FHIR at Scale Taskforce (*FAST*)

Regulatory/Policy barriers to FHIR solutions scalability

Tiger Team Name: Directory, Version and Scale

\*\*Teams to focus first focus on A. and B. and later on C.

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|  | 1. What is the regulatory/policy barrier identified? | 1. Why is this a barrier to scalability? | 1. What are the exiting industry efforts working to remove this barrier? |
|  | HIPAA Minimum Necessary (and with consideration for additionally protected data under federal law and more state privacy laws) | When payers have access to patient’ 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. | Congressional discussions broadly on protecting patient information and need for access to information. Relates to need to use data for only purpose for which it was requested.  NCVHS work on Minimum Necessary: <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2016-Ltr-Privacy-Minimum-Necessary-formatted-on-ltrhead-Nov-9-FINAL-w-sig.pdf>  OCR’s RFI on Privacy: <https://www.federalregister.gov/documents/2018/12/14/2018-27162/request-for-information-on-modifying-hipaa-rules-to-improve-coordinated-care> |
|  | Regulatory mandate for a single named standards (floor/ceiling) | The current practice of naming, in regulation, a technology standard, including the version, as the required and only allow solution for problem restricts the ability to innovate. | ONC/CMS proposed process changes in NPRMs  NCVHS’s Predictability Roadmap in development |
|  | Patient Identifier (person matching issue and cross-industry solutions) | The current legislation restricting the use of a single patient identifier (actually using federal money to establish one) forces the industry to use probabilistic matching and not deterministic matching when dealing with clinical information from multiple sources. | CMS NPRM request for information  CHIME  HIMSS  ONC  AIRA – Immunization Papers / CDC product: <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/deduplication.html> |
|  | Cost of accessing data via FHIR APIs | The industry is moving to a utilization model for access to patient data using FHIR APIs. This can be a form of data blocking if the cost per access/transaction is too high. | ONC NPRM  [Other industry examples of regulating costs/setting caps and learning potential: telecom (break up of Ma Bell; energy]  Aspect of whether pass through charges are regulated? |
|  | Use of NPPES as the repository of endpoints | The NPPES directory is not designed to hold, validate, maintain the information required to appropriately describe the endpoints for FHIR. The current lack of success with Direct is a strong indicator of the issues | CMS NPRM  21st Century Cures  DirectTrust; Carequality; Apple, and more examples of industry efforts |
|  | HIPAA Transactions requiring X12 | The mandated use of X12 and only X12 for the administrative transaction is a significant barrier to innovation and the ability to merge both clinical an administrative information in a single exchange to solve VBC problems. | NCVHS Predictability Roadmap to promote industry use of the exceptions provision within the HIPAA regulations (162.940 – verify citation)  Da Vinci Prior Authorization implementation guide efforts to generate FHIR exchanges into X12 278 |
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