CHANGE HEALTHCARE REGULATORY AND STANDARDS UPDATE

Q2 2020 Update Published: August 14, 2020

Q3 2020 Update Available: November 13, 2020

8.14.2020

CHANGE HEALTHCARE

Table of Contents

CHANGE HEALTHCARE

Timeline

2019

3/3/2019
21st Century Cure Act Rulemaking begins with publication of ONC and CMS NPRMs on Interoperability, Patient Access,

3/28/2019
CMS launches Compliance Review Program for Health Plans and Clearinghouses.

4/10/2019
CMS launches Compliance Review Provider Pilot Program.

12/31/2019
HICN (SSN) – MBI transition period ends. Entities must support MBI only.

Ongoing 2019
Initial Review and Comment, plus second Review and Comment for draft X12 7030 TR3s.

2020

01/01/2020
End of Medicare HICN to MBI Transition Period. MBIs must be used in all administrative transactions.

05/01/2020
Final Rules Issued: ONC and CMS on Interoperability, Patient Access, Information Blocking.

Anticipated

- X12N finalization of version 8010 TR3s (2020 or early 2021); recommend adoption to CMS
- Final Rule Attachments with Acknowledgments
- CMS launch Compliance Review Program for Providers.

X12N v7030™ Public Comment/Review and Finalization of TR3s

Withdrawals

10/28/2019
Final Rule Rescinding the Adoption of the Standard Unique Health Plan Identifier (HPID) and Other Entity Identifier (OEID)
Rule rescinds and deactivates the HPID and OEID as of December 27, 2019.

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Section 1

COVID-19

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Change Healthcare COVID-19 Updates and Resources Hub

- On April 1, Change Healthcare launched our **COVID-19 Updates and Resources Hub**.
- This is an online source of technology, business, and informational resources to give providers and payers guidance on how to maintain administrative, financial, and operational stability during the COVID-19 pandemic.
- Includes archive of Change Healthcare Customer Service Alerts relevant to COVID-19.
- Guidance Specific to Telehealth Benefits: https://www.changehealthcare.com/covid-19/faq-telehealth-benefits-and-coding-for-covid-19
- See the press release.

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Additional COVID-19 Resources

Change Healthcare

http://www.hipaasimplified.com:
Additional information on COVID-19, specifically related to transactions, code sets, and standards, such as general coding guidance.

Federal Government Resource Hub

- https://www.coronavirus.gov/

CDC Resource Hub

- https://www.cdc.gov/coronavirus/2019-ncov/index.html

CMS

- https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page

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Additional COVID-19 Resources, cont.

CMS Waivers & Flexibilities

- https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Resources/Waivers-and-flexibilities

AMA

- https://www.ama-assn.org/delivering-care/public-health/covid-19-2019-novel-coronavirus-resource-center-physicians

AHA

- https://www.aha.org/2020-01-22-updates-and-resources-novel-coronavirus-2019-cov

WEDI

- https://www.wedi.org/2020/03/18/covid-19-resources-information/

(HRSA) COVID-19 Uninsured Program

The Health Resources & Services Administration (HRSA) under the U.S. Department of Health and Human Services (HHS) announced a program to provide claims reimbursement to health care providers and facilities for COVID-19 testing and treatment of the uninsured.

Health care providers who have conducted coronavirus 2 testing or provided treatment for uninsured COVID-19 individuals on or after February 4, 2020 can request claims reimbursement through the program electronically and will be reimbursed generally at Medicare rates, subject to available funding.

Effective May 6, 2020, Change Healthcare is accepting claim submissions to the Health Resources & Services Administration (HRSA) COVID-19 Uninsured Program via Payer ID 95964 - COVID-19 HRSA Uninsured Testing and Treatment Fund.

For more information and to get started, visit:

- COVID-19 Claims Reimbursement Website: https://coviduninsuredclaim.linkhealth.com/
- COVID-19 Uninsured Program Portal User Guide: https://chameleoncloud.io/review/2957-5e98adf692326/prod
- Frequently Asked Questions: https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions

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State Policy Update

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State Issue Regulatory Flexibilities for COVID-19

- Many states are amending or removing regulatory requirements to ensure **healthcare workforce readiness**; e.g.:
  - Licensure
  - Telehealth
- Via changes to **insurance requirements**, states are also addressing financial barriers that may deter people from seeking medical advice and treatment; e.g.:
  - Coverage
  - Cost sharing
  - Surprise billing

Section 2

ASC X12N VERSION 7030™ PUBLIC REVIEW AND COMMENT PERIOD

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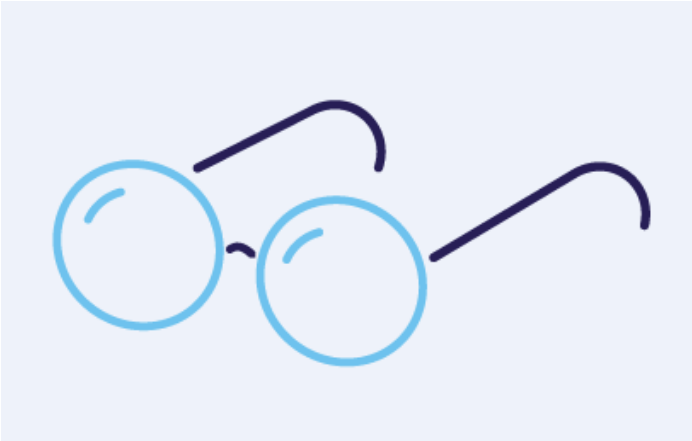
X12N Version 7030™ – Overview

X12N v7030™ Public Comment and Finalization



- Staggered public review and comment periods for version 7030™ of the X12N Type 3 Technical Reports (TR3s) began in the fall of 2016.
- Due to substantive changes resulting from comments received during the initial public comment periods, many TR3s have gone out or will go out for a second public comment period.
- It is anticipated that the functionality developed within the version 7030™ TR3s will be recommended to CMS for adoption.

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X12N Version 7030™ – Upcoming Public Reviews

Initial Public Review Pending

- **Application Reporting for Insurance (824)**: TBA

Second Public Review Pending

- **Implementation Acknowledgment for Health Care Insurance (999)**:
  TBA
- **Health Care Eligibility Benefit Inquiry and Response (270/271):**
  TBA
- **Code Value Usage in Eligibility Benefit Inquiry and Subsequent Response (TR2)**:
  TBA

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X12N Version 7030™ – Finalized/Nearing Finalization

Published

- Benefit Enrollment and Maintenance (834)
- Health Insurance Exchange: Enrollment (834)
- Health Insurance Exchange Related Payment (820)
- Health Care Claim/Payment Advice (835)
- Health Care Claim Pending Status Information (277P)
- Health Care Claim Acknowledgment (277CA)
- Health Care Claim Status Request and Response (276/277)
- Payroll Deducted and Other Group Premium Payment for Insurance Products (820)

Technical Review Under Way

- Additional Information to Support a Health Care Claim or Encounter (275)
- Health Care Services Request for Review and Response (278RR)
- Health Care Services Review Inquiry and Response (278IR)
- Health Care Services Review – Notification and Acknowledgment (278NA)
- Additional Information to Support a Health Care Services Review (275)
- Health Care Claim: Professional (837P)
- Health Care Claim: Institutional (837I)
- Health Care Claim: Dental (837D)
- Health Care Service: Data Reporting (837R)

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X12N Version 7030™ Informational Forums

- X12N holds public Informational Forums for each draft TR3 once the public comments received during their public comment periods have been adjudicated.
- Each Informational Forum gives an overview of the number of comments received and how the comment was adjudicated.
- Resolution of substantive comments are discussed in detail.
- All Informational Forum presentations are available to X12 members at https://x12.imeetcentral.com in the X12N Insurance Workspace. To gain access to this site, email info@X12.org.

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X12N Version 7030™ – Participation

Change Healthcare Encourages Your Participation

- Change Healthcare is actively participating in the v7030™ Public Review and Comment process and we encourage all entities to participate
- For updates to the public-comment period timeline, watch: www.x12.org

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Promotion of Version 7030™ TR3s to Version 8010™

For more information on the Version 8010™ promotion and on the Annual Release Cycle, watch www.X12.org

- The membership of the X12N Insurance Subcommittee has approved promoting the Version 7030™ TR3s to Version 8010™ immediately after they have been published.
- The published 8010™ TR3s for the HIPAA transactions will be recommended for adoption under HIPAA, rather than the 7030™ versions.
- The promotion to version 8010™ will align the X12N TR3s with the base X12 Standard version 8010™, which is the most recent base standard released by X12.
- From a functional perspective, there will be no substantive changes to the 7030™ TR3s, and no loss of or change to functionality added with 7030™.
- The promotion of versioning also positions X12 to begin their proposed Annual Release Cycle, tentatively slated to begin in 2021.

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X12 Annual Release Cycle

- X12 is in the process of implementing an Annual Release Cycle (ARC) for X12 products, including the X12N Insurance Subcommittee TR3s.
- The new release cycle will allow X12 to be responsive to today's rapidly-changing business environment.
- Each annual release of the TR3s will be aligned with the base X12 standard, also released annually.
- Releases will occur at the end of each calendar year.
- Public commenting on published versions will be accepted following each publication. Suggested changes will be considered for the next annual release.

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Section 3

ATTACHMENTS NPRM

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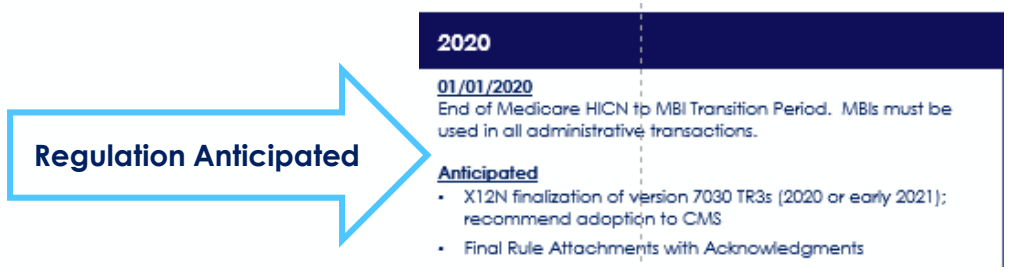
Attachments – Overview



- The Administrative Simplification provisions under the ACA include adoption of transaction standards and operating rules for Attachments.
- Electronic Attachments are electronic transactions that support the transmission of clinical documentation for claims and prior authorizations which require additional clinical information to in order to adjudicate, such as:
  - Health Care Claims/Encounters (837)
  - Health Care Services Review-Request for Review and Response (278)
  - Health Care Services Review-Notification and Acknowledgment (278)
- **A proposed rule establishing Attachment Standards and Operating Rules is anticipated as early as September 2020, per the Unified Agenda of Regulatory and Deregulatory Actions** (RIN 0938-AT38).

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Attachments – Regulatory Roadmap

- NCVHS hearing was held on February 16, 2016, with NCVHS Letter of Recommendation sent to HHS on July 5, 2016.
- Unified Agenda (RIN 0938-AT38) indicate that a proposed rule is anticipated as early as September 2020, with Public Comment Period.
- Proposed Rule is expected to:
  - Adopt standards for health care attachments transactions and electronic signatures to be used in conjunction with health care attachments transactions.
  - Adopt operating rules that require acknowledgments to be used for the eligibility for a health plan, health care claim status, and health care electronic funds transfers (EFT) and remittance advice transactions.
  - Adopt acknowledgments transactions standards for the health care claim status, enrollment and disenrollment in a health plan, health plan premium payments, coordination of benefits, referral certification and authorization, and health care attachments transactions.
  - Modify the standard for the referral certification and authorization transaction from ASC X12 version 5010 to ASC X12 version 6020.

Attachments – Recommendations

On February 16, 2016, the National Committee on Vital and Health Statistics (NCVHS), advisory body to HHS, conducted hearings on the Attachment standards. The following summary recommendations were made by NCVHS to the Secretary of Health and Human Services in a letter dated July 5, 2016:

- Adopt one standard definition of "Attachment," and establish the scope of the transaction.
- Adopt a set of mature, implementable electronic standards for the health care industry to execute the Attachments transaction.
- Define a series of transaction process requirements, including consistency with adopted privacy laws and regulations.
- Take an incremental, flexible implementation approach in no less than five years inclusive of rulemaking.
- Broaden the testing, education, outreach and compliance efforts.
- Ensure alignment of the Attachment standard's regulatory requirements with those adopted for use with Electronic Health Records under the Office of the National Coordinator (ONC) for Health Information Technology's 2015 Edition Certification of Health Information Technology program (i.e., Meaningful Use) and the Medicare Access CHIP Reauthorization Act of 2015 (MACRA)/Merit-Based Incentive Payment System (MIPS).

To see the NCVHS Letter to the Secretary – Recommendations for the Electronic Health Care Attachment Standard, click here.

Attachments – Publications

- HL7 Publications:
  - HL7 CDA® R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 Standard for Trial Use
  - HL7 CDA ® Release 2 Implementation Guide: Exchange of C-CDA Based Documents; Periodontal Attachment, Release 1
  - HL7 CDA® R2 Implementation Guide: Orthodontic Attachment, Release 1 – US Realm (awaiting publication)
- X12, HL7, and the Workgroup for Electronic Data Interchange (WEDI) White Paper:
  - **Guidance on Implementation of Standard Electronic Attachments for Healthcare Transactions**, provides guidance on the implementation of standard electronic attachments for healthcare transactions. See the Resources page at www.wedi.org.

Attachments – Change Healthcare Readiness

- On January 13th, 2020, Change Healthcare announced breakthrough all-payer medical attachments capability that gives providers the ability to dramatically reduce administrative burden associated with document and data exchange with payers.
  - Press Release
  - Podcast
- For more information regarding Change Healthcare's attachments solutions visit:
  - Medical Attachments
  - Dental Attachments

Section 4

CAQH® CORE® OPERATING RULES

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CAQH® CORE® Operating Rule Restructure

This summer, CAQH® CORE® released a restructuring of their Operating Rules from *Phased*-based rule sets to a *Business Transaction*-based model.

- All Operating Rules, including those adopted under federal regulation, have been assigned new Rule numbers and have been repurposed to eliminate references to Phases.
- There were no substantive content changes to any Rules.

For details, see the CAQH® CORE® website at https://www.caqh.org/core/new-operating-rule-structure.

CAQH® CORE® Final Operating Rules – Overview

Former Phase	Applicable Transactions	Rules Define:	Under Regulation *
I	270/271	Infrastructure, connectivity, response time, companion guide, acknowledgments, and data content	Y
II	270/271 276/277	270/271: Expanded data content, AAA error reporting, name normalization. 276/277: Infrastructure, connectivity, response time, companion guide, acknowledgments	Y
III	835 EFT	835: Infrastructure, connectivity, response time, companion guide, acknowledgments; provider enrollment form standardization and online support; 835/EFT reassociation	Y
IV	Remaining HIPAA transactions	Infrastructure, connectivity, response time, companion guide, acknowledgments. Includes final determination timeframe for 278 Request for Review and Response (Prior Authorization)	N
V	278 Request for Review/Response	Data content, proprietary web portal standardization	N

* Regulations exclude acknowledgment-related requirements.

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Change Healthcare Operating Rules Readiness

Change Healthcare clearinghouse services are **CORE Phase III Certified.** To become CORE Phase III certified entities must be CORE-certified on the earlier phases. Our CORE Phase III certification serves as Change Healthcare's exhibit of Operating Rule readiness.

The CAQH Committee on Operating Rules for Information Exchange (CAQH® CORE®) certifies and awards CORE® Certification Seals to entities that create, transmit or use the administrative transactions addressed by applicable Operating Rules. CORE Certification means an entity has demonstrated that its IT system or product is operating in conformance with a specific phase(s) of the Operating Rules.

- Change Healthcare is CORE® Phase I, Phase II, and Phase III certified, as evidenced by our Phase III seal.
- Link to Change Healthcare's CORE Phase III Seal.
- Link to our CORE Voluntary Certification (Clearinghouses tab).
- Additional information regarding the Change Healthcare Operating Rules program can be found on www.hipaasimplified.com.

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NCVHS Hearing on Proposed Rules for Federal Adoption

CAQH® CORE® has requested review by the National Committee on Vital and Health Statistics (NCVHS), advisory body to HHS, to consider federal adoption of three operating rules[1]:

Prior Authorization & Referrals (278) Data Content Rule vPA 1.0 (formerly from Phase V v5.0.0)**:**

This operating rule specifies data content requirements for patient identification, error/action codes, communicating with providers regarding needed information and clinical documentation, status/next steps, and decision reasons to streamline the review and adjudication of prior authorization requests and facilitate faster response times.

Prior Authorization & Referrals (278) Infrastructure Rule vPA 2.0 (formerly Phase IV v4.1.0)**:**

This operating rule specifies prior authorization requirements for response times, system availability, acknowledgements, and companion guides. Specifically, this rule sets response time limits for health plans to request supporting information from providers and make final determinations on prior authorization requests.

Connectivity Rule vC3.1.0 (formerly Phase IV v4.0.0)**:**

This operating rule establishes consistent connectivity requirements for data exchange across the HIPAA Administrative Simplification transactions. Specifically, this rule improves security through stronger authentication requirements and reduces complexity by requiring a single envelope standard. CAQH CORE is proposing that this rule replace the existing CAQH CORE Connectivity Rules v1.1.0 and v2.2.0 and apply across the HIPAA Administrative Simplification transactions including eligibility, claim status, electronic remittance advice (ERA), and prior authorization and referrals.

The Standards Subcommittee of the NCVHS will conduct a virtual hearing on the proposed adoption on these rules on **August 25-26, 2020.** Look here for additional meeting information.

[1] Rule descriptions quoted from the Letter to NCVHS of 2/24/2020 and the Update Letter dated 6/26/2020.

Rules in Development and Priority Issues

Want to get involved?

Email core@caqh.org

or visit
www.caqh.org/core

Connectivity Rule:
The Connectivity and Security Work Group has developed a revised Safe Harbor Rule that aligns with the latest technologies, is payload agnostic, and supports the ONC and CMS Interoperability final rules. The revised rule will be balloted within the Work Group in August/September 2020 and will progress through the full CAQH® CORE® voting process thereafter, with balloting expected to conclude by the end of 2020.

Electronic Attachments Rule (Prior Authorization Use Case):
The Attachments Subgroup has begun rule development on Attachments as related to Prior Authorizations, based on rule opportunities identified by the Attachments Advisory Group. The Subgroup will begin collecting feedback in August/September 2020 and rule development will occur through Q1 2021. Look here for additional information.

Value-Based Payments:
In 2019 CAQH® CORE® launched their Value-Based Payments Advisory Group, which identified five opportunity areas. Three of these opportunity areas will be considered by a CAQH® CORE® Value-based Payments Subgroup or via a pilot launching this fall. Look here for additional information.

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Section 5

NCVHS DRAFT RECOMMENDATIONS PREDICTABILITY ROADMAP

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History

- The Patient Protection and Affordable Care Act (ACA) of 2010 authorized the Secretary of the Department of Health and Human Services (HHS) to establish a Review Committee responsible for evaluating the adopted transaction standards and operating rules. The Secretary designated the National Committee on Vital and Health Statistics (NCVHS), advisory body to HHS, to act as the Review Committee.
- June 2015 testimony gathered from industry stakeholders – including the Standards Development Organizations (SDOs) and the Operating Rules Authoring Entity (ORAE) – indicated that that HIPAA named transaction standards and operating rules are significant steps towards achieving greater administrative efficiencies.
- However, concerns expressed resulted in a letter to HHS with a set of recommendations including the need to*:
  - **Explore the feasibility of expanding the definition of HIPAA covered entities.**
  - **Broaden education.**
  - **Ensure consistency.**
  - **Enforce compliance.**
  - **Adopt the acknowledgment transaction.**
  - **Provide predictability in the adoption of standards, code sets, identifiers and operating rules.**
  - **Ensure responsiveness to evolving changes in health care.**
- After further information gathering, the Standards Subcommittee of the NCVHS developed the **Draft Recommendations for the Predictability Roadmap,** presented to the full committee on September 14, 2018.

*See **Roadmap Narrative**

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Timeline

Change Healthcare supports the draft recommendations of the NCVHS in their February and December 2019 letters to the HHS Secretary.

- **October-November 2018:** Industry stakeholders reviewed the **Draft Recommendations for the Predictability Roadmap**.
- **December 13-14, 2018:** The NCVHS Standards Subcommittee conducted a hearing to hear testimony on these recommendations and incorporated feedback through January 2019
- **February 6-7, 2019:** The full NCVHS reviewed and approved revised draft recommendations.
- **February 13. 2019:** NCVHS issued *letter of recommendation* to HHS.
- **June 4, 2019:** CMS issued response to the NCVHS recommendations.
- **July 10-11 2019:** The NCVHS Standards Subcommittee conducted a visioning session to further discuss barriers to adopting and implementing updated versions of standards and operating rules on a predictable, reliable, and timely basis.
- **December 10, 2019:** NCVHS Recommendation Letter - HHS Actions to Improve the Adoption of Standards Under HIPAA.
- **March 15,2020:** NCVHS 2020 Convergence Project – Initiative to develop recommendations to support convergence of clinical and administrative data with initial focus on the prior authorization transactions and workflow.

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Section 6

FEDERAL POLICY UPDATE

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CMS announcement of the creation of the "Office of Burden Reduction and Health Informatics"

- On June 23rd CMS unveiled a major organizational change announcing the creation of the *Office of Burden Reduction and Health Informatics* to unify the agency's efforts to reduce regulatory and administrative burden and to further the goal of putting patients first.
- Dr. Mary Greene is the Director for the new office.

SAMHSA

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SAMHSA 42 CFR Part 2 Revised Rule

42 CFR Part 2 regulations (***Part 2***) protects patient records created by federally assisted programs for the treatment of substance use disorders (SUD)

- Part 2 recently revised to further facilitate better care coordination while maintaining confidentiality protections against unauthorized disclosure and use

- **What has not changed?**
  - Continues to prohibit law enforcement's use of SUD patient records in criminal prosecutions against patients, absent a court order
  - Continues to restrict the disclosure of SUD treatment records without patient consent – outside of the context of a bona fide medical emergency; or for the purpose of scientific research, audit, or program evaluation; or based on appropriate court order

SAMHSA 42 CFR Part 2 Revised Rule (cont.)

- **Highlights of what is new**
  - **Applicability, Re-disclosure**
    - Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2, unless any SUD records previously received from a Part 2 program are incorporated into such records
  - **Consent Requirements**
    - SUD patient may consent to disclosure of Part 2 treatment records to an entity (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure
  - **Disclosures and Consent**
    - Disclosures for the purpose of "payment and health care operations" are permitted with written consent
  - **Medical Emergencies**
    - Declared emergencies resulting from natural disasters (e.g., hurricanes) that disrupt treatment facilities and services are considered a "bona fide medical emergency," for the purpose of disclosing SUD records without patient consent under Part 2

Federal Transparency Initiatives

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Cost Transparency – Final CMS Rule for Hospitals

- **CMS Final Rule – Hospitals – Effective Date Jan. 1, 2021**
  - Requires each hospital operating within the U.S. to establish, update and make public a yearly list of the hospital's standard charges for items and services provided by the hospital
  - **Standard Charge Definition:**
    - **Gross charge**: The charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts
    - **Discounted cash price**: The charge that applies to an individual who pays cash, or cash equivalent, for a hospital item or service
    - **Payer-specific negotiated charge**: The charge that a hospital has negotiated with a third-party payer for an item or service
    - **De-identified minimum negotiated charges**: The lowest charge that a hospital has negotiated with all third-party payers for an item or service
    - **De-identified maximum negotiated charges**: The highest charge that a hospital has negotiated with all third-party payers for an item or service

Source: https://www.cms.gov/files/document/2019-12-03-hospital-presentation.pdf

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Cost Transparency – Final, Proposed CMS Rules (Hospitals)

- **Two Ways to Make Price Information Public**
  - **Comprehensive Machine-Readable File**
    - A single machine-readable file that contains all five types of standard charges for all the items and services provided by the hospital
  - **Consumer-Friendly Shoppable Services**
    - A consumer-friendly list of some types of standard charges for a limited set of "shoppable services" (including 70 CMS-specified and 230 hospital-selected) provided by the hospital
    - A 'shoppable service' is a service that can be scheduled by a health care consumer in advance

Source: https://www.cms.gov/files/document/2019-12-03-hospital-presentation.pdf

Requirements for Making Public All Standard Charges for All Items and Services in a Machine-Readable Format

- Each hospital location operating under a single hospital license that has a different set of standard charges must separately make public the standard charges that are applicable to that location
- **Required Data Elements**:
  - A description of each item or service
  - All standard charges (gross charges, payer-specific negotiated charges, discounted cash prices, minimum and maximum negotiated charges) that apply to each item or service when provided in, as applicable, the hospital inpatient and outpatient department setting
  - Any code used by the hospital for purposes of accounting or billing for the item or service, for example, HCPCS codes, DRG codes, or other common payer identifier

Source: https://www.cms.gov/files/document/2019-12-03-hospital-presentation.pdf

Cost Transparency – Proposed CMS Rule for Payers

- **CMS Proposed Rule – Health Plans (HHS, DOL, Treasury)**
  - The "transparency in coverage" rule would require health plans (including employer-based plans) to inform members about price and cost-sharing information ahead of time
  - Rule proposes to give consumers real-time, personalized access to cost-sharing information, including estimate of cost-sharing liability for all covered health care items and services through an online tool.
    - Plans would be required to offer this tool to all members and make info available in paper form if requested
    - Through these proposed rules, plans and issuers would also be required to disclose on a public website their negotiated rates for in-network providers and allowed amounts paid for out-of-network providers
  - **Effective date**: One year after publication of final rule.

Source: https://www.cms.gov/newsroom/fact-sheets/transparency-coverage-proposed-rule-cms-9915-p

ONC Certification and Information Blocking Rule

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21st Century CURES Act

- Bipartisan legislation passed in 2016
- Information blocking is illegal for certain actors; penalties were created for some actors if they are found to be information blocking
- Created the definition of information blocking
- Directed the Office of the Inspector General (OIG) as the enforcement arm, including levying penalties; may only level penalties on health IT developers and health information networks (HINs)/health information exchanges (HIEs)
- Directed CMS to create penalties for healthcare providers
- Directed ONC to develop exceptions to the information blocking definition (i.e., define when choosing not to share data is allowed)
- Directed ONC to develop Conditions of Certification, including requiring open Application Programming Interfaces (APIs)

Overview of ONC's Regulation

- Final Rule published in the Federal Register May 1, 2020.
- ONC developed new certification criteria for health IT developers and established policies around what is allowed in their contracts
- ONC defined several important terms as part of the regulation, including which actors are regulated by information blocking
- ONC created a set of exceptions to information blocking that fall into two categories:
  - Withholding Electronic Health Information (EHI) – when are actors allowed to withhold EHI
  - Conditions for sharing EHI – what fees can be charged and what formats EHI data must be in

New EHR and Health IT Developer Capabilities

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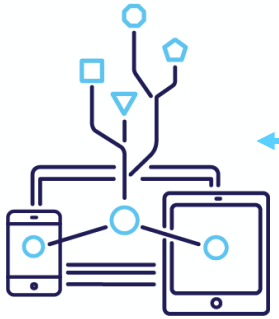
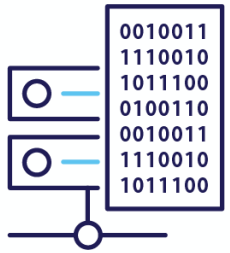
What Are Application Programming Interfaces (APIs)?

Developers
will access your assets through your API to build Mobile Apps and Web Apps based on the data and software you share



The API
provides universal access to whatever assets you choose to share. Developers can "plug in" their apps and data



Assets
Your data and software (and brand) become more valuable by being leveraged by partners, developers, and third-party services.

End Users
Have access to apps that provide richer experiences by leveraging the data and services of other apps.

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Why Should You Care About APIs?

- APIs allow data from the EHR system to be shared with:
  - Other providers who are treating patients
  - Public health agencies
  - Other solutions (i.e., population health, care coordination, etc.)
  - Payers
  - Patients using mobile apps
- Using standardized, certified APIs can lower the overall cost of achieving interoperability and minimize time and resources required for interface development

New Terminology for APIs

- **Certified API Developer:** EHR vendor (or other health IT developer) who has certified APIs under ONC's 2015 Edition
- **API Information Source:** the data holder, typically a healthcare system or provider, but may also be a payer, public health agency, or other data source
- **API User:** person or entity that creates or uses software applications that interact with the "certified API technology" developed by a "Certified API Developer" and deployed by an "API Information Source"
- **FHIR:** Fast Healthcare Interoperability Resources (FHIR) is a standard for APIs that dictates the content, format, and transport of data so that organizations can easily exchange data
- **US Core Data for Interoperability (USCDI):** minimum set of data that certified health IT products must be able to send and receive; will be expanded over time

What Data is Included in USCDI?

First and Last Name	Date of Birth	Address	Phone	Sex
Problems/ Diagnoses	Medications	Medication Allergies	Laboratory Tests Ordered	Laboratory Test Results – if available at discharge
Vitals	Immunizations	Clinical Notes	Procedures	Assessment and Plan of Treatment
Patient Goals	Health Concerns	Care Team Member Names – if known	Unique Device Identifier – i.e. pacemakers, insulin pumps, etc.	Provenance (authorship info)

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Certification Requirements for APIs – What EHR Vendors Should Provide

- EHR vendors must be certified to FHIR Version 4 and accompanying implementation guides enabling the exchange of the USCDI
  - Must use OAuth 2.0 or OpenID to enable patient access – these standards use patient portal credentials provider entities have assigned to patients
- FHIR v4 can be used for more than just the USCDI, but the only APIs that will be certified will be for the USCDI
- The APIs must be made available for access by third-party apps used by patients
- FHIR APIs will be available within 24 months – not immediately available
- Only the Information Source can dictate who has access to these APIs; EHR vendors cannot prohibit other vendors from accessing these APIs

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Electronic Health Information (EHI) Export

- Certified health IT developers that store EHI (equivalent to the HIPAA Designated Record Set) must get certified for the EHI export criterion
- EHR vendors will need to be able to export all EHI in any data format, but provide a data map.
- Two use cases supported with this criteria:
  - Patient access – provide the file to a patient requesting their record
  - Switching EHR vendors or other health IT vendors – provide a file that can be ingested into the new system
- For patient access, system users (i.e. provider or staff) must be able to generate the data export – cannot set it up to require the vendor to help
  - May not charge a fee
- For switching vendors, an administrator would be able to generate it – there may be setup to require the vendor to help
  - Fees must be agreed upon in advance in contracts
- EHI export capability must be available within 36 months+ three-month discretionary compliance delay due to COVID19 pandemic

Who Is Regulated by Information Blocking?

- **Healthcare providers** – HIPAA definition
- **Developers of certified health IT** – note that if a developer has even one portion or component of a product certified, all of their products fall under the information-blocking provisions, even if they're not certified
- **Health Information Network (HIN)/Health Information Exchange (HIE)** - individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information:
  - (1) Among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other
  - (2) That is for a treatment, payment, or health care operations purpose

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What Happens if You Are Found Guilty of Information Blocking?

- May be hit with a False Claims Act penalty for falsely attesting to the Promoting Interoperability program
- Will "fail" the Promoting Interoperability Program:
  - Hospitals will receive a reduction to the applicable percentage increase to the Inpatient Perspective Payment System (IPPS) payment rate for the next CY
  - CAHs' Medicare reimbursement will be reduced from 101% of its reasonable costs to a specified percentage for each year
  - Providers will receive a downward payment adjustment to their Medicare reimbursements
  - For Medicaid only providers – no financial penalties enumerated currently

Information Blocking Exceptions

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Eight Information Blocking Exceptions (provided certain conditions are met)

1) **Preventing Harm** - It will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person
2) **Privacy** - It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy
3) **Security** - It will not be information blocking for an actor to interfere with the access, exchange, or use of EHI in order to protect the security of EHI
4) **Infeasibility -** It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request
5) **Health IT Performance -** It will not be information blocking for an actor to take reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of the health IT
6) **Content and Manner -** It will not be information blocking for an actor to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request to access, exchange, or use EHI
7) **Fees -** It will not be information blocking for an actor to charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI
8) **Licensing -** It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged, or used

Source: https://www.healthit.gov/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf

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CMS Interoperability and Patient Access Rule

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Who Does the CMS Rule Apply To?

- Final Rule published in the Federal Register May 1, 2020.
- Medicare Advantage (MA) Organizations
- Medicaid Managed Care (MMC) Organizations
- State Medicaid Agencies (for FFS)
- CHIP Agencies
- CHIP Managed Care Entities
- Qualified Health Plans (QHPs) on Federally-facilitated Exchanges (if on state-facilitated exchange only – rules do not apply)

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Provision of APIs for Patient Access

- Plans must provide a standardized/open API to enable patient access (via any third-party app) to health plan data by **January 1, 2021**, but enforcement will not happen until **July 1, 2021**
  - Data from January 1, 2016 moving forward must be made available – if the plan has it
- CMS estimates API will cost an average of $1,576,829 per payer
  - no restriction on passing on cost via premium increases
- API requirements will be contractual requirements for managed care organizations (MCOs) – must also be included in state-created capitation rates
- Payers must allow any third party the patient chooses to connect to the API
  - access may only be denied for a documented security issue

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Post Documentation or the API Online

- Payers must post on an open website (not behind paywall) the following documentation to enable any third party to connect to the API:
  - API syntax and function names
  - Required and optional parameters supported; their data types; return variables and their types/structures; exceptions & exception handling methods and their returns
  - Software components and configurations an application must use in order to successfully interact with the API & process response
  - All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API

What Data Available and When?

Within one business day of processing or receipt:

- Adjudicated claims data including data for payment decisions that may be appealed, were appealed, or in the process of appeal
  - For state Medicaid and managed care plans this includes LTSS data, including in-home care, transportation services, and any other LTSS data
- Provider remittances
- Enrollee cost-sharing info
- Encounter data
- Drug formulary, preferred drug list (if scripts are included in plan)
- Clinical data, including lab results – to the extent the plan maintains such data

What Data Standards Must Be Used - API?

- At a minimum, Fast Healthcare Interoperability Resources (FHIR) version 4 (HL7)
- For clinical data, payers must provide the U.S. Core Data for Interoperability (USCDI) in the formats specified in the USCDI standard
- For claims, encounter, and drug formulary data - use the HIPAA administrative standards
- Payers can use any FHIR implementation to meet data provision requirements as long as they use FHIR version 4

FHIR Implementation Guides Available

Implementation Guide	Data Covered in the Guide
HL7 FHIR US Core Implementation Guide STU 3.1.0	USCDI
HL7 SMART Application Launch Framework Implementation Guide Release 1.0.0, including mandatory support for the "SMART" Core Capabilities	Allows for patient authorization via the third-party app by using payer assigned username and password & OAuth 2.0 standard
FHIR Bulk Data Access (Flat FHIR) (v1.0.0: STU 1)	USCDI for multiple patient records at one time – likely not applicable for patient access
OpenID Connect Core 1.0, incorporating errata set 1	Allows for patient authorization via the third-party app
CARIN Alliance Blue Button® Framework and Common Payer Consumer Data Set (CPCDS)	Claims & encounter data
DaVinci Payer Data Exchange US Drug Formulary IG	Drug formulary

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Provision of a Standard API with Provider Directory Data

- By **July 1, 2021**, must provide a FHIR version 4 public API with the following data for all contracted providers and pharmacies (if applicable):
  - Provider name, address(es), phone number(s), and specialties
  - Pharmacy name, address, phone number, number of pharmacies in the network, and mix
- Data must be updated no later than 30 days after a change is received
- Cannot restrict access to this data or require authentication to access it

Requirement to Exchange Data With Other Payers

- By **January 1, 2022**, must have a process for electronically exchanging the USCDI.
  - When USCDI is received from another payer - must incorporate up to 5 years of the data into a current member's record set.
  - When a member switches plans and requests for their data to be sent to new payer, must send the USCDI electronically to new payer
    - Such requests can be made up to 5 years after a member has disenrolled
- Generally, data must be shared in the form and format in which it was originally received (when electronic)

Section 7

CMS COMPLIANCE REVIEW PROGRAM

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CMS Compliance Review Program

- In late 2017, CMS launched its Optimization Pilot in preparation for a full-scale Compliance Review program

Change Healthcare was selected to participate in the Optimization Pilot and was awarded our Certificate of Completion on October 4, 2018. See Change Healthcare Accreditations & Certifications for details.

- In April 2019, CMS began its formal Compliance Review program by selecting nine HIPAA-covered entities for compliance reviews. Any health plan or clearinghouse, not just those working with Medicare or Medicaid, can be selected

- Also in April, CMS launched a volunteer Provider Pilot Program to test the process for reviewing HIPAA Administrative Simplification rules compliance among providers.

For additional information, see https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Enforcements/Compliance-Review-Program.html

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Section 8

CHANGE HEALTHCARE ACCREDITATIONS & CERTIFICATIONS

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HHS Optimization Program Certification

- On October 4, 2018, The U.S. Department of Health and Human Services (HHS), Division of National Standards (DNS) within the Centers for Medicare & Medicaid Services (CMS), recognized Change Healthcare for successfully completing the HHS Optimization Program Pilot of Administrative Simplification transaction standards, code sets, unique identifiers, and operating rules.
- Certificate of Completion

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Change Healthcare Accreditations & Certifications

To demonstrate our continued commitment to assure that applicable Change Healthcare products and services meet industry and regulatory requirements and expectations, we maintain several industry recognized and trusted accreditations and certifications.

Click HERE for more information.

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