discharge
 - Model 3 Post-Acute Care Services Only
 - Minimum 30 days post discharge
- Prospective Payment Bundling
 - Model 4 Inpatient Stay Only
 - Hospital would be responsible for distributing payment to other providers

VALUE-BASED PURCHASING ("VBP")

- Based on 42 quality measures data voluntarily submitted
- Begins for discharges on or after October 1, 2012
 - Must meet or exceed benchmarks for incentive
- Funded by 1% reduction to FY 2013 base operating DRG payments (will increase to 2% by 2017)

VALUE-BASED PURCHASING ("VBP")

- Analyzes 2 Areas of Performance:
 - Clinical Process of Care (17 measures)
 - Patient Experience of Care (8 HCAHPS dimensions)
- Provider receives 2 scores for each measure/dimension
 - Achievement
 - Improvement
- The higher of the 2 scores will be used for VBP

EXCLUSIONS FROM VBP INCENTIVES

- Hospitals subject to payment reductions under Hospital IQR
- Hospitals cited for deficiencies during the performance period that pose immediate jeopardy to the health or safety of patients
- Hospitals without the minimum number of cases or measures

SAMPLE VBP QUALITY MEASURES

- 30-day mortality rates
- Readmission rates for certain conditions
 - Heart failure
 - Pneumonia
 - Infections
- VBP quality measures are also addressed in bundled payment initiatives

INTEGRATED DELIVERY SYSTEMS

- Medicare Shared Savings Program
 - A program that develops a pathway for groups of health care providers to become an ACO
- Pioneer ACO Models

Dartmouth on ACOs

- In the accountable care organization (ACO) model, "... payers identify the primary care patients of a physician-hospital network that is willing to take responsibility for the full continuum of care. A spending target is set for these patients, and if the ACO meets quality benchmarks and reduces perbeneficiary spending below the target, providers receive a share of savings."
- This is referred to as accepting the performance risk (not financial risk) for the health status of patients.

ACO & Shared Savings Program – CMS ACO Rules

- CMS released proposed ACO regulations on March 31, 2011
- Proposed Rule published in April 7, 2011 Federal Register
- Final Rule published in November 2, 2011, Federal Register
- In a coordinated effort, ACO guidance was issued by FTC/DOJ, IRS and CMS/OIG
- The Congressional Budget Office estimates Medicare savings from ACOs of at least \$4.9 billion through 2019

Definition of an ACO

- Initially, combination of a hospital, primary care physicians, and specialists. Potential ACOs include:
 - Integrated Delivery Systems (IDSs)
 - Physician Hospital Organizations (PHOs)
 - Hospital plus multi-specialty groups
 - Hospital and independent practices
 - Ultimately, including other providers (e.g., home health, mental health, SNF, hospice)
 - Associated with a defined population of patients
 - Accountable for total Medicare spending and quality of care for that patient population

ALTERING PROVIDER LANDSCAPE DUE TO REFORM

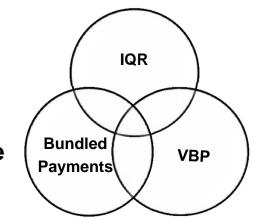
- •Unlike commercial payors, CMS is not permitted to establish narrow provider networks based on quality and efficiency or to vary benefit designs to encourage beneficiaries to see efficient providers
- Payment policy reform begins to address such issues
- •Payment reform encourages providers to collaborate care with affiliates that maintain sufficient measures to provide quality care with greater efficiencies and lower costs

AFFORDABLE INSURANCE EXCHANGE RULES

- •HHS issued final rule on March 12, 2012.
- •Final Rule published on March 27, 2012, Federal Register.
- •Establishes framework for states to establish their health insurance exchanges under Affordable Care Act.
- Exchanges will be operational starting in 2014.

What You Should Be Doing

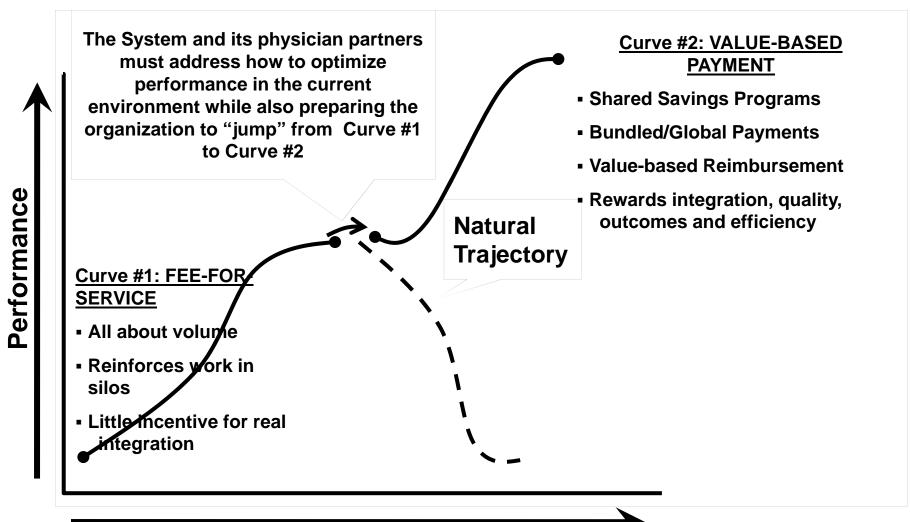
- Evaluate payment, organizational structures, and care models
 - Focus not only on the needs of patients, but payor incentives as well
- Evaluate measures to eliminate avoidable performance loss
 - Hospital readmissions, Never Events, and Hospital-acquired Conditions



- Evaluate governing board's current monitoring systems and processes
 - Quality oversight, accurate coding initiatives, medical necessity measures, and patient safety
- Evaluate operating policies and procedures related to payment reform measures
- Structure governing board direction and review for quality measures and actions

Physician Employment and Provider-Based Services: Ensuring a Compliant Relationship

IT IS UNCLEAR WHERE CMS AND THE COMMERCIAL PAYERS WILL ULTIMATELY LAND



Time

30

RANGE OF PHYSICIAN-HOSPITAL AFFILIATION MODELS

(with projected utilization for next 24-36 months a(with projected utilization for next 24-36 months and current developments)

| Model 1 | Model 2 | Model 3 | Model 4 | Model 5 | Model 6 | Model 7 | Model 8 | Model 9 |
|--|---|---|---|--|---|--|--|--|
| Traditional | Physician Recruitment | Medical Directors & Personal Service Agreements | Management Service Organization (MSO +) | Specialty Institute & Center of Excellence | Joint Managed Care Initiatives | Joint Ventures | Co- Management Agreement | Physician Employment, Foundation & PSA |
| Limited Growth | Limited Growth | Steady Growth | Steady Growth | Steady Growth | High Growth | Moderate to No Growth | Steady Growth | High Growth |
| Expanded bylaw membership requirements Closing of specialty departments. Medical Staff Leadership evaluation and development Use of IT initiatives (EMR, EDI, HIE) to increase alignment | Renewed physician needs assessments Revised service area definitions. New Community Needs assessment requirements Awareness of process importance | Evaluation of commercial reasonable-ness Increased performance accountability More specialty-specific, market-based compensation Expanded responsibilities for clinical integration | Increased support to employed model Expanded role to support other affiliation tactics New role to support care management and related clinical integration functions | Increased use for subspecialty integration Expanded multi-facility, multi-group participants Coordinated clinical, teaching and research missions Used as transitional model | Renewed use for risk models/ relationships Pursue FTC approved "Clinical Integration" Expanded payor-provider alignment (e.g., ACO pilots) Uncertainty of Health Information Exchange (HIE) | Increasing regulatory barriers Growing recognition of operational loversight complexities Physician concerns regarding risk and capital requirements Reduced attraction | Growing use of physicians as co-leaders healthcare Expanded clinical and business outcome responsibilities Perceived as regulatory tolerated Frequently included in service line specific models | Preferred model for newest residents/ fellows Increasing acceptance by all physicians Enhanced demand during market uncertainty Increased Hospital / System appreciation of support requirements More regulatory "friendly" |

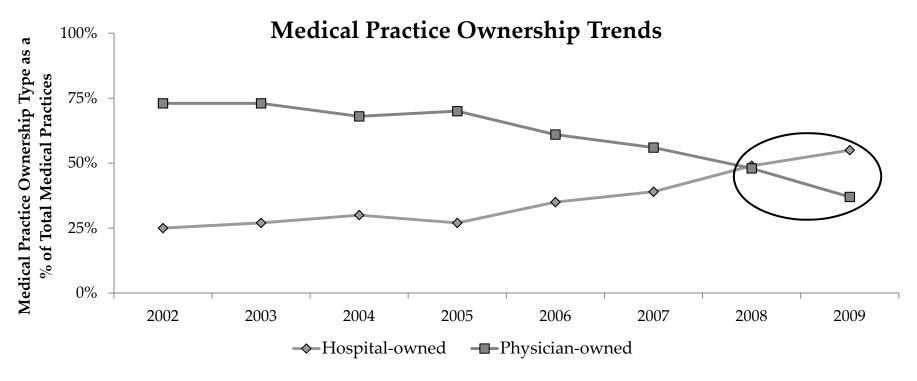
COMPLIANCE ISSUES

- Various Regulatory Issues
 - Fraud & Abuse
 - Stark Law
 - Civil Monetary Penalties
 - Exempt Organization Laws
 - Antitrust
 - Corporate Practice of Medicine
 - Physician Payment Sunshine Act
- Use of Consultants for Determining Fair Market Value

PHYSICIAN PRACTICE ACQUISITIONS

- Changes to reimbursement have increased interest in physician practice acquisition, particularly among cardiologists, orthopedists, oncologists, Gls and other specialists.
- Several models exist for acquiring physician practices that provide greater flexibility for both hospitals and physicians.

GENERAL TRENDS AFFECTING PHYSICIAN-HOSPITAL RELATIONSHIPS



- » In 2009, MGMA found that the share of hospital-owned practices reached 55% vs. 30% in 2004
- » Hospitals have been increasingly employing physicians, in part to position themselves to become a accountable care organizations
- » Physicians are increasingly seeking employment in order to "lock-in incomes" in a declining reimbursement environment, shifting this risk from their practices to the hospital

COMMON ISSUES IN PRACTICE ACQUISITIONS

- Managing expectations, with respect to control, purchase price and compensation.
 - Fair market value for tangible and intangible assets.
 - Fair market value compensation methodology.
 - Allow physicians day-to-day control of practice.
 - Sufficient reserved powers.
 - Term of employment agreement.
- Conducting thorough due diligence to identify potential pitfalls.
 - Be reasonable as process is likely new to physicians and staff.

COMMON ISSUES IN PRACTICE ACQUISITIONS (cont'd)

- Consider "provider-based" opportunities.
 - Potential Medicare and commercial reimbursement advantages.
 - Allows hospital to brand a seamless delivery of care.
 - Required reporting relationships need to be managed to avoid creating issues with physician practice leadership.
 - Must consider life and safety code requirements.
 - Impact of potential negative publicity associated with facility fees.

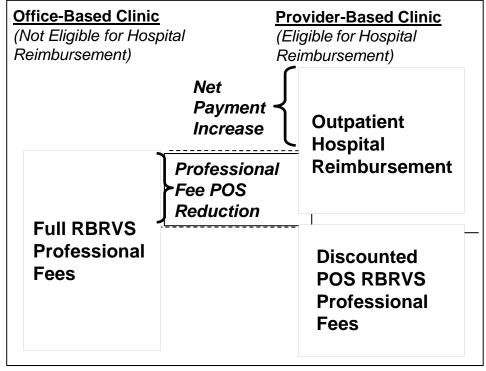
A PRACTICAL GUIDE TO PROVIDER-BASED SERVICES OVERVIEW

In conjunction with the change in physician/hospital alignment, many organizations are pursuing a transition of ancillary (and perhaps other) services to a provider-based billing model.

- There is typically a Medicare provider-based reimbursement advantage.
- The magnitude of this advantage has increased significantly in recent years for selected ancillary services (e.g., diagnostic cardiology).
- Models that call for the physician assets to transfer to the hospital are often accompanied by a transition in billing model.
- The magnitude of payment differential for commercial payors will vary.

Source: ECG

Reimbursement Opportunity of Provider-Based Clinics



NOTE: Not to scale.

OPERATIONAL AND REGULATORY CONSIDERATION CURRENT REQUIREMENTS: EXPLAINED

On- and Off-Campus Facilities

- Licensure The facility and the main provider must be operated under the same license. This
 requirement does not apply in those areas where the state requires a separate license for the
 provider and the facility or does not permit licensure of the provider and the facility under a
 single license.
- Clinical Integration The clinical services of the provider and the facility must evidence clinical integration through six factors:
 - Professional staff at the facility have clinical privileges at the provider.
 - Provider maintains same monitoring and oversight of the facility as it does for any other department.
 - Medical director for the facility maintains a reporting relationship with the CMO or other similar official at the provider that has the same frequency, intensity and accountability as any other medical director.
 - Medical staff committees of the provider are responsible for the medical activities of the facility.
 - Medical records for patients treated in the facility are integrated with those of the main provider.
 - Inpatient and outpatient services between the facility and the provider are integrated.

OPERATIONAL AND REGULATORY CONSIDERATION CURRENT REQUIREMENTS: EXPLAINED (cont'd)

On- and Off-Campus Facilities

- Public Awareness Patients must be aware that they are entering the provider's facility and will be billed accordingly.
- Financial Integration The financial operations of the facility are fully integrated within the financial system of the provider, as evidenced by:
 - Shared income and expenses.
 - Costs arising from the facility reported in appropriate cost center of provider.
 - Financial status of the facility incorporated and readily identified in the provider's trial balance.
- Location Generally, the facility is located on the provider's main campus or within a 35-mile radius of the campus of the hospital that is the potential main provider.

OPERATIONAL AND REGULATORY CONSIDERATION CURRENT REQUIREMENTS: EXPLAINED (cont'd)

Off-Campus Facilities Only

- Ownership and Control The facility seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by:
 - Business enterprise that constitutes the facility is owned 100% by the provider.
 - The facility and the provider have the same governing body.
 - The facility and the provider are operated under the same organizational documents.
 - The provider has final responsibility for administrative decisions, approval of contracts with outside parties, personnel decisions (e.g., hiring, firing, and employee benefits), and approval of medical staff appointments.
- Administration and Supervision The facility seeking provider-based status has a reporting relationship with the main provider that is equal in frequency, intensity, and accountability as other existing departments, as evidenced by:
 - The facility is operated under the provider's direct supervision.
 - The facility is operated under the same monitoring and oversight as any other department.
 - The facility and the provider have integrated billing services, records, human resources, payroll, employee benefits, salary structures, and purchasing services. The same employees handle these administrative functions for the facility and the provider, or either the provider contracts these functions out under the same agreement or, if contracted out separately, manages the contract for the facility.

OPERATIONAL AND REGULATORY CONSIDERATION CURRENT REQUIREMENTS: EXPLAINED (cont'd)

Special Arrangements

- Joint Ventures In order to obtain provider-based status, a facility operated as a joint venture must:
 - Be partially owned by at least one provider.
 - Be located on the main campus of a provider who is a partial owner.
 - Be provider-based to the one provider on whose campus the facility is located.
 - Meet all other requirements applicable to provider-based facilities.
- **Management Agreements** A facility that is not located on the provider's campus and is operated pursuant to a management agreement must also encompass the following:
 - Main provider must employ the staff of the facility who are directly involved in the delivery of patient care (except for management and staff who furnish patient care that would be paid under a Medicare fee schedule established under 42 CFR, Part 414).
 - Administrative functions of the facility are integrated with those of the provider.
 - Provider has significant control over the operations of the facility.
 - Provider itself holds the management contract.

COMMUNITY HEALTH NEEDS ASSESSMENTS

- Four new requirements for nonprofit hospitals to obtain and maintain 501(c)(3) status
 - Community Health Needs Assessment
 - Financial Assistance Policy
 - Free and discounted care generally
 - Emergency care
 - Limitation on Charges
 - Billing and Collection Practices
- Generally effective for tax years beginning after March 23, 2010
 - Hospitals have three years to complete their first community health needs assessment (12/31/13 for CY taxpayers, 6/30/13 for FY June 30 taxpayers)

- Applies to all "hospital organizations"
 - Operates a facility recognized as a hospital under state law
 - Open question is it a separate "hospital facility" if not separately licensed for state law purposes?
 - Any other organization determined by the Treasury Secretary to have hospital care as principal exempt function or purpose
 - If more than one hospital facility, must meet the requirements separately as to each hospital facility, whether or not incorporated
 - Not treated as described in IRC 501(c)(3) for each hospital facility that fails to satisfy the requirements

- Community health needs assessment
 - Must be conducted once every three years for community served by each facility
 - Including community input and public health expertise
 - Community Input: from persons who represent the broad interests of the community served by the facility
 - Public Health Input: including those with special knowledge of or expertise in public health, and
 - Must make the results "widely available"
 - Copies at business office, each hospital facility?
 - Posted on the hospital's website?

- Community health needs assessment (Cont'd)
 - Adopt an implementation strategy
 - Note that prioritizing the needs identified depending on costs, available resources, efforts of others may be relevant in explaining why some identified needs were not addressed
 - Form 990 must include a description of how the nonprofit hospital is addressing the needs identified
 - If some of those needs are not being addressed, an explanation as to why not
 - Also must attach audited financial statements
 - \$50,000 excise tax for failure to comply (IRC 4959); incomplete or inaccurate return

- Review of community benefit activities of nonprofit hospitals by IRS once every 3 years
- Annual reports (and 5-year trend study due 4/22/15) from Treasury (in consultation to HHS) to Congress on charity care, bad debt and cost shortfalls from public programs for (c)(3), governmental and proprietary hospitals
 - Reduced ranks of the uninsured may lead to pressure for Congress or IRS to set bright line expenditure minimums for (c)(3) status
- May overlap with state law requirements

OTHER HOSPITAL REPORTING REQUIREMENTS

- Various State Reporting Requirements
 - Require reporting on activities, resource allocation; no concept of prioritization or evidence-based standards
 - May be included in:
 - CON/licensure standards where applicable
 - Community Benefit Reporting
 - Property Tax Exemption
 - State version of Schedule H (Oregon)

OTHER HOSPITAL REPORTING REQUIREMENTS

- FASB changes for 2011 would require accounting for charity care based on cost (direct and indirect), regardless of charges, prevailing rates, revenues
 - What effect will this have on tracking community benefit?
- Official Statement; secondary market disclosures
- The occasional Congressional inquiry ...

GETTING STARTED ON A CHNA

- Identify relevant community served
- Develop process for seeking community input
- Consider avenues for possible public health input
 - Hospital Planning Staff
 - State and Local Health Departments
 - Centers for Disease Control
 - Consultants
- Design the assessment tool with a view toward:
 - Range of services available from the hospital
 - Reasonable budget for implementation
 - Facilitating Schedule H reporting
- Remember the CHNA is an ongoing process

PUTTING IT IN CONTEXT ... THE FOUR PHASES OF CHNAS

- Community health needs assessment is a cyclical, iterative and evolving process
- Preserve flexibility for local circumstances and institutional resources ... not one size fits all
- Important in terms of
- Opportunity to improve health of community, contain costs
- Part of general push toward quality-based payment
- Compliance and avoiding federal tax penalties and perhaps state penalties or more onerous future requirements
- Four phases, each affecting the others
- Phase One: Design
- Phase Two: Conducting the Assessment
- Phase Three: Developing an Implementation Strategy
- Phase Four: Implementation and Reporting

- Phase One Design
 - Assemble internal team; consider whether/when to retain consultant to assist
 - Identify community served (self-defined, nondiscriminatory)
 - Initial list of potential need areas ... a starting point
 - From most recent CHNA or community benefit report
 - Include additional strategic initiatives not identified in prior CHNA or community benefit report
 - Identify existing sources of appropriate data (e.g., local public health agencies, associations, consultants)
 - Develop process for seeking public input and prioritizing needs
 - Design the assessment tool(s) with a view toward a reasonable budget for implementation
 - Clearly communicate intent is to prioritize based on level of need and available resources
 - Board oversight of process a flexible standard

- Phase Two Conducting the Assessment
 - Factor in community demographics and previously identified needs from existing databases; consider hospital's particular services and capabilities
 - Develop approach for obtaining public health input from other sources identified in Phase One, which may include:
 - Hospital Planning Staff, Medical Staff
 - Trade Associations
 - State and Local Health Departments
 - Centers for Disease Control, World Health Organization
 - Other (e.g., community foundations, consumer groups)
 - Determine whether it is necessary to conduct surveys, focus groups or interviews of Stakeholders (patients/family, uninsured, public health officials, educators)
 - Determine whether to retain consulting/survey firm to conduct CHNA and/or interpret results
 - Refine questions as necessary for future CHNAs

- Phase Three Developing an Implementation Strategy
 - Review results of CHNA and prioritize needs for the community served by the hospital facility
 - Rank degree of need in absolute terms
 - Determine which priority needs match hospital's strengths
 - Identify resources available to the hospital organization for addressing community needs; develop proposal for budget approval process
 - Determine other organizations or government agencies that also may be addressing certain priority needs (review CHNAs, community benefit reports, certificate of need filings, agency budgets/strategic plans)
 - Reassess composition of the implementation team

- Phase Four Implementation and Reporting
 - Assign responsibility for carrying out community need items from approved budget
 - Monitor progress on implementation
 - Publicize results (website, annual report, copies at each facility or business office)
 - Report implementation on Form 990
 - Describe basis for prioritizing community needs (assuming the hospital organization is not in a position to address all identified needs on its own)
 - Explain, attach copies of implementation strategy (becomes a public document, e.g., Guidestar, so do not include information that is proprietary and confidential)

ROLES OF STAKEHOLDERS

- IRC 501(r)(3) requires that the CHNA process include <u>input</u> from:
 - People representing broad interests of <u>the community served</u>
 by the hospital facility, including people with special knowledge or expertise in public health
- Webster's defines input as "advice, opinion, comment"
- Compare "market survey" concept for strategic planning ...
 hospitals may already be obtaining significant community input
- Notice 2011-52 would prescribe three specific categories as the minimum sources of public input related to the community served:
 - Special knowledge or expertise in public health (not defined)
 - Federal, tribal, regional, state or local agencies
 - Leaders, representatives or members of underserved, minority and chronic disease populations

ROLES OF STAKEHOLDERS

- There are many variables to be considered by hospital boards and management as they define "community served":
 - Distribution of discharges and outpatient visits (zip codes)
 - Underserved, disadvantaged or minority populations
 - Community Hospitals (density of hospitals and other providers in the area, range of services/acuity)
 - Academic Medical Center/Teaching & Research Hospitals
 - Specialty Hospitals and Centers of Excellence
 - Critical Access Hospitals
 - Religious Hospitals
- Notice 2011-52 notes flexibility, assumes primarily geographic
- May be local, regional or national; may not coincide with a state health planning area or strategic planning "market"

ROLES OF STAKEHOLDERS

- Hospital boards and management will have several key task areas to address in conducting and operationalizing a CHNA, including:
 - Defining the community served
 - Designing survey, focus group and interview questions
 - Managing the process
 - Collating and interpreting the results
 - Prioritizing needs to be addressed
 - Developing work plan for implementation of strategies, programs and activities to address the community needs
- Public health agencies may have experience to share from their own accreditation processes.

PRIVACY/HIPAA

ENFORCEMENT

- OCR Ramp Up
 - New Director
 - Audits
 - Mass Gen; Cignet
- States' Attorneys General
 - State Law
 - Return on Investment



STATUS OF HIPAA REGULATIONS

- Interim Final Regulations
- Waiting for the Final, Final Regulations
- "Accounting of Disclosures" Regulations



Meaningful Use The Stages to Come

Meaningful Use

- HITECH provisions of the American Recovery and Reinvestment Act of 2009 authorized CMS to pay incentives to providers to promote the adoption and use of electronic health record ("EHR") systems.
- To qualify for incentive payments, providers were required to demonstrate "meaningful use" ("MU") of the technology.
- CMS and the Office of National Coordinator for Health Information Technology ("ONC") of DHHS responsible for drafting and implementing the MU regulations.

Meaningful Use Stages

- Stage 1
 - Final Rule published July 2010
 - Focus on implementing EHR
- Stage 2
 - Proposed Rule published March 2012
 - 77 Fed. Reg. 13698
- Stage 3
 - Expected to be implemented in 2015

Meaningful Use Stages

- Stage 1
 - Focus on establishing EHR
- Stage 2 Proposed Rule
 - Focus in two primary areas
 - Improved structure for capturing health information
 - Increasing the exchange of information between providers

- Delay implementation of Stage 2 criteria
 - If attested in 2011, must implement Stage 2 in 2014 and Stage 3 in 2016
 - All others, required to demonstrate 2 years at each MU Stage
- To avoid penalties in 2015, hospitals and eligible providers ("EPs") must:
 - Attest to MU in 2012, or
 - Attested to 1st year of MU by July 1, 2014
 - (Oct. 1, 2014 for EPs)

- Generally, establishes Stage 1 optional items as required core items in Stage 2
- New Requirements for:
 - Computerized prescription order entry ("CPOE") threshold includes labs and radiology orders
 - CPOE measure based on percentage of all orders (departure from measurement based on 1 order per patient)
 - Patients must have the ability to view, download and transmit health information
 - Public health reporting to cancer and other specialized monitoring registries

- Required Measures
 - Introduction of new requirements
 - Increased thresholds for Stage 2 minimums
 - Hospitals must report:
 - 16 core objectives
 - 2 of 4 optional objectives
 - EPs must report
 - 17 core objectives
 - 3 of 5 optional objectives

- Clinical Quality Measures are distinct MU category
 - Still not finalized, but must be electronically transmitted in 2014 (not tied to particular Stage)
- Required Clinical Quality Measures
 - EPs: 12 Measures
 - Some required, some selected from potential list of measures
 - Hospitals: 24 Measures
 - 50 possible Measures are proposed
 - At least 1 from each Quality Domain

Meaningful Use Impact & Issues for Industry

- Significant impact on vendors to adjust to requirement modifications
- New systems will need to be installed to base designs for many of the requirements
- Most providers will need major EHR upgrades
- Continued improvements by ONC for the nationwide health information network (NwHIN) Exchange:
 - Support functions like patient discovery and query for and retrieve documents
 - Connect 3.3
- Stage 2 Proposed Rule
 - Focus in two primary areas
 - Improved structure for capturing health information
 - Increasing the exchange of information between providers



SOCIAL MEDIA



- Exploding means of communication
- Not all uses are bad or problematic
- Better, faster method for widespread distribution of information (and breaches)
- Attention as an area of vulnerability
- Still basic compliance....







Thank you. Questions?

Kevin Lyles, Esq. Partner, Jones Day kdlyles@jonesday.com (614) 281-3821

Diane Meyer
Chief Compliance and Privacy Officer
Stanford University Medical Center
DMeyer@stanfordmed.org
(650) 724-2572

Frank E. Sheeder, Esq.
Partner, DLA Piper
frank.sheeder@dlapiper.com
(214) 743-4560

Additional Media: www.thecomplianceblog.com www.healthcarelawmatters.com Twitter:@hclawyer



