Recent regulation and legislation

The emergence of laws have spurred the growth and mandate of EHR adoption

- **The American Recovery and Reinvestment Act of 2009 (ARRA)** (Pub.L. 111–5), commonly referred to as the Stimulus or The Recovery Act, was an economic stimulus package enacted by the 111th United States Congress in February 2009 and signed into law on February 17, 2009, by President Barack Obama.
  - ARRA included the enactment of the Health Information Technology for Economic and Clinical Health Act, also known as the HITECH Act.
  - The Patient Protection and Affordable Care Act (PPACA), commonly called the Affordable Care Act (ACA) or "Obamacare", is a United States federal statute signed into law by President Barack Obama on March 23, 2010. Together with the Health Care and Education Reconciliation Act, it represents the most significant regulatory overhaul of the U.S. healthcare system since the passage of Medicare and Medicaid in 1965.

Total health care spending: $353.5 billion

- $86.8 billion for Medicaid
- $25.8 billion for health information technology (EHR) incentive payments
- $25.1 billion to provide a 65 percent subsidy of health care insurance premiums for the unemployed under the COBRA program
- $25 billion for health research and construction of National Institutes of Health facilities
- $10 billion for Community Health Centers
- $1.3 billion for construction of military hospitals
- $1.1 billion to study the comparative effectiveness of healthcare treatments
- $1 billion for prevention and wellness
- $1 billion for the Veterans Health Administration
- $950 million for healthcare services on Indian reservations
- $500 million for community mental health centers
- $500 million for a temporary moratorium for certain Medicare regulations
Meaningful Use Incentives: Eligible Providers

There are two EHR Incentive Programs. CMS oversees the Medicare EHR Incentive Program, and the state Medicaid agencies manage the Medicaid EHR Incentive Program. The two programs are similar, but there are some differences between them.

<table>
<thead>
<tr>
<th>Medicare EHR incentive program</th>
<th>Medicaid EHR incentive program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Run by CMS</td>
<td>Run by Your State Medicaid Agency</td>
</tr>
<tr>
<td>Medicare beneficiary eligibility</td>
<td>Medicaid beneficiary eligibility</td>
</tr>
<tr>
<td>Payment over 5 consecutive years</td>
<td>Payment over 6 years, does not have to be consecutive</td>
</tr>
<tr>
<td>Providers must demonstrate meaningful use year to year to receive incentive payments.</td>
<td>Providers who are only eligible for the Medicaid program do not receive payment adjustments.</td>
</tr>
</tbody>
</table>

EHRs...why is an effective implementation/sustainment a big deal?

- Healthcare - 20% of GDP - $3.4T will soon flow through EHRs
- Enterprise-wide impact to 100% of clinicians, RCM, management and patients
- Financial and operational integrity and transparency of reporting
- Compliance and regulatory focus
- Quality and safety – Greater transparency and commitment
- EHR security challenges throughout implementation/operation
- Advanced analytics – Leveraging to identify/assess process, risk, and controls

PwC

EHRs...healthcare regulators are watching

Focus from regulatory/other bodies
- Top Priority in OIG 2014-2018 Strategic Plan
- American Recovery and Reinvestment Act of 2009 (ARRA)
- Patient Protection and Affordable Care Act (PPACA)
- The Joint Commission
- State "Patient Bill of Rights"
The CMS is committed to preventing fraud, waste, and abuse in EHRs. CMS has issued guidance to its contractors that medical record keeping within an EHR deserves special considerations and that the original content, the modified content, and the date and authorship must be identifiable. However, CMS realizes that additional guidance is needed and intends to work with its contractors in the development of the effective guidance and tools in an effort to detect fraud vulnerabilities in the area of EHRs.

Mikki O'Neal, MBA, CCRP, CCRC, CHCRC
Manager, Institutional Compliance Office
The University of Texas MD Anderson Cancer Center
Common EHR Implementation Compliance Challenges

- Variable organizational structure, process and procedures.
- Multiple sources of data and systems.
- Communication between departments
  ‣ Scheduling
  ‣ Billing
  ‣ Administration
  ‣ Clinical and research staff

Common EHR Implementation Compliance Challenges

- Historically, research teams are allowed to document a majority of research interactions with the subjects.
- Many research staff have never been introduced to clinical documentation requirements or clinical research billing.
- Varying definitions of "research billing".

Considerations Before or During Validation

- Specific documentation training for research teams.
- Early involvement and collaboration with the research staff that understand the day to day workflow.
- Policy and procedure review at department and institutional level.
Considerations Before or During Validation

- Where will source of truth reside?
- How will information be communicated between the Clinical Trial Management System (CTMS) and the EHR?
- How will research only visit data be integrated into the EHR and will that impact the EHR design?

EHRs...The Joint Commission is watching: sentinel events

Default Values

0.25 mg/mL
0.5 mg/mL
0.75 mg/mL
1.0 mg/mL
1.25 mg/mL
1.5 mg/mL
1.75 mg/mL
**EHRs... quality and safety errors while we and others were watching**

- **Closed Loop**
  - 75% of actionable test results never communicated to the patient
  - 75% of test results are falsified, leading to mistrust and mismanagement

- **Copy & Paste**
  - 20% of actionable test results not communicated
  - Nonactionable patient conditions are interpreted as normal and normal patient conditions are interpreted as abnormal

- **Alert Fatigue**
  - Medication alerts are overridden by physicians

- **Medication Damage**
  - Inappropriate calculations and rounding for pediatric weight-based medication dosing

- **Transitions of Care**
  - Information not recorded or communicated to ensure reliable and complete care

**Sources:**
- Archives of Internal Medicine (2009) 169:1123
- Critical Care Medicine Study (2013)

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**EHRs... Quality Measure Reporting**

<table>
<thead>
<tr>
<th>TYPE</th>
<th>DESCRIPTION</th>
<th>EXAMPLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structure</td>
<td>Assesses the characteristics of a care setting, including facilities, personnel, and/or policies related to care delivery.</td>
<td>Does an intensive care unit have critical care specialists on staff at all times?</td>
</tr>
<tr>
<td>Process</td>
<td>Determines if services provided to patients are consistent with stated clinical care.</td>
<td>Does a doctor ensure that his or her patients receive recommended cancer screenings?</td>
</tr>
<tr>
<td>Outcome</td>
<td>Evaluates patient health as a result of the care received.</td>
<td>What is the survival rate for patients who experience a heart attack?</td>
</tr>
<tr>
<td>Patient Experience</td>
<td>Provides feedback on patients’ experiences of care.</td>
<td>Do patients report that their provider explains treatment options in ways that are easy to understand?</td>
</tr>
</tbody>
</table>

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**Internal Controls Defined**

Different definitions of Internal Controls:

- **Internal Control** is a process designed to provide reasonable assurance regarding the achievement of objectives in the following three categories:
  1. **Effectiveness and Efficiency of Operations**: Processes are doing what they are intended to do (achieving their objectives) and doing so in an efficient manner (making good use of available resources).
  2. **Compliance with Laws and Regulations**: Actions are consistent with all applicable laws and regulations.

At a high level:
- An internal control involves anything that controls risks to an organization.
Overview of controls

Internal controls are the policies and procedures that an organization puts into place in order to protect its assets, ensure its accounting data is correct, maximize the efficiency of its operation and promote an atmosphere of compliance among its employees. There are three main types of internal controls: preventative, detective, and corrective.

- **Preventative** - Preventative internal controls are put into place to keep errors and irregularities from happening.
- **Detective** - Detective internal controls are designed to find errors after they have occurred.
- **Corrective** - Corrective internal controls are put into place to correct any errors that were found by the detective internal controls.

Types of controls – reporting controls, interface controls, automated controls, manual controls, compliance controls, security controls, data conversions, etc.

No Fast and Easy Solutions...

Thank you

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