



# Confidentiality and Secondary Use

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Monday, October 16<sup>th</sup>

2:45 - 4:00 PM



# Types of Architectures

Federated

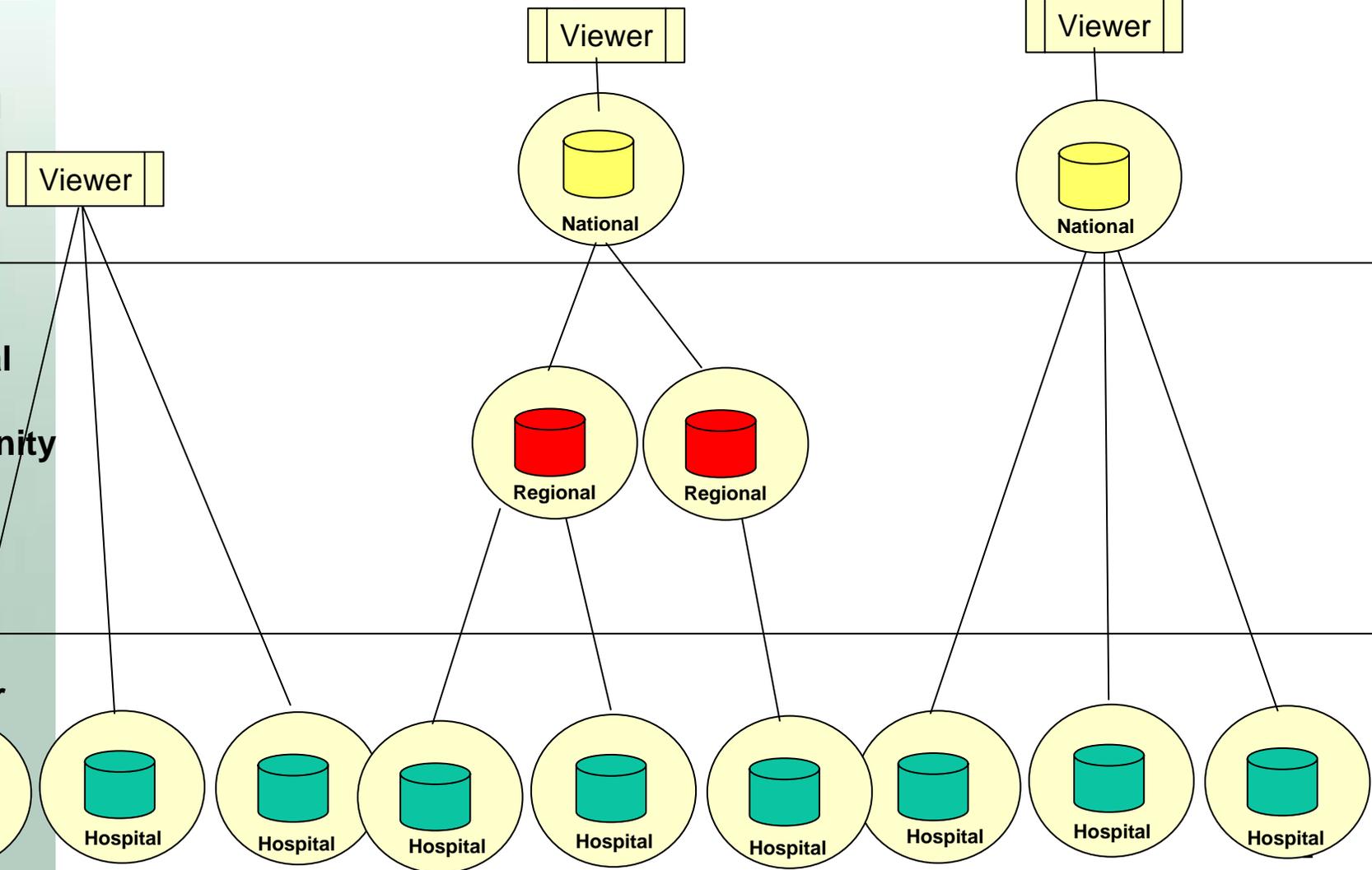
Hybrid

Centralized

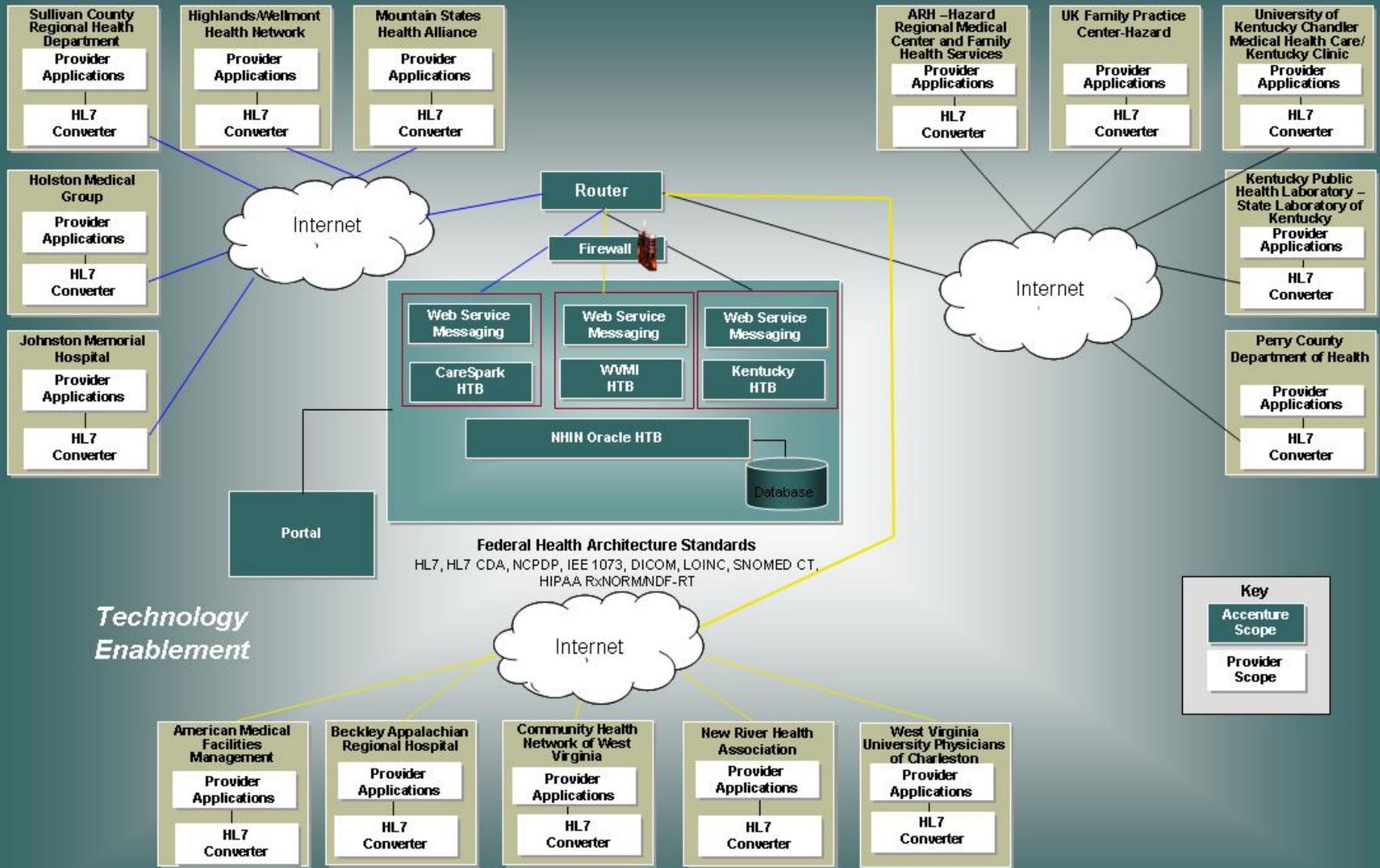
National

Regional  
or  
Community

Provider

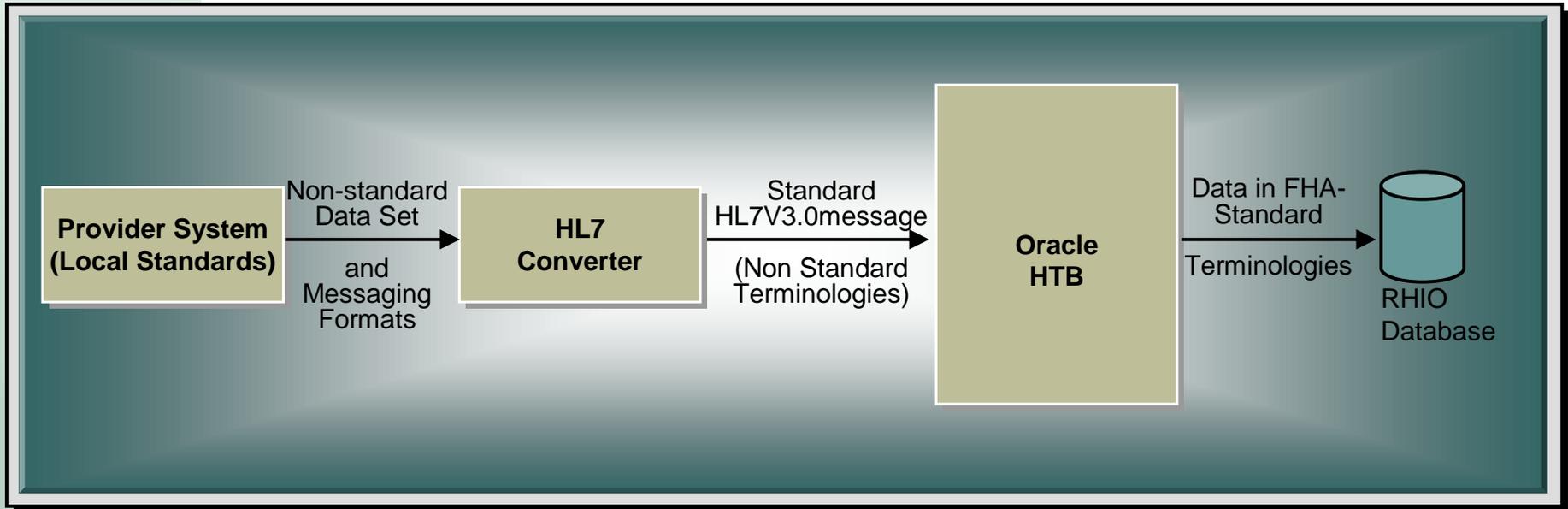


# Our Approach





Our approach results in the collection of data from multiple legacy systems that is normalized to the HL7 v3.0 message format and FHA terminology standards





# Issue #1 - Inter-organizational coordination required to carry out the data gathering, anonymization and data delivery activities

- **Patient Rights**
  - Should explicit patient consent be required (Explicit “Opt In”) before a patient’s anonymized data is used?
  - Should the patient be the one to determine if relinking is allowed?
- **Incentives and Financing of Aggregated Data**
  - Is there an inherent right (eminent domain) to use anonymized patient data for improving healthcare
  - Should patients be paid to use their anonymized data for improving healthcare?
  - Who should finance the activities necessary for secondary uses?
- **Governance of Data**
  - Data Covered Under HIPAA exemptions for Public Health and Law Enforcement activities
  - Data not Under HIPAA exemptions
    - Is there a difference between how one would treat anonymized data based on whether it can be relinked or not?
    - Who owns the data and under what circumstances can different entities access it? Is the access the same for regulators and industry?
    - Is Institutional Review Board (IRB) approval necessary for using aggregated data for research purposes? What IRB has jurisdiction?
    - Should a public-private foundation be established to enable secondary data usage?



## Issue #1 - Inter-organizational coordination required to carry out the data gathering, anonymization and data delivery activities

- **Pros of Hybrid Approach**

Aggregation, standardization and anonymization can be placed where they can be done most efficiently

Data analysis requires aggregation

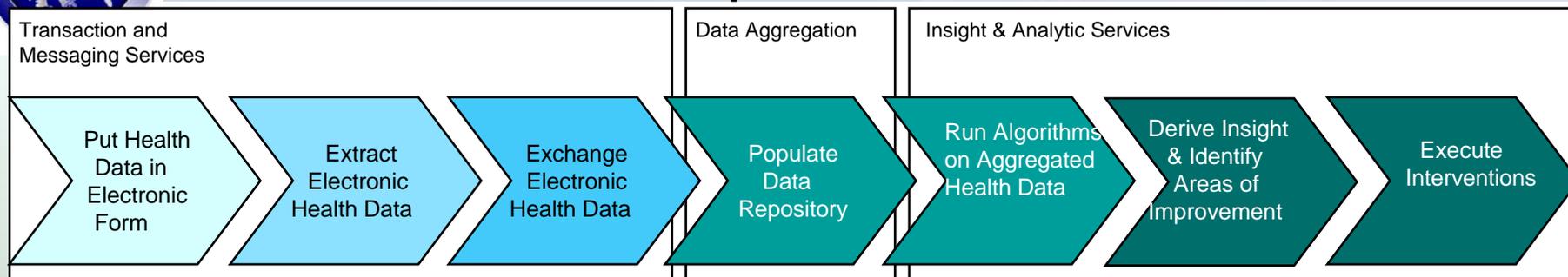
### **Cons**

More data is centralized than in federated model

Need to synchronize data



## Issue #2 - Standardization of the methodologies needed to accomplish this intent



- **Getting data into electronic form**
- **Secondary use requires terminology/messaging services and standards to support robust data analytics**
- **Need for standard methods regarding:**
  - Data extraction
  - Messaging
  - Terminology mapping
  - Anonymization
- **Key Point – This is a much higher bar than merely exchanging documents but enables not only secondary use for clinical research but also decision support applications**



## Issue #2 - Standardization of the methodologies needed to accomplish this intent

- **Heavy emphasis on data standardization**
  - Pros
    - Critical for public health, care management, clinical research
    - Much more robust data analysis is possible
    - Normalized data can drive decision support
  - Cons
    - Hard to do!
    - Document Storage with meta tagging is easier to implement
  
- **Flexible Hybrid Architecture**
  - Pros
    - Allows for increased control of where data resides (Federated vs. Centralized)
  - Cons
    - Increases technical complexity and impacts performance
    - Central storage of data may be unacceptable to some parties



## Issue #3 - Data Persistence Requirements

- **Where does data normalization occur?**
  - At the source as it is created (edge)
  - At the local provider level organization before it leave their environment (edge)
  - As it is mapped to regional/community databases (edge)
  - As it is mapped at the NHIN level (core)
- **Different architectures for OLTP and OLAP**
- **Performance issues with Federated architectures when data normalization and anonymization need to occur**



# Data persistence requirements of the our approach

## Pros of Hybrid Approach

## Cons

Robust data analysis requires aggregation

Privacy Concerns

Better performance

Data synchronization

Hybrid allows some degree of local control of data

Architecture allows each system to be optimized for its purpose