Regulatory Changes and Implications to the Health Care Industry

February 13, 2013
Outline

1. Health Care Industry Overview
2. Regulatory Landscape
3. Health Reform and the PPACA
4. State Health Insurance Exchanges (HIX)
5. Health Information Exchanges (HIE)
6. ICD-10
7. Electronic Health Records and Meaningful Use
8. HIPAA and Patient Data Security
1. Health Care Industry Overview
Health Care Industry Overview

- The U.S. spends more than any other country on health care (>\$2 trillion annually) with expenditure forecast to grow 4% annually.

- In March 2010, the U.S. enacted the Patient Protection and Affordable Care Act (PPACA) to reform health care by expanding access to quality care at lower costs. PPACA expands insurance coverage by add more than 30 million patients to the health care system.

- The private sector dominates the supply of health care products and services in the U.S. The government plays a regulator and payer role.

- In 2009, of the entire US population of 294 million, 14% were covered by Medicare, 18% were covered by Medicaid, while private insurance covered 56 million (53%). The remaining 44 million (15%) were uninsured.

- Despite top-line growth, both providers and health plans are challenged with maintaining profitability and implementing PPACA and other regulatory requirements. PPACA presents new care delivery, reimbursement and distribution models, with significant impacts to both sectors. Both will need to make investments in core administration, technology (electronic health records, ICD-10), alignment, compliance and pay for quality initiatives. Further consolidation, cost cutting, and diversification initiatives are also underway.

Source: The Economist Intelligence Unit, Factiva, analyst reports, Kaiser Foundation, Thomson M&A
Demographics: Aging Population and Growing Disease Burden Drive Health Care Spending

- U.S. health care spending is projected to grow more than 4 percent annually through 2014.
  - **Aging population**: Seniors are estimated to account for 14 percent of the country’s total population in 2014, up from 13 percent in 2009, according to the Economist Intelligence Unit.
  - **Disease burden**: According to a 2010 report by the Robert Wood Johnson Foundation, the number of U.S. patients suffering from chronic diseases will increase 7 percent to 157 million in 2020, from 147 million in 2010.

Source: The Economist Intelligence Unit, World Health Organization, Forbes, Robert Wood Johnson Foundation
Providers: U.S. Hospital Market Highly Fragmented

- The U.S. hospital industry is a localized industry consisting of almost 6,000 hospitals. The top five players account for less than 15 percent of revenue. The majority of hospitals are not-for-profit.

- IBIS World projects the $757 billion industry will grow 4.9 percent annually between 2011 and 2016, driven by a growing senior population and insured customer base. CMS projects the PPACA individual mandate will expand insurance coverage to 32 million additional patients by 2014. However, shrinking reimbursement and increased capital requirements may limit profits.
Providers: New Reform Models Encourage Integrated Delivery and Tie Payment to Quality and Outcomes

• Health reform legislation through the HITECH Act and PPACA is shifting the health care provider business model away from volume-based incentives to quality incentives in order to reduce costs while improving outcomes. Analysts project that reform initiatives, including value-based purchasing, medical home, accountable care organization (ACO) and bundled payment pilots, will increase:
  – Linkages between performance (outcomes, costs) and payments/incentives.
  – Integration of physicians, hospitals and long term care providers.
  – Access to health services by under-served populations.
  – Alignment of coverage with evidence.

• ACOs and other similar models are generating interest among providers. An ACO is a “local health care organization that is accountable for 100 percent of the expenditures and care of a defined population of patients.” To qualify as an ACO, an entity must ensure “adequate” participation of primary care physicians and “work together to provide evidence-based care in a coordinated manner.” CMS released additional ACO guidelines in April 2011, which could lead to challenges in implementing the ACO against proposed reimbursement.

Payers: Mature Sector with Government and Private Players; Focused on Meeting Health Reform Requirements

Insurance Coverage by Type of Payer (2009)

<table>
<thead>
<tr>
<th>Type of Payer</th>
<th>Percentage of Total U.S. Population</th>
<th>Employer: 55%</th>
<th>Individual: 8.9%</th>
<th>Medicaid: 15.7%</th>
<th>Medicare: 14.3%</th>
<th>Military Health: 4.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private</td>
<td>63.9%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>30.6%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government and Private (Combo)</td>
<td>11.2%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>16.7%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: There are overlaps among population pools covered under the various segments.
Source: U.S. Census Bureau

Top Private Payers (January 2011)

<table>
<thead>
<tr>
<th>Company</th>
<th>Market Share by Revenue 2010</th>
<th>Membership (Millions) on March 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>UnitedHealth Group</td>
<td>14.9%</td>
<td>34.0</td>
</tr>
<tr>
<td>Wellpoint</td>
<td>8.6%</td>
<td>34.2</td>
</tr>
<tr>
<td>Aetna</td>
<td>5.1%</td>
<td>17.8</td>
</tr>
<tr>
<td>Humana</td>
<td>5.3%</td>
<td>10.9</td>
</tr>
<tr>
<td>CIGNA</td>
<td>~2.2%</td>
<td>11.4</td>
</tr>
</tbody>
</table>

Source: IBIS World (May 2011), Membership from Regulatory Filings (10Qs)

• According to IBIS World, the $677 billion U.S. health and medical insurance industry could grow 5 percent annually through 2016.

• Health care reform provides the payer sector with opportunities and challenges. PPACA includes reform initiatives that will increase the number of insured lives, but possibly limit profitability. New delivery, distribution, and payment models outlined in PPACA may lead to greater innovation and change among payers.

• The weakened U.S. economy is negatively impacting insurers. States are decreasing Medicaid reimbursement levels due to budget shortfalls, while the federal government is seeking to curtail Medicare spending levels. Commercial payers are reporting declining fully insured membership and lower employer spending on benefits.

Payers: Near-Term Focus on Cost-Cutting, Consolidation, and Diversification to Align with Reform

- PPACA payment, delivery, and operating requirements may enable innovation, offering plans opportunities to find new ways to distinguish themselves.
  - **New models of care delivery and payment:** New models of care delivery (patient-centered medical home, ACOs) and payment (bundled payment, shared savings) will change reimbursement methodology and relationships with providers.
  - **New distribution and marketing platforms:** State-based exchanges will be the primary distribution channel for the newly insured and over time will assume a greater role in the employer market, becoming the dominant channel to market products.
  - **New products:** Actuarially equivalent plans will give way over time, to standard benefit packages that can more easily be compared on the basis of price and quality. Add-on products will become an important source of differentiation.*
  - **Investment in Information technology:** PPACA requires health plans to achieve uniform standards for electronic transactions by 2013. ICD-10 compliance is also mandated.

* Source: Deloitte’s Dbrief “Health Reform: Smart First Steps for Health Care Organizations”, April 2010
2. Regulatory Landscape
Regulatory Landscape: Extensive Regulatory Structure

**Federal**

- **Department of Health and Human Services (HHS)**
  Federal entity for making and implementing U.S. health policy. Coordinates 11 operating divisions engaged in tasks including research, public health, food and drug safety, grants and other funding, and health insurance.

  - **Centers for Medicare & Medicaid Services (CMS)**
    Regulates payers and providers. Administers Medicare, works with states to administer Medicaid and State Children’s Health Insurance Program (SCHIP).

  - **Food and Drug Administration (FDA)**
    Regulates drugs and devices, including their manufacturing, marketing, and use.
    - **Center for Drug Evaluation and Research**: Regulates over-the-counter and prescription drugs and consumer health products. Includes the Division of Drug Marketing, Advertising, and Communications (DDMAC) to regulate drug promotions.
    - **Center for Biologics Evaluation and Research**: Regulates biologic therapies including blood products and vaccines.
    - **Center for Devices and Radiological Health**: Regulates medical devices, and radiation-emitting electronic medical and non-medical products such as X-ray machines and microwave ovens.
    - **Other**: Includes centers for regulating veterinary medicine, food and nutrition, and tobacco products.

**State**

In addition to the above federal entities, there is a department for health in each state. These departments are responsible for policies, regulations, and programs ensuring the health of the state’s residents.

*Source: Government websites*
Regulatory Landscape: Reform Aims to Enhance Health Care Access and Quality at Lower Costs; Impacting Companies Across Sectors

Overview of Major Recent Regulations

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description:</strong> Enacted in March 2010; seeks to ensure health insurance coverage for most Americans and improve health care quality in the U.S. It also intends to control health care costs in the country.</td>
<td><strong>Description:</strong> Drives the adoption of electronic health records, health information exchanges, and other health IT, to improve clinical outcomes.</td>
<td><strong>Description:</strong> In January 2009, DHHS ruled that that all health care entities using ICD-9 diagnosis and procedure codes must migrate to ICD-10 by October 1, 2013. The migration is aimed to improve health care quality and efficiency by accelerating health IT adoption.</td>
</tr>
<tr>
<td><strong>Implications:</strong></td>
<td><strong>Implications:</strong> Investments and process changes to adopt technology could drive up payer and provider costs in the near term.</td>
<td><strong>Implications:</strong> Payer and provider costs and operations are the most affected, as they transform their systems and processes to migrate to ICD-10.</td>
</tr>
<tr>
<td>– Expansion of insurance coverage will potentially add new customers and boost revenue for drug and device makers, health plans, and providers.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– However, margins for health care companies could be adversely affected by several provisions, especially those controlling health care costs. PPACA provisions likely to lower company profitability include reimbursement cuts, drug rebates, taxes, and fees.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Deloitte website, Kaiser Family Foundation website
Patient Protection and Affordable Care Act (March 2010)

**Coverage and Insurance Market Reforms**
- Accessible and affordable coverage for all individuals
- Medicaid expansions, individual and employer tax credits, health insurance exchanges
- Premium reviews, guaranteed issue, elimination of lifetime limits and pre-existing condition exclusions

**Payment and Delivery System Reforms**
- Promoting quality instead of volume of care
- Comparative effectiveness research
- Accountable care organizations, medical homes, value-based purchasing, payment bundling

**Financing Strategies**
- Sustainable funding to pay for reform provisions
- Taxes and fees on industry and certain individuals

<table>
<thead>
<tr>
<th>Number of Newly Insured</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>32 million/10 years</td>
<td>$938 billion/10 years</td>
</tr>
</tbody>
</table>
Legislation: changes intended in PPACA, HITECH

Goals: integrated delivery, performance based payments, risk-pool redistribution

**Delivery system changes**

- Increased linkage between performance (outcomes, costs) and payments/incentives
- Increase integration of physicians, hospitals and long term care providers
- Increased access to health services by under-served populations
- Increased alignment of coverage with evidence

**Insurance system changes**

- Elimination of pre-existing condition, lifetime and annual limits for insurance plans
- Required coverage of preventive health services without co-payments
- Creation of health insurance exchanges in each state to facilitate access to affordable insurance and manage subsidized purchases by individuals and employers
- Federal-state regulation of insurance plan coverage, premiums, and medical expenditures

---

**Consumerism**

Preventive health, individual insurance, personal health records

**Primary Care 2.0**

Home monitoring, retail medicine, (long-term care) LTC, medical homes, scope of practice expansion, health coaching

**Comparative Effectiveness/EBM**

Personalized medicine, bundled payments, provider adherence/performance-based payments liability reforms

**Health Information Technology**

EHR (HiTech), health information exchanges, fraud detection administrative simplification, clinical data warehousing, ICD-10, direct to consumer e-medicine
Implementation timeline

*Its implementation will span five election cycles and occur simultaneous with efforts to reduce the federal deficit, restore economic growth, and reduce unemployment.*

**Economic recovery, Clinical Innovation, Demand**

<table>
<thead>
<tr>
<th>2010 - 2013</th>
<th>2014 - 2016</th>
<th>2017 +</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rules, Regulations &amp; New Funding</td>
<td>Mandates, Pilots &amp; Exchanges</td>
<td>“New Normal”</td>
</tr>
<tr>
<td>Insurance compliance: MLR, premiums, coverage</td>
<td>Individual mandate</td>
<td>Physician-hospital alignment</td>
</tr>
<tr>
<td>Coordination: state-federal governments, agencies</td>
<td>Health exchanges</td>
<td>Industry convergence</td>
</tr>
<tr>
<td>Rules, guidelines, task forces, agencies</td>
<td>Employer pay or play</td>
<td>Convergence: Public health &amp; delivery system</td>
</tr>
<tr>
<td>Excise taxes—insurance, medical devices, drug companies</td>
<td>Demonstration/pilot programs:</td>
<td>Volume to value</td>
</tr>
<tr>
<td></td>
<td>• Accountable care organizations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Value-based purchasing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Episode based payments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Medical home</td>
<td></td>
</tr>
</tbody>
</table>

ICD-10, Electronic Medical Record, Comparative Effectiveness implementation
Legislation: the "five big bets" in PPACA

• **Individual mandate:** Will the uninsured and newly eligible for Medicaid enroll? Will the insured increase by 32 million as targeted?

• **Employer exit:** Will employers drop health benefits after 2016 to facilitate direct consumer engagement and their reduce operating costs? Will their employees purchase through the exchanges, or go without?

• **State capabilities:** Will states be able to manage their expansion new responsibilities and obligations? Can states manage population-based health (Medicaid, CHIP, workers comp) & insurance risk effectively?

• **Delivery system costs:** Will delivery system reforms -accountable care organizations, value-based purchasing, medical homes, bundled payments, comparative effectiveness-- reduce costs over time?

• **Quality:** Are Americans ready for limits based on cost and comparative effectiveness?
### Legislation: key themes in “new normal”

<table>
<thead>
<tr>
<th>Focus</th>
<th>Old theme</th>
<th>New theme</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>End user</strong></td>
<td>“Patient”</td>
<td>“Consumer”</td>
</tr>
<tr>
<td><strong>Structure</strong></td>
<td>Fragmentation; Two Tiers</td>
<td>Consolidation, Integration; Three Tiers</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>Opinion-based</td>
<td>Data driven medicine</td>
</tr>
<tr>
<td><strong>Physician role</strong></td>
<td>Trusted source as individual caregiver</td>
<td>Trusted source in team-based, data-driven model with shared decision making</td>
</tr>
<tr>
<td><strong>Incentives for Providers</strong></td>
<td>Volume</td>
<td>Value (price, service, outcomes)</td>
</tr>
<tr>
<td><strong>Incentives for Consumers</strong></td>
<td>Access, quality of life</td>
<td>Access, financial accountability, quality of life</td>
</tr>
<tr>
<td><strong>Reputation</strong></td>
<td>Word of mouth</td>
<td>Evidence of performance</td>
</tr>
<tr>
<td><strong>Costs</strong></td>
<td>Costs: GDP + 3%</td>
<td>GDP + 1%</td>
</tr>
</tbody>
</table>
4. State Health Insurance Exchanges (HIX)
Health Insurance Exchanges: Background, Purpose and Key Challenges

Although the Patient Protection and Affordable Care Act (PPACA) provides some guidance to support Exchange development, States will play a significant role in structuring the role of the Exchange and defining regulations to guide plan participation.

### Background
- As one of the central features of the Patient Protection and Affordable Care Act (PPACA), Health Insurance Exchanges are expected to be operational in all states by January 1, 2014.
- The advent of Exchanges is predicted to transform the healthcare marketplace, particularly for individual and small group segments.
- As a strategic imperative, health plans across the country are examining a range of scenarios and deconstructing the predicted impact of Exchanges to determine readiness and launch preparatory efforts.

### Purpose of Exchanges
- Foster competition and value-based consumer purchasing decisions.
- Improve transparency and consumer understanding of insurance (pricing, benefit design).
- Serve as a central point of information and provide consumers with comparative plan benefit information in a standardized format.
- Provide consumers with quality data and member satisfaction scores to supplement decision making.

### Key Challenges
- Many open questions exist regarding actual Exchange implementation and functions.
- States will have additional flexibility to further define regulations and Exchange functions.
- Participation may be based on competitive plan bids.
- States may further mandate benefit designs (beyond what is specified in the PPACA).
- Separate Exchanges may be operated for individual and small group segments.

Given these key challenges and so many unknowns that still remain, it is clear health Exchanges will present a change in the way health plans currently do business.
Core Exchange Capabilities

Despite the various operating models HIX can function under, Exchanges will be required to fulfill the following roles and responsibilities:

- **Advisor/Navigator**
  - Provide assistance in navigating the shopping and enrollment process

- **Marketing/Public outreach**
  - Promote the exchange and regulate marketing of products and services

- **Eligibility/Subsidy determination**
  - Determine who may participate and who is eligible for subsidies

- **Product availability/Specifications**
  - Decide which carriers and products will be available and what information is required

- **Comparison shopping tools**
  - Provide tools that consumers and small businesses can use to identify, review, and select products and prices

- **Enrollment and eligibility maintenance**
  - Support standard enrollment processes and ongoing maintenance

- **Customer service**
  - Respond to inquiries, grievances, and appeals

- **Premium collection/Reconciliation**
  - Determine premium obligations and combine with subsidies to ensure payment for coverage

- **Federal/State coordination**
  - Manage numerous intragovernmental data and process interactions and dependencies
Exchanges are a lynchpin of reform

The Affordable Care Act establishes state health insurance exchanges (HIX) as regulated, online marketplaces for individual and small group coverage.

- Administered by states within federal guidelines
- Targeting individual consumers and small groups up to 100 employees in 2014
- Expanding to groups over 100 in 2017 at state discretion
- Determine eligibility for Medicaid and Children's Health Insurance Program (CHIP) and enroll individuals in those programs when appropriate
- Administer federal subsidies to individuals below 400% of the federal poverty limit
- Offering comparable products, pricing, and consumer information
- Operating at state, substate, or regional level
Exchanges aim to provide and enable consumer choice and affordability

Exchanges will offer more standardized products, distribution, and administration.

- Online enrollment
- Rating/pricing
- Plan designs
- Quality and patient satisfaction ratings
- CHIP/Medicaid enrollment

HIX

- Electronic interfaces
- Subsidy administration
- Risk adjustment
- Coordination with Medicaid/CHIP

<table>
<thead>
<tr>
<th>Product design</th>
<th>Pricing/Underwriting</th>
<th>Sales and distribution</th>
<th>Enrollment and eligibility</th>
</tr>
</thead>
</table>
| • Minimum essential benefits coverage  
  • Actuarially equivalent benefit packages  
  – Bronze: 60%  
  – Silver: 70%  
  – Gold: 80%  
  – Platinum: 90%  
• Catastrophic for under 30s  
• Out-of-pocket limits  
• No annual or lifetime limits | • Guarantee issue and renewability  
• Limited underwriting  
  – Geography  
  – Family status  
  – Age (3:1)  
  – Smoking (1.5:1)  
• No preexisting conditions  
• Risk adjustment | • Standard marketing requirements  
• Roles of brokers and rules for on versus off exchange products  
• Standard quality, price, and satisfaction ratings | • Standardized enrollment  
• Online, mail, over the phone, and in-person  
• Subsidy eligibility management  
• Coordination with Medicaid and CHIP |
Many stakeholders play key roles in exchanges

Small employers
- Select plan level(s)
- Pay premiums
- Track fines

Brokers, navigators, community partners
- Help customers enroll
- Provide information
- Role will likely vary by state

Individual customers
- Screen
- Compare plans and enroll
- Change plans
- Request mandate exemptions

Employees of small businesses
- Screen
- Compare plans
- Enroll
- Change plans

Health insurance exchange business processes and systems

Health plans
- Submit plans for listing
- Maintain plan information, benefits, quality, cost, and providers
- Receive enrollments and premiums

Customer service, operations, vendors
- Support phone and mail enrollments
- Help customers
- Manage grievances
- May aggregate premium payments

Social services programs
- Receive eligibility referrals

Exchange governing body
- Set exchange business policy
- Certify and rate plans
- Approve exemptions
- Make vendor/carrier selection

Federal and state agencies/systems
- Create rules
- Send/receive tax, premium, and other information used for verification, enrollment, and risk adjustment
Exchanges will transform the individual and small group health insurance markets

By 2020, exchanges could represent a potential 46 million member, consumer-oriented marketplace

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. insured population</td>
<td>262 million</td>
<td>313 million</td>
</tr>
<tr>
<td>Group insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial groups</td>
<td>154 million</td>
<td>136 million</td>
</tr>
<tr>
<td>SHOP</td>
<td>21 million</td>
<td></td>
</tr>
<tr>
<td>Individual Exchange</td>
<td>28 million</td>
<td>4 million</td>
</tr>
<tr>
<td>Individual</td>
<td>14 million</td>
<td>129% increase</td>
</tr>
<tr>
<td>Government programs</td>
<td>94 million</td>
<td>124 million</td>
</tr>
<tr>
<td>Government</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Programs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uninsured</td>
<td>47 million</td>
<td>23 million</td>
</tr>
<tr>
<td>Uninsured</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Deloitte 2010–2020 Market Enrollment Analysis
Note: Not all numbers add due to rounding.
### Implications for employers

**Choices, choices, choices…**

<table>
<thead>
<tr>
<th>Time frame</th>
<th>Small employers (1–50)</th>
<th>Midsized employers (51–100)</th>
<th>Large employers (100+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014+</td>
<td>Benefits or penalty?</td>
<td>Benefits or penalty?</td>
<td>Health benefit strategy:</td>
</tr>
<tr>
<td></td>
<td>Talent impact?</td>
<td>Purchase through exchange or broker?</td>
<td>Benefits or penalty?</td>
</tr>
<tr>
<td></td>
<td>Purchase through exchange or broker?</td>
<td>Defined benefit or contribution?</td>
<td></td>
</tr>
</tbody>
</table>

- Employers will have choices to make as exchanges debut, and those choices may change as exchanges develop and broaden over time.
- Decisions about exchanges must consider talent implications, geographic variation, benefit structure, etc.
Implications for providers
Indirect impacts could be significant

• Exchanges will be the channel through which a lot of individuals will get insurance for the first time
• More people will be covered by insurance products obtained through exchanges
• More transparency of underlying medical costs and quality of providers
• More impactful for safety net hospitals, which are used to serving low-income and uninsured populations
5. Health Information Exchanges (HIEs)
“The goal is to have information flow seamlessly and effortlessly to every nook and cranny of our health system, when and where it is needed, just like the blood within our arteries and veins meets our bodies’ vital needs.”

DAVID BLUMENTHAL
- Professor at Harvard Medical School
- Chief Health Information and Innovation Officer at Partners HealthCare in Boston
- Former US National Coordinator for Health Information Technology under President Obama
Background – ARRA, HITECH

American Recovery and Reinvestment Act (ARRA)

The ARRA – facts and figures:

- 1st major initiative of the Obama Administration
- Appropriates $787 billion dollars across a broad spectrum of government programs
- Health IT funding includes incentives and appropriations from the HITECH Act and other health IT initiatives such as Telehealth.

HITECH Priority areas include:

- Electronic Health Records (EHR)
- Health Information Exchanges (HIEs)
- Privacy/Security
- Outcome Registries
- Promotion of HIT Standards and Interoperability

ARRA includes the HITECH Act to accelerate the adoption of interoperable electronic health records and other HIT as well as to promote health information exchange. HITECH is also funded by non-ARRA dollars.
The goal of HIEs is to integrate and share health data among key industry stakeholders

- Current HIE development is driven by various integration models, local, regional and state-wide.
- Previous HIE initiatives dating back to the 1990s were locally focused and served individual health systems and their affiliates, and faced significant challenges to adoption.
- Increased federal support and funding is driving continued investment, with expected returns in the areas of information flow, quality of care and system efficiency.

HHS, through the Office of the National Coordinator (ONC) has deployed more than $500M to accelerate HIE across all 50 states and D.C.

Stakeholders across the system are expecting key benefits from HIEs:

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Expected Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providers</td>
<td>• Track outcomes to support incentive programs</td>
</tr>
<tr>
<td></td>
<td>• Access to longitudinal health data for better treatment selection</td>
</tr>
<tr>
<td></td>
<td>• Improved provider-patient communication and coordination of care</td>
</tr>
<tr>
<td>Public Health Agencies / Government</td>
<td>• Access to bio-surveillance data</td>
</tr>
<tr>
<td>Payors</td>
<td>• Overall system cost reduction</td>
</tr>
<tr>
<td>Patients</td>
<td>• Ability to view personal health information</td>
</tr>
<tr>
<td></td>
<td>• Enhanced security for personal health information</td>
</tr>
</tbody>
</table>

States (including D.C.) receiving various levels of HIE investment:
Providers, public health agencies, labs and the government form the data-sharing networks today

Stakeholder Landscape

- Patients
- Health Information Exchange
  - Diagnostic Centers/Reference Labs
  - Public Health Disease Surveillance
  - Health & Human Services
  - Hospitals and Community Health Centers
  - Primary Care and Specialty Physicians
  - Pharmacies and PBMs

Role TBD
National, Regional and State Health Plans

Examples of Data Exchanged
- Acute, Emergency, LTC, Primary, Specialty, Outpatient admissions and discharge data
- Diagnoses and procedure codes
- Lab orders and results
- Medication orders and fulfillment and medication reconciliation
- Provider follow up instructions and clinical notes
- Public health bio-surveillance, mental health and substance abuse
Integrated delivery systems provide a model for how health plan-driven care-management programs could be strengthened by access to HIE data

Elements of integrated systems....

- Focused on the same population of patients
- Operational and professional integration across payment and care delivery functions
- Enterprise-wide clinical decision support (via EHR)

...can be leveraged by plans to provide similar results across non-integrated providers

- Obtain comprehensive medical records & history to enable deeper insight into the care members need
- Empower case managers to be true health care system guides and address fragmentation in the provider network
- Use data to identify catastrophic illnesses earlier

The interest in data sharing for plans is in rendering more effective the care coordination models that exist today. Providers, in turn, may begin to view health plans as true partners in care management.
A range of questions regarding HIEs remain open and present potential risks

### Key Questions

- Will plans be permitted to access electronic clinical records data?
- Will plans be subjected to meaningful use requirements?
- Can revisions to legislation serve as a deterrent to HIE implementation?
- Is there potential for data governance issues with respect to sharing information across HIEs that have different data standards?
- How will consent management be handled in an HIE environment?

### Initial Viewpoints

- Awaiting clarity from HHS on whether secondary use will be regulated
- There is a potential for HHS defining “meaningful use” for plans differently than they do for providers, may be tied to accreditation or may include cost avoidance requirements
- While legislative changes are possible, the ONC has already awarded over $500 million dollars to states as a part of initial funding
- Data interoperability across platforms is a main concern; need to develop data standards to ensure consistency of data types as well as data being captured.
- Must incorporate consent processes to help inform patients about their participation rights; discussions continue around granularity of consent required
6. ICD-10
What is ICD-10?

• ICD is the International Classification of Diseases
• Published by the World Health Organization (WHO)
• Alphanumeric designations given to every diagnosis, description of symptoms, and cause of death
• Current list of codes is ICD-10, published in 1990
• Most providers in the US today use ICD-9 codes, developed in the 1970s.
The US Lags Behind the Rest of the World

Most industrialized countries have wholly adopted ICD-10, except the US.
Why are ICD Codes Important?

Accurate and detailed coded medical data are the basis for a full range of critical health care issues, such as:

• Reimbursement
• Medical processes and outcomes
• Reporting and trending
• Quality of care
• Health research
• Regulatory compliance
The ICD-10 Mandate

The driver behind adopting the ICD-10 coding structure is increased accuracy in specifying medical conditions and improved consistency with WHO standards.

**Code Set Changes**

**Hospitals & Physicians**

- **ICD-9-CM (Diagnosis)**
  - 3-5 characters
  - > 14,000 unique codes

- **ICD-10-CM**
  - 3-7 characters
  - > 68,000 unique codes

**Hospitals**

- **ICD-9-CM (Procedure)**
  - 2-4 characters
  - > 4,000 codes

- **ICD-10-PCS (Inpatient)**
  - 7 characters
  - > 72,000 unique codes

- More codes: ICD-10 is nearly 5 times larger
- More clinical specificity in the code structure
- Technical changes to the code set

Simply stated, the science of medicine has outgrown the ICD-9 code set.
The Basics of the ICD-10-CM Change

The ICD-10-CM diagnosis code set replaces the ICD-9 code set. The value of ICD-10 is its additional granularity for diagnosis and procedure codes.

An example of structural change

<table>
<thead>
<tr>
<th>ICD-9</th>
<th>ICD-10-CM</th>
</tr>
</thead>
<tbody>
<tr>
<td>X X X</td>
<td>X X X X X</td>
</tr>
<tr>
<td>Category</td>
<td>Category, anatomic site, manifestation</td>
</tr>
</tbody>
</table>

An example of one ICD-9 code represented by multiple ICD-10 codes

<table>
<thead>
<tr>
<th>ICD-9</th>
<th>ICD-10-CM</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 5 0 6 1</td>
<td>E 1 0 4 0, 1 4 4, 1 0 4 9</td>
</tr>
<tr>
<td>Diabetes mellitus with neurological manifestations, type I not stated as uncontrolled</td>
<td>Type 1 diabetes mellitus with diabetic neuropathy, unspecified, mononeuropathy, amyotrophy, other neurological complication</td>
</tr>
</tbody>
</table>

Mapping ICD-9 to ICD-10 codes is a complex task
What are the Impacts of ICD-10?

Stakeholders throughout the healthcare value chain will be impacted.

**Business Operations**
- Procedures
- Policies

**Technical**
- Software Upgrades - In-House & Purchased Applications
- Electronic Transactions

**Care Management**
- Medical & Treatment Policy
- Medical Management
- Reimbursement

**Transition**
- Change Management
- Training

**Laboratories**
**Clearinghouses**
**Payers**
**Software Vendors**
**3rd Party Administrators**

**Employers**
**Suppliers**
**Providers**
**Members**
**National Organizations**
Considerations for Provider Preparation

Provider readiness will have a great impact on reimbursement accuracy

**People**
- Significant training for coders, clinicians and hospital staff
- Cost implications for training – time away from day job, cost of training itself, backfill costs
- Additional resources may be required to support the transition period (coders, IT staff, etc.)

**Process**
- Providers will need to re-assess paper-based processes to accommodate for major code set expansion
- Reimbursement and documentation audits may become more frequent during transition
- Improper coding may delay reimbursement

**Technology**
- Leverage EHR/EMR to facilitate ICD-10 transition, where possible
- Cost implications for updating software, databases, interfaces and other systems
- Testing prior to ICD-10 preparation will be key

**ICD-10 Implications**
- ICD-10 will have substantial impact on INPATIENT facility claims which utilize both ICD diagnosis and procedure codes
- OUTPATIENT and primary care practices, which mainly rely on ICD diagnosis codes for professional claims, will experience a secondary impact

**Revenue Impacts**
- ICD-10 changes could adversely affect provider cash flow and the payer-provider relationships
7. Electronic Health Records and “Meaningful Use”
Investing in Electronic Health Records (EHR)

Sections of the American Recovery and Reinvestment Act 2009 ("ARRA") known as The Health Information and Clinical Health Act ("HITECH Act") provide grants and payment incentives for physicians, hospitals, nursing homes and other health care entities to adopt and make meaningful use of technology designed to create and manage electronic health records ("EHR"s) so that every American has an EHR by 2014.

The act allocates approximately $19 Billion to health information technology projects including:

- The investment in health IT Infrastructure to facilitate a nationwide health information network
- The endorsements of standards to manage the infrastructure
- The provision of incentives through Medicare and Medicaid reimbursement to assist physicians and hospitals in acquiring EHR technology
• The HITECH Act accelerates the adoption of interoperable electronic health records and other health information technology, as well as to promote health information exchange.

• The HITECH Act allocated $27 billion dollars of payment incentives to physicians and hospitals for achieving “Meaningful Use” (MU) of certified Electronic Health Records (EHRs).

• To obtain Medicare incentive funding, providers must commence “Meaningful Use” of EMR technologies between 2011 and 2015.

• Hospitals are eligible to receive both Medicare and Medicaid Incentives simultaneously. Physicians who are eligible for both Medicare or Medicaid incentives must choose one.
Meeting “Meaningful Use” requires comprehensive and systemic planning and change

**Certified EHR Technology**
Assess vendor readiness and self-certification capability to meet Meaningful Use

**Clinical Quality Measures**
Evaluate technology and operational workflow capabilities for Clinical Quality Measures and outline capability gaps

**Meaningful Use Objectives**
Summarize major challenges, risks, gaps, based on current implementation timelines and roadmap to proposed Meaningful Use definitions

**Meaningful Use Assessment**
Evaluate the organization’s readiness to comply with criteria

**Standards and Privacy & Security**
Perform system, document review and interviews to understand current Privacy and Security plans and use of standards to meet HITECH requirements
Security & Privacy for Meaningful Use Compliance

Security and privacy is part of the core set of Meaningful Use objectives, specifically to implement systems to protect privacy & security of patient data in the HER.

Key Takeaways
- Prescriptive requirements include transport layer security, message integrity, and auditing & logging capabilities as part of EHR Technology certification
- Modifications to HIPAA Privacy & Security rules includes extending applicability to Business Associates, patient access to electronic medical records, updated definitions regarding use and disclosures of PHI, and further clarity on enforcement and penalties for non-compliance
- Breach notification process and response considered an active requirement for EHs and EPs

Key Challenges
- Standards-based security risk analysis methodology, process, and enablement
- Compliance initiatives in addition to Meaningful Use must be addressed, including HIPAA Privacy & Security and ICD-10 implementation
- Maturity of EHR Technology, specifically security and privacy functionality in line with criteria
- Security & privacy to support interoperability – e.g. establishing trust in HIE deployment

Implications
- Adoption of a security risk analysis process and scope to demonstrate completion of Stage 1 measure
- EPs may have to carry the burden of managing systems and application security as EHR is deployed
- Improvement in enterprise security management, privacy and compliance, and governance
- Investment in data protection solutions to limit regulatory and reputational risk as a result of a security breach
8. HIPAA and Patient Data Security
Health Care organizations face a wide array of security requirements

**Regulatory Requirements**
- HIPAA Security & Privacy Rules
- HITECH Act
- FACTA Red Flag Rule
- Title 21 CFR Part 11
- CMS Information Security
- Various state security & breach notification laws

**Industry Standards**
- ISO 27000 series standards on information security
- NIST Special Publication 800 series
- ANSI Healthcare Information Technology Standards Panel
- COBIT

**Self-Regulatory Frameworks**
- PCI DSS
- Joint Commission standards on information security and continuity
- EHNAC's Healthcare Network Accreditation Program (HNAP-EHN)

**Customer Requirements**
- Requirements from customer's industry regulation
- Additional contractual requirements with customers

**Health Care Security & Privacy Program**
Introduction to HIPAA

What is HIPAA?

Signed into law on August 21, 1996 by President Clinton, Health Information Privacy and Accountability Act or “HIPAA” seeks to assure health insurance portability, reduce health care fraud and abuse, guarantee security and privacy of health information, and establish standard health care transactions. This regulation applies to “covered entities.”

Who are the Covered Entities?

- Health care providers (i.e., hospitals, nursing homes)
- Health care clearinghouses (i.e. billing services, community information systems)
- Health plan buyers and providers (i.e. employers that offer healthcare plans)
HIPAA Privacy

What is Privacy?

- The right of individuals to keep information about themselves from being disclosed
- HIPAA is in essence the first comprehensive federal law to protect the privacy of health information and guarantee Residents access to such information

What is HIPAA Privacy Rule?

The privacy rule defines what information you must protect, as contrasted with the security rule which defines how you must protect information.

The HIPAA Privacy Rule limits when a Covered Entity may use or disclose Protected Health Information to a Third Party, provides Residents with certain rights with respect to their own PHI, and imposes certain “administrative” duties upon each covered entity.

What does it mean?

The covered entity must limit the use, disclosure or request to the minimum necessary to accomplish the intended purpose of the use, disclosure or request of PHI.
Important Definitions

Protected Health Information (PHI) means information relating to the health or condition of a Resident, the provision of care to a Resident, or the payment for the provision of health care to a Resident that identifies the Resident and is transmitted or maintained in any form.

Use means the sharing, employment, application, utilization, examination, or analysis of information within ABC.

Disclosure means the release, transfer, provision of access to, or divulging in any other manner, of information outside ABC.

Minimum Necessary means using or disclosing only those items that are required to meet the need.

Third Party means anyone other than the Resident or ABC.
A closer look at HITECH Act’s impact on security and privacy

<table>
<thead>
<tr>
<th>REQUIREMENT</th>
<th>DETAILS</th>
<th>EFFECTIVE DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>New HIPAA Business Associates</td>
<td>❖ Requires that new entities that were not contemplated when HIPAA was written (such as Personal Health Record vendors, Regional Health Information Organizations, HIEs, etc.) are subject to the same privacy and security rules by requiring Business Associate contracts and treating these entities as Business Associates under HIPAA</td>
<td>2/17/2010</td>
</tr>
<tr>
<td>Breach Notification</td>
<td>❖ Establishes a federal security breach notification requirement for unsecured protected health information (unsecured PHI) and personal health records (PHR)</td>
<td>9/23/2009</td>
</tr>
<tr>
<td>Disclosure Restrictions</td>
<td>❖ An individual is permitted to request a covered entity not send its PHI to a health plan for purposes of carrying out payment or health care operations for a service when paying for the service fully out-of-pocket ❖ Covered entities are required to limit the use, disclosure, or request of PHI to the limited data set to the extent practicable; or the minimum necessary if needed by the entity</td>
<td>2/17/2010</td>
</tr>
<tr>
<td>Accounting of Disclosures</td>
<td>❖ Covered entities must produce, upon request, an accounting of all disclosures of the individual’s PHI, including routine disclosures over a three-year period ❖ Business associates must produce, upon request, an accounting of disclosures of PHI for treatment, payment, and health care operations</td>
<td>1/1/2011 through 1/1/2014 based on acquisition of electronic health records</td>
</tr>
<tr>
<td>Prohibition on Sale</td>
<td>❖ A covered entity or business associate is prohibited from receiving direct or indirect remuneration for any PHI without a HIPAA authorization from the applicable individual, subject to exceptions</td>
<td>No later than 2/17/2011</td>
</tr>
<tr>
<td>Marketing &amp; Fundraising</td>
<td>❖ Marketing and fundraising activities now require specific authorization as they are no longer covered under the health care operations definition. Also, individuals have the right to opt-out of any communication that relates to fundraising</td>
<td>2/17/2010</td>
</tr>
<tr>
<td>Enforcement</td>
<td>❖ Strengthens enforcement of HIPAA security &amp; privacy rules and penalties for noncompliance ❖ Provides for enforcement of HIPAA by State Attorneys General and local law enforcement</td>
<td>Increase in civil penalties and enforcement by State AGs 2/17/2009 Penalties for willful neglect by 2/17/2011</td>
</tr>
</tbody>
</table>
# Breach Notification Requirements

<table>
<thead>
<tr>
<th>Party</th>
<th>Applicable Data</th>
<th>Notification Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Covered Entities</strong></td>
<td>Unsecured protected health information: Information that can be reasonably used to identify an individual that is maintained by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual that is not secured through the use of a technology or methodology specified by the Secretary</td>
<td>Notify each individual whose unsecured protected health information has been, or is reasonably believed to have been, accessed, acquired, or disclosed as a result of such breach</td>
</tr>
<tr>
<td><strong>Business Associates</strong></td>
<td></td>
<td>Notify the covered entity of a breach of unsecured protected health information that it accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses on behalf of a covered entity</td>
</tr>
<tr>
<td><strong>Vendors</strong></td>
<td>Unsecured PHR identifiable health information: Information collected from an individual that can be reasonably used to identify an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual that is not secured through the use of a technology or methodology specified by the Secretary</td>
<td>Notify each individual who is a citizen or resident of the United States whose unsecured PHR identifiable health information was acquired by an unauthorized person as a result of such a breach of security</td>
</tr>
<tr>
<td><strong>Third Party Service Providers</strong></td>
<td></td>
<td>Notify the vendor of a breach of security.</td>
</tr>
</tbody>
</table>

## All Parties

<table>
<thead>
<tr>
<th>Content of Notice</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>A brief description of what happened, including the date of the breach and the date of the discovery of the breach</td>
</tr>
<tr>
<td>2.</td>
<td>A description of the types of unsecured protected health information that were involved in the breach</td>
</tr>
<tr>
<td>3.</td>
<td>The steps individuals should take to protect themselves from potential harm resulting from the breach</td>
</tr>
<tr>
<td>4.</td>
<td>A brief description of what the covered entity involved is doing to investigate the breach, to mitigate losses, and to protect against any further breaches</td>
</tr>
<tr>
<td>5.</td>
<td>Contact procedures for individuals to ask questions or learn additional information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Timelines</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Notice must be made within 60 calendar days after the discovery of a breach</td>
</tr>
</tbody>
</table>
Penalties and enforcement under the HITECH Act

**Penalties**
- New **penalty tiers** per HIPAA violation (maximum per year):
  - Unknowing ($25K)
  - Reasonable cause ($100K)
  - Willful neglect ($250K)
  - Uncorrected willful neglect ($1.5M)
- Civil and **criminal liability** for HIPAA violations extended to **business associates**
- **Mandatory** investigations and civil penalties for violations due to willful neglect

**Enforcement**
- Expanded resources and **significant funding** for HHS enforcement
- **State Attorneys General** authorized to pursue actions on behalf of state citizens
- Vendor breaches enforced by the **Federal Trade Commission** as unfair and deceptive acts or practices

**Notable Past Incidents**
- Providence Health & Services incident
- CVS pharmacy incident - $2.24M penalty, plus consent agreement
Karolyn Woo-Miles, Sr. Manager
Deloitte & Touche LLP
Karolyn has more than 13 years of experience working with large hospital systems in California, Washington, Arizona and New Mexico on a variety of compliance and operations related engagements. Her consulting career has been specialized in compliance auditing and monitoring activities, gap assessments, internal control management, policy and procedure development, and process re-design and improvement. Her advisory services are focused on regulatory compliance matters such as 340b compliance, Medicare and Medicaid/Medi-Cal billing compliance, physician arrangements, compliance program requirements, financial and compliance acquisition due diligence.