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EHR Update on Regulations and Standards to Plan Your Roadmap

June 9, 2022



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Presenters



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Discussion Topics



**Interoperability
Concepts**



**Policy and
Regulation**



**Impact on
Organizations**



**What is
Happening Now**

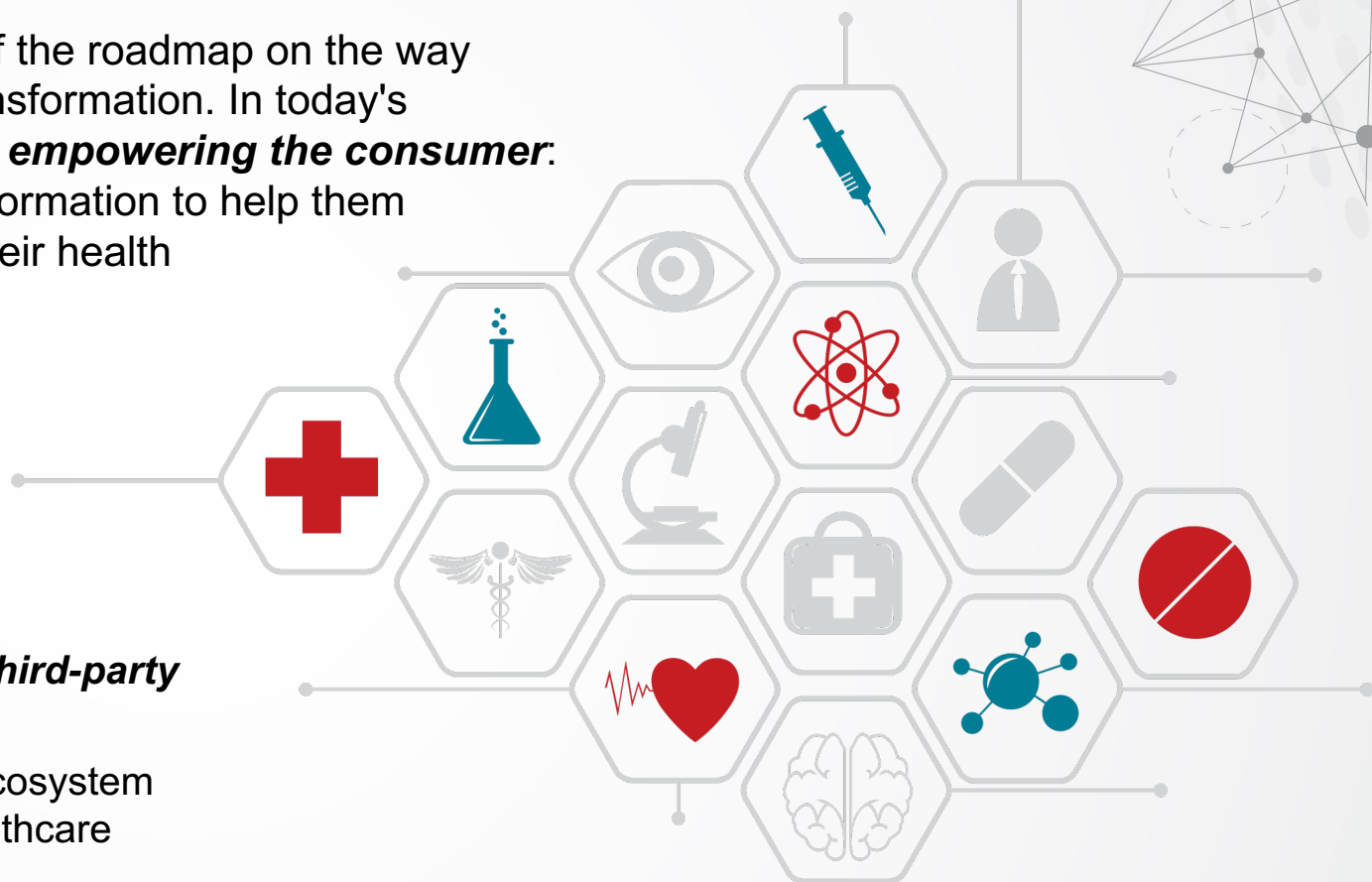


What's Next

What is Interoperability in Healthcare?

Interoperability is a **foundational component** of the roadmap on the way to the next generation of Healthcare's digital transformation. In today's healthcare market, interoperability is focused on **empowering the consumer**: members, patients and their care givers, with information to help them **better manage their health** and, on enabling their health care providers with comprehensive healthcare information in support of better care.

- Interoperability provides the infrastructure, tools and services that:
 - **Allows consumers to easily retrieve and share their clinical data**
 - Ensures patients can **use their data with third-party applications of their choice**
 - Enables all participants in the healthcare ecosystem to easily access and use all necessary healthcare information, with **consumer approval and appropriate privacy and security safeguards**



**Interoperability =
Integration + Context + Privacy & Security**

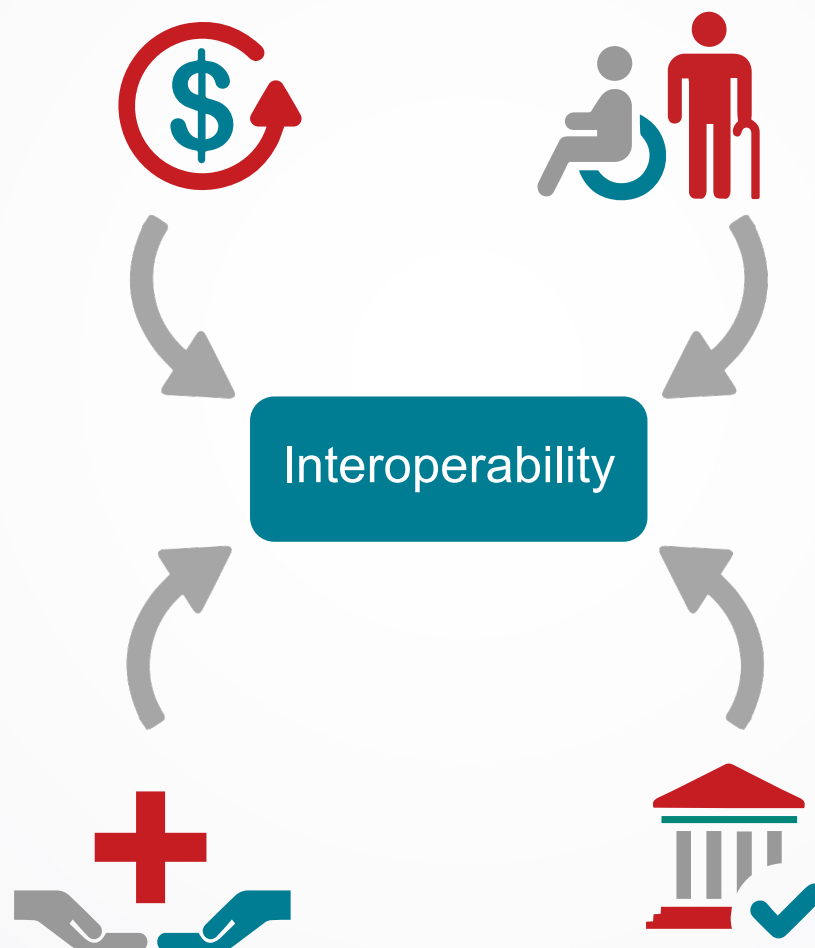
Demand for Interoperable Clinical Data is Growing

Shift to Value-Based Care

- Focus on outcomes
- Innovation in business models and use of technology
- Shared Upside/Downside between payers/providers

Quality and Safety

- Improve information and attestation in workflow
- Follow agreed upon best practices
- Unlock payer data to care givers



Consumer Demand

- Ease of Access
- Clear understanding of benefit and coverage
- Ability to see cost/quality data
- Patients manage own data
- Ensure privacy and security

Regulatory Requirements

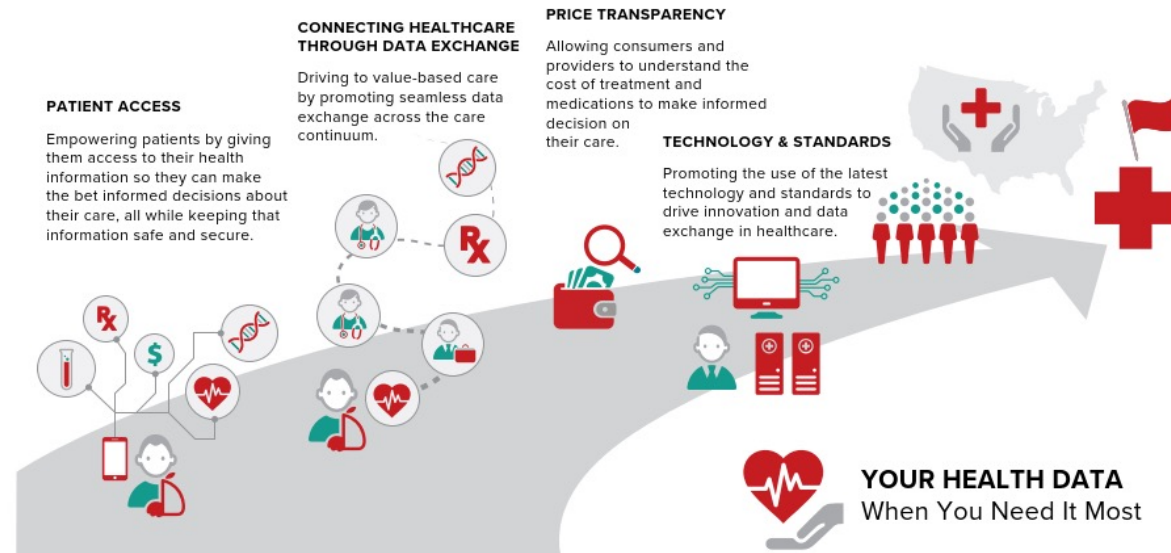
- Data Blocking
- Coverage Portability
- Price Transparency
- Ensure privacy and security

Policy and Regulation: May 2020 Final Rules

In May 2020, the Department of Health and Human Services (HHS) released two rules related to interoperability. Both final rules implemented **interoperability** and **patient access provisions** of the 21st Century Cures Act.

Agency	Rule
ONC	Information blocking
	Mandatory use of USCDI and APIs
	Mandatory use of FHIR™ and NCPDP Script
CMS	Payer to payer data exchange
	Patient Access API
	Provider Directory
	ADT notifications
	Frequency of dual eligible reporting

2020 ONC Cures and CMS Interoperability and Patient Access final rules are part of an evolutionary process



Risks and Opportunities



Health Systems/Providers

RISKS

- Major shift in mindset required related to patient data
- Increased competition around the shop-ability of healthcare services

OPPORTUNITIES

- Administrative simplification/burden reduction
- Accountable Care Organizations (ACOs) can access needed patient data



EHR / Health IT Vendors

RISKS

- Data Blocking rules may require new business models
- Potential burden on development roadmap
- Increased competition for provider customers

OPPORTUNITIES

- Partnership and revenue opportunities
- Product Differentiation
- Standardization of APIs and data sets help to minimize development costs



Patient / Caregiver

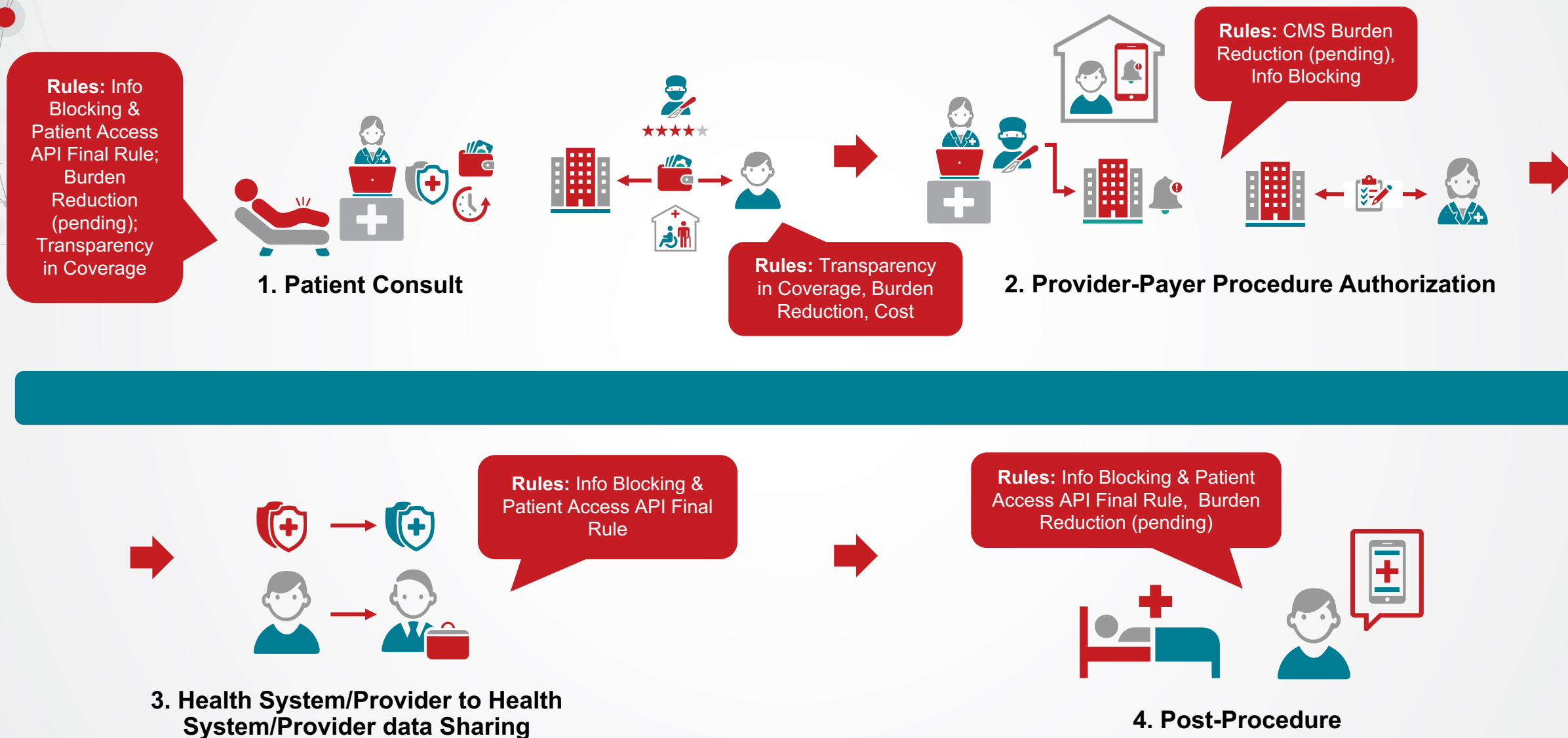
RISKS

- Must carry the burden of protection of their own data
- Proliferation of “bad actors” in the marketplace

OPPORTUNITIES

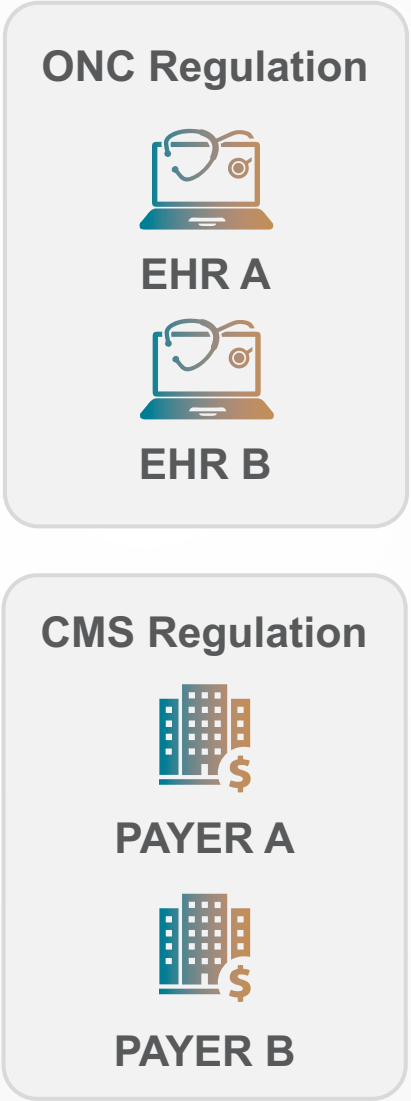
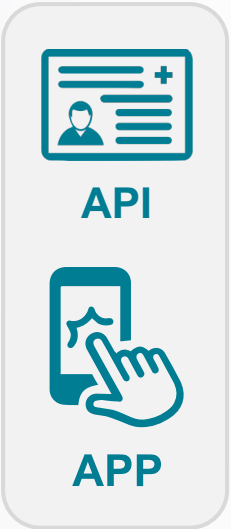
- Higher quality of care at a lower price
- Empowerment to manage own healthcare data

Sampling of APIs in Patient Journey

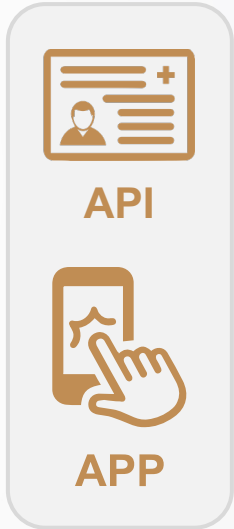


Regulation and Enforcement Is Shifting

Consumer Directed-B2C
COVERED UNDER FTC, NOT HIPAA



Covered Entities and BAA-B2B
REGULATED UNDER HIPAA



The Regulations are not complete. There is still more to come...



Open Questions

- Will a new HIPAA be required to be enacted?
- Mobile App Privacy Attestation
- Role of Trusted Exchange Framework and Common Agreement (TEFCA)



Financial penalties for non-compliance

- Still under discussion with Office of Inspector General (OIG)
- Impact of Public “Shaming” method



National Patient Identifier

- Legislative changes required to remove funding ban
- Privacy concerns



Price Transparency

- What's next after Transparency in Coverage and Prescription price transparency



Regulatory Timeline

ONC Information Blocking Rule Timeline



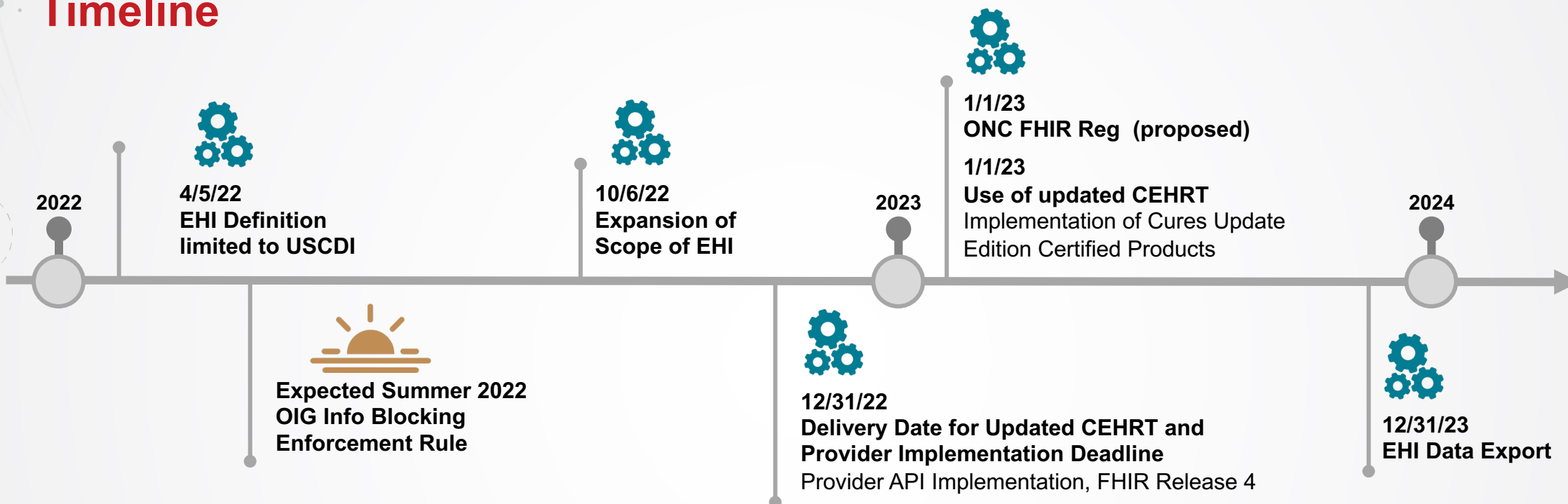
IN
EFFECT



COMPLIANCE
ENFORCED



ON THE
HORIZON



ON THE HORIZON

- *Burden Reduction: CMS published Jan '21, then pulled back Proposed Rule mandating use of Da Vinci Guides for Prior Authorization (PA) CMS moved a new proposed rule into Consolidated Agenda signally PA rulemaking underway*
- *OIG Information Blocking Enforcement Rule*
- *Anticipating proposed changes in HIPAA privacy rules from OCR forthcoming later in 2022 including how HIPAA begins to integrate FHIR*

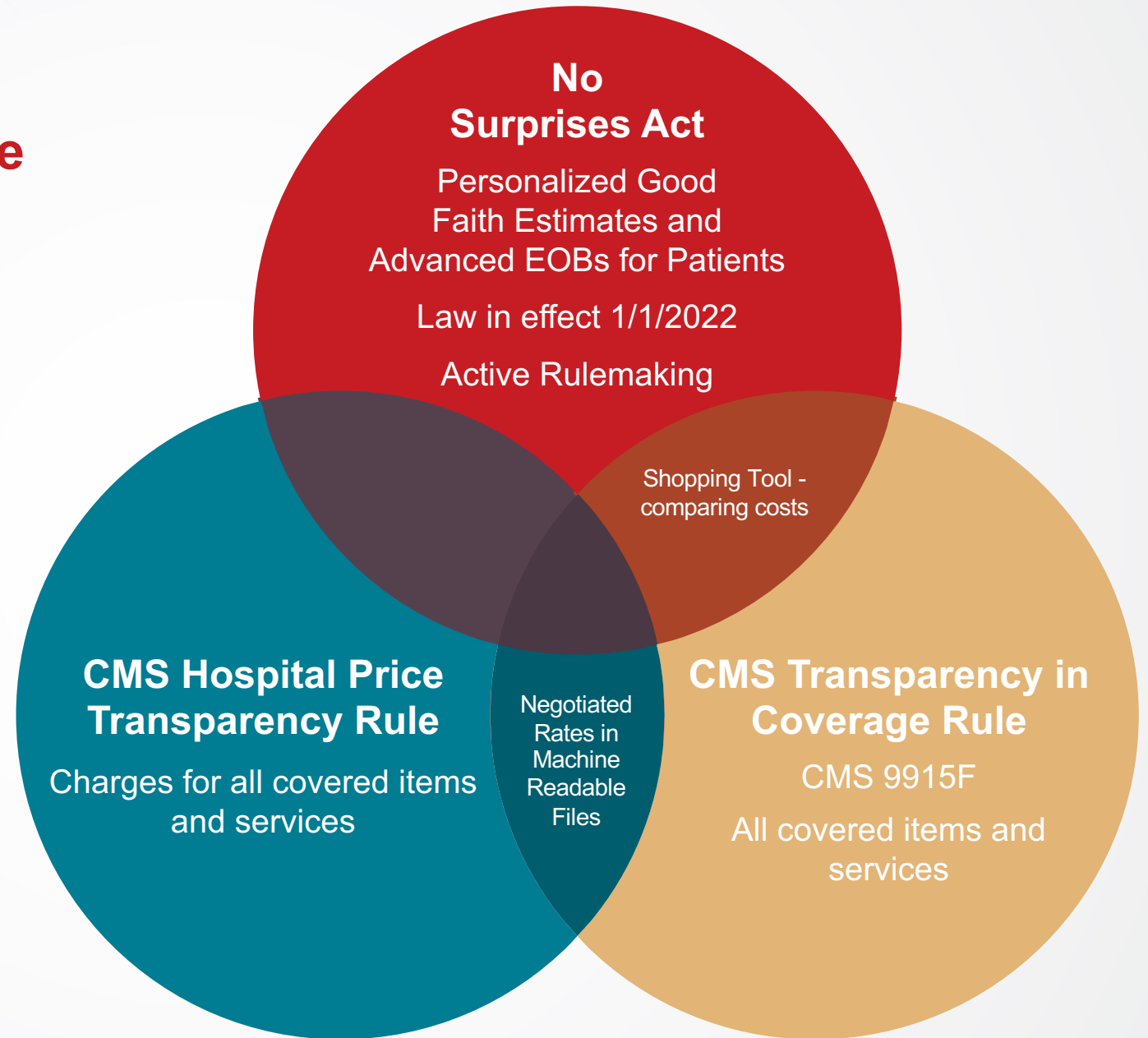
Terminology:

EHI: Electronic Health Information
USCDI: United States Core Data For Interoperability
ONC: Office of National Coordinator
FHIR: Fast Healthcare Interoperability Resources
CEHRT: Certified Electronic Health Record Technology
OIG: Office of Inspector General



Cost Transparency Regulation Landscape

- Increased regulatory activity at Federal level
- Aimed at delivering unprecedented cost transparency for healthcare services
- Industry waiting for clarification on timelines and shopping tool synergies from regulators
- No Surprises Act is three agency rule
- Solutions will require multiple standards (NCPDP, FHIR, X12)
- Need to think about how to support providers



Price/Cost Transparency Timeline



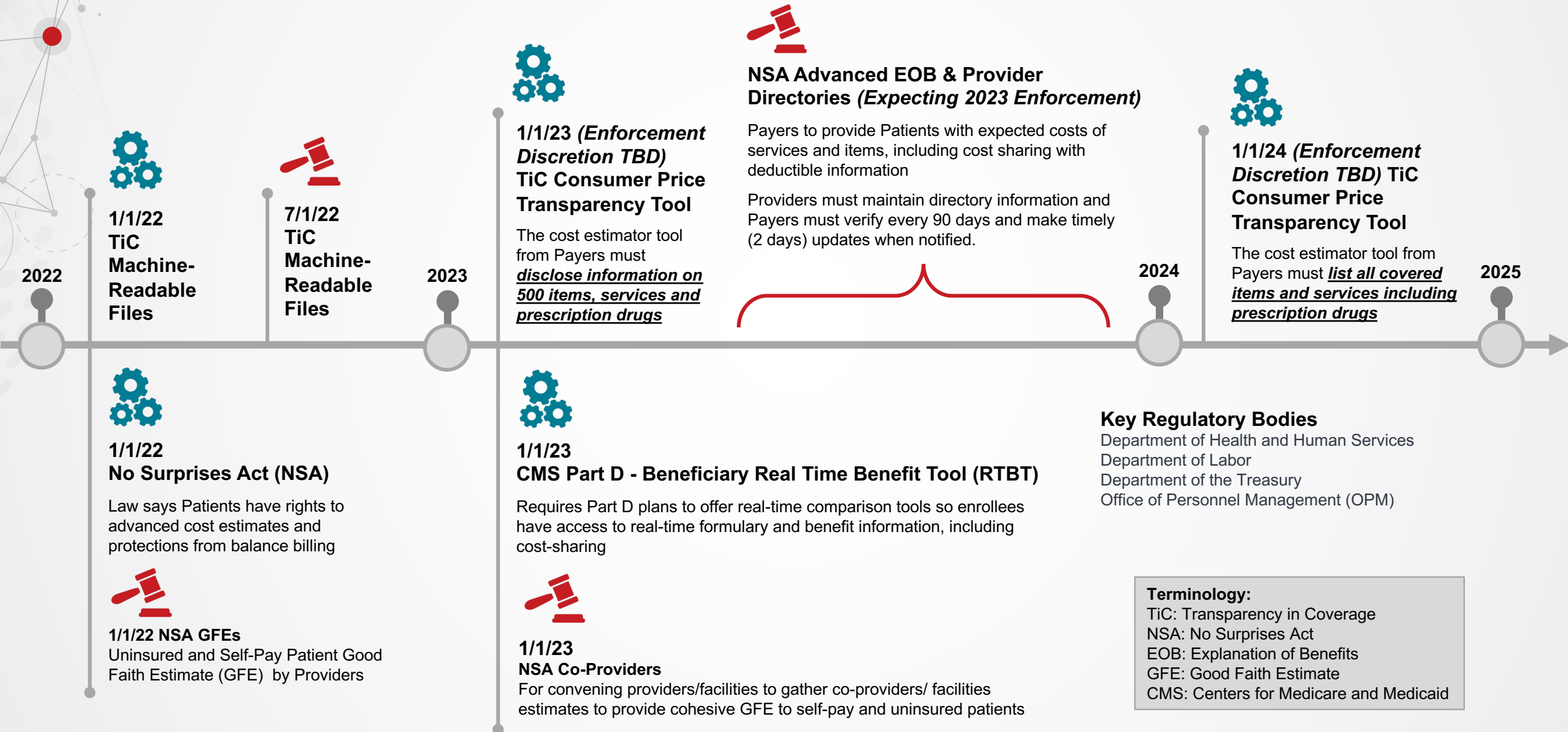
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The Shift to APIs and the acceleration through HL7 Accelerator Programs

Why Are Standards So Important?

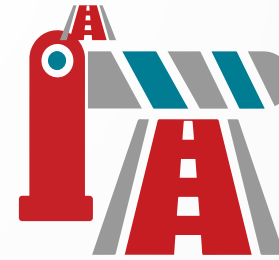
- Standards are agreed-upon methods for connecting systems together and may pertain to
 - security
 - data transport
 - data format or structure
 - the meanings of codes or terms.
- Standards are defined, updated, and maintained by standards development organizations (SDOs) through a collaborative process involving the audience that will be using the standards



Saves money



Saves time



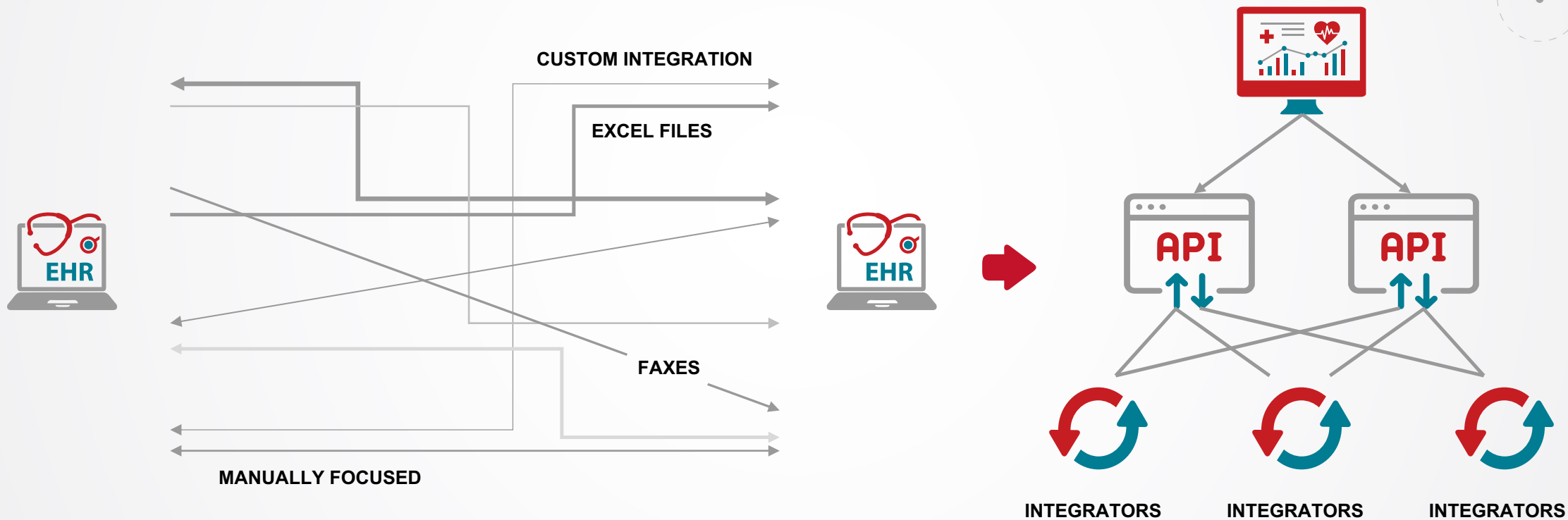
Removes barriers



Required by Policy
& Regulation



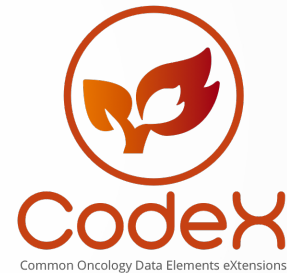
Why is Shift to APIs from Documents Important?





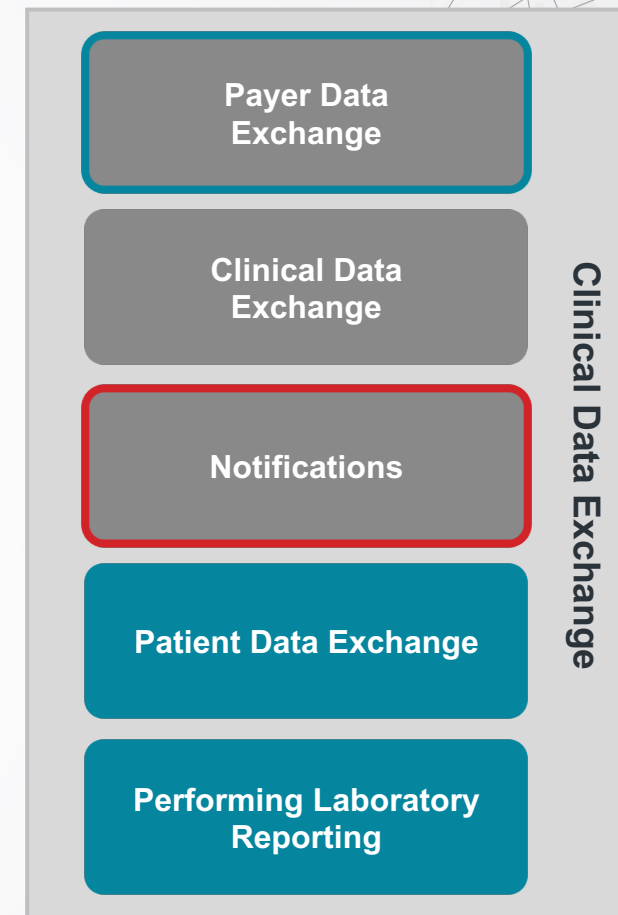
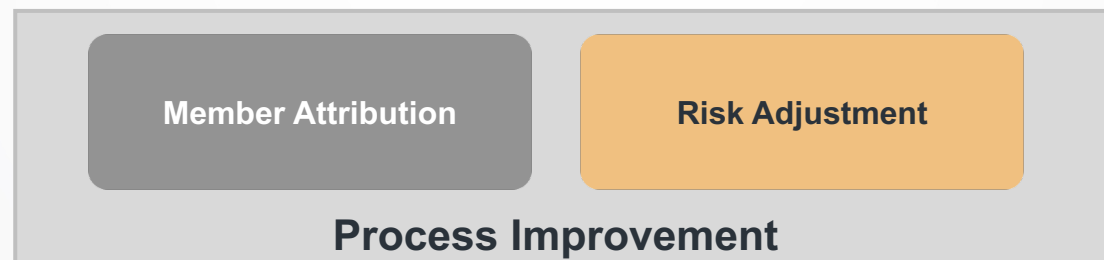
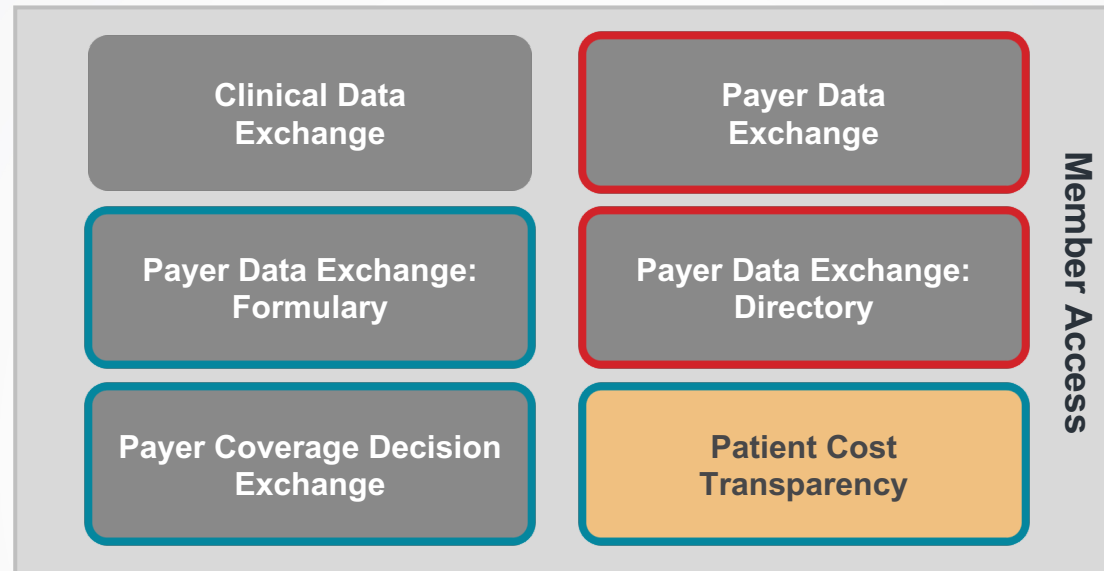
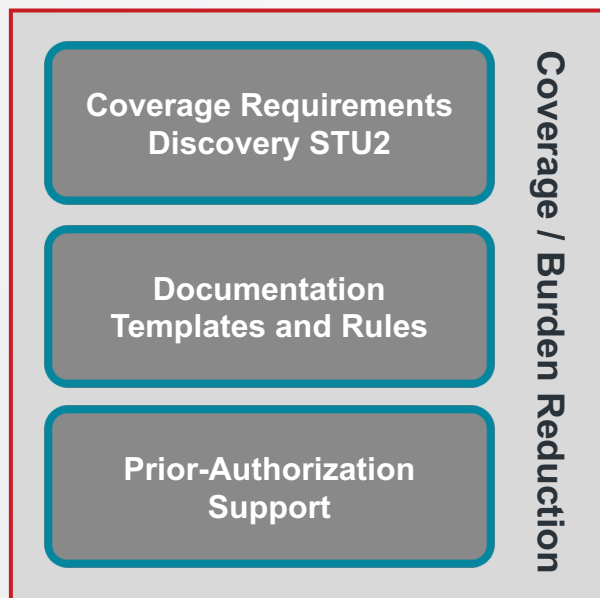
Tools & Capabilities from HL7® FHIR® Accelerator Programs

- Argonaut Project: **Exchange and foundational tools** to move data in/out EHRs and other HIT vendors
- CARIN Alliance: **Consumer-facing exchange of data** (Blue-Button and Consumer facing RTPBC)
- Da Vinci: **Data sharing and workflows needed for value-based care**, provider and payer led
- Gravity Project: Focused on **data exchange of social risk factor data**
- CodeX: Focused on creation of **national platform for interoperable cancer data modeling**
- Vulcan: Focused on **exchange of data** in order to bridge existing gaps between clinical care and clinical research
- *FAST*: Foundational tools, standards and best practices to scale FHIR across industry
- Helios: Focused on strengthening the **data-sharing capabilities of public health systems**



Da Vinci Use Case Focus Area

- ☒ Aligned with specific ONC or CMS rule
- ☐ Named or supports final CMS or ONC rule



Key Takeaway

Opportunities for vendors to implement APIs to support providers in VBC contracts (eg, Gaps in Care, Burden Reduction, Cost Transparency)



Consumer Digital Identity Proof of Concept

- CARIN Alliance along with several partners, announced a pilot program for a digital identity proof of concept.
- The idea is to allow an individual consumer to create a NIST 800-63 IAL2 identity proofed credential from a certified CSP (eg, ID.Me or AllClear ID) one time and then use that single credential to authenticate with multiple end points and systems including patient apps, payers, providers etc.
- This would essentially be a Single Sign On for healthcare apps and portals across the industry
- CARIN has partnered with ONC and CMS to “observe” this pilot and will be working with multiple stakeholders as part of this pilot program. A sampling of companies is listed below:
 - B.Well (Application), MaxMD (application), One Record (application)
 - Cambia Health (Payer), CVS Health (Payer), Kaiser (Payer), Providence Health Systems (Provider)
 - ID.Me (CSP), EMR Direct (CSP), AllClear ID (CSP)

Key Takeaway

Vendors should monitor pilot program given ONC and CMS are observing. Prior to any regulatory activity, may be an opportunity for vendors to incorporate into patient portal

Gravity Data Sets Completed to Date

To identify data elements and associated value sets to represent Social Determinants of SDOH information documented in electronic health records (EHRs) across four clinical activities: screening, diagnosis, goal setting, and intervention activities.



Food security



Financial Insecurity, Material Hardship, Employment Status



Housing instability, Homelessness and Inadequate Housing



Educational Attainment



Transportation access

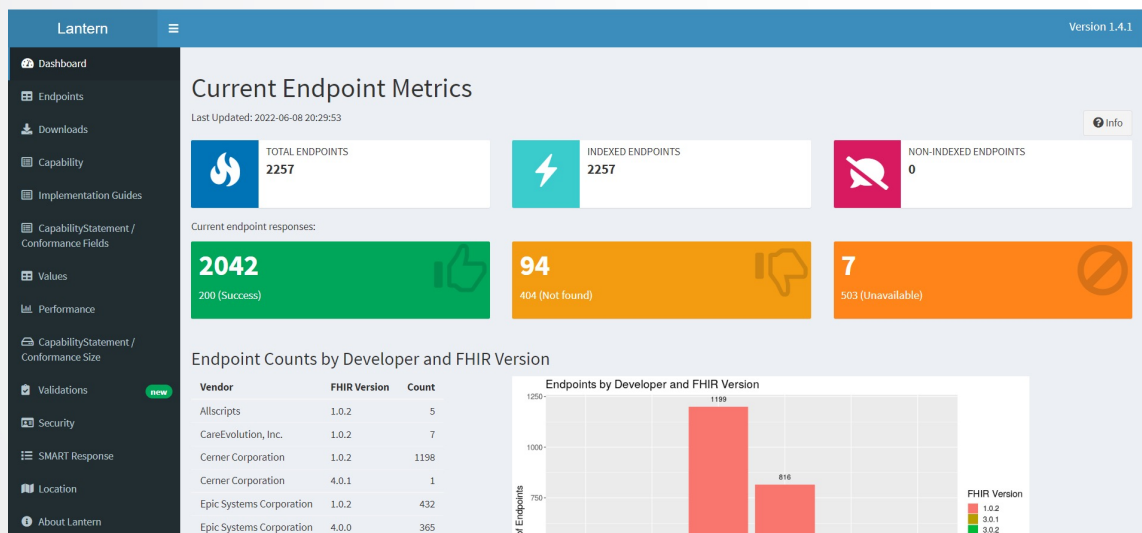


Stress, Social Connection, Intimate Partner Abuse, Elder Abuse

The Lantern Project



- Regulatory Text: 45 CFR 170.404(b)(2)
 - Certified API Developers must publish service base URLs for all Health IT Modules certified to § 170.315(g)(10) that can be used by patients to access their EHI
- ONC created Lantern to work with stakeholders on proposed guidance for certified API developers to conform to the Cures Act Final Rule (Cures Rule) requirements on FHIR “endpoint” list publication
- Ensure certified APIs can be accessed and used “without special effort,” as part of API Conditions and Maintenance of Certification



Key Takeaway

ONC's Lantern tool helps identify active endpoints & can make it easier for apps to interact with FHIR APIs nationwide



What's Next?

Current Stats on Information Blocking

From April 5, 2021 – April 30, 2022.

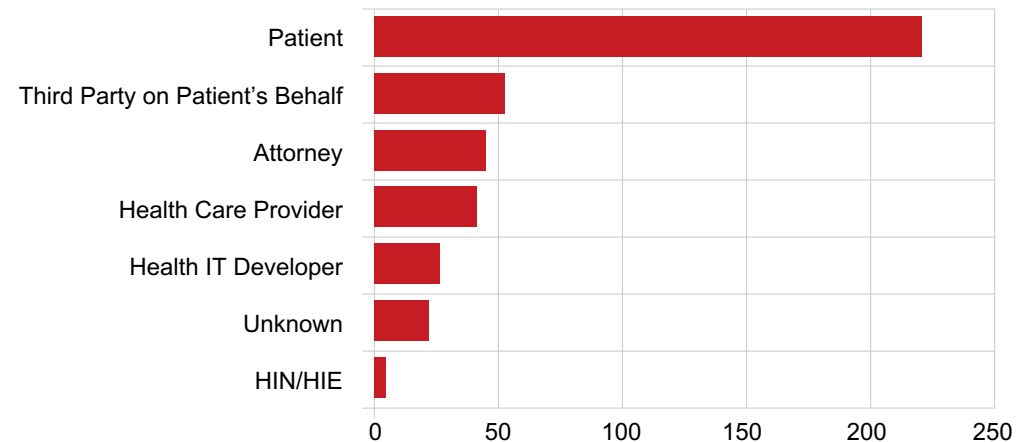
Information on submissions received through the Report Information Blocking Portal

Total number of information blocking portal submissions received	393
Total number of possible claims of information blocking	364
Total number of submissions received that did not appear to be claims of potential information blocking	29

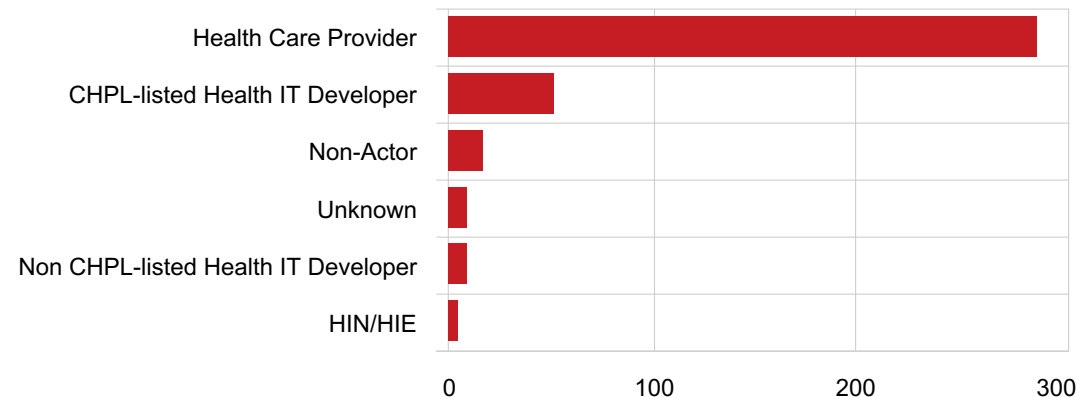
Key Takeaway

ONC is tracking and reporting on information blocking claims on a monthly basis. Of the 46 claims against HealthIT developers, 42 are against those who participate in the ONC HealthIT Certification program

Claim Counts by Types of Claimant



Claim Counts by Potential Actor



New Announcement from ONC: Proposed “Advisory” Role for Information Blocking Claims

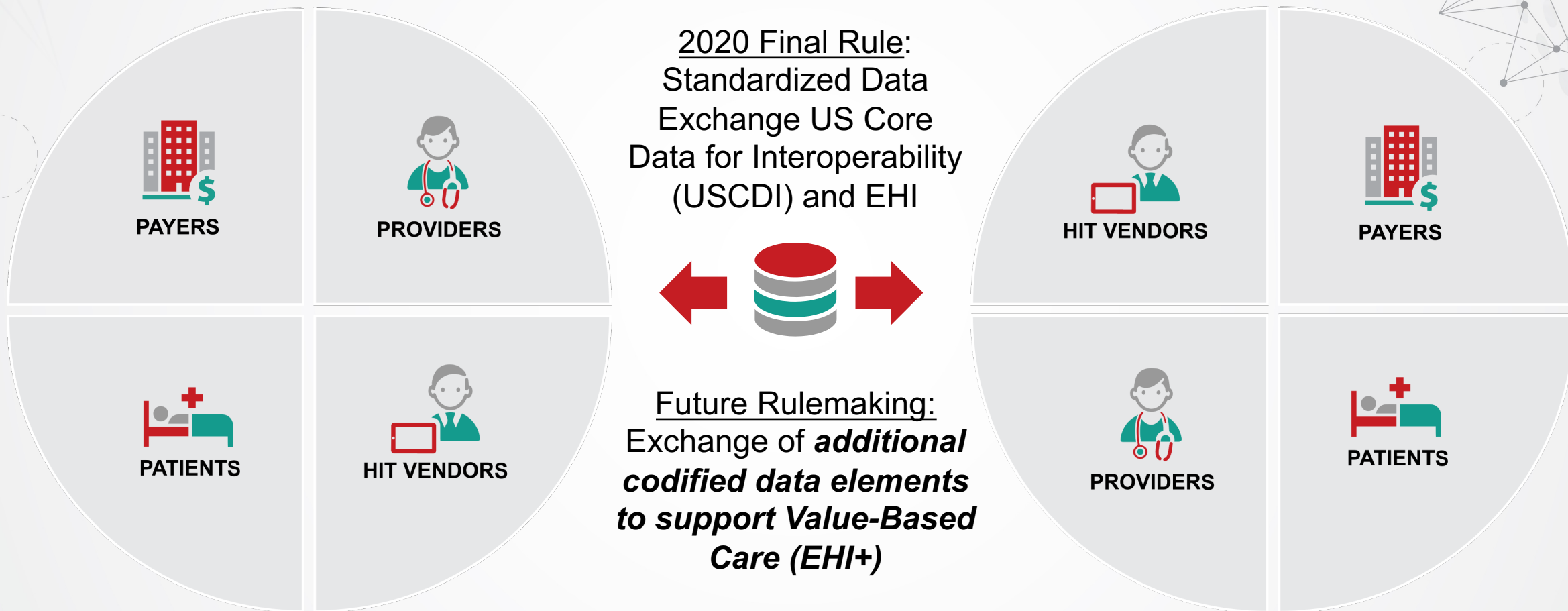


- **Recently announced in ONC HealthIT Buzz**
- FY23 President’s Budget includes a request for new authority for ONC to be able to issue binding advisory opinions for the information blocking regulations (45 CFR Part 171).
- ONC currently provides guidance on information blocking, but does not have to provide a specific “actor” with a definitive, binding answer to an information blocking question in a way that would help the actor with compliance details relevant to its particular situation
- *The requested new authority* would give ONC the ability to issue a binding advisory opinion to advise whether a specific practice would constitute information blocking, including whether an exception would or would not be met given the facts and circumstances.
- The advisory opinion would be binding

Near and Mid-Term Priorities Outlined by ONC National Coordinator

Topic	Overview	POCP Estimated Timeline
Expansion of Scope of Permitted Data Sharing beyond treatment only data	ONC is looking to broaden the definition of interoperable data beyond the HIPAA definition of EHI. This could include SDoH data, public health data, and equity objectives	Near-term
TEFCA	ONC wants to answer the question, “How can we use TEFCA to make interoperability easier?”	Mid-Term
API Write Capabilities	Current focus of APIs is on read-only. ONC is interested in a wide-variety of use cases including write-capabilities back into a patient record. Argonaut is testing	Mid-Term
Health Equity By Design	Impact of technology and standards has been an after-thought in the past. ONC will continue to take health equity into consideration on all policy decisions	Ongoing

What's Next: Expanding Data Exchange



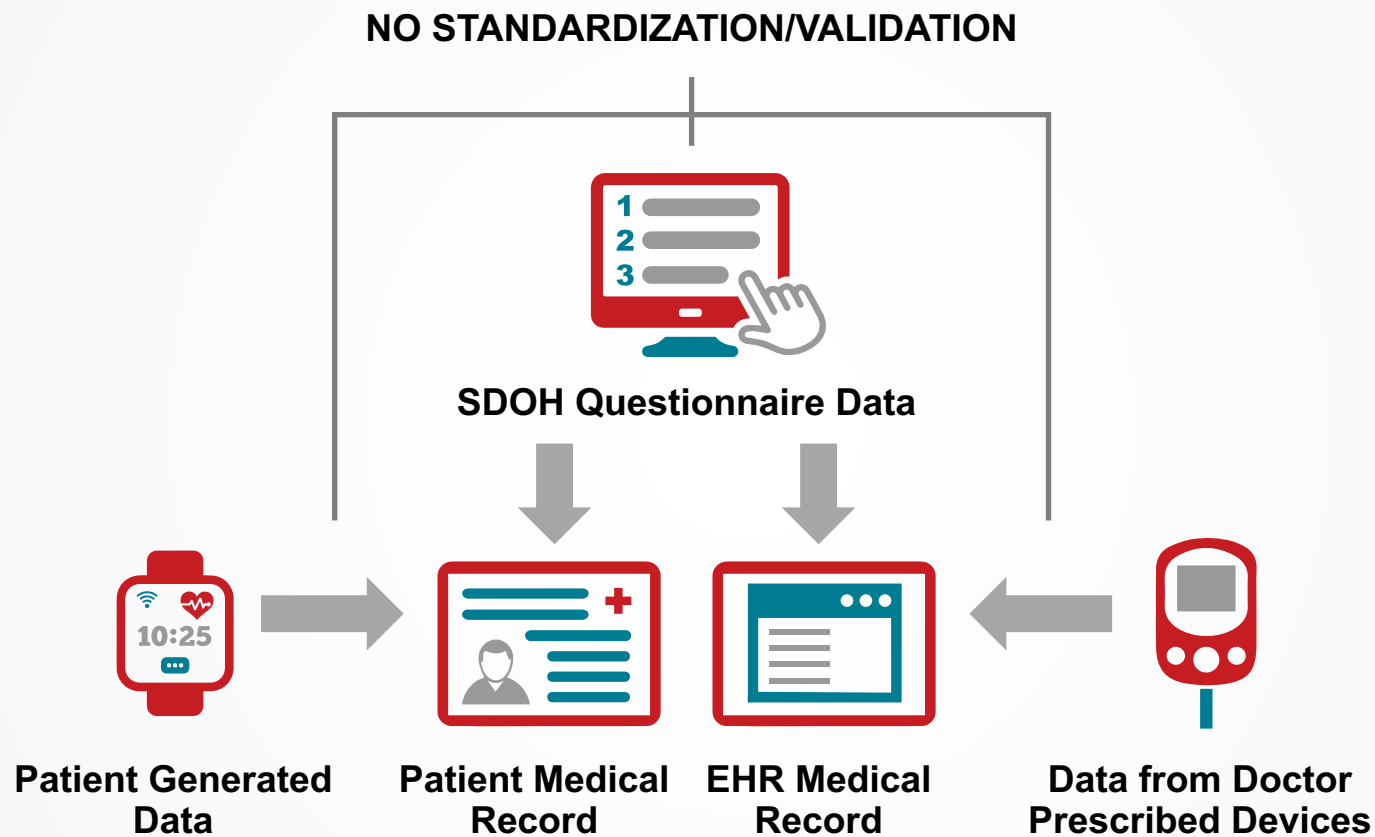
What's Next: USCDI V2 and ONC Standards Version Advancement Process

Key Takeaway

ONC has adopted a Standards version advancement process (SVAP) which allows HIT vendors to voluntarily update their systems to newer versions of the standard without rulemaking. USCDI V2 was approved in Fall, 2021 but not mandatory for certification.

Allergies and Intolerances <ul style="list-style-type: none"> Substance (Medication) Substance (Drug Class) Reaction 	Goals <ul style="list-style-type: none"> Patient Goals SDOH Goals 	Procedures <ul style="list-style-type: none"> Procedures SDOH Interventions
Assessment and Plan of Treatment <ul style="list-style-type: none"> Assessment and Plan of Treatment SDOH Assessment 	Health Concerns <ul style="list-style-type: none"> Health Concerns 	Provenance <ul style="list-style-type: none"> Author Time Stamp Author Organization
Care Team Member(s) <ul style="list-style-type: none"> Care Team Member Name Care Team Member Identifier Care Team Member Role Care Team Member Location Care Team Member Telecom 	Immunizations <ul style="list-style-type: none"> Immunizations 	Smoking Status <ul style="list-style-type: none"> Smoking Status
Clinical Notes <ul style="list-style-type: none"> Consultation Note Discharge Summary Note History & Physical Procedure Note Progress Note 	Laboratory <ul style="list-style-type: none"> Tests Values/Results 	Unique Device Identifier(s) for a Patient's Implantable Device(s) <ul style="list-style-type: none"> Unique Device Identifier(s) for a Patient's Implantable Device(s)
Clinical Tests <ul style="list-style-type: none"> Clinical Test Clinical Test Result/Report 	Medications <ul style="list-style-type: none"> Medications 	
Diagnostic Imaging <ul style="list-style-type: none"> Diagnostic Imaging Test Diagnostic Imaging Report 	Patient Demographics <ul style="list-style-type: none"> First Name Last Name Previous Name Middle Name (including Middle Initial) Suffix Sex (Assigned at Birth) Sexual Orientation Gender Identity Date of Birth Race Ethnicity Preferred Language Current Address Previous Address Phone Number Phone Number Type Email Address 	Vital Signs <ul style="list-style-type: none"> Diastolic Blood Pressure Systolic Blood Pressure Body Height Body Weight Heart Rate Respiratory Rate Body Temperature Pulse Oximetry Inhaled Oxygen Concentration BMI Percentile (2 - 20 Years) Weight-for-length Percentile (Birth - 36 Months) Head Occipital-frontal Circumference Percentile (Birth - 36 Months)
Encounter Information <ul style="list-style-type: none"> Encounter Type Encounter Diagnosis Encounter Time Encounter Location Encounter Disposition 	Problems <ul style="list-style-type: none"> Problems SDOH Problems/Health Concerns Date of Diagnosis Date of Resolution 	

What's Next: Write Capabilities



What's Next: Burden Reduction (Medical Prior Authorization)

Commentary and questions:

1. 144 comments received, now in quiet period during rule making or updated guidance from ONC
2. Bulk of Commentary focused on Testing, Timing – mix of positive support and SLOW down
3. Major provider, payer associations and organizations commented

“Although the three Da Vinci IGs show promise, they are not yet in a state of maturity that is sufficient for adoption in certification.” ~ Association

“The proposed three Implementation Guides (IGs) are a good first step towards supporting ePA functionality. However, we believe it is vital to introduce them in a phased manner due to the complexity surrounding these IGs lest there is a possibility of poor adoption.” ~ EHR Vendor

Guidance Areas:

- Certification by all involved in the PA process, including intermediaries; Certification timelines should be tiered
- Need real-world testing and piloting
- To ensure wide scale adoption, ONC should work with CMS to outline a roadmap for ePA that leverages the Certification Program, the Information Blocking rule, and the Interoperability rules to outline consistent requirements for all stakeholders

“We urge ONC and CMS to explore incentivizing provider adoption of technology for prior authorization processes”

<https://www.federalregister.gov/documents/2022/01/24/2022-01309/request-for-comment-medical-prior-authorization-standards-implementation-specifications-and>



Key Questions and Takeaways

This is an **Interoperability Journey...**

- ❑ **How will you prioritize?**
 - Regulatory Mandates – market demand – value - feasibility
- ❑ **How will you Design and build a sustainable roadmap? What is your strategy?**
 - Build, buy, partner - Minimally Viable Product vs Fully Featured - Product Differentiation - Revenue potential
- ❑ **How can/will this change my market?**
 - Competition - Product design - Network demands
- ❑ **How can you support provider and patient access and interoperability?**
 - Look at everything through a provider/patient lens

Who is Point-of-Care Partners?



Who We Are...

- **National consultancy** since 2002 (35+ states, 110+ Associates) *focusing on healthcare* Interoperability across the Payer, Delivery, Health IT Vendor, HIE, Government, and Pharma ecosystem
- Comprehensive staff of widely respected national experts, with most Associates having > **15-25 years** experience in the Interoperability field
- Engaged and leadership roles with **Standards bodies and Accelerators** across the Interoperability spectrum, including HL7, HIMSS, Da Vinci, CARIN, NCPDP, and numerous others



What We Do...

- Leading interoperability subject matter experts working on projects such as:
 - Strategy and value engagements for national and regional payers, EHR and HealthIT vendors
 - Establishing and adjusting Interoperability roadmaps
 - Development of standards and strategy for implementation
 - Automations of Prior Authorization, Patient Cost and Benefits, Specialty Medication Enrollment
- Program, Project Management and use case lead role(s) across Da Vinci, CARIN, Codex and FHIR at Scale Taskforce (FAST) and other cross-functional industry projects

Thank You

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