Laboratory Interoperability Plan

Karen W. Dyer, MT(ASCP), DLM

Acting Director, Div. of Laboratory Services

Centers for Medicare &Medicaid Services

Background

- ONC developed action plan for achieving laboratory interoperability that aligns with the 10 year Vision to Achieve an Interoperable Health IT Infrastructure.
- CMS CLIA and CDC brought into workgroup after basic plan already developed.

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Laboratory Interoperability

- Laboratory Interoperability will enable:
  a. Greater exchange of standards-based test reports and orders between laboratories, EHRs, PHRs, consistently matched to the right patient
  b. Providers and Patients to support patient-centered care delivery
  c. Enable providers and patients to receive laboratory results in an electronic and standard format

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Building Blocks

I. Lab information exchange is supported by the creation and adoption of content, format, transport and security standards.

II. Standards for certification requirements for both lab information systems and electronic health record systems are established to ensure basic capabilities are supported for laboratory interoperability.

III. Laboratory test reports are exchanged among and across networks in a secure, authenticated and authorized manner for providers, patients, and their personal representatives.

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Building Blocks

IV. Business, clinical, and regulatory environments foster patients' ability to access their laboratory information in an electronic format that allows them to make meaningful comparisons and transmit results to other healthcare providers.

V. Laboratory standards for information exchange are developed and maintained by Standards Development Organizations and other organizations.

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Block 1

- Laboratory content standards (LOINC, UCUM, SNOMED) refined, adopted and provided in national database of recommended vocabulary sets.
- Develop laboratory application program interfaces (APIs) for use by application developers
- Genetics and anatomic pathology are called out as separate data reporting requirements.

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Block 1

- Patient originated testing (self-testing, patient ordered or direct access testing) included as part of HIE. Origin of data must be clearly identified
- Laboratory information consistently matched to correct PHI (develop/adopt patient matching standards as proposed by ONC Interoperability Roadmap) with adoption by labs

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Block 2

- Adopt standards for LIS certification requirements to enable interoperability between providers (EHRs) and laboratories for ordering and results delivery
- Adopt standards for LIS certification requirements to enable communication of interoperable results to patients (requires electronic access to laboratory results).

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Block 2

- Adopt standards for EHR certification requirements to enable communication of equivalent interoperable laboratory report detail to patients (via PHRs, portals etc.) as is communicated to providers

Block 3

- Create standards, policies, processes to enable the electronic management of consent for information exchange with patients and their representatives
- LISs, portals have ability to remotely identify patients/personal representatives via electronic authentication/authorization protocols
- EHRs have ability to communicate flags to the LIS in regards to potentially harmful health information that could potentially harm a patient or another person.

Block 3

- LISs have ability to received flags regarding potentially harmful health information
- Genomic data is used in patient care/patient centered research in a way that is secure and respects privacy of the patient

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Block 4

- Incentivize laboratories to send the same, comparable laboratory report to patients as sent to providers. Report should be in a standardized, structured and consumer friendly format.
- Providers incentivized to send same comprehensive report they receive from the laboratory to patients in a standardized, structured format.
- Patients have the ability to receive, view, download and transmit laboratory report detail in a standardized, structured format.

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Block 5

- Multi-stakeholder federal governing body created and implemented, operating under 2010 HIT Policy Committee principles
- Establish regulatory authority to oversee and enforce adoption of laboratory information exchange standards by providers and laboratories.

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Concerns

1. No defined ways of measuring baseline data and/or implementation progress at the 3, 6, 10 year intervals.
2. Increased burden on laboratories to implement all of the suggested strategies.
3. Change does not happen rapidly in dealing with information systems, due to existing contracts in place and the need for/lack of technical staff to implement such changes.

Concerns

4. Some suggested strategies deal specifically with EHRs and are outside the purview of CLIA.
5. Under CLIA regulations, genomics/ anatomic pathology results not called out as separate reporting issues – they are considered test results, must follow the regulations at §493.1291 laboratory test report requirements.
6. There are no implementation plans, only limited definitions of goals

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Current suggested strategies

- Establish a laboratory information system certification program within CLIA (or MU certification)
- Create laboratory incentive program similar to Meaningful Use incentives

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Current suggested strategies

- Develop CLIA requirements for the use of standard laboratory codes sets (LOINC, SNOMED, UCUM, EDOS) by laboratories
- Develop a common API for application developers and require laboratories to use this API

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Current suggested strategies

- Adoption of interoperability standards by LISs (in addition to EHRs, PHRs and HIEs)
- Development and adoption by laboratories of consent management standards

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Current suggested strategies

- Establish LIS certification requirements for identity management, including CLIA guidance for remote identity, authentication and access management.
- Increased education for laboratories, patients, providers, application developers in regards to CLIA requirements and patient access to laboratory reports (create inter-agency plan)

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Current suggested strategies

- Create inter-agency group with representation from private sector to oversee the coordination of work conducted by various standards groups
- Determine which agencies/organizations will monitor/enforce implementation and use of interoperability standards by LISs.

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Problems

- There is no regulatory requirement for laboratories to implement the actions recommended in this document.
- The Plan provides no rationale to laboratory management regarding the potential advantages of interoperability

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Next Steps

- CMS, CDC, and the FDA propose to work with ONC to revise the Laboratory Interoperability Action Plan

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY

Contact Information

- Karen W. Dyer

  karen.dyer@cms.hhs.gov

  Office: 410-786-3531

CLIA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS & QUALITY