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Regulatory and Standards Update

Q1 2023 Update Published: February 15, 2023
Q2 2023 Update Published: May 17, 2023
Q3 2023 Update Published: September 21, 2023

Agenda

1 ASC X12 Subcommittee Update

2 Medicare and Medicaid Programs: Prior Authorization NPRM

3 Administrative Simplification: Attachments NPRM

4 CAQH®CORE Operating Rules

5 Centers for Medicare & Medicaid Services (CMS) Updates

6 Federal Policy and Regulations: Price Transparency

7 No Surprises Act

8 HIPAA Privacy Rule NPRM

9 ONC Certification and Information Blocking Rule

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Timeline

2021	2022	2023

01/21/2021

CMS published proposed "Proposed Modifications to the HIPAA Privacy Rule"

07/13/2021

Interim final rule issued: "Requirements Related to Surprise Billing: Part 1"

09/10/2021

NPRM published proposed "Reporting Requirements Regarding Air Ambulance Services, Agent, and Broker Disclosures, and Provider Enforcement"

09/30/2021

Interim final rule issued: "Requirements Related to Surprise Billing: Part II"

11/23/2021

Interim final rule issued: "Prescription Drug and Health Care Spending"

01/24/2022

RFI for ePA (electronic pre-authorization)

05/23/2022

CAQH CORE submits operating rule recommendations to NCVHS

June 2022

X12 started work on a use case implementation guide for the Good Faith Estimate (GFE) portion of the No Surprises Act

06/08/2022

X12 submits version 8020 recommendations to NCVHS

07/28/2022

USCDI v3 published

12/13/2022

NPRM - Medicare and Medicaid Programs: Advancing Interoperability and Improving Prior Authorization Processes

12/21/2022

NPRM – Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard

01/18-19/2023

NCVHS Standards Subcommittee Hearing on Requests for New and Updated Transaction Standards and Operating Rules

03/13/2023

Comments due: NPRM – Medicare and Medicaid Programs: Advancing Interoperability and Improving Prior Authorization Processes

03/21/2023

Comments due: Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard

04/11/2023

X12 submits the second set of 8030 recommendations to NCVHS

06/14/2023

NCVHS Full Committee Meeting:

- CAQH CORE recommendations are supported by NCVHS
- X12 recommendations are not supported "at this time" by NCVHS

07/31/2023

X12 submits a response letter to NCVHS asking them to reconsider their recommendation

08/03/2023

NCVHS meets to discuss ICD-11

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ASC X12N Subcommittee Update

X12 Recommendations to NCVHS

The Strategy

Overview

Recommended to move from 005010 to 0080next

- 0080next is the most current version when the NPRM is published (008020, 008030, etc.)

X12 plans a phased approach rather than an entire suite of transactions

X12 made two sets of recommendations

All recommended transactions are accompanied by the X12 developed XML schema

Recommendation Letters: https://x12.org/news-and-events/x12-recommendations-to-ncvhs

Recommendations

Set 1 008020 – June 8, 2022

- X323 Health Care Claim: Professional (837)
- X324 Health Care Claim: Institutional (837)
- X325 Health Care Claim: Dental (837)
- X322 Health Care Claim Payment/Advice (835)

Set 2 008030 – April 11, 2023

- X329 Health Care Claim Status Request and Response (276/277)
- X333 Benefit Enrollment and Maintenance (834)
- X334 Payroll Deducted and other Group Premium Payment for Insurance Products (820)

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NCVHS' Recommendation on the Updated Version of the X12 Standards and Implementation Guides

Deciding factors

NCVHS stated that adopting 008020 vs. an entire suite would result in multiple versions being utilized concurrently. They expressed concerns about cross-capability between the different versions.

Additionally, 008020 didn't address ICD-11 or the new NDC format

Virtual Credit Cards (VCC)

The VCC was added to the X322 Health Care Claim Payment/Advice (835). Provider's expressed concerns over unauthorized use even though the usage is situational in the implementation guide. NCVHS encourages HHS to develop and publish additional VCC guidance.

Unique Device Identifier (UDI)

The concern is specific to the DI portion of the UDI. NCVHS encourages the FDA to review stakeholder comment letters and testimony to understand the concerns the collection of UDI codes.

"NCVHS recommends that HHS not adopt the version 008020 update for the four specified transactions (Health Care Claim (Institutional, Professional, and Dental) and the Claim/Remittance **at this time**"

NCVHS Recommendation letter: https://ncvhs.hhs.gov/wp-content/uploads/2023/06/Recommendation-Letter-Updated-Version-of-X12-Standard-June-14-2023.pdf

X12's Response, Next Steps, and Industry Impact

X12's Response

X12 leadership submitted a rebuttal letter to NCVHS on 7/31/2023 for the first set of recommendations.

The letter addressed each concern reported by NCVHS.

X12 asked for NCVHS to reconsider their recommendation

Letter can be found here.

Next Steps

X12 decided to pause on additional recommendations.

X12 and NCVHS continue to discuss the recommendations and next steps.

The X12 008020 Proof of Concept will provide additional justification to why these recommended transactions are necessary
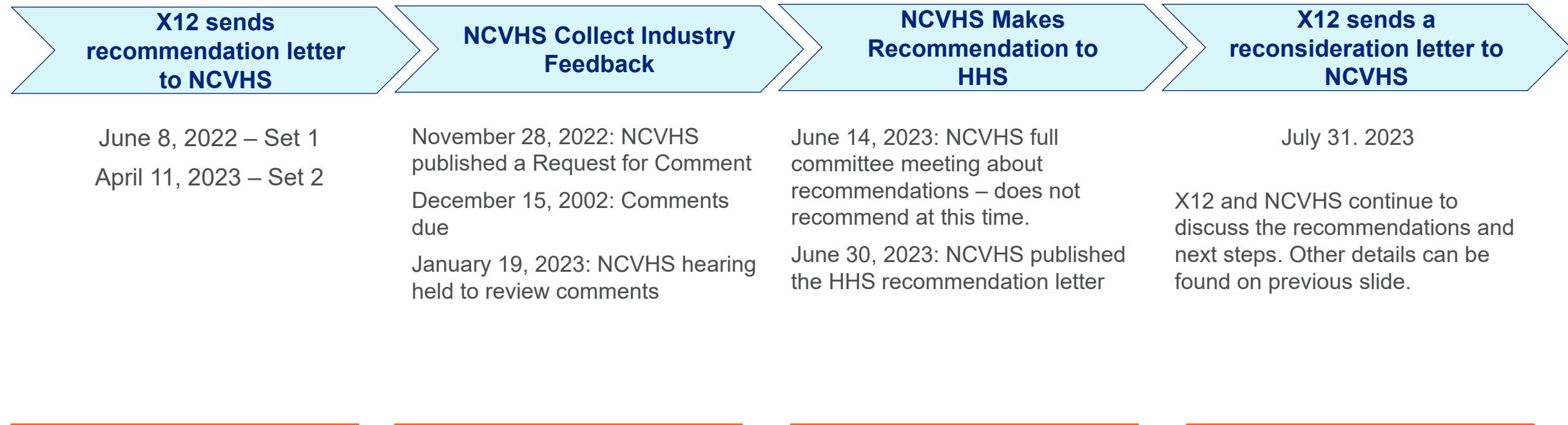
Industry Impact

The 005010 is static and does not contain the enhancements in the most recent versions, 0080next. These enhancements were added to assist in streamlining the claims and remittance transactions.

A few enhancements to note; factoring agents' inclusion, original claim submission date, more detailed source of payment codes, and pre-determination instructions in the claim transactions.

The impactful list of enhancements can be found here.

X12's Recommendation Timeline and Next Steps

X12 sends recommendation letter to NCVHS	NCVHS Collect Industry Feedback	NCVHS Makes Recommendation to HHS	X12 sends a reconsideration letter to NCVHS
June 8, 2022 – Set 1 April 11, 2023 – Set 2	November 28, 2022: NCVHS published a Request for Comment December 15, 2002: Comments due January 19, 2023: NCVHS hearing held to review comments	June 14, 2023: NCVHS full committee meeting about recommendations – does not recommend at this time. June 30, 2023: NCVHS published the HHS recommendation letter	July 31. 2023 X12 and NCVHS continue to discuss the recommendations and next steps. Other details can be found on previous slide.

X12 008020 Proof of Concept (PoC) Pilot

What is the PoC Pilot

X12's Proof of Concept (PoC) Program was created to provide X12 licensing partners with early access to the newest versions and related artifacts in order to better understand the implementation implications while verifying that the expected business benefits of these new versions and transactions are achievable.

Participation Benefits

Early access to new versions of X12 standards, derivatives, and related exclusive content

Understand the changes between the current HIPAA mandated transactions and the proposed new versions.

Verify the impact - benefits, opportunities, challenges and potential cost to upgrade.

Opportunities to collaborate with trading partners, service and software vendors.

Promote your offerings with X12's support.

Help our organization and the industry by seizing the benefits presented in the new transaction version.

X12 Resources and Scope

X12 is providing all X12 resources needed to participate.
- Glass licenses
- Table Data
- XML Schema Definitions (XSD)
- Test Files

Scope:
008020X323 Health Care Claim: Professional (837)
008020X324 Health Care Claim: Institutional (837)
008020X325 Health Care Claim: Dental (837)
008020X322 Health Care Claim Payment/Advice (835)

Update

There are 12 companies participating in the PoC, including health plans, providers, clearinghouses, and software vendors. These entities are testing the 008020 recommended transactions and version cross-capability.

The PoC continues with most participants still building and testing the recommended transactions, even in light of the NCVHS recommendation.

X12 008030X370 Health Care Good Faith Estimate – new guide!

X12 is developing a new implementation guide to support the Good Faith Estimate (GFE) requirements of the No Surprises Billing Act.

This is a use case-level based implementation guide built off of the well-defined implementation instructions to provide the health care industry with an efficient solution based on X12's broadly implemented Health Care Claim (837) transaction sets. The guide encompasses requirements for professional and institutional GFEs to support the cost-transparency call for in the No Surprises Billing Act. The X370 GFE guide supports a patient-centric 837 message that can easily translated into a message delivered directly to the patient.

X12® Annual Release Cycle (ARC)
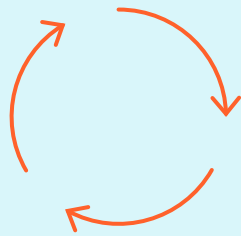
Visit www.X12.org for developments

Overview

- X12's Annual Release Cycle (ARC) is in place for all X12 products, including the X12N Insurance Subcommittee implementation guides.

- ARC allows X12 to be responsive to today's rapidly changing business environment.

- Each annual release of the implementation guides is aligned with the base X12 standard that also releases annually.

- Public comments on the proposed guides are welcome after each publication. Suggested changes will be considered for the next annual release.

- Releases occur at the end of each calendar year and available in Glass, X12's online viewer, in Q1 of each year.

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X12® Insurance Subcommittee TR3s Version 8020™ - Publication Status

Available in X12's online viewer, Glass

- Health Care Eligibility Benefit Inquiry and Response (270/271)
- Premium Payment Grace Period Notification (271)
- Health Care Provider Directory (274)
- Additional Information to Support a Health Care Claim or Encounter (275)
- Additional Information to Support a Health Care Services Review (275)
- Personal Health Record Data Transfer Between Health Plans (275)
- Health Care Claim Status Request and Response (276/277)
- Health Care Claim Acknowledgment (277CA)
- Health Care Claim Pending Status Information (277P)
- Health Care Claim Request for Additional Information (277RFAI)
- 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)

- Application Reporting for Insurance (824)
- Benefit Enrollment and Maintenance (834)
- Health Insurance Exchange: Enrollment (834)
- Plan Member Reporting (834)
- Health Care Claim Payment/Advice (835)
- Health Care Claim: Professional (837P)
- Health Care Claim: Institutional (837I)
- Health Care Claim: Dental (837D)
- Health Care Service: Data Reporting (837R)
- Provider Enrollment for EDI Services (838)
- Implementation Acknowledgment for Health Care Insurance (999)
- Payroll Deducted and Other Group Premium Payment for Insurance Products (820)

Under Non-Versioned Technical Reports>Reference Models (TR2):
Code Value Usage in Eligibility Benefit Inquiry and Subsequent Response

X12® Insurance Subcommittee TR3s Version 8030™ - Publication Status

Available in X12's online viewer, Glass

- Personal Health Record Data Transfer Between Health Plans (275)
- Post-adjudicated Claims Data Reporting: Professional(837)
- Post-adjudicated Claims Data Reporting: Institutional (837)
- Post-adjudicated Claims Data Reporting: Dental (837)
- Provider Enrollment for EDI Services (838)
- The Application Reporting for Insurance (824)
- Health Care Claim Payment/Advice (835)
- Health Care Claim: Professional (837)
- Health Care Claim: Institutional (837)
- Health Care Claim: Dental (837)
- Health Care Service: Data Reporting (837)
- Health Care Services Review – Inquiry and Response (278)
- Health Care Services Review Notification and Acknowledgment (278)
- Health Care Claim Status Request and Response (276/277)
- Health Care Claim Acknowledgment (277)
- Health Care Claim Pending Status Information (277)
- Health Care Eligibility/Benefit Inquiry and Information Response (270/271)
- Benefit Enrollment and Maintenance (834)

- Health Care Claim Request for Additional Information (277)
- Additional Information to Support a Health Care Claim or Encounter (275)
- Health Care Services Review – Request for Review and Response (278)
- Additional Information to Support a Health Care Services Review (275)
- Premium Payment Grace Period Notification (271)
- Health Insurance Exchange Related Payment (820)
- Health Insurance Exchange: Enrollment (834)
- Implementation Acknowledgment for Health Care Insurance (999)
- Payroll Deducted and Other Group Premium Payment for Insurance Products (820)

Under Non-Versioned Technical Reports>Reference Models (TR2):
Code Value Usage in Eligibility Benefit Inquiry and Subsequent Response

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Call to Action – we ask you to participate!

There isn't a better time to get involved with X12! There are many workgroups to choose from and we welcome anyone who would like to contribute in one or more of them.

You do not need to be an X12 subject matter expert or even understand what X12 does today. Only the passion to learn, collaborate with others internally and externally, and take the initiative to contribute. Some benefits of being a part of X12 are:

- Help influence positive change for both the industry and Optum
- Help Optum build relationships with X12 leadership and other potential partners
- Understand what is happening in the industry and how changes could impact Optum

The time commitment is 2-4 hours a month, based on the workgroup and when they meet. The standing meetings are 3 times a year, in person, and the workgroups meet an average of 2-3 hours a day for 3-4 days.

Please reach out if you are interested in being a part of X12.

- Tara Rose – rose.tara@optum.com

Visit www.X12.org for more information

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Medicare and Medicaid Programs; Prior Authorization NPRM

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Proposed Rule: Medicare and Medicaid Programs; Advancing Interoperability and Improving Prior Authorization Processes

On December 13,2022, the Centers for Medicare & Medicaid Services published a proposed rule to improve the electronic exchange of healthcare data and streamline processes related to prior authorization.

The proposed rule would:

- Place new requirements on Medicare and Medicaid programs: Medicare Advantage (MA) organizations, state Medicaid fee-for-service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs) (with some noted exclusions/exceptions).
- Adds a new Electronic Prior Authorization measure for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program and for MIPS eligible clinicians under the Promoting Interoperability performance category of MIPS.

Most of the implementation dates in the proposed rule would begin in 2026.

The proposed rule also includes 5 Requests for Information (RFIs).

Optum and Change Healthcare collaboratively drafted and submitted comments to the NPRM on March 13, 2023.

Final Action date: December 13, 2025

The federal register proposed rule publication can be found here: https://www.federalregister.gov/documents/2022/12/13/2022-26479/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability

The CMS fact sheet can be found here: https://www.cms.gov/newsroom/fact-sheets/advancing-interoperability-and-improving-prior-authorization-processes-proposed-rule-cms-0057-p-fact

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Administrative Simplification: Attachments NPRM

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Attachments - Overview

Notice of Proposed Rulemaking published on December 21, 2022

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 that require additional clinical information in order to adjudicate, such as: Health Care Claim: (837)
- Health Care Services Review Request and Response (278)

From the NPRM Executive Summary:

"In determining the necessity of a health care service as part of making a coverage decision, health plans often require additional information that cannot adequately be conveyed in the specified fields or data elements of the adopted prior authorization request or health care claims transaction. If adopted as proposed, this proposed rule would support electronic transmissions of this type of information, which should have the effect of decreasing the use of time and resource-consuming manual processes such as mail or fax often used today to transmit this information."

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Proposed Rule: Administrative Simplification: Adoption of Standards for Health Care Attachment Transactions and Electronic Signatures

On December 21,2022, the Office of the Secretary, Department of Health and Human Services, published a proposed rule to adopt standards for "health care attachments" transactions, which would support both health care claims and prior authorization transactions, and a standard for electronic signatures to be used in conjunction with health care attachments transactions.

The proposed rule would:

- Place new requirements on HIPAA covered entities and their business associates to support the proposed transaction standards 24 months after the effective date of the final rule.
- Modify the HIPAA referral certification and authorization transaction standard to move from the X12 278, Version 5010, to theX12 278, Version 6020.

Optum and Change Healthcare collaboratively drafted and submitted comments on March 21, 2023

Final Action Date: April 2024

The federal register proposed rule publication can be found here:
https://www.federalregister.gov/documents/2022/12/21/2022-27437/administrative-simplification-adoption-of-standards-for-health-care-attachments-transactions-and

The CMS fact sheet can be found can be found here: https://www.cms.gov/newsroom/fact-sheets/administrative-simplification-adoption-standards-health-care-attachments-transactions-and-electronic

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Proposed Rule: Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures

The following standards are listed in the Health Care Attachments proposed rule:

Attachments related:

- X12N 275 -Additional Information to Support a Health Care Claim or Encounter (006020X314), September 2014; IBR approved for §162.2002(d).

- X12N 275 -Additional Information to Support a Health Care Services Review (006020X316), August 2021; IBR approved for §162.2002(c).

- X12N 277 -Health Care Claim Request for Additional Information (006020X313), September 2014; IBR approved for §162.2002(e).

- HL7 CDA R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 –March 2017; IBR approved for§162.2002(a).

- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1—Introductory Material, June 2019 with Errata; IBR approved for §162.2002(b).

- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2 —Templates and Supporting Material, June 2019 with Errata; IBR approved for §162.2002(b).

Attachment Type Value Set:

- Logical Observation Identifier Names and Codes (LOINC) developed and maintained by the Regenstrief Institute, Inc.

Prior Authorization Related:

- X12N 278 -Health Care Services Request for Review and Response (006020X315), September 2014; IBR approved for §162.1302(e).

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Attachment Readiness

Optum and Change Healthcare Readiness

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- UnitedHealthcare has implemented unsolicited attachments with Optum.

- UnitedHealthcare is implementing solicited in Q1 of 2024.

- For more information regarding Optum and UHC's solution for attachments visit:

  - UHC Unsolicited Attachments.

Change Healthcare

- Change Healthcare announced a breakthrough all-payer medical attachments capability, which gives providers the ability to dramatically reduce administrative burden associated with document and data exchange with payers.

  - Press Release

- For more information regarding Change Healthcare's attachments solutions visit:

  - Medical Attachments

  - Dental Attachments

CAQH® Core Operating Rules

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CAQH® CORE Operating Rule Recommendations to NCVHS

Updated and New Operating Rules

Overview

On May 23, 2022, CORE submitted a letter to NCVHS asking them to recommend these updated or new operating rules to HHS for federal adoption.

CAQH CORE recommendation letter: https://ncvhs.hhs.gov/wp-content/uploads/2022/09/CAQH-CORE-Board-Letter-to-NCVHS-re-New-Updated-OR-052322-508.pdf

Recommendations

Updated Infrastructure Operating Rules:

- CORE Eligibility and Benefits (270/271)
- CORE Claim Status (276/277)
- CORE Payment and Remittance (835)

Updated Operating Rules:

- CORE Connectivity Rule vC4.0.0
- CORE Eligibility and Benefits (270/271) Data Content Rule

New Operating Rules:

- CORE Eligibility and Benefits (270/271) Single Patient Attribution Data Content Rule
- CORE Attachments Health Care Claims Infrastructure and Data Content Rules
- CORE Attachments Prior Authorization Infrastructure and Data Content Rules

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CAQH® CORE Operating Rule Recommendations to NCVHS

Infrastructure Rule Updates

Infrastructure rules apply across transactions. They establish basic expectations on how the US data exchange system works, like being able to track response times across trading partners. Rules can be used with any version of the standard.

Benefits to the Industry

- All sets of operating rules includes an infrastructure rule that includes requirements for processing mode, response time, system availability, connectivity, acknowledgments, and companion guides.

- Increases system availability requirements up-time to 364 hours annually.

- Quarterly system downtime update allows for longer, less frequent periods of downtime.

- Providers will have improved access to the data they need to better serve the patient at time of service.

Infrastructure Rule Updates

Transactions:

- CORE Eligibility and Benefits (270/271)
- CORE Claim Status (276/277)
- CORE Payment and Remittance (835)

	Existing Rule	Update
Weekly System Availability	86% per calendar week	90% per calendar week
Quarterly System Availability	No current requirement	24 additional hours of system downtime per quarter
Connectivity	Phase 1 & 2 Connectivity Rules (vC.1.1.0 & vC.2.2.0)	vC.4.0.0
Companion Guide	Follow format and flow of CORE Master Companion Guide	Updates to support non-X12 transactions

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CAQH® CORE Operating Rule Recommendations to NCVHS

Connectivity Rule Update: vC4.0.0

The rule is a single, uniform Connectivity Rule supporting administrative and clinical data exchange.

HIPAA-Mandated Rule

- Use of public internet connection and HTTP transport standards to establish industry Safe Harbor
- Username and Password with optional use of digital certificate authentication.
- Use both SOAP and MIME messaging standards.
- Defined metadata to relieve burden of implementation and reduce variances across industry.
- Supports batch and real time
- Specifies error handling processes and messing requirements
- Requires development and implementation of a capacity plan.

Connectivity Rule Updates

- Continues Safe Harbor Connectivity requirements to support SOAP messaging standards
- Incorporates HTTPS and more stringent security standards – TLS 1.2 or higher
- Requirement to use digital certification for authentication – X.509
- Implementation of stronger authorization standards – OAuth 2.0
- Support for the exchange of Attachment transactions – including X12 275, HL7 C-CDA, FHIR, etc.
- Support standard-agnostic REST style web resources
- Messaging in human-readable JAVA format.
- Support API integration and versioning standards.

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CAQH® CORE Operating Rule Recommendations to NCVHS

Benefits to the industry: Connectivity Rule Update: vC4.0.0

➤ Aligns Connectivity Rule vC4.0.0 to support frameworks proposed in the CMS and ONC interoperability rules, including the use of REST and other API technology.

➤ Establishes a Safe Harbor that aligns with existing IT implementations and supports emerging trends for exchanging data. Continues to support SOAP and adding support for using REST.

➤ Supports the intersection of administrative and clinical data exchange by adding support for attachment transactions and publishing a single updated rule for all transactions addressed in the CAQH CORE Operating Rules, even those in development.

➤ Updates the national floor guiding connectivity communication in the industry.

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CAQH® CORE Operating Rule Recommendations to NCVHS

Eligibility & Benefits: Updated and New Data Content Rules

The rule is a single, uniform Connectivity Rule supporting administrative and clinical data exchange.

HIPAA-Mandated Rule

- Real-time response within 20 seconds
- Batch response by next day
- Support detailed responses for 52 Service Type Codes
- Return patient responsibility for co-pay, co-insurance, and deductible
- Return benefit information at least 12 months into the past and up to end of current month
- Standard character usage, cases, prefixes, and suffixes
- Follow defined error reporting using AAA error codes

Data Content Rule Updates

- Tiered benefit coverage must be returned
- Support 126 additional Service Type Codes
- Return maximum and remaining benefits for 10 Service Type Codes
- Indicate if the included Service Type Codes or procedure codes require a prior authorization or certification
- CMS place of service codes must be used for telehealth
- Eligibility and benefit information to be returned at the procedure code level for PT, OT, surgery, and imaging
- NEW: Single Patient Attribution Data Content Rule requires returning patient attribution status and effective dates of attribution

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CAQH® CORE Operating Rule Recommendations to NCVHS

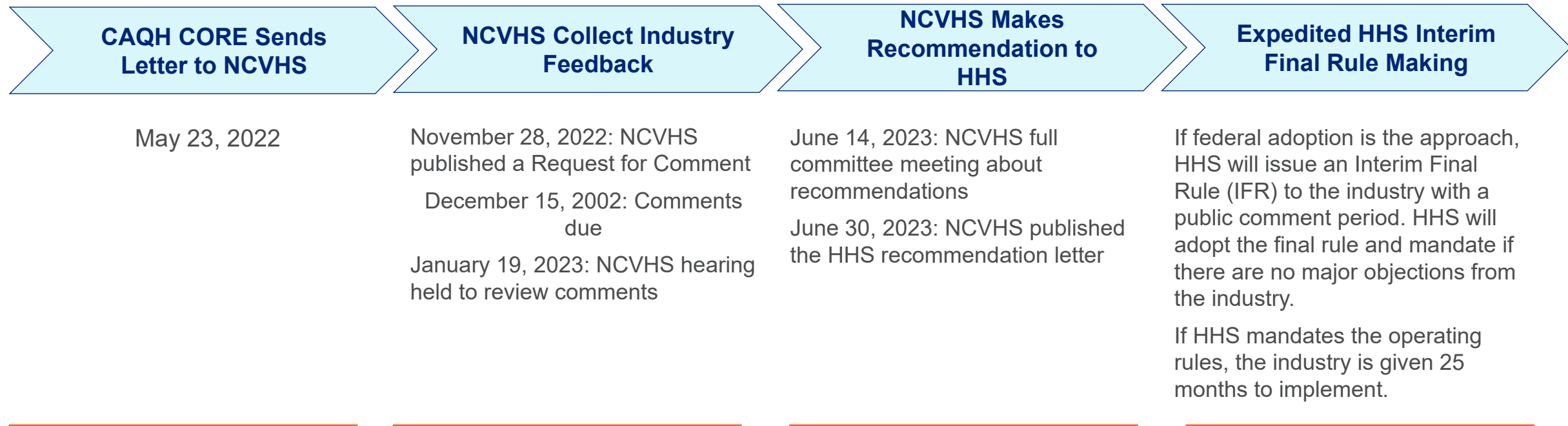Benefits to the industry: Eligibility & Benefits Data Content Rule

➢ Updates to these rules ensures pressing industry needs are met while supporting the opportunity to achieve significant cost and time savings.

➢ Based on the 2022 CAQH Index, this gives the industry an opportunity to save $11.78 per eligibility and benefit verification transaction when switching from a manual to electronic process.

➢ Eligibility and Benefit Operating Rules will be updated as new standard versions are put forward, showing the ongoing collaboration between CORE and standards development organizations (SDOs).

➢ Addresses telemedicine, prior authorization, and dictating the provision for more granular data about enrollee benefits and involvement with value-based payment models.

NCVHS Recommendation to HHS

During the full subcommittee meeting on June 14, 2023, NCVHS announced their recommendation to HHS. NCVHS published the CAQH CORE recommendation letter on June 30, 2023. A copy of that letter can be found at this link: https://ncvhs.hhs.gov/wp-content/uploads/2023/07/Recommendation-Letter-Updated-and-New-CAQH-CORE-Operating-Rules-June-30-2023_Redacted-508.pdf

	Proposed Operating Rules	NCVHS Rulemaking Recommendation
Updated	CORE Eligibility and Benefits (270/271) Infrastructure Rule CORE Claim Status (276/277) Infrastructure Rule CORE Payment and Remittance (835) Infrastructure Rule	Recommended HHS conduct rulemaking to federally adopt
Updated	CORE Connectivity Rule vC4.0.0	Recommended HHS conduct rulemaking to federally adopt
Updated	CORE Eligibility and Benefits (270/271) Data Content Rule	Recommended HHS conduct rulemaking to federally adopt
New	CORE Eligibility and Benefits (270/271) Single Patient Attribution Data Content Rule	Recommended HHS conduct rulemaking to federally adopt
New	CORE Attachments Health Care Claims Infrastructure Rule CORE Attachments Health Care Claims Data Content Rule CORE Attachments Prior Authorization Infrastructure Rule CORE Attachments Prior Authorization Data Content Rule	Do not conduct rulemaking to adopt
	CORE Certification Requirement Language	Do not conduct rulemaking to adopt

CAQH®CORE Recommendation Timeline and Next Steps

CAQH CORE Sends Letter to NCVHS	NCVHS Collect Industry Feedback	NCVHS Makes Recommendation to HHS	Expedited HHS Interim Final Rule Making

CAQH CORE Sends Letter to NCVHS

May 23, 2022

NCVHS Collect Industry Feedback

November 28, 2022: NCVHS published a Request for Comment

December 15, 2002: Comments due

January 19, 2023: NCVHS hearing held to review comments

NCVHS Makes Recommendation to HHS

June 14, 2023: NCVHS full committee meeting about recommendations

June 30, 2023: NCVHS published the HHS recommendation letter

Expedited HHS Interim Final Rule Making

If federal adoption is the approach, HHS will issue an Interim Final Rule (IFR) to the industry with a public comment period. HHS will adopt the final rule and mandate if there are no major objections from the industry.

If HHS mandates the operating rules, the industry is given 25 months to implement.

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CAQH® CORE Operating Rule Restructure

CAQH®CORE has restructured its 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 Active Workgroups

Health Care Claims Subgroup

The subgroup works with CORE to assist with identifying how potential CAQH CORE Data Content Rules can enhance the health care claims workflows with a focus on preliminary opportunity areas.

Review Work Group

This work group's goal is to update, review, and refine existing and newly drafted Operating Rules currently under development per the formal CORE Voting Process.

CORE EFT & ERA Enrollment Data Task Group (EDTG)

This task group updates the EFT & ERA Enrollment Data rules to meet current business and security needs. This includes streamlining workflows, detecting fraud, and simplifying provider enrollment in EFT/ERA.

Value Based Payment (VBP) Subgroup

This subgroup develops CAQH CORE Data Content and Infrastructure Operating Rules affecting the methodologies and administration of value-based payment models.

Want to know more? Reach out to CAQH CORE at CORE@CAQH.org

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CAQH® CORE Operating Rules – Federally Mandated

Operating Rules	X12® TR3	Rules Defined
Eligibility and Benefits	X12/005010X279A1 (270/271)	Data content, Infrastructure, connectivity, response time, companion guide, acknowledgments*. Adopted as Phase I and Phase II.
Claim Status	X12/005010X212A1 (276/277)	Infrastructure, connectivity, response time, companion guide, acknowledgments*. Adopted as Phase II.
Payment and Remittance	• X12/005010X221A1 (835) ACH CCD+	Infrastructure, connectivity, response time, companion guide, acknowledgments*, ERA and EFT reassociation, CARC/RARC/CAGC/NCPDP Reject Reason Code uniform use; ERA and EFT enrollment. Adopted as Phase II and III.

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CAQH® CORE Operating Rules – Voluntary Adoption

Operating Rules	X12® TR3	Rules Defined
Health Care Claims	X12/005010X222A2 (837P) X12/005010X223A3 (837I) X12/005010X224A3 (837D)	Infrastructure, connectivity, response time, companion guide, acknowledgments.
Prior Authorization and Referrals	X12/005010X217 (278)	Data content, proprietary web portal standardization, final determination timeframe, infrastructure, connectivity, response time, companion guide, acknowledgments.
Benefit Enrollment	X12/005010X220A1 (834)	Infrastructure, connectivity, response time, companion guide, acknowledgments.
Premium Payment	X12/005010X218 (820)	Infrastructure, connectivity, response time, companion guide, acknowledgments.
Patient Attribution (Value-Based Payment)	X12/005010X279A1 (270/271)X12/005010X318 (834)	Single patient attribution requirements for the Health Care Eligibility Benefit Inquiry and Response (270/271). Attributed patient roster requirements for member reporting (834): data content, infrastructure, connectivity, response time, companion guide, acknowledgments.
Connectivity Rule v4.4.0	N/A	An update to prior connectivity rules. Not yet rolled to earlier operating rule sets; see http://www.caqh.org/corefor additional information.

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CAQH® CORE Operating Rules – Voluntary Adoption (continued)

Operating Rules	X12® TR3	Rules Defined
Attachments: Prior Authorization	X12/005010X217 (278)X12/006020X315 (275)X12/006020X257 (824)	Requirements for attachments relating to the Health Care Services Request for Review and Response (final ballot issued).
Attachments: Claims	X12/005010X222A2 (837P), X12/005010X223A3 (837I), X12/005010X224A3 (837D) X12/006020X315 (275)X12/006020X257 (824)	Requirements for attachments relating to the claims transactions (final ballot issued).
Eligibility & Benefits Data Content Updates	X12/005010X279A1 (270/271)	Updates to the Eligibility & Benefits Data Content Rule (final ballot issued).
Infrastructure Rule Updates	All transactions	Updates to system availability requirements (final ballot issued).

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OptumInsight & Change Healthcare Operating Rules Readiness

CERTIFIED CORE. CLEARINGHOUSE PRODUCT Phase III

A CAQH Initiative

Optum and 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.

- Optum and Change Healthcare are 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 Optum & Change Healthcare's CORE Voluntary Certification (clearinghouse tab)
- Additional information regarding the Change Healthcare operating rules program can be found on www.hipaasimplified.com.

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Centers for Medicare & Medicaid Services (CMS) Updates

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Medicare Drug Price Negotiation

In August of 2022, the Inflation Reduction Act (IRA) was signed into law. This law provides Medicare with the ability to negotiate the prices of certain high expenditure, single source drugs that do not have a generic or biosimilar competitors.

- On March 15, 2023, CMS published the initial guidance for the

  o Negotiated prices will be effective beginning in 2026.

- On June 30, 2023, CMS issued revised guidance detailing the requirements of the Medicare Drug Price Negotiation Program for the first round of negotiations.

  o First round of negotiations will occur in 2023 and 2024.

- On August 29, 2023, CMS announced the drugs selected for the first cycle of the Medicare Drug Price Negotiation Program.

Fact sheets can be found on CMS.gov.

The States Advancing All-Payer Health Equity Approaches and Development Model (AHEAD)

In the AHEAD Model, CMS will partner with states to redesign statewide and regionwide health care delivery to improve the total population health of a participating state or region by improving the quality and efficacy of care deliver, reducing health disparities, and improving health outcomes.

The AHEAD Model also includes specific payment models for participating hospitals and primary care practices as a tool to achieve Model goals.

CMS aims to strengthen primary care, improve care coordination for people with Medicare and Medicaid, and increase screening and referrals to community resources like housing and transportation to address social drives of health through the AHEAD Model.

Federal Policy and Regulations:
Price Transparency

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The Lower Costs, More Transparency Act

On September 8, 2023, the Lower Costs, More Transparency Act was introduced to Congress. This new legislation requires that hospitals, payers, laboratories, imagining providers/facilities, and ambulatory surgery centers report fees they will charge patients through machine-readable files and mandates healthcare insurers and pharmacy benefit managers (PBM) disclose drug rebates and discounts.

- PBM's would be required to provide employers with semiannual prescription drug spending data. This could include total out-of-pocket spending and formulary placement rationale.

- Medicare Advantage organizations would need to report to HHS when they share common ownership with providers, PBMs, and pharmacies.

- The Medicare Payment Advisory Committee would be mandated to report on vertical integration between these parties.

The LCMT Act details.

Price Transparency Requirements For Hospitals Final Rule

On November 27, 2019, the <u>Price Transparency Requirements for Hospitals to Make Standard Changes Public</u> final rule was published in the Federal Register with an effective date of Jan. 1, 2021, which established requirements for hospitals operating in the United States to create, update, and make public a list of their standard charges for the items and services that they provide.

Below is a summary of major provisions:

- Defines a "hospital," "items and services," and five types of "standard charges" that hospitals are required to make public. Federally owned/operated facilities are deemed to have met all requirements.

- Establishes requirements for making public a machine-readable file for all items and services provided by the hospital.

- Establishes requirements for making public 300 "shoppable" services that are displayed and packaged in a consumer-friendly manner, plus a policy to deem hospitals that offer internet-based price-estimator tools as having met this requirement.

- Establishes methods for monitoring, and actions that would address, hospital noncompliance.

More information on this rule can be found <u>here.</u>

Transparency in Coverage Final Rule

On November 12, 2020, the Transparency in Coverage final rule was published in the Federal Register with an effective date of Jan. 11, 2021, with a goal of bringing greater competition to the private healthcare industry.

- Requires most group health plans, health insurance issuers in the group, and individual markets to disclose price and cost-sharing information to participants, beneficiaries, and enrollees.
- An initial list of 500 shoppable services (determined by CMS) will be required to be available via the internet-based self-service tool for plan years beginning on or after Jan. 1, 2023.
  - The remainder of all items and services will be required for these self-service tools for plan years that begin on or after Jan.1, 2024.

- Most non-grandfathered group health plans or health insurance issuers offering non-grandfathered health insurance coverage in the individual and group markets will be required to make publicly available three separate machine-readable files, including detailed pricing information. Negotiated rates for all covered items and services between the plan or issuer and in-network providers.
  - Historical payments to, and billed charges from, out-of-network providers.
  - Detail the in-network negotiated rates and historical net prices for all covered prescription drugs by plan or issuer at the pharmacy location level.

More information the rule can be found here.

Note enforcement discretion and guidance in the August 2021 CMS FAQ (questions 1-4).

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HIPAA Privacy Rule and Reproductive Health Care NPRM

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Notice of Proposed Rule (NPRM) to Modify the HIPAA Privacy Rule and Reproductive Health Care

On April 12, 2023 the Office for Civil Rights (OCR) provided notice of a proposed rule to modify the HIPAA Privacy Rule to support Reproductive Health Care, proposing to strengthen privacy protections by prohibiting the use or disclosure of PHI by regulated entities.

The proposed changes to the HIPAA Privacy Rule and Reproductive Health Care include:

- Prohibits the use of PHI in a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care.

- The identification of any person for the purpose of initiating such investigations or proceedings.

The proposal, the prohibition would apply where the relevant criminal, civil, or administrative investigation or proceeding is in connection with:

- Reproductive health care that is sought, obtained, provided, or facilitated in a state where the health care is lawful and outside the state where the investigation or proceeding is authorized.

- Reproductive health care that is protected, required, or expressly authorized by federal law, regardless of the state in which the health care is provided.

- Reproductive health care that is provided in the state where the investigation or proceeding is authorized and is permitted by the law of the state in which such health care is provided.

On April 17, 2023, the proposed rule was formally published in the Federal Register a comment window due date of June 16, 2023.

ONC – HHS Security Risk Assessment (SRA) Tool

HHS Security Risk Assessment (SRA) Tool

- ONC and the HHS Office for Civil Rights have released version 3.4 of the popular SRA Tool.

- This tool is designed to aid small and medium sized healthcare organizations in their efforts to assess security risks.

- The latest version of the SRA Tool contains a variety of feature enhancements based on user feedback and public input.

- For more information and access to the SRA Tool, visit the <u>Security Risk Assessment Tool</u> on HealthIT.gov.

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