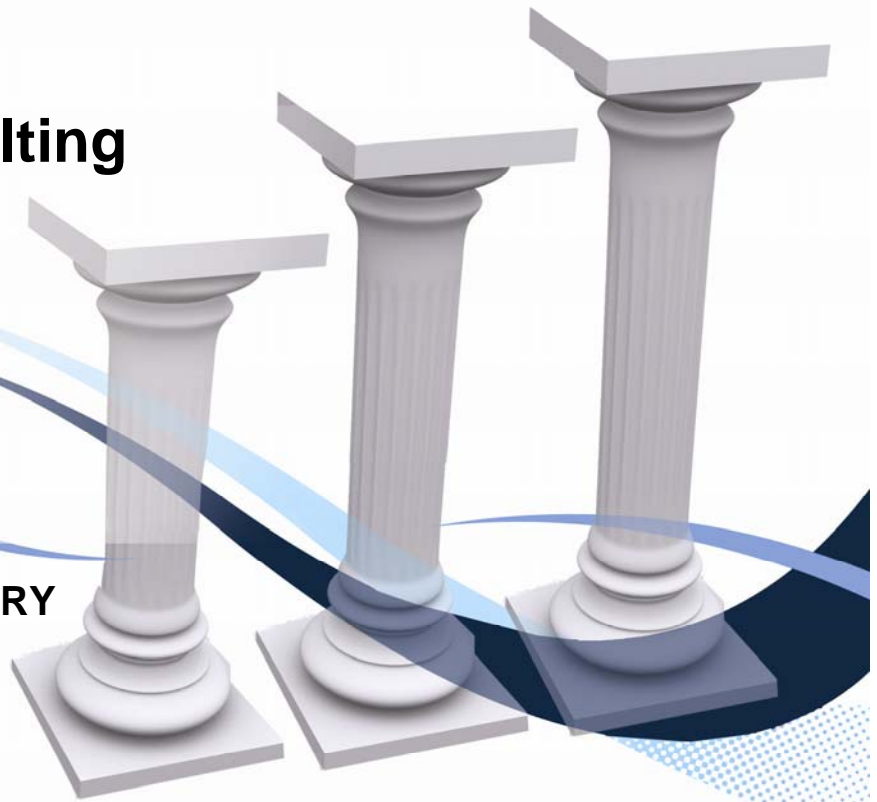


# Public Consulting Group, Inc.

## HITECH REGULATORY CROSSROADS

June 16, 2010



PCG | Public Focus. Proven Results.™

## Introduction

**Jan Paterson, Esq., PMP**

- Health law attorney with Medicaid and Medicare program planning subject matter expertise.
- State HIE Strategic and Operational Planning experience
- State Medicaid Health Information Technology Planning experience
- Worked with state government organizations to plan, implement and operate complex Medicaid systems
- Responsible for Medicaid program and policy planning and implementation
- Extensive legal and professional organization management and planning experience.
- Provided support for Medicaid Management Information Systems, Decision Support and Data Warehouse procurements.

## Agenda

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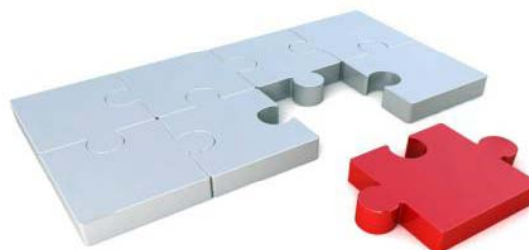
- ✓ **Review and overview of status of new Federal regulations relating to health information exchange and the Health Information Technology for Economic and Clinical Health Act (HITECH)**
- ✓ **Discuss the intersections between each of the regulations with each other and other Federal regulatory schemes**
- ✓ **Review “caution points”**
- ✓ **Have some fun with the analogy to the “Wheel of Fortune”**



## Regulatory Overview – By Agency

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- **Primary Federal Agency Regulations**
  - Centers for Medicare and Medicaid Services (CMS)
  - Office of the National Coordinator (ONC)
  - Office for Civil Rights (OCR)
- **Secondary Federal Agency Regulations**
  - SAMHSA
  - AHRQ
  - Other – DEA,
- **Impact of State Regulations**



## The Intersection of Regulatory Scheme

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Page 5

## CMS Meaningful Use

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Page 6

# CMS – Meaningful Use - NPRM

- Medicare payment incentives for those “eligible providers” that become “meaningful users” of “certified” EHR technology
- Medicaid payment incentives for those “eligible providers” that adopt, implement or upgrade EHRs in the first year of eligibility and become “meaningful users” of EHRs in their second year and beyond.
- Defines “meaningful use”
  - Stage 1
  - Stage 2
  - Stage 3
- Defines “eligible provider” Provides formulas for definition of % Medicaid patients

# CMS Meaningful Use NPRM Cont.

Medicare vs Medicaid in ARRA		
Details From CMS Draft Rule	Medicare	Medicaid
Implementation Requirement	– Feds will implement – Option nationally	– Voluntary for States to implement – May not be an option in every State
Fee Reductions for not Meaningful users	2015	No Medicaid fee schedule reductions
Meaningful Use Requirements	1 year except payment year <b>ONE</b> only will be 90 consecutive days	Adopt/Implement/ Upgrade option for 1st participation year
Maximum Incentive for Eligible Professionals	\$44,000	\$63,750
Last Year to Initiate Program (EP)	2014	2016
Last Payment in Program	2016	2021
Payment Adjustments (Penalties) Start	2015	No Medicaid fee schedule reductions
Professionals Eligible for Incentives	Only physicians as defined in Social Security Act Doctor of Medicine (MD) Doctor of Osteopathy (DO) Doctor of Podiatric Medicine (DPM) Doctor of Chiropractic (DC) Doctor of Optometry (OD) Doctor of Dental Surgery (DDS)	5 types of Eligible Professionals (1) A physician (2) A dentist (3) A certified nurse-midwife (4) A nurse practitioner (5) A physician assistant practicing in a Federally Qualified Health Center or Rural Health Clinic, which is so led by a physician assistant
Hospitals Eligible for Incentives	Subsection (d) hospitals (hospitals that are part of the Inpatient Prospective Payment System) and Critical Access Hospitals	3 types of hospitals – Acute Care, Children's, Cancer Hospitals

## CMS Meaningful Use Intersections

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- HIPAA – OCR
- Standards and Certification Interim  
Final rule – ONC
- Establishment of Certification Programs  
NPRM ONC-



## OCR – HIPAA – Original Rules

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### Health Insurance Portability and Accountability Act

- Title I – Protected health insurance for those who lost or changed jobs
- Title II
  - Administrative Simplification
    - Privacy Rule
    - Transaction and Code Sets
    - Security Rule
    - Unique Identifier Rule
    - Enforcement Rule



## OCR HITECH HIPAA Privacy

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- February 2010 – new rules and more enforcement
  - Breach notification
  - Expanded power of rules to cover “Business Associates”
  - Expanded privacy and security requirements
  - Added more enforcement penalties



## OCR HIPAA Breach Notification

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- Enforcement beginning February, 2010
- Covered Entities to notify individuals whose “unsecured PHI” has been or is reasonably likely to have been accessed, acquired or disclosed as the result of a breach.

**\*\*\*\* unlike many State laws this breach applies to PAPER or EHR\*\*\*\***

- Limited certain uses and disclosures of protected health information (PHI)
- Increased individual rights relating to PHI maintained in EHRs
- Increased enforcement and penalties for HIPAA violations

## HITECH – Business Associates

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- **Changed enforcement of the Privacy Rule from CMS to OCR –**
- **Extended Privacy and Security Rule to Business Associates of Covered Entities**
  - **Security Rule – administrative, technical and physical safeguards**
  - **Privacy Rule – disclose Protected Health Information consistent with the requirements of 45 CFR 164**
  - **Subject to the new and enhanced penalties**
  - **Patients have to be able to access their info in the electronic health record**
  - **Providers have to account for disclosures in the EHR**

**\*\*\* Intersection with the CMS Meaningful Use Rule \*\*\*\***

## OCR HITECH HIPAA Privacy

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- **The OCR and ONC have developed a “Privacy and Security Framework and Toolkit” for exchange of individually identifiable information**

**“Provides a consistent approach to address privacy and security challenges related to electronic health information exchange through a network for all persons – regardless of the legal framework that may apply to an organization.”**

**<http://www.hhs.gov/healthit/privacy/framework.html>**

## HIPAA OCR Intersections

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- **Similar breach notification provisions have been implemented by the Federal Trade Commission (FTC)**
- **Patient Safety and Quality Improvement Act of 2005 and the rules promulgated**
- **HRSA – Ryan White Comprehensive AIDS Resources Emergency (CARE) Act**
- **SAMHSA - - Substance Abuse Treatment Program Information**
- **CMS – Enforces the Administrative Simplification Standards that don't relate to health information privacy**



## ONC – Standards Rule – Interim Final

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- **Applicability – Eligible professionals and eligible hospitals. Plus any health care provider who wants to use certified EHR technology for quality, safety and efficiency improvements**
- **Definitions**
- **Initial set of standards – Directly support CMS proposed meaningful use Stage 1 objectives**
- **Implementation Specifications**
- **Certification Criteria - focused on meaningful use**
- **“Incremental Approach”**



## ONC – Standards Rule

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- **Initial Sets:**
  - Standards
  - Implementation specifications
  - Certification criteria
- **Final rule – “sometime in 2010**
- **Companion rule to CMS Meaningful Use**
- **Supports Stage 1 MU criteria**
- **Rely on existing standards for interoperability**
  - HL7
  - NIST
  - IHE
- **Rely on existing classification and nomenclature**
  - SNOMED
  - CT
  - ICD-9 and 10
  - LOINC
  - NCPDP
  - RxNORM



## ONC Standards Rule Intersections

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- **CMS MU – Payment of Medicaid and Medicare incentives**
- **Establishment of Certification Programs NPRM ONC-**
- **HIPAA – Privacy, Security and Transactions and Code Sets**
- **Medicare Part D Voluntary Prescription Action of 2003 – eprescribing standards**
- **DEA – eprescribing for controlled substances –**



## ONC – Certification Program Rule

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- **One NPRM Two final rules**
  - **Temporary Certification Program**
    - **Operational for MU Stage 1**
    - **Final rule due at the same time as the final rule for the MU and Standards and Certification criteria rule**
  - **Permanent Certification Program**
  - **Operational for MU Stage 2 and beyond**
  - **Anticipated final rule “early fall”**



## ONC – Certification Program Rule Intersections

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- **ONC Standards Rule**
- **CMS MU Rule**



# Importance of the Rules and their Intersections

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Page 21

## Questions

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Page 22