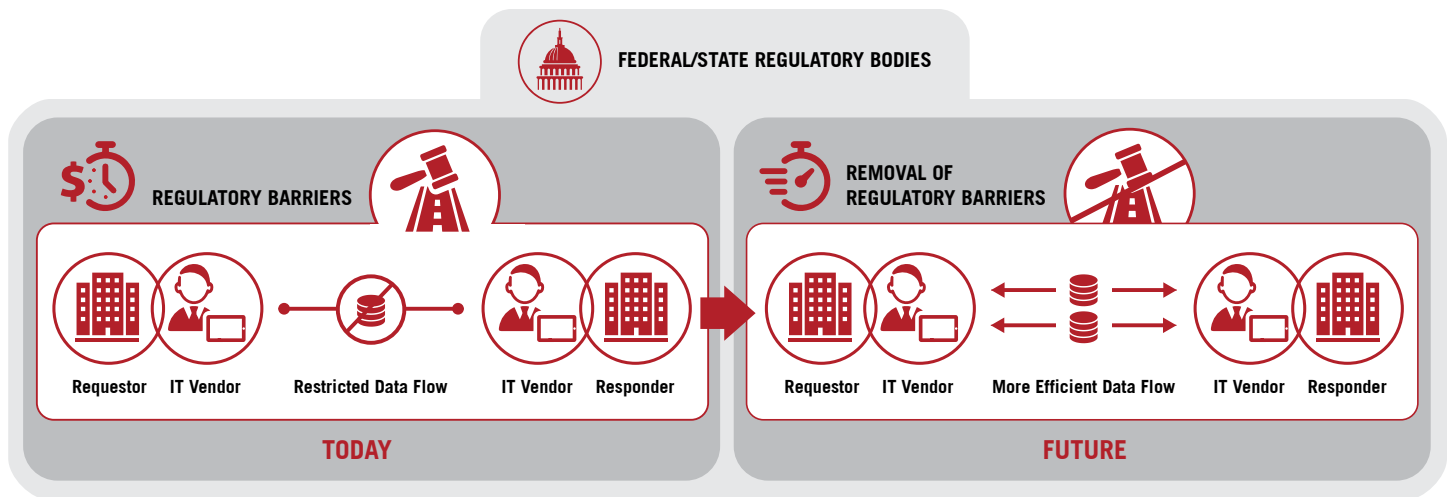# Regulatory/Policy Barriers to HL7® FHIR® Solutions Scalability

The FHIR at Scale Taskforce (*FAST*) has identified regulatory and policy barriers that need to be addressed in order to scale Fast Healthcare Interoperability Resources (FHIR) as a ubiquitous capability that enables wide-scale clinical information exchange between providers, payers, and other stakeholders.

These barriers include the HIPAA minimum necessary regulations, the naming of a standard In a way the limits innovation, the lack of a single patient identifier, and the cost of accessing data via FHIR Application Programming Interfaces (APIs).

The industry is interested in scaling FHIR use. The most recent Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rulemaking (NPRM) and the Office of the National Coordinator for Health IT (ONC) NPRM (published in the federal register on March 4, 2019) call for widespread use of APIs to enable consumers to access their health data and foster industry-wide adoption. However, the following regulatory and policy barriers impede scalable FHIR adoption, and they are the focus for which *FAST* will identify potential solutions:

1. **HIPAA Minimum Necessary**
2. **Regulatory Mandate for a Single Named Standard**
3. **Patient Identifier**
4. **Data Blocking**
5. **Use of NPPES as the Repository for Endpoints**
6. **HIPAA Transactions Requiring X12**

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HIPAA MINIMUM NECESSARY

When payers have access to patients' medical records using FHIR, the question of "minimum necessary" will become a significant issue since the current human mediated response will no longer take place. However, having direct access to clinical data allows the industry to reduce provider burden by decreasing the number of manual interventions providers need to manage to exchange data with payers and other providers. Instead of setting the bar at the "minimum necessary," which can be interpreted differently by different stakeholders, the industry will need to move away from concerns about data access and shift toward defining the stated purpose for using the data (e.g., "I need access to these data for quality reporting measures"), which then becomes the approved use.

Industry Efforts: Congressional discussions are taking place on protecting patient information, the need for access to information, and the use of data for only the purpose for which it was requested. The *FAST* team will assess the progress of related initiatives including the following:

- National Committee on Vital and Health Statistics (NCVHS) work on Minimum Necessary
- Office for Civil Rights (OCR) Request for Information (RFI) on Privacy

REGULATORY MANDATE FOR A SINGLE NAMED STANDARD

The current practice of naming a technology standard in regulation, including the version, as the required and only allowed solution for the problem restricts the ability to innovate. The ONC NPRM is working to address this issue by providing a floor (i.e., required minimum), but allowing innovation and the ability to adopt new versions as they occur as long as stakeholders support backward compatibility.

Industry Efforts: The *FAST* team will assess the progress of related initiatives including the following:

- Proposed process changes in the ONC NPRM and the CMS NPRM
- NCVHS Predictability Roadmap in development

PATIENT IDENTIFIER

The current legislation restricting the use of federal money to establish a single patient identifier forces the industry to use probabilistic matching based upon demographic information, which can lead to errors, when dealing with clinical information from multiple sources. While there have been improvements in probabilistic matching, the industry should also look toward other possible solutions such as portability of member health plan and medical record identification. As members move from plan to plan, perhaps their payer/subscriber identifiers and provider medical record numbers can move with them.

Industry Efforts: The *FAST* team will assess the progress of related initiatives including the following:

- ONC NPRM Request for Information
- CMS NPRM Request for Information
- College of Healthcare Information Management Executives (CHIME)
- Healthcare Information and Management Systems Society (HIMSS)
- Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2020

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DATA BLOCKING

The industry is moving to a utilization model for access to patient data using FHIR APIs. As FHIR makes information readily available within an encounter clinical workflow and through multiple mobile, portable and wearable devices in real time, the volume of transactions will increase exponentially. If there is limited access to this information, or the cost per access/transaction is too high, this will constitute a new form of data blocking. The CMS NPRM is working to address both of these issues.

Industry Efforts: The *FAST* team will assess the progress of related initiatives including the following:

- ONC NPRM
- Industry examples of regulating costs, setting caps, or managing "pass through" charges in regulated environments such as telecom or energy

USE OF NPPES AS THE REPOSITORY FOR ENDPOINTS

The National Plan and Provider Enumeration System (NPPES) directory is not designed to hold, validate, and maintain the information required to appropriately describe the endpoints for FHIR. The current low rate of publication of Direct addresss in NPPES is a strong indicator of the issues.

Industry Efforts: The *FAST* team will assess the progress of related initiatives including the following:

- CMS NPRM
- 21st Century Cures Act
- DirectTrust

- Carequality
- Apple
- Additional industry examples to be identified

HIPAA TRANSACTIONS REQUIRING X12

The mandated use of X12 and only X12 for the administrative transactions is a significant barrier to both innovation and the ability to merge both clinical and administrative information in a single exchange to solve value-based care problems.

Industry Efforts: The *FAST* team will assess the progress of related initiatives including the following:

- NCVHS Predictability Roadmap to promote industry use of the exceptions provision within the HIPAA regulations (45 CFR 162.940)
- Da Vinci Prior Authorization implementation guide efforts to integrate both FHIR and X12 standards in a single end-to-end exchange between a provider and payer