Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

Issues Surrounding the Electronic Exchange of Laboratory Data

Clinical Laboratory Improvement Advisory Committee

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Outline

- Background
- Overview of October 20, 2009 HIT Policy Information Exchange Workgroup Meeting
  - Stakeholder Presenters
  - Recurring Themes
  - Workgroup Recommendations
- Next Steps
  - Short Term
  - Long Term

Background

- **American Recovery and Reinvestment Act (ARRA)**
  - Established Incentive Program for the Meaningful Use of Certified Electronic Health Record (EHR) technology by an Eligible Professional
    - CMS: Notice of Proposed Rulemaking (NPRM) on Incentives Program and Meaningful Use
    - ONC: Interim Final Rule (IFR) on Standards and Certification Criteria

Background (continued)

- **Electronic Exchange of Laboratory Data is Key to Health Information Exchange**
- **Various Concerns Expressed by Stakeholder Groups**
  - ONC wanted to have an open forum for stakeholders to express concerns
  - ONC asked the HIT Policy Committee Information Exchange Workgroup to hold a hearing on issues surrounding the electronic exchange of laboratory data

October 20th Hearing

- **Invited Speaker Stakeholder Groups**
  - Laboratories
    - Large Laboratories
    - Small Laboratory
    - Public Health Laboratory
  - Provider
  - EHR Vendors
  - HIE
  - Policy Experts
  - CMS

Major Themes/ Impediments

- Standards/Technological Impediments
- Business Impediments
- Regulatory Impediments
- Identifying Best Practices

Standards/Technological Impediments

- Lack of Uniform Standard for Data Transmission
- Lack of Universal Compendium/Vocabulary
- Lack of Method to Identify Patients
- Use of Legacy LIS Systems

Business Impediments

- Cost of Custom Interface Development, Implementation, and Testing
- Number of Interfaces/Ability of Payors to Direct Laboratory Business

Regulatory Impediments

- Authorized Person/State Law Issues
- Interpretations of CLIA, 42 CFR § 493.1291

Next Steps

- **Short Term (By February 2010)**
  - CLIA Survey and Certification Letter (CMS)
  - Option paper regarding patient access to lab results (ONC)
  - HIT Policy Committee recommendations
- **Long Term**
  - Policy Committee recommendations/additional deliberations
  - ONC/CMS working group
  - Monitor/feedback on Survey and Certification Letter (CMS)

Next Steps: Short Term

Short Term: CMS Survey and Certification Memo

- **Audience**
  - State CLIA Contacts
  - State CLIA Enforcement Entities
  - State Medicaid Directors
  - State HIT Coordinators
  - Laboratories
- **Content**
  - Updated CLIA Interpretive Guidance
  - Frequently Asked Questions

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Short Term: Survey and Certification Memo

- **FAQ**
  - CMS anticipates that the use of departmentally recognized standards for transmission of laboratory results would reduce laboratories' frequency for verification of the accuracy of the transmission of results
    - Transmission Standard: HL7 2.5.1
    - Vocabulary Standard: LOINC
  - Interpretive Guidance
    - CLIA does not require "eye ball" verification of results sent electronically
    - Simultaneous transmission of lab results to authorized persons and/or agents of the authorized person and/or persons responsible for using the test results, as noted on the laboratory requisition, is permissible
    - CLIA does not require both a paper and electronic copy of the test result

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Short Term: Survey and Certification Letter Timeline

- **November 2009- February 2010**
  - Survey and Certification Memo drafted and vetted internally at CMS, ONC and OGC for approval
  - Late January: Letter published by CMS
- **February-March 2010**
  - All-States call to monitor and receive feedback from States
  - Drafting of second set of FAQs to help with stakeholder education

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Next Steps: Long Term

Long Term Next Steps

- **Policy Committee Recommendations/ Additional Deliberations**
  - Direct the HIT Standards Committee to recommend standards, certification criteria, or implementation specifications
- **ONC/CMS Working Group**
  - Focus on areas that CLIA interpretive guidance cannot resolve/address
- **Monitor/Feedback on Survey and Certification Letter**
- **Possible Regulatory Changes**
  - Last resort if issues cannot be fixed from an ONC standards perspective or through CLIA interpretive guidance.

Questions?

- **Contact Information:**
  - Jonathan.Ishee@hhs.gov
  - General Information: http://healthit.hhs.gov
  - Information and Materials from the October 20, 2009 Hearing: http://healthit.hhs.gov/HITPolicyMeetings