Understanding the New Federal Data Interoperability Requirements and Implications for Health Plans

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Basic Overview

What?

Joint CMS-ONC **federal regulatory effort** to improve the ability of patients, plans, and providers to:

1. Access 2. Exchange 3. Use

health information to support better care decisions and health outcomes.

2,000+ pages of rules finalized March 9, 2020.

ONC final regulations: https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf

CMS final regulations: https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf

How?

Data Exchange and Data Interoperability
Leverage modern technologies and set data standards to enable seamless flow of data between organizations and application systems.

Information Blocking
Prevent practices that restrict authorized access, exchange, and use of electronic health information.

Who enforces?	**ONC**	**CMS**
Who is impacted?	Health IT developers	Payers Providers States

When?

Requirements Impacting Payers

Major deadline #1: July 2021
(delayed from Jan. 2021 due to COVID-19)

Major deadline #2: January 2022

Deadlines vary for other entities

Why?

Health care has made a lot of progress in building information highways . . .

but many still do not connect.

Private sector interoperability efforts have also made significant progress . . .

but growth has been uneven and largely voluntary.

Impact on Payers

Three Core Capability Requirements for Payers

	Deadline	Definition	Data Required
Patient Access API (modeled on Medicare's Blue Button API)	July 1, 2021	At consumer's direction, make all patient data available using universal FHIR standard to developers of third-party apps for consumers to access	Claims/encounters,[1] clinical (USCDI),[2] Rx formulary Must provide within 1 business day
Provider Directory API	July 1, 2021	Make all provider and pharmacy network data available using FHIR standard to developers of third-party apps for public to access	Provider and pharmacy directories
Payer-to-Payer Data Exchange	January 1, 2022	When a consumer changes health plans, at their direction, new and old plan must exchange information about the consumer *Note: Only applies to plans, not state Medicaid/CHIP agencies.*	Clinical (USCDI) Must update within 30 days of changes

1. Including encounters with capitated providers, provider remittance, and enrollee cost-sharing data.
2. USCDI = US Core Data Interoperability, a standardized clinical data set with specific data classes and elements. See appendix for additional details.

Key Takeaways

Blue Button inspired. The fingerprint of the Blue Button 2.0 API that CMS developed for Medicare FFS can be seen throughout the regulations — especially in the Patient Access API.

Consumer-directed and centered. Consumers must approve all sharing of their health plan data with third-party apps.

Standardized. Third-party apps, health plans, and hospital EHRs will use a common data format and exchange technology called Fast Healthcare Interoperability Resources (FHIR), allowing organizations to connect to each other regardless of the application system used by each organization.

Transparent and pro-competitive. Health plans must allow any third-party app to access health plan data if approved by an authorized consumer. This prevents information blocking and encourages competition among third-party apps to create useful tools.

Privacy and security. HIPAA requirements for data sharing still apply to health plans and all covered entities, but third-party apps are regulated by the Federal Trade Commission and do not have the same HIPAA requirements.

Mandated. Federal enforcement adds unprecedented heft to these regulations and distinguishes them from private-sector interoperability efforts relying on voluntary participation.

345 Unique CMS Payers Impacted

Medicaid and CHIP

- State FFS
- Managed care plans (MCOs)
- Prepaid inpatient health plans (PIHPs)
- Prepaid ambulatory health plans (PAHPs)

- In California, includes county mental health plans, Drug Medi-Cal ODS plans

Medicare

- Medicare Advantage HMOs, POS, and PPOs
- (FFS already compliant due to Blue Button 2.0)

- Including SNPs
- In California, includes CMC plans

Exchange

- QHPs on the FFE (exemption available)

Are Plans Ready to Comply?

Highlights from Compliance Planning Sessions with 7 Medi-Cal Plans:

- Significant challenges with timing, bandwidth, and new technical capabilities

(CMS estimates implementation takes 6+ months, costs $788K–$2.5M per entity)

- Cross-functional, complex implementation
- Focused first on meeting the minimum requirements but interested in the larger potential of what these rules make possible
- Strong collaboration interest among plans

One Last Takeaway

These rules set the floor, not the ceiling, for what's possible. Achieving this level of interoperability can unlock a wide range of use cases that enable value-based care.

Example use cases for the interoperability enabled by federal rules:

- Provider-to-plan data transmission: Encounter notifications, quality measure reporting
- Plan-to-provider data transmission: Flag gaps in care, process prior authorizations
- Plan-to-plan data exchange: Reduce duplicative care, identify gaps in care as patients move between plans

Want to learn more? See Appendix B.

Learn More

This resource was developed with support from the California Health Care Foundation.

To learn more about CHCF's growing body of work on data exchange issues, visit chcf.org and subscribe to the Data Exchange newsletter.

Contact Hong Truong, MPH, senior program investment officer at CHCF.

Appendix A: Additional Data Compliance Details

Required Data Standards for Plans

Technical Standards

1. HL7 Fast Healthcare Interoperability Resources, Release 4.0.1	FHIR® R4	Foundation for API Data Exchange
2. SMART on FHIR Application Launch Framework IG Release 1.0.0 (a profile of Oauth 2.0 specification), including mandatory support for SMART on FHIR Core Capabilities	OAuth	Foundation for Privacy and Security
3. OpenID Connect, version 1.0, incorporating errata set 1	OpenID	

Content and Vocabulary Standard

US Core for Data Interoperability, version 1	USCDI	Foundation for Data

USCDI US Core Data For Interoperability

The Office of the National Coordinator for Health Information Technology

Allergies and Intolerances *NEW

- Substance (Medication)
- Substance (Drug Class) *NEW
- Reaction *NEW

Assessment and Plan of Treatment

Care Team Members

Clinical Notes *NEW

- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals

Health Concerns

Immunizations

Laboratory

- Tests
- Values/Results

Medications

Patient Demographics

- First Name
- Last Name
- Previous Name
- Middle Name (incl. middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address *NEW
- Previous Address *NEW
- Phone Number *NEW
- Phone Number Type *NEW
- Email Address *NEW

Problems

Procedures

Provenance *NEW

- Author Time Stamp
- Author Organization

Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs

- 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) *NEW
- Weight-for-length Percentile (Birth - 36 Months) *NEW
- Occipital-frontal Head Circumference Percentile (Birth - 36 Months) *NEW

For more info:

HealthIT.gov/USCDI

Patient Access API: Clinical Data Do's and Don'ts

MUST include ALL data for ALL covered services

- Including behavioral health, LTSS claims, dental, and Medicare supplemental benefits — for which a claim or encounter is generated or adjudicated
- Including subcontracted, capitated, or delegated services
- Including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal

CANNOT segment or direct specific segments of data, including behavioral health, to be made available via the Patient Access API.

DO NOT need to do any additional audit or review *beyond current practice* or change current plan-provider contract language.

Patient Access API: Required Drug Formulary Data

- Medicaid/CHIP
  - Preferred drug list

- Medicare Advantage with Part D (MA-PDs)
  - Covered Part D drug and tiered formulary structure or UM procedures (step therapy, prior authorization, quantity limits)

- QHPs on FFEs are exempt

Same update time frame that exists for health plan formulary information today

Provider Directory API: Required Data

(Note: QHPs on FFEs are exempt)

- Updated no later than 30 calendar days after a health plan receives the provider directory information or receives updates to the provider directory information
- Consent and authentication requirements do not apply — already public information

Provider Network	Pharmacy Network
1. Name	1. Pharmacy name
2. Address	2. Address
3. Phone number	3. Phone number
4. Specialty	4. Number of pharmacies in the network
	5. Type of pharmacy, such as “retail pharmacy”

API Documentation

Required

Health plan must make API documentation publicly accessible (website or publicly accessible hyperlink) and include the following information:

1. API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns
2. The software components and configurations an application must use in order to successfully interact with the API and process its response(s)
3. All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API

API Must Be Transparent and Publicly Accessible

Can’t Do

- Health plans cannot require any preconditions or additional steps for third-party apps to access the API documentation.
- For example, health plans cannot impose any of these:
  - Fee for access to API documentation
  - Requirement to receive copy of API documentation via email
  - Requirement to register or create an account to receive the API documentation
  - Requirement to read promotional materials or agree to receive future communications before making the API documentation available

Routine Testing and Monitoring

Required

- Health plan must conduct routine testing and monitoring, and update as appropriate, to ensure API functions properly.
- Including assessments to verify that an individual enrollee can access only the claims or encounter data or other PHI that belong to that enrollee
- CMS will provide best practices and API testing tools.
- Testing requirement is accounted for in CMS budget estimates.

Optional

- Health plans can define their own time frame intervals for testing and monitoring.

Deny or Discontinue API Access

Optional (recommended)

Health plan may decline to approve or may terminate third-party app's connection to the health plan's API.

Conditions

- If payer determines that such access presents unacceptable security risk to health plan's systems
- Must be based on objective, verifiable criteria that are applied consistently

Third-Party App Attestation

Optional (recommended)

- Health plan may request third-party app to attest to certain privacy and security provisions in the app's privacy policy prior to granting the app access to the health plan's API.

- If the third-party app does not attest that its privacy policy meets the health plan's criteria, health plan can inform beneficiaries that they should exercise caution before opting to disclose their information with the app.

- CMS references templates
  - ONC Model Privacy Notice and CARIN Alliance Code of Conduct

3rd-Party App Attestation

Can’t Do

- Health plan cannot discriminate in its implementation.
  - If health plan requests attestation of one app, it must request it for all apps.
  - Implement consistently, using defined and objective criteria

- Health plan cannot deny access if approved and at the direction of the beneficiary, regardless of attestation response (or delayed or no response) from third-party app.
  - Unless the third-party app poses a security risk to health plan’s systems

Two-Factor Authentication (2FA)

Optional (recommended)

- Health plans may require 2FA as part of the authentication process.
- Oauth 2.0 provides support for 2FA.
- Significantly increases security:
  - Industry-accepted best practice
  - Routinely used across many sectors
  - Known to beneficiaries
  - Low administrative burden
- ONC Final Rule adds new requirement as part of certification: Health IT developers must attest to whether they support multifactor authentication.

Token Management

Optional (recommended)

- Health plans may require a token be valid for at least three months:
    - ONC Final Rule requires at least three months for certified health IT.
    - Considered industry best practice

Beneficiary Education

Required

- Health plans must provide educational materials about privacy and security considerations when selecting a third-party app.
- Materials must be at an easily accessible location on health plan's website.
- CMS will provide templates to meet this requirement.

Optional

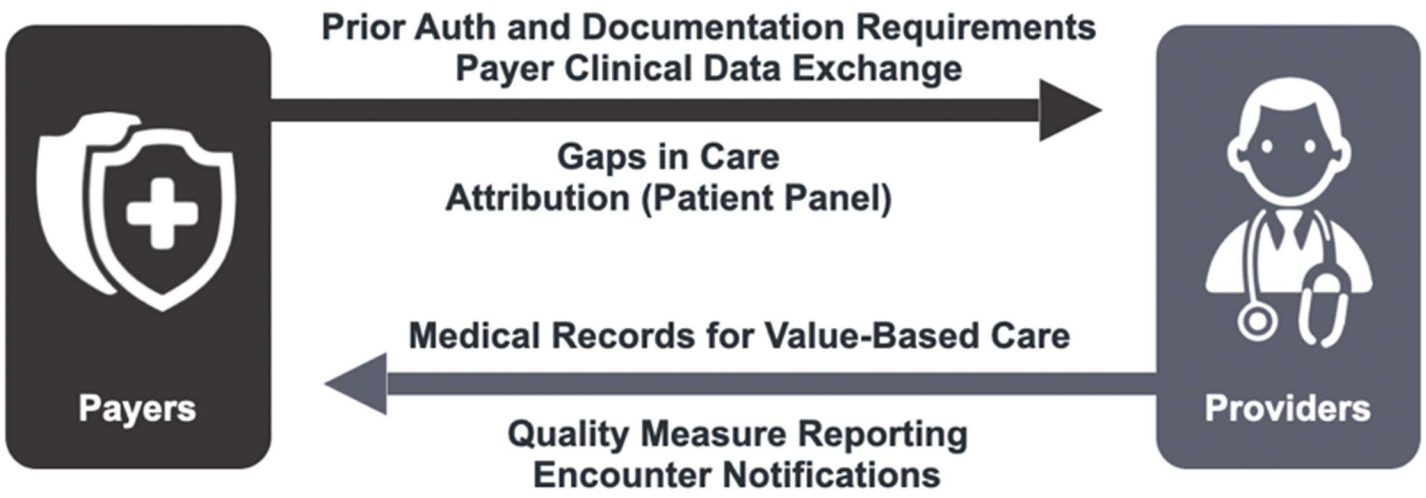
- May share through other communication mechanisms with enrollees
- Can tailor materials to the patient population (e.g., language, literacy levels)

Appendix B: Additional Use Case Opportunities

HL7 Da Vinci Project

- Private sector initiative comprised of 45+ **providers, payers, and technology vendors** working together to accelerate the adoption of FHIR to support value-based care data exchange
- Defines business problems, identifies the corresponding data exchange requirements to create draft standards, which are in the form of **implementation guides** and **sample software code**

Use Cases



Multi-Stakeholder Membership

PROVIDERS

YAMA Medical Group
Cedars-Sinai
*RUSH
*Sutter Health
MultiCare Connected Care
OHSU
Providence St. Joseph Health
Texas Health Resources
UNC Health Care
Weill Cornell Medicine

INDUSTRY PARTNERS

HIMSS
*HL7 International
NCQA Measuring quality. Improving health care.

EHRs

*Allscripts
athenahealth
*Cerner
*Epic
healow | Insights

PAYERS

*Anthem
*BlueCross BlueShield Association
*Blue Cross of Idaho
Blue Cross Blue Shield Blue Care Network of Michigan
BlueCross BlueShield of Alabama
BlueCross BlueShield of Tennessee
*CAMBIA
*CMS
*Cigna
CVS Health
CENTENE Corporation
GUIDEWELL
*HCSC
*Humana
*Independence
*UnitedHealthcare

VENDORS

casenet
*cognosante
*edifecs
infor
InterSystems Health | Business | Government
juxly
mcg
*OPTUM
*surescripts
*ZeOmega

DEPLOYMENT

Availity
MiHIN

For current membership: http://www.hl7.org/about/davinci/members.cfm

*Indicates a founding member of the Da Vinci Project.
Organization shown in primary Da Vinci role, Many members participate across categories.

About the Use Cases

QUALITY IMPROVEMENT

Data Exchange for Quality Measures enables automation of quality measure reporting.

Gaps In Care & Information exchanges open and closed gaps in care and notifies providers and payers of those gaps.

COVERAGE/BURDEN REDUCTION

Coverage Requirements Discovery gives providers real-time access to payer approval requirements, documentation and rules at point of service to reduce provider burden and support treatment planning.

Documentation Templates and Payer Rules creates electronic versions of administrative and clinical requirements, including payer coverage criteria, by pre-populating data requirements using existing EHR data in provider workflow.

Prior-Authorization Support enables provider, at point of service, to request authorization (including all necessary clinical information to support the request) and receive prompt adjudication responses from the payer.

MEMBER ACCESS

Clinical Data Exchange is the sharing of clinical data generated by providers with payers or other industry partners

Patient Cost Transparency standardizes the method of requesting and exchanging cost information at the point of decision making among payers, providers and patients.

Payer Coverage Decision Exchange shares information between payers to support continuity of care and coverage, and minimize documentation and reporting burdens for patient and providers.

Payer Data Exchange shares clinical data generated by payers with providers.

Payer Data Exchange: Directory provides a listing of addresses of payers and providers to support identification of in-network providers.

PROCESS IMPROVEMENT

Risk Based Contract Member Identification enables payers and providers to exchange information that identifies members of a patient population associated with a particular risk-based contract.

Chronic Illness Documentation for Risk Adjustment shares information between provider and payer to provide supporting documentation of chronic illnesses with regard to determining risk.

CLINICAL DATA EXCHANGE

Health Record Exchange Framework establishes general overarching framework for Health Record Exchange. HRex includes any Da Vinci profiles that may be used across multiple implementation guides.

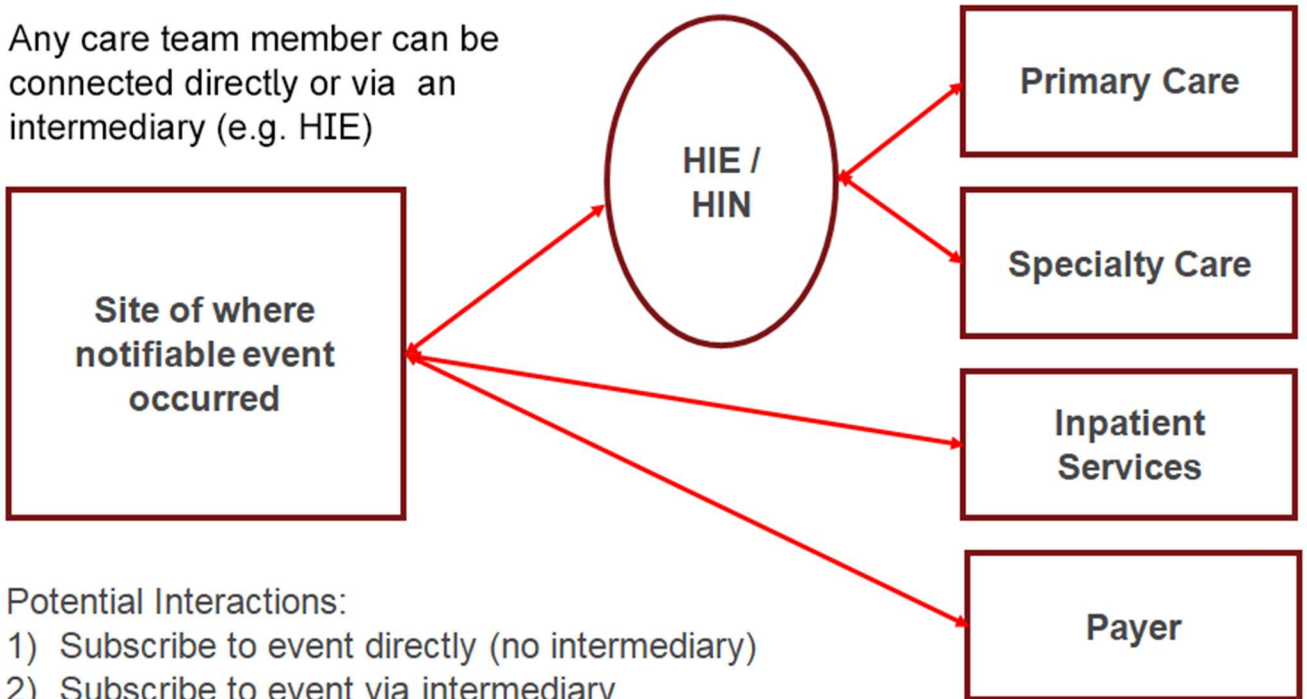
Health Record Exchange: Patient Data Exchange is the sharing of clinical data generated by providers with patients

Notifications (formerly known as Alerts) support the real-time exchange of messages that impact patient care, such as being admitted to the hospital, and value-based or risk-based services.

Performing Laboratory Reporting enables labs to share results with providers and payers in real time.

Example Case: Alerts/Notifications

Admit/Discharge Notifications, Clinical and Administrative Events



Potential Interactions:

1) Subscribe to event directly (no intermediary)
2) Subscribe to event via intermediary
3) Push to "registered" member (perhaps via payer care team information)
4) Push to intermediary

https://1up.health

Old Way

- Bespoke one-off point integrations
- Faxes . . .
- Certain parts of care continuum outside hospitals not available