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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
Q4 2023 Update Published: December 2023

Agenda

1. ASC X12 Subcommittee Update
2. Medicare and Medicaid Programs: Prior Authorization NPRM
3. CAQH®CORE Operating Rules
4. NCVHS Full Committee Meeting
5. Centers for Medicare & Medicaid Services (CMS) Updates
6. ONC Update
7. HL7 Da Vinci FHIR Update
8. Price Transparency
9. HIPPA Privacy Rule and Reproductive Health Care NPRM

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Timeline

2022

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

2023

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

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)

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

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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

X12 will testify at the next NCVHS meeting on 11/29-11/30/2023

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.

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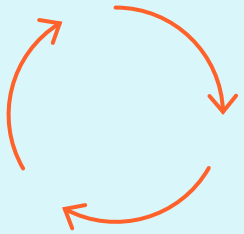
X12 008030X370 Health Care Good Faith Estimate – new guide!

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

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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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X12® Insurance Subcommittee TR3s Version 8040™ - Publication Status

Available in X12's online viewer, Glass

X323 – Health Care Claim: Professional (837)
X324 – Health Care Claim: Institutional (837)
X325 – Health Care Claim: Dental (837)

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X12N Fall Standing Meeting

October 1-11, 2023

Onsite: October 1-5, 2023

Cincinnati, OH

X12 Corporate & Operations Update

Winter Attendance

130 registered

Licensing Update

2,770 various licenses

80 Commercial Use Partners

115 Internal Use Partners

103 Developer Licenses

4,130 Glass and User Licenses

Industry Engagement

Building Relationships

X12's NCVHS Reconsideration Request

WEDI PoC Update Presentation

Education

Info Center

The Info Center can be found at X12.org/Resources

New Documents available:

- X12N Subcommittee Overview
- Repeating Data Elements
- Wordbook Overview

In the Spotlight: Procedures Review Board (PRB)

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Maintenance Request (MR) Update

Maintenance Requests

2023 Statistics as of October:
Completed: 36
In Process: 164

Fall Standing Ballot: 37 MRs
Approved 10/4: 35
Pulled back 10/4: 2
Approved 10/5: 2

View MRs: https://mr.x12.org/
Submit an MR: https://x12.org/resources/forms/maintenance-requests

X12N Maintenance Request Timeline 2023

- Impact Assessments (IA) returned by the last Monday of every odd-numbered months will be in the next subcommittee comment period
- Subcommittee comment periods are 14-calendar days
- Workgroups/Development Groups have 30-calendar days to review, accept, or update the IA after the subcommittee comment period
- Subcommittee MR pass/fail ballots occur at the next in person standing meeting

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Workgroups that met: X12N Business Task Group (TGB)

WG1 Benefit Information	WG2 Claims, Encounters, and Attachments	WG3 Payment Information	WG5 Claim Status and Acknowledgment
270/271 – Health Care Eligibility/Benefit Inquiry and Information Response	837 - Health Care Claim Professional, Institutional, and Dental 275 – Additional Information to Support a Health Care Claim/Encounter	835 – Health Care Claim Payment/Advice	276/277 - Health Care Claim Status Request and Response 277RFAI – Health Care Claim Request for Add'l Information 277CA – Health Care Claim Acknowledgment 277PEND – Health Care Claim Pending Status Information

WG7 P&C Policy Admin	WG10 Services Review	WG15 Provider Information	WG16 Enrollment & Premium Payment	WG22 Health Care Data Reporting
820 – Mortgage Notification, Billing, and Payment	275 - Additional Information to Support a Health Care Services Review 278 - Health Care Services Review Request and Response	274 – Health Care Provider Directory and Health Care Provider Information 838 – Trading Partner Profile	820 – Payroll Deducted and Other Group Premium Payment for Insurance Products 834 – Health care Enrollment and Maintenance	837 – Post-adjudicated Claims Data Reporting 834 – Health Care Enrollment and Maintenance

Note: This is a list of transactions that each workgroup is currently responsible for maintaining. The transaction responsibility can shift, go across multiple workgroups, and/or new transactions added to any workgroup's responsibility list.

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Workgroups that met: X12N Coordination Task Group (TGC) Breakout

WG2 Request for Interpretation	WG8 Regulatory Advisory/Collaboration	WG9 Documentation
Facilitates X12N's responses to Request for Interpretation (RFI)	Facilitates the processing of change requests submitted by the Designated Standards Maintenance Organizations (DSMO), drafts X12N feedback related to regulatory activities, and briefs the subcommittee chair on final health care industry regulations that impact X12N.	Develops technical solutions that address the business requirements developed by X12N TGB work groups

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X12N Harmonization Task Group (TGH)

TGH

Harmonization

Accountable for consistency within and across the technical reports X12N maintains. The group is responsible for developing introductory and explanatory content for inclusion in the technical reports and for ensuring consistent use of segments and elements, consistent wording in situational rules and notes, and for confirming the same or correlated codes are included on the code lists as appropriate.

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Next meeting

- Winter 2024 Standing Meeting
- Sparks, NV
- January 21-31, 2024
- Onsite: January 21-25
- Watch for registration announcements from X12, via the Industry Constituents distribution, and Yammer. Be sure you register!

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

Medicare and Medicaid Programs; Prior Authorization NPRM

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 rule was sent to OMB for finalization on October 25, 2023. OMB has up to 3 months for review

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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CAQH® Core Operating Rules

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.

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

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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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Operating Rules in Development or Modification

Benefit Enrollment and Maintenance Data Content Rule

Benefit Enrollment and Maintenance Infrastructure Rule

Attributed Patient Roster Data Content Rule

Attributed Patient Roster Infrastructure Rule

Health Care Claims Data Content Rule

Claim Acknowledgment Data Content Rule

Payment and Remittance EFT Enrollment Data Content Rule and Companion Guide

Payment and Remittance ERA Enrollment Data Content Rule and Companion Guide

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).

OptumInsight & Change Healthcare Operating Rules Readiness

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.

National Committee on Vital and Health Statistics (NCVHS) Full Committee Meeting

November 29-30, 2023

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NCVHS Full Committee – Modernization 1.0

Modernizing the Standards Driven Healthcare Information Infrastructure & Ensuring the Privacy and Security of Data Exchange

NCVHS to build on previous work:

- Predictability Roadmap
  - Industry-driven standards development and adoption
  - Regular updates: more frequent but smaller updates
  - Enhanced pre-adoption testing
  - Building in value assessment – including Return on Investment (ROI), burden, and societal benefits
- Convergence 1.0 & 2.0 & Intersection of Clinical and Administrative Data Task Force (ICAD)
  - Harmonization and Integration of standards
  - Convergence of administrative and clinical data to meet business needs

NCVHS Full Committee – Modernization 1.0

Additional Initial Topics for the Privacy, Confidentiality, and Security (PCS) Subcommittee

Topic

- Cybersecurity – Strengthen the HIPAA Security Rule – Consider other areas that were not included in the previous recommendation letters.
- Examine “Beyond HIPAA” issues to include a long-term course of action to develop recommendations for the use and protection of health information that is not protected by HIPAA as well as non-covered entities that do not fall under HIPAA.
- Protection of Public Health Data – What might a public health version of HIPAA include?

Partners and Collaborators

- ONC
- CMS
- Office of Civil Rights (OCR)
- Academy Health
- Center for Disease Control (CDC)
- Office of Minority Health (OMH)
- National Institute of Standards Technology (NIST)
- The Cybersecurity and Infrastructure Security Agency (CISA)
- Health Resources and Services Administration (HRSA)
- National Institutes of Health (NIT)
- Office of Women’s Health (OWH)
- Indian Health Service (HIS)

NCVHS Subcommittee on Standards Update

Presented during the NCVHS meeting on November 30, 2023

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Subcommittee on Standards – 2023 Year in Review

X12 and CAQH CORE Recommendation Proposals

- X12 v8020 recommendation for claims and ERA, not recommended at this time
- X12 v8030 recommendation for Claim Status, Benefit Enrollment & Maintenance, and Payroll Deducted and Other Group Premium Payment for Insurance.
  - On hold at the request of CMS
- Recommended to HHS: CAQH CORE Operating Rules for Eligibility & Benefit, Claim Status, and ERA transactions and Connectivity Rule vC4.0.0

Collaborations and Presentations

- Workgroup EDI (WEDI)
  - May: ICD-11 Update
  - November: Subcommittee and ICD-11 Update

Planning Documents

- NCVHS Proposed Project Scope draft: Modernizing the Standards Driven Healthcare Information Infrastructure & Ensuring the Privacy and Security of Data Exchange – Modernization 1.0

X12 v008020 Post-Recommendation Correspondence

Date	Author	Topic
July 27, 2023	X12 Cathy Sheppard, X12 CEO	• Point by point review of NCVHS's rationale for the recommendation. • Request for reconsideration of the Committee's recommendation.
July 28, 2023	FDA Jeffrey Shuren, MD, JD Director, Center for Devices and Radiological Health	• In response to NCVHS' comments specific to stakeholder concerns noted in the Committee's June 14 letter, FDA assured NCVHS that FDA has engaged with stakeholders sufficiently to address unresolved concerns regarding barriers to implementing the use of UDI in the claim transaction, noted by NCVHS. • "We are available to answer any questions you may have and look forward to future developments on this matter." • "We urge the committee to work expeditiously to resolve open issues with the Version of the X12 Standard for Claims and Electronic Remittance Advice Transactions (Version 008020) and recommend adoption so that UDI information can be captured and exchanged."
August 1, 2023	Brigham & Women's Hospital Joel S. Weissman, PhD Dan C. Krupka, PhD	• Request that NCVHS reconsider its decision to recommend that CMS not move forward with the adoption of the new X12 claim standard. • "We are particularly concerned that the decision will indefinitely delay the transmission of unique device identifier (UDI) data from providers to payers thereby indefinitely delaying the establishment of a sorely needed post-market surveillance system for medical implants."
August 24, 2023	University of California, San Francisco et al. Sanket Dhruva, MD, HHS	• Making the case for critical patient, public health, regulatory science, and healthcare delivery reasons to move forward with the update to specifically include the DI portion of the UDI in claims. DI inclusion is beneficial for the entire medical device ecosystem – most importantly to ensure that only safe and effective medical devices are used in clinical care for diagnosis and treatment and to ensure that UDI (and DI) are available to transmit key information that is otherwise not systematically available to patients, clinicians, health systems, regulators, industry, and those engaged in post market safety surveillance for medical devices. • JAMA Internal Medicine Viewpoint "Unique Device Identifiers for Medical Devices at 10 Years" published online August 21, 2023
September 12, 2023	The Clearinghouse Cooperative Exchange Pam Grosze, Board Chair	• Point by point review of NCVHS's rationale for the recommendation • "While we understand the concerns the committee raised, we believe that they are not of great enough concern to postpone these needed updates, and that they can be handled in future versions and instructions."

Subcommittee on Standards – Work Plan for 2024 and Beyond

I. Discuss next steps for the X12 set 2 proposal with Full Committee
II. Compile lessons learned from Standards Development Organizations (SDO) conversations and discuss with Full Committee
III. Compile planning documents and draft a timeline for the Modernization 1.0 priority topics
IV. Other emergent projects, as assigned by the Full Subcommittee

Modernization 1.0 – Topic 1

Process owners: Standards & Privacy, Confidentiality, and Security Subcommittees

Topic	Q4 2023	Q1 2024	Q2+ 2024
Modernizing Standards-Driven Information Infrastructure across the Healthcare Ecosystem	• Draft Project Scope • Discuss with Executive Subcommittee • Discuss/obtain consensus at November FC meeting • Begin work on the timeline, projects, identified, collaborators, resource needs, and workplan	• Continue project scope, resource needs, and workplan with identified collaborators • Discuss with ONC and NSG for additional refinement	• Discuss in April 2024 at the Full Committee meeting

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Modernization 1.0 – Topic 2

Process owners: Standards & Privacy, Confidentiality, and Security Subcommittees

Topic	Partners/Collaborators	Potential Considerations
Review relevance of HIPAA in the current healthcare ecosystem	• ONC • CMS • Office of Burden Reduction & Health Informatics (OBRHI) Office of Civil Rights (OCR) • Federal Trade Commission (FTC) • Office of Minority Health (OMH) • Office of Women's Health (OMH) • Health Resources and Services Administration (HRSA)	• Expand the definition of covered entities • Expand the definition of the HIPAA standards • Expand policy requirements for covered entities • Long-term course of action to develop and implement recommendations for use and protection of health information that is not HIPAA protected • Implications of the Dobbs ruling • Role of AI

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Modernization 1.0

Additional Initial Proposed Topics for the Subcommittee on Standards to consider

Topic

- Where might the NCVHS vision and objectives/recommendations fit into the ONC and HHS 2020-2025 strategic plan?
- Examine mature and emerging standards and how they can co-exist to support current and future business needs
- Review relevance of HIPAA in the current healthcare ecosystem
- Harmonization of Standards and Data

Partners and Collaborators

- ONC
- CMS
- Designated Standards Maintenance Organizations (DSMO)
- Office of Civil Rights (OCR)
- Office of Burden Reduction & Health Informatics (OBRHI)
- Federal Trade Commission (FTC)
- Standards Development Organizations

Strengthening the HIPAA Security Rule

NCVHS was charged with studying and identifying “privacy, confidentiality and information security measures to protect individually identifiable health information”

The Office of Civil Rights (OCR) found that covered entities and business associates were not consistently compliant in implementing the Security Rule’s requirements

Proposed Recommendations to the HIPAA Security Rule:

- Require that covered entities and business associates implement a security program, and the rule specify the same minimum-security controls for all covered entities and business associates.
- Require that covered entities and business associates adopt a risk-based approach in their security program.
- Include a step-by-step risk analysis procedure within the Security Rule.
- Define compensating controls more specifically in the Security Rule and provide examples.
- Reinforce the need to evaluate AI systems and data within the Privacy and Security Rule as part of risk analysis for all and new technology.
- Standardize cyber incident reporting and harmonize any such requirements in the HIPAA rules with incident reporting provisions applicable to healthcare critical infrastructure actors and healthcare federal contractors.

CMS Update to NCVHS – Administrative Simplification Enforcement

Enforcement

HIPAA Non-Security/Privacy Enforcement by NSG

Potential violations of rules for:

- Electronic Transactions
- Operating Rules
- Code Sets
- Unique Identifiers

File a complaint through:

- Administrative Simplification Enforcement and Testing Tool (ASETT)

HIPAA Security/Privacy Enforcement By OCR

Potential violations of:

- Health information privacy rights
- Privacy, Security, or Breach Notifications Rules

File a complaint through:

- OCR Complaint Portal
- Health Information Privacy Complaint Package

CMS Update to NCVHS – Administrative Simplification Enforcement

HIPAA Enforcement Clarification

NSG enforces Administrative Simplification Standards

Responding to complaints about non-compliance

Conducting proactive compliance reviews

Covered Entities

- Healthcare providers that submit transactions electronically
- Health Plans
- Clearinghouses

Goals

Reduce the burden on compliant entities who conduct transactions with trading partners that aren't compliant

Streamline billing and insurance-related functions allowing providers and health plans to spend less time on these tasks

CMS Process can be found here:

CMS Process Flow for Complaints

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CAQH® CORE Update to NCVHS – Certification Enforcement

Organizations that create, transmit, or use the healthcare administrative and financial transactions address by CORE Operating Rules can become CORE-Certified. To achieve certification, organizations must:

- Abide by CORE Certification Policies
- Adopt CAQH CORE Operating Rules
- Pass CORE Certification Testing
- Attest to HIPAA compliance

CORE Certification Enforcement

- The policy allows the industry to monitor, regulate, and correct itself to avoid or prepare for enforcement audits and penalties.
- The process is a progressive and collaborative approach. An enforcement complaint requires documentation of five instances of non-conformance.

Entities that can file a complaint

- Any healthcare provider that is an end-user of a CORE-certified product/service if the provider believes the CORE-certified organization is not conforming to the CORE Operating Rules
- Any CORE-certified organization involved in an alleged non-conformant transaction, e.g., vendors, clearinghouse, health plans, etc.

ICD-11 NCVHS Workgroup Update

Second RFI issued on October 16, 2023 – comments are due January 12, 2024

- The RFI is posted in the Federal Register

NCHVS is seeking input on ICD-11:

- Content requirements
- Burden reduction opportunities
- Governance
- Impact on standards, systems, workforce, and resource needs

Next Steps:

- 2023 – Completed: Deliver the Phase 1 Workgroup Findings Report to NCVHS Full Committee
- 2024 – Analyze responses received from second RFI – then report to NCVHS Full Committee with findings
- 2024 – Develop additional/new findings, analyses, discussion points

ICD-11 NCVHS Workgroup on Timely and Strategic Action to Inform ICD-11 Policy

ICD-11 Facts

- Adopted by the WHO in 2019
- Became effective January 1, 2022
- Three components of ICD-11 use:
  - Mortality: US adoption is a requirement of membership in WHO; non-discretionary
  - Morbidity: US health care and public health
  - Morbidity: US health care billing and payment. US adoption would have to be as a HIPAA-mandated medical code set

ICD-11 Activities

- August 2019: expert roundtable meeting
- November 2019: NCVHS recommended that HHS evaluate the impact of different approaches to the transition and implementation of ICD-11 in the US for mortality and morbidity classification to guide policy and decision making.
- September 2021: NCVHS recommended that HHS conduct research to evaluate the impact of different approaches to the transition to and implementation of ICD-11. Conduct outreach and communicate regularly to the US health care industry about the ICD transition.

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ICD-11 NCVHS Workgroup on Timely and Strategic Action to Inform ICD-11 Policy, continued

Goals for US Implementation

- Avoid a repeat of the protracted and costly US transition from ICD-9 to ICD-10 by developing a shared understanding of lessons from the ICD-10 planning process/transition, and understanding differences between ICD-10 and ICD-11.
- Conduct research to inform a relatively smooth transition from ICD-10 to ICD-11 for morbidity coding.
- Identify work needed to avoid the need for a Clinical Modification.
- Identify key topics and messages to communicate to the industry to foster early stakeholder engagement and preparation for the transition to ICD-11.

Phase 1 Key Events

- RFI issued on June 13, 2023
  - 18 responses received. Responses can be found here.
- August 3, 2023: Expert roundtable meeting
  - Presents opportunities supporting modernization, potential for burden reduction, and automation.
  - Stakeholder understanding of technical implementation costs is lacking. Coordinated governance and funding are needed.
  - Education and workforce challenges and changes could be profound.

Centers for Medicare & Medicaid Services (CMS) Updates

Final Rules for CY2024 Medicare Payment Policies

Physician

- Overall payment rates under the PFS will be reduced by 1.25% in CY 2024 comparted to CY 2023
- Significant increases in payment for primary care and other kinds of direct patient care
- Payment when practitioners train caregivers to support patients with certain diseases or illnesses (e.g. dementia) in carrying out a treatment plan
- Finalizing coding and payment changes to better account for resources involved in furnishing patient-centered care involving a multidisciplinary team of clinical staff and other auxiliary personnel
- Medicare Part B coverage and payment under the Medicare Physician Fee Schedule for services of marriage and family therapists (MFTs) and mental health counselors (MHCs) when billed by these professionals

Final Rules for CY2024 Medicare Payment Policies, continued

Outpatient PPS – Hospital Price Transparency

- Standardizing of Files and Data Elements for Enhanced Consumer Access and Readability
- Improved Accessibility for Oversight – footers with links, and text files with locations
- Affirmation statements required along with additional enforcement

Home Health

- Medicare payments to HHAs in C 2024 will increase in the aggregate by 0.8% or $140 million compared to CY 2023, based on the finalized policies
- Significant negative adjustment due to changes in payment policy

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 Medicare Drug Price Negotiation Program.
  - 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.
  - 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.

The Office of the National Coordinator (ONC) for Health IT

- Published Version 1.1 of the Common Agreement on November 3, 2023. Version 1.1 updates Version 1.0, published in January 2022, in preparation for data sharing through the Trusted Exchange Framework and Common Agreement (TEFCA)

- The updated Common Agreement includes specific technical and clarifying changes that are accompanied by updates to the Qualified Health Information Network (QHIN) Technical Farmwork (QTF), FHIR Roadmap, and standard operating procedures

HL7 FHIR® Update

HL7 – The Da Vinci Project

The Da Vinci Project is a “private-sector initiative that accelerates the adoption of HL7 FHIR as the standard to support and integrate value-based care (VBC) data exchange across communities” with the goal of helping providers and payers positively impact clinical, quality, cost, and care management outcomes. These impacts will enable providers to have the right data when they need it for patient-centered care.

Optum (including legacy Change Healthcare) and United Healthcare are members of the Da Vinci Project.

The roundtables are open to Da Vinci Project members and members of the public:

The Da Vinci Project site can provide more information.

The HL7 Confluence site has more detailed information about the Da Vinci Project and the ability to join the Da Vinci Listserv.

HL7 Gender Harmony Project

The goal of the Gender Harmony Project is to formerly integrate both sex and gender vocabulary into clinical care because sex and gender are no interchangeable. Both sex and gender influence health outcomes and gender-marginalized individuals face significant barriers to adequate and culturally responsive healthcare, which leads to numerous health disparities for these individuals. The project explains the meaning and use of:

- Gender Identity (GI)
- Sex Parameter for Clinical Use (SPCU)
- Recorded Sex or Gender (RSG)
- Name to Use (NtU)
- Pronouns

The project participants were members included Da Vinci, FHIR, ONC, X12, health plans, and vendors/clearinghouses.

HL7 Cross Paradigm Implementation Guide: Gender Harmony - Sex and Gender Representation, Edition 1 published on September 29, 2023.

History on the group's work can be found on the Gender Harmony Confluence site.

HL7 Patient Cost Transparency (PCT) Project

The Patient Cost Transparency Project enables standard exchange of healthcare cost for items, services, and collection of services among payers, providers, and patients. The goal is to support transparency for patients with accurate and timely access to cost of healthcare prior to services being rendered so patients can be better agents of their healthcare dollars. The guide creates standards to reduce administrative burden based on the regulations in the No Surprises Act. Standards:

- Good Faith Estimates (GFE)
- Advanced Explanation of Benefits (AEOB)

The Patient Cost Transparency Implementation Guide specification is a Standard for Trial Use.

To get involved, visit the PCT Confluence site.

Federal Policy and Regulations: Price Transparency

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 Price Transparency Requirements for Hospitals to Make Standard Changes Public 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 here.

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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).

HIPAA Privacy Rule and Reproductive Health Care NPRM

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.

Agenda stage of rulemaking: Final Rule Stage

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