

# Plugging into Interop: How Changing Interoperability Regulations are Impacting HIN/HIEs



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# 2024 Key Interop Developments for HIN/HIEs



- ✓ [HTI-1 Final Rule](#) (1/9/2024)
- ✓ [CMS Interoperability and Prior Authorization Final Rule](#) (2/8/2024)
- ✓ [CURES Act Final Rule](#) (42 CFR Part 2) (2/16/2024)
- ✓ [HHS Reproductive Health Final Rule](#) (4/26/2024)
- ✓ [TEFCA 2.0](#) (Eff. 7/1/2024 and changes ongoing)
- ✓ [HTI-2 Proposed Rule](#) (Cmt. period closed 10/4/2024)
- ✓ State Level
  - Compliance deadlines for California ([AB 352](#)) and Maryland ([HB 812](#)) data segmentation laws
  - New Tennessee Information Blocking / Payer Interop Law ([SB 2012](#))
  - California DxF and renewed interest/focus on state HIN/HIE laws
  - Renewed interest/focus on whether state health data laws are extra-territorial
- ✓ Litigation
  - Texas v HHS (complaint filed)
  - Real Time Medical Systems v PointClickCare (PCC) (on appeal)
  - Particle Health v Epic (complaint filed)



# The *Complexity* and *Volume* Demands Focus and Intention



# Where to Start?

- What's the core purposes of my business / key business goals? Who are my participants?
- What jurisdictions am I doing business in?
- From what jurisdiction(s) do my participants' EHI originate?
- What type(s) of EHI do I maintain and in what manner (form/format)?
- What are my supported use cases (purpose of use)?
- Who can participate in my HIN/HIE or receive EHI from my HIN/HIE?
- Will I participate in TEFCA (or other state, regional or national exchange frameworks?)
- Will I support my participant's compliance with the laws that apply to them?

# Next Steps

Once the business goals and relevant laws / frameworks are identified...

Set out the ***business requirements*** necessary to meet the business goal in compliance with the legal / framework requirements





# Scenario: Illustrating the Process



# Checklist: Based on the Scenario

- ✓ USCDI v3 and FHIR ready
- ✓ Administrative and technical solutions to....
  - Support HIPAA-based access rights
    - Ex: limiting HIE participation to HIPAA-regulated entities, technically coding access/queries to specific use cases (purpose of use), imposing date/content restrictions to meet minimum necessary standards on applicable purpose of use-based access/queries, presenting context-specific attestations based on user role and/or purpose of use code
  - Identify sensitive data and support consent-based and medical emergency access
    - Ex: 42 CFR Part 2 data segmentation and consent management; similar state-based segmentation and consent management for non-treatment use cases
  - Support CMS-mandated APIs for payers
    - Ex: limiting Medicaid payer data disclosures to in-network providers, treating provider attestations
  - Support Individual Access Services (IAS): facilitated and brokered
  - Support for TEFCA
    - Ex: unique purpose of use codes, opt-in/out to initiating node and/or responding node, delegate process
- ✓ Documentation of IBR exceptions that support these decisions
  - Contracts: Manner; Fees; Licensing; Health IT Performance
  - Policies and Procedures: Privacy; Preventing Harm; TEFCA
  - Infeasibility Determinations and Notices