# Communication and Electronic Health Records

**Ms. Megan E. Sawchuk, MT(ASCP)**

CLIAC Meeting
February 15, 2012
Atlanta,  Georgia

# Outline

- Background
- Activities of CDC Informatics Team
- Institute of Medicine Report
- Error Reporting
- Questions for CLIAC Consideration

# Background

- **CLIAC September 2011**
  - Lab test report elements: The absence of some test report information in the EHR may result in patient safety issues
  - EHR implementation: Communication issues are important and barriers may exist to safe and effective use of laboratory information
  - Committee Recommendation: *"Implement a work group to outline the scope of issues related to communication of laboratory testing information and propose approaches to address these issues for discussion by CLIAC."*

# CDC Informatics Team
# Division of Laboratory Science & Standards

**Project Lead**

- Ms. Megan Sawchuk

**Team**

- Ms. Nancy Anderson
- Dr. Nancy Cornish
- Ms. MariBeth Gagnon
- Dr. Devery Howerton
- Dr. Ira Lubin
- Ms. Anne Pollock
- Ms. Elizabeth Weirich
- Dr. Barbara Zehnbauer

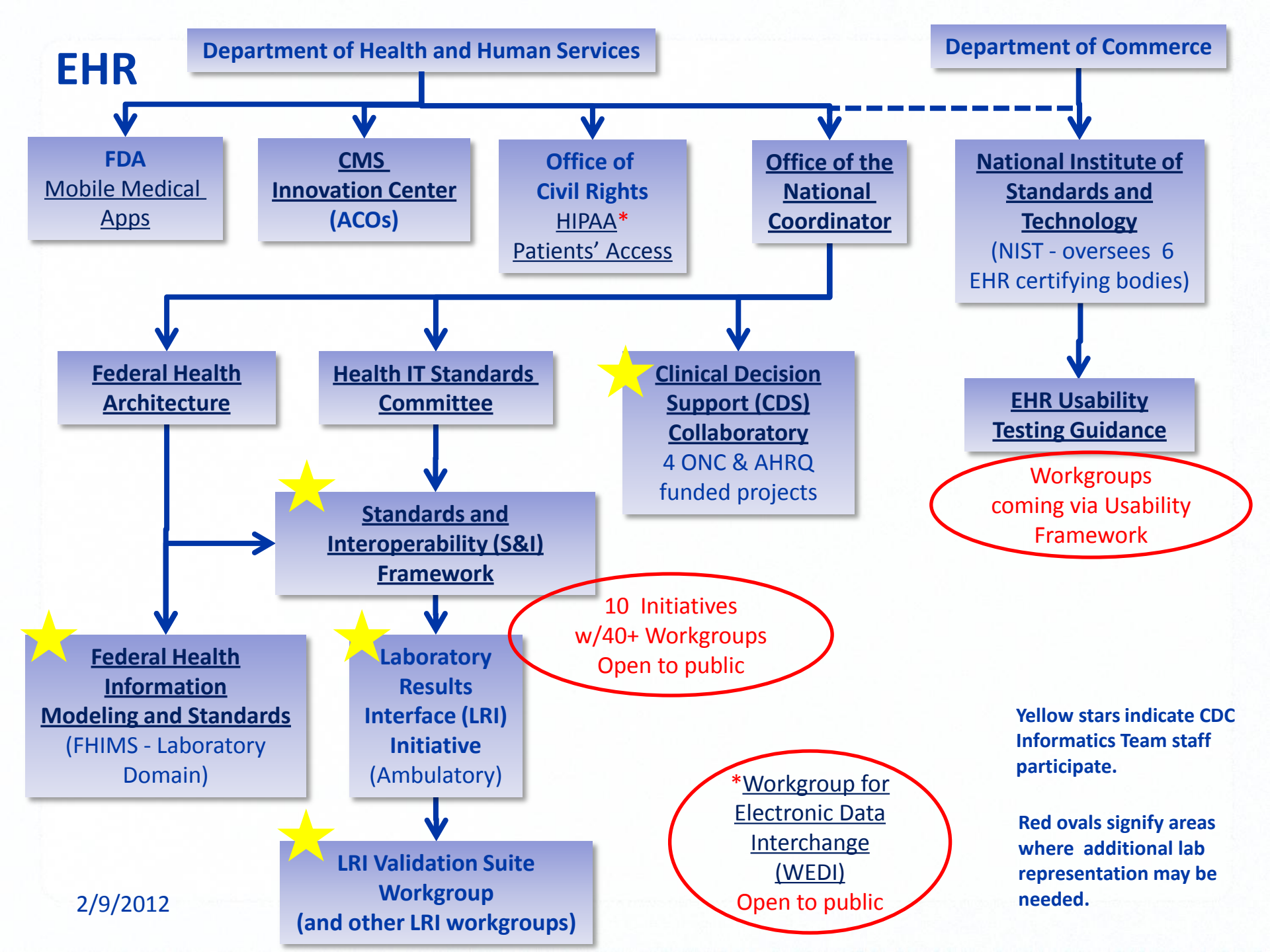
# CDC Informatics Team
# Division of Laboratory Science & Standards

- **First step: Categorized CLIAC member comments and identified the following primary focus areas:**
  - Engagement of the laboratory profession
  - Interoperability
    - Degree to which information can be successfully exchanged via an interface
  - Usability & Contextuality
    - Degree to which information is conveyed as intended
    - Degree to which information can be interpreted in relation to other factors, e.g. clinical information, demographics, environment

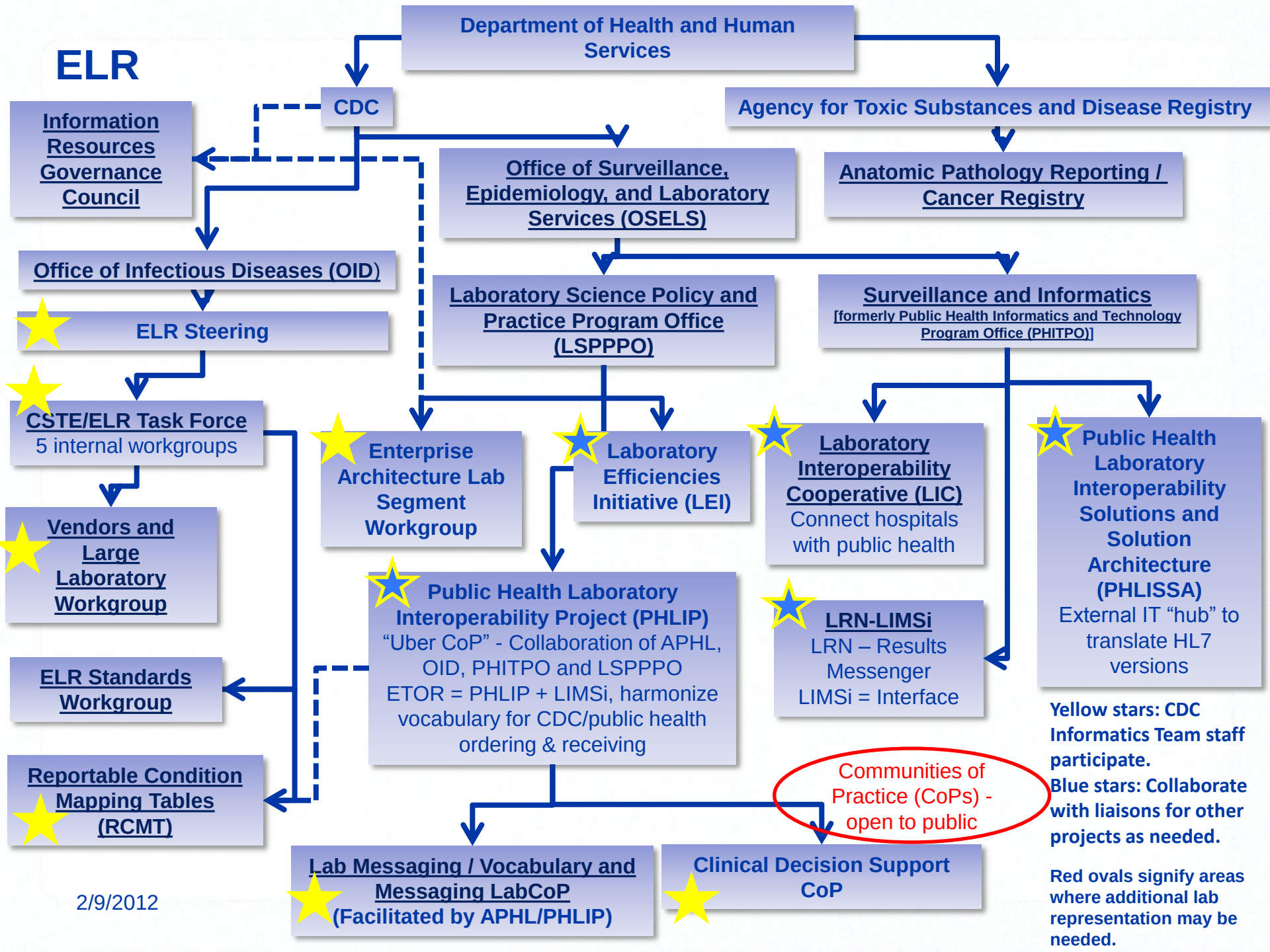
# CDC Informatics Team
# Division of Laboratory Science & Standards

- **Second step: Created "bubble chart" of major workgroups**
  - Electronic Health Record (EHR)
  - Electronic Laboratory Reporting (ELR)

- **CDC Informatics Team members monitor national activities and participate on a number of workgroups**


EHR
Department of Health and Human Services
Department of Commerce
FDA
Mobile Medical Apps
CMS Innovation Center (ACOs)
Office of Civil Rights
HIPAA*
Patients' Access
Office of the National Coordinator
National Institute of Standards and Technology
(NIST - oversees 6 EHR certifying bodies)
Federal Health Architecture
Health IT Standards Committee
Clinical Decision Support (CDS) Collaboratory
4 ONC & AHRQ funded projects
EHR Usability Testing Guidance
Workgroups coming via Usability Framework
Standards and Interoperability (S&I) Framework
10 Initiatives
w/40+ Workgroups
Open to public
Federal Health Information Modeling and Standards
(FHIMS - Laboratory Domain)
Laboratory Results Interface (LRI) Initiative
(Ambulatory)
LRI Validation Suite Workgroup
(and other LRI workgroups)
*Workgroup for Electronic Data Interchange (WEDI)
Open to public
Yellow stars indicate CDC Informatics Team staff participate.
Red ovals signify areas where additional lab representation may be needed.
2/9/2012

# ELR




Yellow stars: CDC Informatics Team staff participate.

Blue stars: Collaborate with liaisons for other projects as needed.

Red ovals signify areas where additional lab representation may be needed.

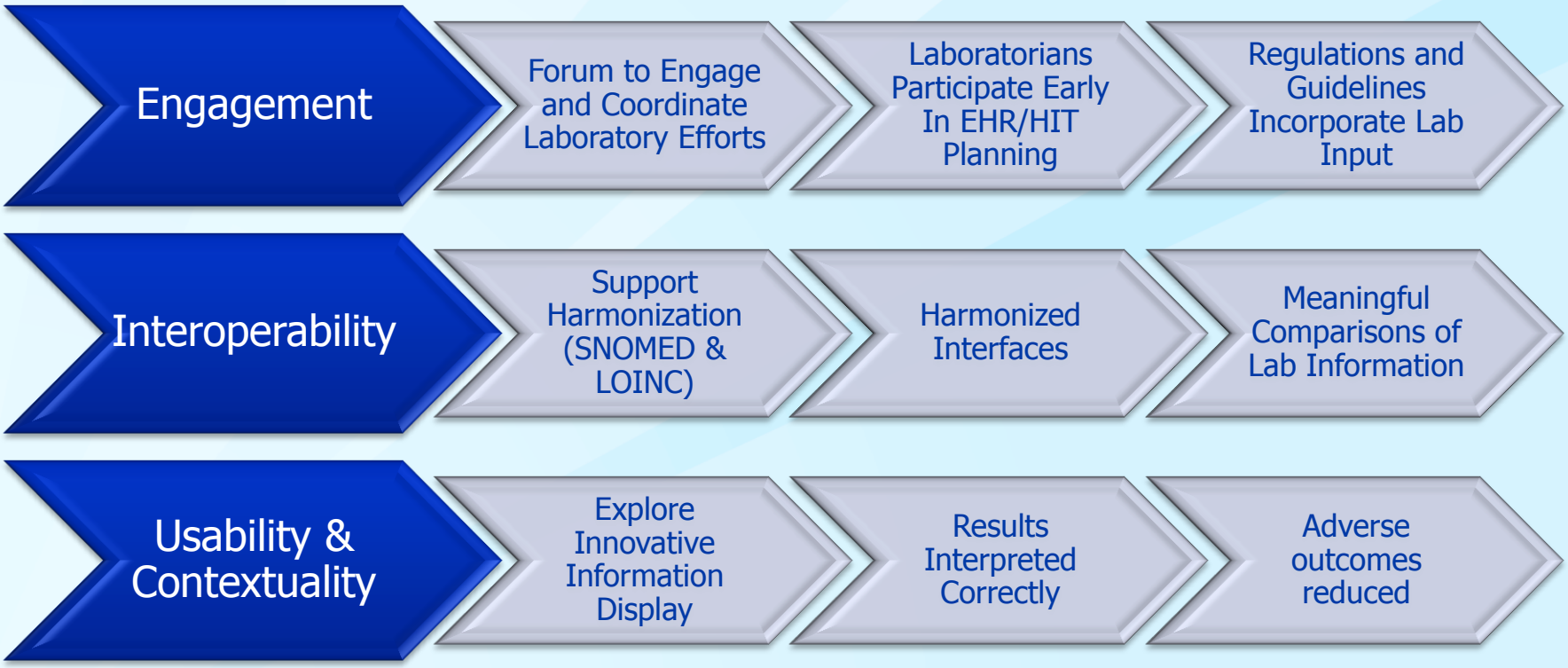
2/9/2012

# CDC Informatics Team Activities

- **ELR: Laboratory Community of Practice**
  - Standardizing SNOMED terminology for public health reporting
  - Develop standing committee to review SNOMED and LOINC changes
- **EHR: Standards & Interoperability Framework**
  - Laboratory Results Interface Initiative (Ambulatory)
    - Vocabulary
    - Implementation Guide Analysis
    - Validation Suite
    - Pilots
  - Coordinated crosswalk of EHR certification requirements with CLIA, CAP, COLA and The Joint Commission test report requirements http://wiki.siframework.org/LRI+Pilots+WG
- **EHR: NIST Usability Guidance**
  - Reviewed and provided comments (NISTIR 7804)

# Next step: Communication in Informatics Project

## Logic Model



**VISION:**

***LABORATORY INFORMATION CONTRIBUTES TO OPTIMIZED HEALTHCARE DECISION MAKING.***

# Communication in Informatics
## Team Project Proposal

- **Engagement**
  - Establish committee of laboratory professionals and experts
  - Implement communication plan
  - Facilitate national EHR/ELR workgroup participation
- **Interoperability**
  - Continue participation in CDC workgroups
  - Publish white paper on challenges and opportunities
  - Facilitate implementation of solutions
- **Usability & Contextuality**
  - Facilitate collaboration and exploration of innovative means to integrate laboratory information in the EHR
  - Integrate other CDC initiatives in collaborative efforts, including CLIHC™, LMBP, and Molecular Genetics Results Interpretation

# Emerging Regulatory Landscape
## Team Continuing to Monitor

- **Office of the National Coordinator (ONC)**
  - EHR Standards and Certification
- **Centers for Medicare and Medicaid Services (CMS)**
  - Meaningful Use
  - Patients' Access to Test Reports
  - Accountable Care Measures
- **Office of Civil Rights (OCR)**
  - Privacy and Security
  - Patients' Access to Test Reports
- **Food and Drug Administration (FDA)**
  - Mobile Medical Apps Guidance
- **National Institute of Standards and Technology (NIST)**
  - Usability Guidance

| Agency | Regulation name | Citation | Resource |
|---|---|---|---|
| ONC | **EHR Standards and Certification**<br>Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule | 45 CFR Part 170 | http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf |
| CMS | **Meaningful Use**<br>Medicare and Medicaid Programs; Electronic Health Record Incentive Program | 42 CFR Parts 412, 413, 422, and 495 | http://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17207.pdf |
| CMS & OCR | **Patients' Access to Test Reports**<br>Proposed changes to the Clinical Laboratory Improvement Amendments (CLIA) and the Health Insurance Portability and Accountability Act (HIPAA) | *42 CFR 493.1291*<br>*45 CFR 164.524* | http://www.gpo.gov/fdsys/pkg/FR-2011-09-14/pdf/2011-23525.pdf |
| OCR<br><br>ONC | **Privacy and Security**<br>Health Insurance Portability and Accountability Act (HIPAA)<br><br>Health Information Technology for Economic and Clinical Health Act (HITECH), Subtitle D , as enacted by the American Recovery and Investment Act of 2009 (ARRA) | 45 CFR Parts 160, 162, and 164<br><br>Public Law 111-5 | http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/adminsimpregtext.pdf<br><br>http://www.gpo.gov/fdsys/pkg/PLAW-111publ5/content-detail.html |
| HHS & ONC | **Electronic Eligibility and Enrollment**<br>Patient Protection and Affordable Care Act (PPACA) | Public Law 111-148 | http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/content-detail.html |
| FDA | **Mobile Medical Applications - Draft**<br>Guidance for Industry and Food and Drug Administration Staff | Issued July 21, 2011 | http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm |
| NIST | **EHR Usability Guidance - Draft**<br>Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records | NISTIR 7804 | http://www.nist.gov/healthcare/usability/upload/Draft_EUP_09_28_11.pdf |

***EMAIL THE CDC'S INFORMATICS TEAM IF YOU KNOW OF EHR OR ELR ACTIVITIES NOT IDENTIFIED IN THIS PRESENTATION AND WHICH MAY HAVE NATIONAL IMPACT.***


**LABHIT@CDC.GOV**

***"Medicine used to be simple, ineffective, and relatively safe. Now it is complex, effective, and potentially dangerous."***

-Sir Cyril Chantler of the Kings Fund

# Institute of Medicine Report

- **Health IT and Patient Safety: Building Safer Systems for Better Care**
  - Released November 8, 2011
  - Recognizes unique intersection in time of rapidly evolving technology and healthcare reform
  - Acknowledges there is limited data on the safe use of Health IT
  - Offers a vision for better integration of safety science into a Health IT
  - Identifies threats and opportunities in Health IT
    - Threats to patient safety include poor user-interface design, poor workflow, and complex data interfaces
    - Features that contribute to safe use include interoperability and usability

http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx

# Institute of Medicine Report

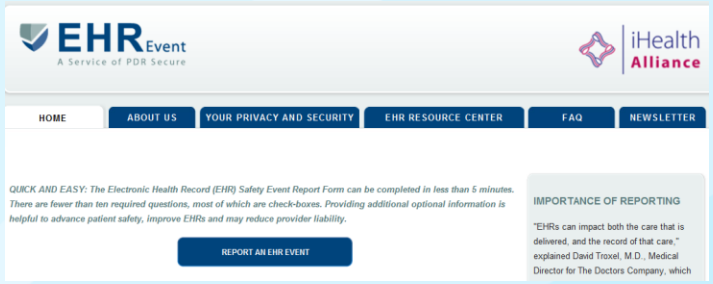
- **Health IT and Patient Safety: Building Safer Systems for Better Care**
  - Makes 10 recommendations supporting concepts of:
    - Increased research and oversight by HHS, ONC, AHRQ
    - Free exchange of information and public reporting
    - New HealthIT safety council
    - Adverse event reporting and independent federal agency for investigations
- ***Recommendation 9a***
  - *"…If progress toward safety and reliability is not sufficient as determined by the Secretary, the Secretary should direct the FDA to exercise all available authority to regulate EHRs, health information exchanges, and PHRs."*

http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx

# Reporting EHR Laboratory Information Issues

- **FDA's MedWatch:**
  - EHRs and other HealthIT computer systems are medical devices
  - Adverse Event Report Forms (Mandatory and Voluntary): http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
  - Online Reporting (Voluntary Only): https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
  - Mandatory reporting: Death and serious injury within 10 work days

# Reporting EHR Laboratory Information Issues




- **EHRevent.org:**
  - https://www.ehrevent.org/
  - Supported by iHealth Alliance, over 100 state and specialty medical societies and FDA liaisons
  - Entirely voluntary
    - Incident: An EHR event that reached a patient, whether or not the patient was harmed.
    - Near Miss: An EHR event that is not believed to have impacted a patient.
    - Non-Patient Issue: An incident or near miss that impacted staff, employee(s), visitor(s).
    - Unsafe Condition: A circumstance that increases the probability of an EHR event.

***"Perfection is not attainable, but if we chase perfection we can reach excellence."***

-Vince Lombardi

Questions for CLIAC Consideration

# COMMUNICATION AND ELECTRONIC HEALTH RECORDS

# Questions for CLIAC Consideration Communication and Electronic Health Records

1. ***Does CLIAC have comments or guidance on the proposed Communication in Informatics project?***

2. ***Are there other EHR or ELR workgroups or activities that should be included on the "bubble chart"?***

3. ***Are there other databases in which healthcare professionals are reporting issues with laboratory information in the electronic health record?***

# References

- **ONC**
  - S&I Framework: http://wiki.siframework.org/Home
  - Clinical Decision Support http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__cds_collaboratory/1230
- **NIST - EHR Usability Framework**
  - http://www.nist.gov/healthcare/usability/framework.cfm
- **FDA Mobile Medical Apps**
  - http://www.fda.gov/medicaldevices/productsandmedicalprocedures/ucm255978.htm
- **Council of State and Territorial Epidemiologists (CSTE) & CDC ELR Task Force**
  - http://www.cste.org/dnn/ProgramsandActivities/SurveillanceInformatics/tabid/346/Agg1419_SelectTab/3/Default.aspx
- **CDC Communities of Practice (CoPs)**
  - http://www.cdc.gov/phcommunities/
- **Workgroup for Electronic Data Interchange (WEDI)**
  - http://www.wedi.org/

**For more information please contact Centers for Disease Control and Prevention**

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