

# Anatomy of a **Cures Act Compliance** Solution for Your EHR

Healthcare industry is evolving at a rapid pace, especially in the post COVID-19 era. Some of the primary drivers for the change include regulations, innovative solutions, educated patients and their comfort in using and trusting new technologies. In this environment, healthcare providers will be looking to use EHR/EMR software that is Cures Act compliant by December 31, 2022. By then, all large EHR vendors will have already implemented everything they need and have their EHR systems fully certified. If you are a small or medium-sized EHR vendor, you may still be struggling with the new requirements and how to go about getting certified without making a sizable investment and maintaining certification as your systems get implemented or updated in the real world.

The good news is you still have time to get certified before the deadline—but it's critical for you to get started as soon as possible. This white paper provides a technical breakdown of key steps to ensure you achieve certification with time to spare.

## **Critical considerations of the Cures Act as it relates to EHR software**

The Cures Act was created to provide patients, providers, and payers secure and unfettered access to electronic health information. In doing so, it calls upon the healthcare industry to standardize application programming interfaces (APIs), paving the way for technological innovation and removing barriers to quality care by democratizing access to health record data.

Access to information is at the core of the ONC Cures Act Rule. The Act articulates regulations designed to prevent information blocking by providers, health IT developers, health information exchanges (HIEs), and health information networks. Health information under the rule defines data interoperability as outlined in the United States Core Data for Interoperability (USCDI)

IT architectures must interface and interact with all necessary systems to facilitate access to health record data for all stakeholders, including patients, providers, and payers. Systems must comply with these requirements and achieve certification by the end of 2022 or risk significant regulatory fines and possible criminal code violations.

Clearly, the definition of information blocking seems to be broad and open-ended. Because of this, ONC also allows eight classifications of exceptions in two distinct categories. For more detailed information on Cures Act Final Rule exceptions, visit HealthIT.gov.

# **What changes must be made to your current EHR software?**

So, what do these regulations mean in terms of changes you must make in your EHR software?

## **Here are the baseline considerations:**

Cures Act certification requirements mandate that patient data stored in your EHR or other electronic forms must be available to patients and third-party apps using U.S. Core Data for Interoperability (USCDI) and FHIR APIs.

**Assuming your EHR System is already fully developed and deployed for healthcare providers, you have two choices:**

1. Re-architect your software and implement it using USCDI data formats and FHIR APIs.
2. Implement or develop a bolt-on FHIR façade that will:
  - a. Expose the FHIR APIs to the external apps requesting data in USCDI format
  - b. Support an external app registration and authorization server
  - c. On the fly, transform the requested data from your native format to USCDI and fulfill the request

## **Option 1 versus Option 2:**

**Option 1:** Larger healthcare organizations may well have the resources to devote. Still, the challenges of developing such solutions are costly, labor-intensive, and highly nuanced, requiring extensive IT capabilities and deep pockets to accomplish.

**Option 2:** Given the December 31 deadline, this is the most viable and least complicated approach. When you consider the rate at which technology advances today, current talent shortages, and an increasingly volatile data security environment, it makes more sense for organizations of any size to choose an FHIR Server Façade bolt-on solution.

# What you need to know about FHIR Server Façade Solutions

Several FHIR Server Façade solutions are currently available in the market, each designed to integrate with your EHR System with the express goal of accomplishing Cures Act compliance.

A common question among EHR software vendors is, what is the level of integration effort required from the EHR team, and perhaps more importantly, how do you evaluate a bolt-on FHIR Server Façade solution to ensure a successful and cost-effective certification outcome?

**Here are some questions that you may want to consider before selecting a solution provider for your EHR Cures Act compliance.**

***What if I don't want to allow external apps to access the EHR data directly?***

A two-stage request and response workflow may be your preferred option to ensure your security team is on board with the solution. A two-stage data access request and response requires an intermediate stage between the FHIR Façade and the database access layer to queue requests for the data access layer to select and execute the requests asynchronously. If your solution vendor supports an intermediate stage queuing framework, it will significantly reduce the integration and testing efforts.

***Do we need to implement a Clinical Data Repository (CDR) for the EHR certification?***

No, CDR is not required, and your solution vendor should be able to get your EHR certified without implementing a CDR solution for your enterprise. There is nothing wrong with implementing a CDR. However, implementing an enterprise-level CDR will add complexity, significant additional effort, and cost given the fast-approaching deadline. An ideal solution vendor supports the CDR implementation option but does not require a CDR for the Cures Act compliance certification.

***What about data access requests from my providers to other EHR systems?***

Interestingly, the capability of your providers using your EHR system to access data from other providers or EHR systems is NOT required for the Cures Act compliance certification. But, as you can reasonably surmise, this optional capability is highly critical to your providers. Even if you do not plan to implement this feature before the December 31, 2022 deadline, make sure you select a solution vendor who can implement this solution for your multi-tenant EHR system.

*How do I track usage statistics for external apps accessing your data or your providers requesting data from other EHR systems?*

Once the Cures Act compliance solution is implemented, you will need to track the number of requests made by external systems and requests made by your providers to other external systems. In addition to the audit logs, the tracking information can help you monetize the provider requests. If this feature is of interest, a solution vendor with built-in support for usage statistics will save time and effort during solution integration.

*How do I know if my EHR database has all the required data to meet the compliance requirements?*

Since the data is being mapped and transformed on the fly, questions arise about what happens if a required data item is missing from the EHR database. This must be addressed during end-to-end testing for all certification scenarios, which will identify the missing data and create an appropriate response for the missing data. A solution vendor with a complete certification scenario-based test plan and testing will ensure that all such issues are addressed in advance of the final certification step.

*Can the bolt-on solution integrate seamlessly with existing users and workflows?*

Your solution providers should ideally have minimal impact on the existing system. There are two key areas to consider: no impact on existing user management processes and no impact or change in the existing EHR workflows used by providers.

*What process is used by the selected vendor to get the EHR certified?*

Check how your solution provider plans to take the system through the certification process. You should look for a solution provider who intends to use certification test cases to complete each sprint—essentially, a litmus test that will ensure a successful certification outcome.

## **Features to Look for in a Bolt-On FHIR Server Façade Solution**

Cures Act compliance is not just implementing FHIR Servers or FHIR APIs, and it cannot be met simply by standing up an open-source FHIR Server.

## Here is a list of core capabilities a bolt-on FHIR Server Façade Solution should have

- FHIR APIs. FHIR APIs must be present to support access from external or internal applications.
- FHIR Server for specific EHR Tenants. The FHIR solution must support single-patient API and multi-patient (Bulk API) access.
- Authorization Services. SMART on FHIR is a universal API standard enabling provider and patient app authorization and backend authorization.
- Auditing Services. Your IT environment must offer the ability to audit access and monetize the APIs.
- Integration with EHR Database. Schema-agnostic integration with the EHR database.
- User and Client Management: App registration, activation, and deactivation on demand.
- Time Synchronization: Network Time Protocol (NTP) enablement.
- Security. SSL, PKIs, and other advanced encryption protocols.
- Attestation & Documentation: API documentation, security, and privacy signoff, complete mapping between UI and FHIR APIs.
- Sandbox Creation and Maintenance. Sandboxing supports safe testing and validation of external apps before deployment.
- Support for real-world testing plans. To balance, assess, and assure value to the end-user.
- Managing FHIR versions and updating processes. View updates, fixes, and FHIR versions to ensure ongoing compliance and operability.

All these capabilities must be pluggable into the EHR without requiring any heavy lifting or development effort by the EHR vendor. In addition, the FHIR Server Façade vendor must be able to provide an integration plan based on data-driven certification testing.

**The steps are as follows:**

## Assess & Backlog Planning

Analyze requirements and develop an integration backlog

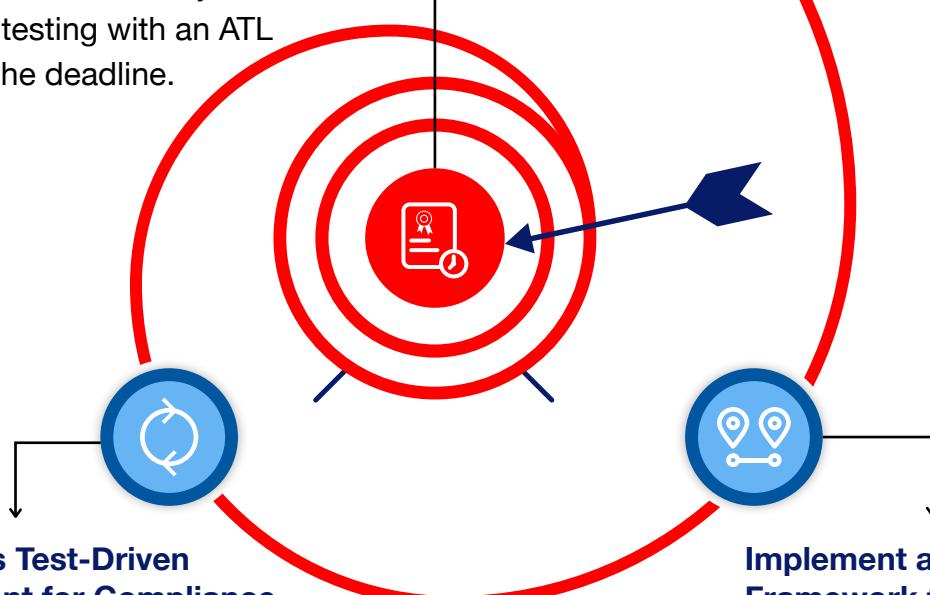


## Gaps and Mapping

Conduct a walk-through of each supported data element (including missing data) to the EHR database to enable fully compliant data/code mapping.

## Schedule certification testing with an accredited test lab (ATL)

Plan ahead and schedule your certification testing with an ATL well before the deadline.



## Continuous Test-Driven Development for Compliance

Use the ONC certification test use cases and scenarios to conduct continuous testing and validation of completed tasks.

## Implement an End-to-End Framework for Compliance

Implement and test each API for end-to-end compliance.

# Preparing for Certification Testing

The final link in the chain is for you to estimate the level of effort distribution between the FHIR Server Façade Solution vendor and your team. Ensuring you have the right solution for your needs and adequate resources to support the integration effort is critical. In general, most integration tasks can be supported by the FHIR Server Façade vendor. One notable exception is the task of “Integration with the EHR Database,” however, even this process can be handled by the vendor if you provide database schemas in advance.

The InteropX Cures Act Compliance solution is a certified product, providing all the above-mentioned required components for your EHR system. Working with InteropX

experts assures your implementation and deployment are seamless and non-invasive. Our team works closely with yours to ensure your organization is up to speed on best practices and becomes certified before the deadline.

Though there are many solutions on the market today, InteropX offers several differentiators that elevate the system's value. Our ultimate goal is to help you worry less about IT complexities so you can focus on what you do best.

## InteropX Benefits

InteropX specializes in healthcare data compliance, but we're not just a faceless IT vendor. We are solutions architects with industry-leading experience across multiple healthcare verticals, and we understand the big-picture regulatory requirements as well as we do your organizational and financial goals.

### Fastest Time-to-Result



We offer rapid compliance certification readiness, helping you achieve results in as little as two to three months, assuming all dependencies are satisfied.



### Dedicated Team



Our clients enjoy a dedicated project manager and a multi-functional team who will work with you to implement and deliver a seamless and successful EHR software integration.



### End-to-End Cures Act Compliance Solution



InteropX is a complete solution from start to finish, culminating with a successful Cures Act certification.



### Ongoing Support



Changes in the FHIR framework are inevitable. We will ensure you have continuous support for new versions, USCDI changes, and other regulatory changes that may impact the implemented InteropX solution.



### Flexible, Nimble Solution

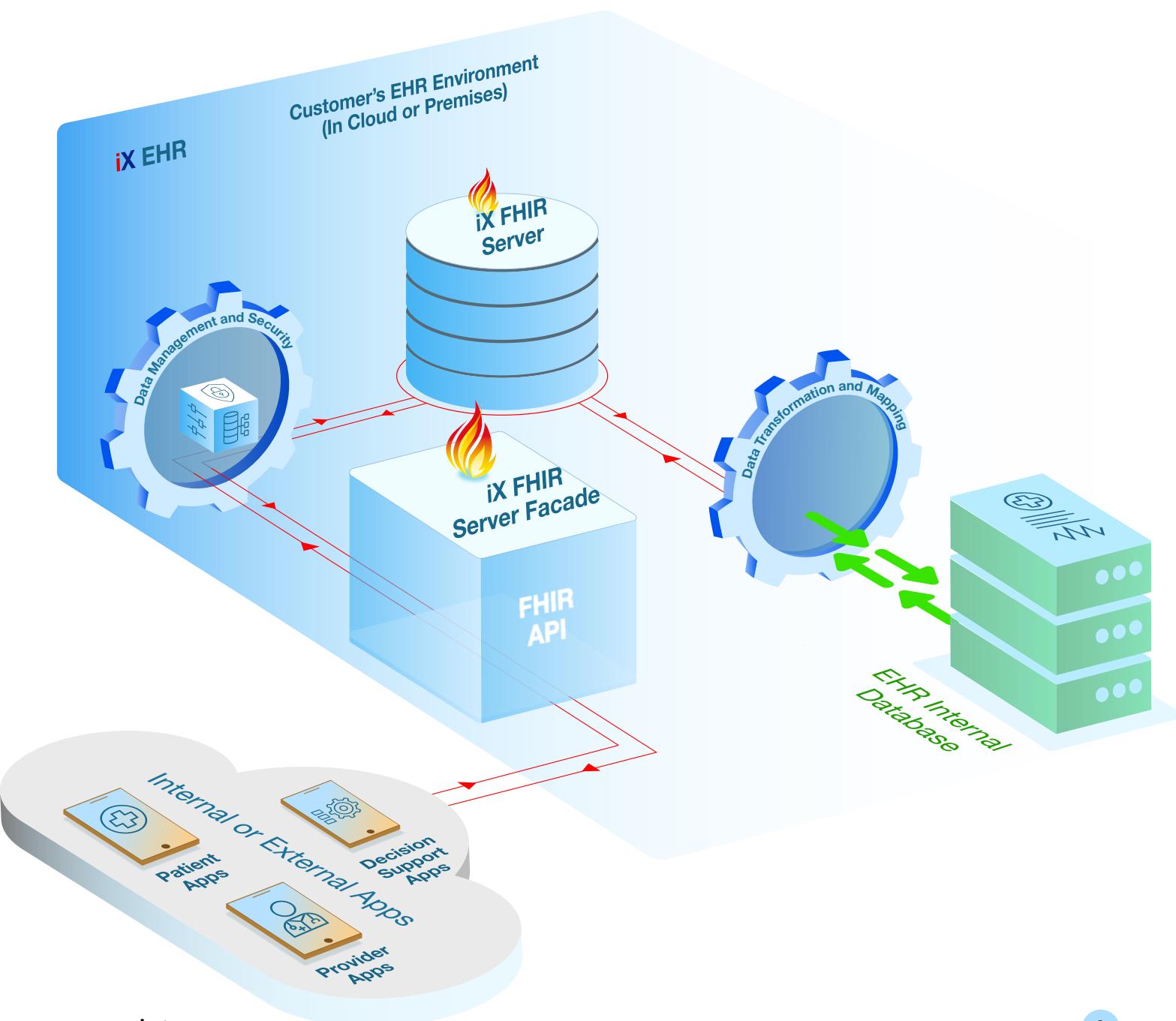


Our highly flexible InteropX architecture is modular, ensuring we can build out the solution you need without impacting your existing EHR software or employee workflows. No CDR or data migration is required, and all future CMS and ONC regulatory requirements can be added as new modules to the implemented solution.

# Complete Cures Act Compliance Solution

InteropX EHR is the only solution in the market that provides a complete Cures Act compliance solution package including:

- Certified FHIR Façade and FHIR Server ready for integration with your EHR system
- Support for two-stage access to the database access layer
- Support your providers to access patient data from other (external) EHR systems. This feature is not required for certification but essential for your providers
- Certification test readiness and full support through testing with an Authorized Test Lab (ATL) to ensure that your EHR is fully certified.



## CONCLUSION

InteropX is the only comprehensively packaged solution in the market that includes an optional bidirectional data exchange which allows your providers to access data from other EHRs, simplifying complexities and accelerating time-to-result.

InteropX provides the most compelling business use case in being efficient, cost-effective, and complete, delivering the best possible ROI without impacting existing resources and business priorities.

Once InteropX is functional on your system, your team will enjoy simplified workflows, faster results, and zero worries about Cures Act compliance. With the deadline fast approaching, waiting is no longer an option.



## GET IN TOUCH

Speak to us about getting started with our iX EHR solution or to request your demo



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