

MyHealthEData

The Final Interoperability Rules and What They Mean for Health Plans

**Blue Cross Blue Shield Association
Legal Department Cooperative**

March 31, 2020

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Blue Cross Blue Shield Association is an association of independent Blue Cross and Blue Shield companies.

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AGENDA

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1. Status of the "Final" Rules; Application; Terminology
2. Patient Access API
3. Payer to Payer Data Exchange
4. Provider Directory API
5. Interacting with App Developers
6. Privacy Concerns
7. Blue Plan To Do List

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Status of the “Final” Rules; Application; Terminology

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Two HHS “Final” Rules

CMS—Interoperability and Patient Access Rule

- Applies (primarily) to Health Plans regulated by CMS
- Requires Interoperable Exchange of ePHI—
 - Patient Access API
 - Payer-Payer data exchanges
- Requires Provider Directory API

ONC—Interoperability, Information Blocking, and Certification Program

- Applies (primarily) to Providers, App Developers
- Establishes standards for Interoperability

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Status of “Final” Rules

- Published on CMS website on March 9
- *Not published* in Federal Register
- *Not “on file at the Office of the Federal Register”*

(As of 11:15 am, 3/30/2020)

- So, are they “Final Rules”?



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What Plans are Subject to Final Rules?

- Medicare Advantage Organizations
- Medicaid Managed Care Plans
- CHIP Managed Care Plans
- QHP Issuers on FFEs
- State Medicaid, CHIP Agencies
- Some plans are exempt from certain requirements . . .

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Terms to know

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Standards-Based API

- Application Programming Interface
- Allows Apps to “Interface” with Health Plan (or other entity) to obtain data
- Automatic operation (once App developer passes security checks)
- Standardized data

FHIR (pronounced “Fire”)

- Fast Healthcare Interoperability Resources
- Standard for health-related APIs
- Initially developed for exchange of Electronic Health Records
- Facilitates Interoperability

USCDI

- United States Core Data for Interoperability
- Standardized set of data elements & classes of data elements
- Class “Allergies & Intolerances” includes elements “Medications,” “Food substances,” etc.

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Terms to know

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Interoperability

- Enables the **secure exchange** of ePHI with, and use of ePHI by recipient **without special effort** on the part of the user
- Allows for complete access, exchange, and use of all ePHI as authorized under applicable State or Federal law; and
- Does not constitute “information blocking.”

Information Blocking

- A practice likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information
- If conducted by various entities **other than** health plans
- *E.g.*, implementing nonstandard health information technology

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Patient Access API

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Patient Access API

• “Unleash data to give patients control”

- “Patients have unencumbered access to their health information”
- In “format that is practical, useable, and easily shared”
- “Empowering patients to share their health information with any:
 - Provider;
 - Application; or
 - Researcher they choose”
- “Bringing an end to the days of trapping patient records in closed systems”

• Based on Medicare Blue Button

- Medicare beneficiaries: 53,000,000
- Blue Button users (signed up since 2010): 53,000
- Estimated cost per plan (range: \$788,414 - \$2,365,2430) (primary estimate \$1,576,829)

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Patient Access API

Implement & maintain standards-based API

- To permit third-party Apps to retrieve data
- With approval and direction of enrollee (or enrollee's personal rep.)
- Using common technologies and
- Without special effort from enrollee

Must provide in standardized format:

- Adjudicated claims (within 1 business day of adjudication)
- Encounter data (within 1 business day of receipt)
- Clinical data (e.g, lab test results) **if maintained by plan** (1 business day)
- USCDI content "**where applicable** to the data type or [data] element"

Effective January 1, 2021

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Patient Access API

Using "Common Technologies"

- Widely used and readily available technologies (smart phones, computers, tablets)
- To request, receive, use and approve transfer of the data through the open API

Without special effort by enrollee

- Data must meet Interoperability standards
- API must be accessible by third-party software

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Patient Access API

Adjudicated claims include:

- Claims that were or may be appealed (or are under appeal)
- Claims going back to January 1, 2016 (5 years of data)

Claims data to include:

- Provider remittances
- Enrollee cost-sharing

MA-PD Plans & Medicaid/CHIP MCOs must also include:

- Data for adjudicated prescription drug claims
- Formulary data: covered/preferred drugs,
- Tiered formulary structure or utilization management applicable to those drugs

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Privacy

Original plan—disclose under right to access

- Pursuant to Omnibus HIPAA Amendments,
- Individual can direct disclosure of access information to 3rd Party
- Ciox decision overturned, except for PHI in providers' EHRs

HIPAA-compliant Authorization

- Member must authorize disclosure not otherwise permitted by Privacy Rule
- Blue Plan must retain copy of authorization for six years from “signature”

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Privacy & security educational material

- Must provide on easily accessible location on public website
- Non-technical, easy-to-understand language
- “Informed stewards” of their health information
- Explain advantages/disadvantages, risks

Information to include:

- Steps to consider in protecting privacy & security of information
- Factors to consider in selection of App (including “secondary uses”)
- Overview of what entities are/are not subject to HIPAA
- How to submit complaints to OCR & FTC

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Optional Warning

App Developer Attestations

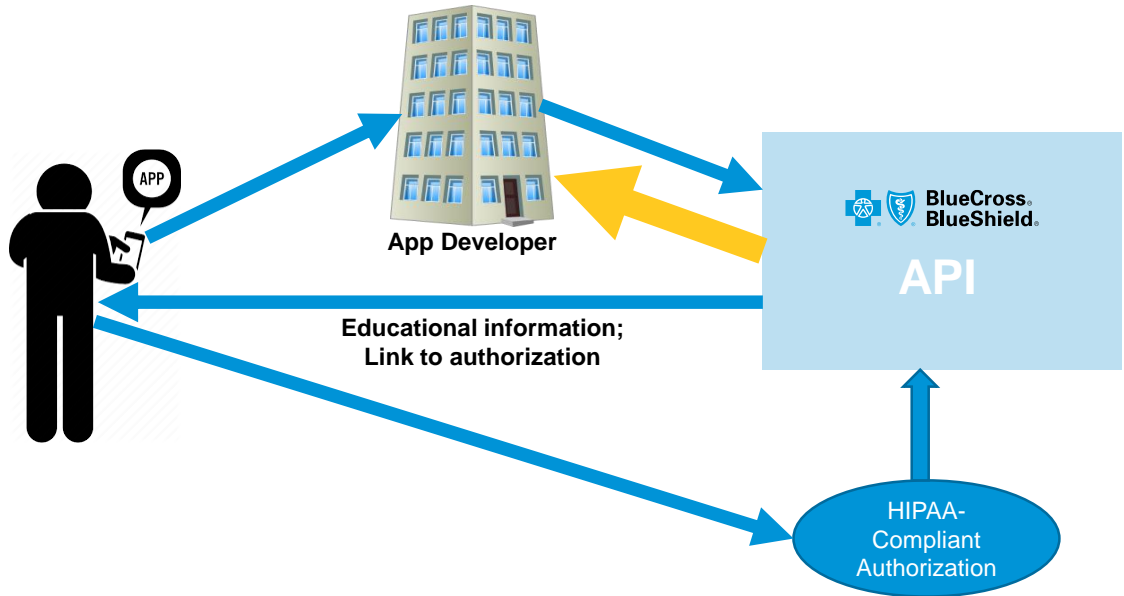
- Has a privacy policy written in plain language
- How information is accessed, used disclosed
- Whether information may be sold (now of future)
- Requires express consent from member for use/disclosure/sale
- Will App access other member data?
- Policy for discontinue App’s access & disposal of data

Warning to Member

- Inform member that App did not make attestations
- Advise member to reconsider use of this App
- But must honor request, unless member opts out

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Patient Access API

Negotiated Rates?

Proprietary Information?

CMS Response:

- Cost information already available to patients
- Apps allow provision of information in format to get maximum benefit to patient
- Benefits of making information available to patients outweigh concerns

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Payer to Payer Data Exchange

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Payer to Payer Data Exchange

Electronic data exchange with other payers

- USCDI data classes and data elements
- Applies to data received over previous 5 years

With enrollee's approval and direction, must:

- Receive current enrollee's data from another payer
- Incorporate current enrollee's information into records
- Send current or former enrollee's information to another payer

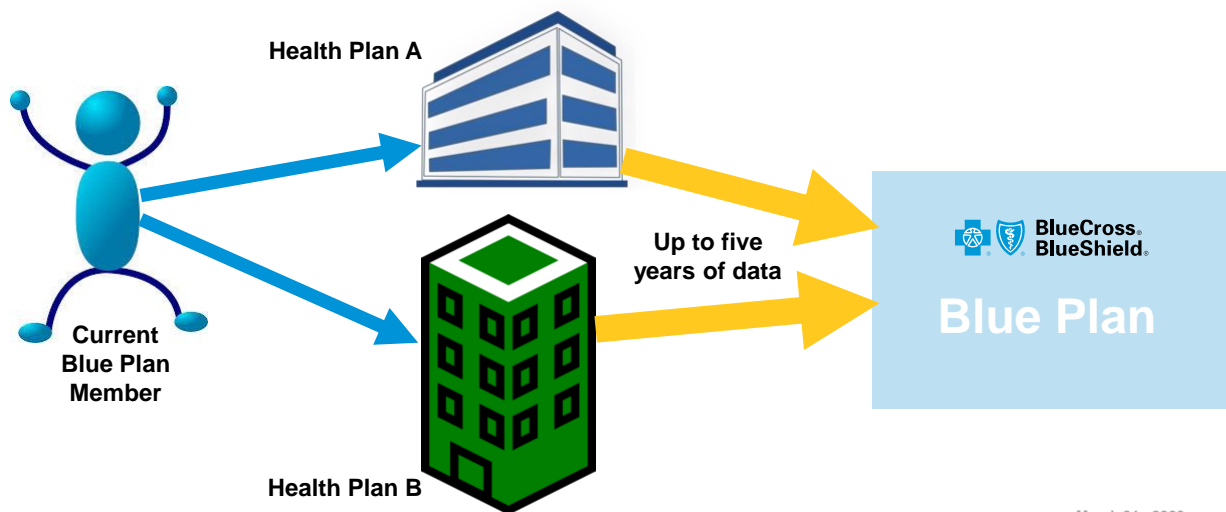
Forward data from one payer to another

- In same form and format received

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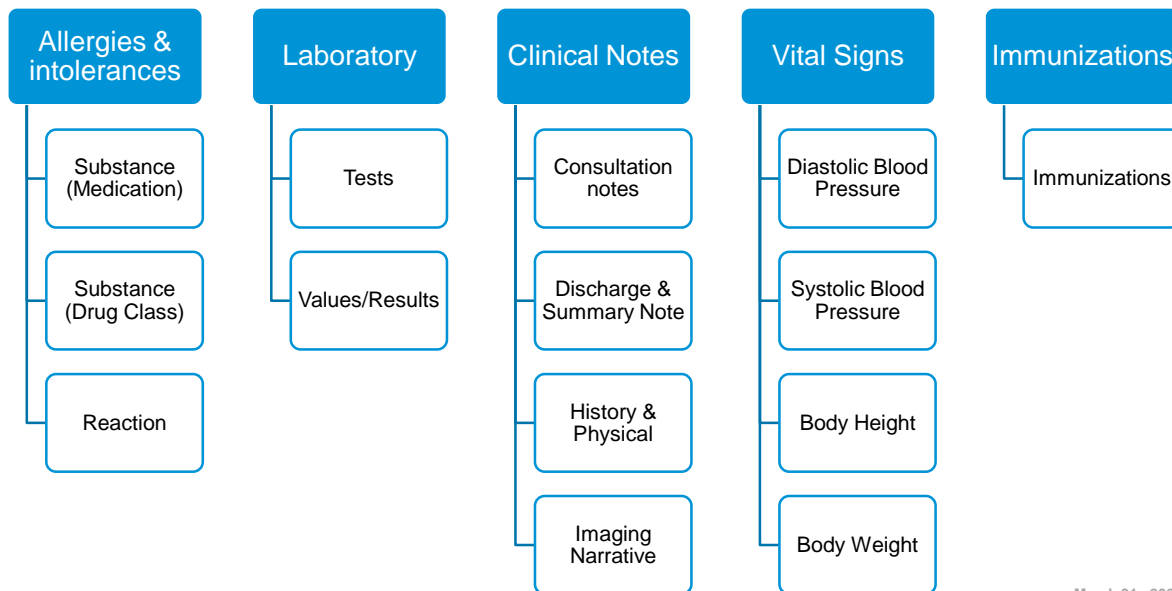
Patient-Directed Coordination of Care



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USCDI Data Classes and Data Elements



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Payer to Payer Data Exchange

Maintain USCDI data classes & data elements

- Only data “received”: **NOT** required to “seek out and obtain” data
- Crosswalk relevant claims data into USCDI data classes/elements
- Maintain USCDI data received from other plans
- Electronic form & format received

“Incorporate” data into “enrollee’s record”

- **Not** required to rely on (or use) data
- But must include data in “the record [plan] maintains for each enrollee”

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Provider Directory API

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Provider Directory API

Implement and maintain Provider Directory API:

- Complete and accurate provider directory (including pharmacies, where applicable)
- Names, addresses, phone numbers, specialties
- Updated within 30 calendar days

Other Requirements

- Comply with ONC technical standards (but not privacy and security standards)
- Include number of pharmacies in network and “mix” (e.g., “retail”)
- Publicly accessible
- Effective January 1, 2021

Does not apply to QHPs on FFEs

- Current requirements deemed sufficient

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Interacting with App Developers

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Documentation requirements for APIs

- Publicly accessible (website or links)
- Commonly available technology
- No preconditions/additional steps
- Technical information necessary to sync App to API

Conduct routine testing, monitoring, updating to ensure:

- API functions properly
- Fully implement privacy/security features (Patient Access API)

Denial of App's access to API—permitted *only* if:

- Security Rule risk assessment
- Unacceptable risk to PHI in plan's system
- Objective, verifiable criteria, applied consistently

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Privacy Concerns

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Oversight of Apps “beyond CMS authority”

- App’s privacy policy is best protection
- FTC regulates Apps’ use/disclosure of PII outside scope of HIPAA

FTC Act makes unlawful—

- “unfair or deceptive acts or practices in or affecting commerce”

“the FTC may bring an enforcement action against, for example, a health IT app developer whose promises—whether in the app’s privacy policy, user interface, FAQs, or elsewhere—depart from its practices.”

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Blue Plan To Do List

**IT
Personnel:
Develop—**

- Patient Access API (by Jan. 1, 2021)
- Provider Directory API (by Jan. 1, 2021)
- Payer-to-Payer data exchange process (by Jan. 1, 2022)

**Legal (by
Jan. 1,
2021):**

- Enrollee education materials;
- Attestations/warnings (*optional*);
- Business associate contracting (*PBM, mental health claim adjudication*);
- Provider contracting (*data disclosure*);
- Disclaimer—accuracy of data

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MyHealthEData QUESTIONS

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