CHANGE HEALTHCARE REGULATORY AND STANDARDS UPDATE

Q2 2022 Update Published: May 16, 2022

Q3 2022 Update Available: August 15, 2022

5.16.2022

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Timeline

2020

01/01/2020
End of Medicare's HICN to MBI transition period; MBIs must be used in all administrative transactions

05/01/2020
Final rules issued: ONC and CMS on interoperability, patient access, and information blocking; compliance deadlines 2020 through 2023

11/12/2020
Transparency In Coverage final rule issued

12/27/2020
No Surprises Act signed into law

2021

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 I"

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"

2022

01/19/2022
ONC released USCDI v3 for comment

01/24/2022
- RFI for ePA (electronic pre-authorization) issued with 60-day comment period, ending 03/25/2022

Anticipated
- X12® finalization of version 8020 TR3s; recommend adoption to CMS
- Final rule on attachments
- CMS to formally launch Compliance Review Program for providers
- Additional rulemaking for the remaining No Surprises Act provisions

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Section 1

ASC X12N SUBCOMMITTEE VERSION 8020™ FINALIZATION

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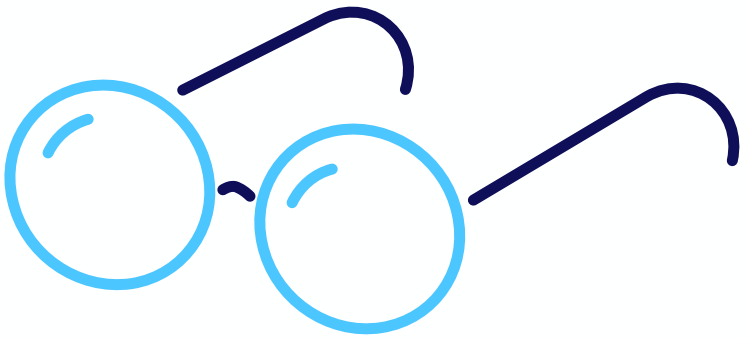
X12N Version 7030™—TR3 Development Complete

X12N v7030™ /8010™ /8020™ Finalization



Development of version 7030™ of the X12N Insurance Subcommittee TR3s is now complete and is available online using X12®'s Glass viewer.

See X12®'s Licensing Program for information on accessing Glass.

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Promotion of Version 7030™ TR3s to Version 8020™

- In preparation for a recommendation for adoption of updated TR3s under HIPAA, X12® has promoted Version 7030™ TR3s to Version 8020™.
- The promotion to Version 8020™ aligned the X12N TR3s with the base X12 Standard Version 8020™.
- From a functional perspective, there will be no substantive changes to the 7030™ TR3s and no loss of or change to functionality added with 7030™.
- The promotion to Version 8020™ also positions X12® to maintaining their proposed Annual Release Cycle, which began in 2019.

For more information on the Version 8020™ promotion and on the Annual Release Cycle, visit www.X12.org

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X12® Insurance Subcommittee TR3s Version 8020™—Publication Status

- 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 Eligibility Benefit Inquiry and Response (270/271)—**7030™ Pending Promotion to 8020™**
- 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)
- Plan Member Reporting (834)
- Health Insurance Exchange: Enrollment (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)

Under Non-Versioned Technical Reports>Reference Models (TR2):

- Code Value Usage in Eligibility Benefit Inquiry and Subsequent Response

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Recommendation for Federal Adoption

Visit
www.X12.org

- At X12®'s Winter 2022 Standing Meeting in January, X12® announced that the process of recommending Version 8020™ of the HIPAA transactions to the U.S. Department of Health and Human Services (HHS) for adoption under federal regulation will begin this year.
- It is expected that transactions will be recommended in a sequenced manner, based on business priority and logical sets of transactions. Details have not yet been announced.
- In the regulatory workflow, the National Committee on Vital and Health Statistics (NCVHS), advisory body to HHS, will perform the initial assessment via hearings, ROI/budgetary considerations, and other assessments.
- The NCVHS will then make its recommendations to HHS.

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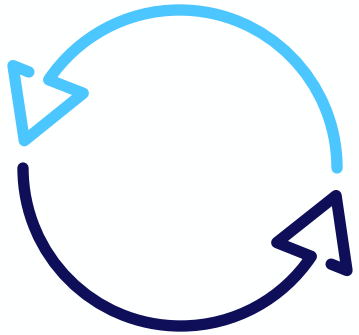
X12® Annual Release Cycle



Visit
www.X12.org for developments

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

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X12N—Participation in TR3 Development

Change Healthcare Encourages Your Participation

- Change Healthcare actively participates in the development of the X12N Insurance Subcommittee TR3s.
- All entities are encouraged to participate.
- The X12® data maintenance process allows anyone to request a change to a TR3 or the X12® Standard. To submit a data maintenance request, see https://x12.org/resources/forms/maintenance-requests.

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Section 2

ATTACHMENTS NPRM

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Attachments—Overview

Anticipated
- X12N recommended adoption to CMS
- Proposed or Final Rule on Attachments

- 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 Claims/Encounters (837)
  - Health Care Services Review-Request for Review and Response (278)
- **A proposed rule establishing attachment standards and operating rules was scheduled for January 2022, per the Unified Agenda of Regulatory and Deregulatory Actions** (RIN 0938-AT38).

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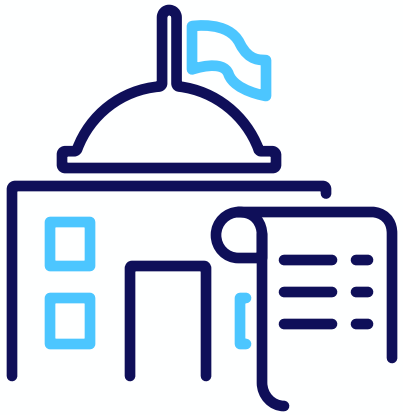
Attachments—Regulatory Roadmap



- NCVHS hearing was held on Feb. 16, 2016 with NCVHS Letter of Recommendation sent to HHS on July 5, 2016.
- Unified Agenda (RIN 0938-AT38) indicated that a proposed rule was scheduled for January 2022 with Public Comment Period.
- Proposed rule is expected to:
  - Adopt standards for health care attachments transactions and electronic signatures to be used in conjunction with health care attachments transactions.
  - Modify the standard for the referral certification and authorization transaction.
  - Adopt standards for electronic signatures to be used in conjunction with health care attachments transactions.

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Attachments—Recommendations

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

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

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

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Attachments—Change Healthcare Readiness

- Change Healthcare announced 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

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Section 3

CAQH® CORE OPERATING RULES

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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.

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CAQH® CORE Operating Rules—Federally Mandated

Operating Rules	X12® TR3	Rules Define
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	X12/005010X221A1 (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.

* Regulations exclude acknowledgment-related requirements.

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CAQH® CORE Operating Rules—Voluntary Adoption

Operating Rules	X12® TR3	Rules Define
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.

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CAQH® CORE Operating Rules—Voluntary Adoption (cont.)

Operating Rules	X12® TR3	Rules Define
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/core for additional information.
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).

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CAQH® CORE Operating Rules—Voluntary Adoption (cont.)

Operating Rules	X12® TR3	Rules Define
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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Change Healthcare Operating Rules Readiness

Change Healthcare clearinghouse services are **CORE Phase III Certified.**

To become CORE Phase III certified, entities must be CORE certified on the earlier phases. Our CORE Phase III certification serves as Change Healthcare's exhibit of Operating Rule readiness.

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

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

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Section 4

CMS COMPLIANCE REVIEW PROGRAM

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CMS Compliance Review Program

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

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

- In April 2019, CMS began its formal Compliance Review Program by selecting nine HIPAA-covered entities for compliance reviews. Any health plan or clearinghouse, not just those working with Medicare or Medicaid, can be selected.
- Also in April 2019, CMS launched a volunteer Provider Pilot Program to test the process for reviewing HIPAA Administrative Simplification Rules compliance among providers.

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

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HHS Optimization Program Certification

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

Certificate of Completion

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Section 5

FEDERAL POLICY AND REGULATIONS

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PRICE TRANSPARENCY

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PRICE TRANSPARENCY REQUIREMENTS FOR HOSPITALS FINAL RULE

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Price Transparency Requirements for Hospitals

On Nov. 27, 2019, the Price Transparency Requirements for Hospitals to Make Standard Charges 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 the rule can be found **here**.

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TRANSPARENCY IN COVERAGE FINAL RULE

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Transparency in Coverage Final Rule

On Nov. 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 on the rule can be found **here**.

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

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NO SURPRISES ACT

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No Surprises Act—Summary Overview

On Dec. 27, 2020, the No Surprises Act was signed into law as part of the Consolidated Appropriations Act of 2021, Public Law 116-260.

The No Surprises Act seeks to protect consumers from surprise medical bills and includes transparency regarding in-network and out-of-network deductibles, out-of-pocket limitations, and other health plan and provider provisions and patient protections.

Most sections of the act reflect a legislated effective date of Jan. 1, 2022. The Department of Health and Human Services, Department of the Treasury, and Department of Labor are developing regulations to implement the many provisions of the act.

Please reference the Consolidated Appropriations Act of 2021 Bill for the full text of the No Surprises Act provisions.

On August 20, 2021, CMS issued a guidance document entitled "FAQS About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49."

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Part I Interim Final Rule

7/13/21: "Requirements Related to Surprise Billing; Part I"

- Published in Federal Register as interim final rule with requests for comments.
- Comment window closed on 9/7/21.
- Part I Regs are silent on Section 111 – Advanced EOB.

Federal Register Link

CMS Fact Sheet

Notable inclusions on Part I, but not limited to:

- Bans balance billing for emergency services. Cost sharing for emergency services must be determined on an in-network basis.
- Requires that patient cost sharing—such as copayments, co-insurance, or a deductible—for emergency services and certain non-emergency services provided at an in-network facility cannot be higher than if such services were provided by an in-network provider; and any cost-sharing obligation must be based on in-network provider rates.
- Prohibits OON charges for items or services provided by an OON provider at an in-network facility, unless certain notice and consent is given. Providers and facilities must provide patients with a plain-language consumer notice explaining that patient consent is required to receive care on an OON basis before that provider can bill the patient more than in-network cost-sharing rates.

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Air Ambulance Services NPRM

9/16/21: "Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement"

- Published in Federal Register as notice of proposed rulemaking with requests for comments.
- Comment window closed on 10/18/21.

Federal Register Link

CMS Fact Sheet

Notable inclusions, but not limited to:

- New reporting requirements regarding air ambulance services.
- New disclosures and reporting requirements regarding agent and broker compensation.
- New procedures for enforcement of Public Health Service Act (PHS Act) provisions against providers, health care facilities, and providers of air ambulance services.
- New disclosure and reporting requirements applicable to issuers of individual health insurance coverage and short-term, limited-duration insurance regarding agent and broker compensation.
- Revisions to existing PHS Act enforcement procedures for plans and issuers.

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Part II Interim Final Rule

10/7/21: "Requirements Related to Surprise Billing; Part II"

- Published in Federal Register as interim final rule with requests for comments.
- Part II Regs are silent on Section 111 – Advanced EOB.
- Comment window closed on 12/6/21.

Federal Register Link

CMS Fact Sheet

Notable inclusions on Part II, but not limited to:

- Establishes the federal independent dispute resolution (IDR) process that OON providers, facilities, providers of air ambulance services, plans, and issuers in the group and individual markets may use to determine the OON rate for applicable items or services after an unsuccessful open negotiation.
- Addresses good faith estimates of health care items and services for uninsured or self-pay individuals and the associated patient-provider dispute resolution process. The HHS-only interim final rules apply to selected dispute resolution (SDR) entities, providers, facilities, and providers of air ambulance services.

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Third Interim Final Rule

11/23/21: "Prescription Drug and Health Care Spending"

- Published in Federal Register as interim final rule with requests for comments.
- Third IFR issued in 2021.
- Comment window closed on 1/24/22.

Federal Register Link

CMS Fact Sheet

Notable inclusions, but not limited to:

- Provisions are applicable to group health plans and health insurance issuers offering group or individual health insurance coverage.
- Requires applicable plans to submit certain information about prescription drugs and health care spending to federal departments to increase transparency.

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Change Healthcare NSA Capability Grooming

- Change Healthcare convened a multidivisional internal task force to evaluate the Act's requirements and align with and leverage our existing capabilities and strengths.
- We are engaging industry standards and advocacy groups to assure systematic and standardized approaches to technical components.
- We have opened readiness dialogues with plans and third-party administrators.
- We welcome collaborative partnerships to align our solutioning to meet client needs within regulated effective dates.
- We are continuing to explore several approaches, all within current strengths and capabilities as to be preemptive and adaptable as subsequent regulations are published.

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Change Healthcare Solutions

We offer, and continue to develop, solutions tailored to help you comply with the No Surprises Act, support billing transparency, and help you implement consumer cost protections. Solutions include:

- Medical Network
- API Solutions
- Cost Transparency
- TrueView™
- AEOB Workflow (new)
- Communication EOB and ID Cards
- ConnectCenter
- Authorization and COB

Please reach out to your account representative for more information.

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No Surprises Act—Section Breakdown (Summary)

Section 102. Health insurance requirements regarding surprise medical billing.

In general, requires health plans to hold patients harmless from surprise medical bills. For certain services, patients are only required to pay their in-network cost-sharing amount (e.g., deductibles, coinsurance, copayments, or similar charges).

- Coverage of Emergency Services: This requires health insurers to cover emergency services without prior authorization regardless of whether the health care provider furnishing services is a participating provider or a participating emergency facility.
- Coverage of Nonemergency Services Performed by Nonparticipating Providers at Certain Participating Facilities: This prevents health insurers from imposing a cost-sharing requirement that is greater than the cost-sharing requirement that would apply if furnished by a participating provider. Cost-sharing payments count toward any in-network deductible and out-of-pocket maximums (as applicable) in the same manner as if furnished by a participating provider.

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No Surprises Act—Section Breakdown (Summary)

Section 103. Determination of out-of-network rates to be paid by health plans; independent dispute-resolution process.

Encourages reimbursement resolution through open negotiation and establishes an independent resolution process through which health providers and insurers can resolve out-of-network reimbursement issues.

- Allows a 30-day open-negotiation period for providers and insurers to settle out-of-network claims.
- If the parties are unable to reach a negotiated agreement, they may access a binding arbitration process—referred to as Independent Dispute Resolution (IDR)—in which one offer prevails.
- The IDR process will be administered by independent, unbiased entities, with no affiliation to providers or insurers.

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No Surprises Act—Section Breakdown (Summary)

Section 104. Health care provider requirements regarding surprise medical billing.

- Prohibits out-of-network facilities and providers from sending patients balance bills for more than the in-network cost-sharing amount; in the surprise billing circumstances defined in Section 102.
- Prohibits certain out-of-network providers from balance-billing patients unless the provider gives the patient notice of their network status and an estimate of charges 72 hours prior to rendering out-of-network services, and the patient provides consent to receive out-of-network care. In the case of appointments made within 72 hours of receiving services, the patient must receive the notice the day the appointment is made and consent to receive out-of-network care.

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No Surprises Act—Section Breakdown (Summary)

Section 105. Ending surprise air ambulance bills.

- Patients are held harmless from surprise air ambulance medical bills. Patients are only required to pay the in-network cost-sharing amount for out-of-network air ambulances (including attributing the bill to the in-network deductible). Air ambulances are barred from sending patients balance bills for more than the in-network cost-sharing amount.
- Follows a similar open negotiation and Independent Dispute Resolution (IDR) as summarized in Section 103 to resolve out-of-network reimbursement issues.

Section 106. Reporting requirements regarding air ambulance services.

- Requires air ambulance providers to submit two years of cost and metrics data to the Secretary of HHS and the Secretary of Transportation, and insurers to submit two years of claims data related to air ambulance services to the Secretary of HHS. Requires the secretaries to publish a comprehensive report summarizing the information submitted.
- Establishes an advisory committee to establish quality, patient safety, and clinical-capability standards for air ambulances.

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No Surprises Act—Section Breakdown (Summary)

Section 107. Transparency regarding in-network and out-of-network deductibles and out-of-pocket limitations.

- Requires health plans offering group or individual health insurance to include on the participant's insurance card the amount of the in-network and out-of-network deductibles, in-network and out-of-network out-of-pocket maximum limitations, and a telephone number and website address through which plan participants can seek assistance.

Section 108. Implementing protections against provider discrimination.

- Requires the Secretary of HHS, Secretary of Labor, and Secretary of the Treasury to issue a rule implementing protections against provider discrimination.

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No Surprises Act—Section Breakdown (Summary)

Section 109. Reports.

- Requires HHS to conduct a study on the effects of the provisions in the Act.
- Requires the Government Accountability Office (GAO) to submit to Congress a report on the impact of surprise billing provisions and a report on the adequacy of provider networks to include recommendations to improve the adequacy.

Section 110. Consumer protections through application of health-plan external review in cases of certain surprise medical bills.

- Allows for an external review to determine whether surprise-billing protections are applicable when there is an adverse determination by a health plan or issuer.

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No Surprises Act—Section Breakdown (Summary)

Section 111. Consumer protections through health-plan requirement for fair and honest advance-cost estimate.

- Requires health plans offering group or individual health insurance to provide an "Advanced Explanation of Benefits" to give patients transparency for each scheduled item or service, including:
  - The network status of the provider or facility.
  - Good faith estimates of provider or facility charges, the plan's payment responsibility, and the patient's payment responsibility.
  - Additional disclaimers.

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No Surprises Act—Section Breakdown (Summary)

Section 112. Patient protections through transparency and patient-provider dispute resolution.

- Health care providers and facilities must verify, three days in advance of service and not later than one day after scheduling of service, what type of coverage the patient is enrolled in and provide notification of the good faith estimate of the expected charges for scheduled items or services.
- Requires the Secretary of HHS to establish a patient-provider dispute-resolution process for uninsured individuals for charges that are substantially in excess of the estimate.

Section 113. Ensuring continuity of care.

- If a provider changes network status, "continuing care patients" have up to a 90-day period of continued coverage at in-network cost-sharing rates to allow for a transition of care to an in-network provider. The plan or issuer must notify continuing-care patients of network changes and their right to elect to receive continued transitional care.

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No Surprises Act—Section Breakdown (Summary)

Section 114. Maintenance of price-comparison tool.

- Beginning on or after Jan. 1, 2022, a plan or issuer is required to offer price-comparison guidance to consumers by telephone and website to compare the amount of cost sharing that an individual would be responsible for paying when furnished with a specific item or service by a given provider.

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No Surprises Act—Section Breakdown (Summary)

Section 115. State all payer claims databases.

- Establishes a grant program for eligible states to establish or improve a State All Payer Claims Database. Grants will be awarded for a period of three years in an amount of $2,500,000 ($1,000,000 in Year One and Year Two, $500,000 in Year Three).
- Requires grant recipients to make data available to authorized users, including researchers, employers, health insurance issuers, third-party administrators, and health care providers for quality improvement and cost-containment purposes. The secretary may waive these requirements if a State All Payer Claims Database is substantially in compliance.
- Requires the secretary to establish a standardized reporting format and guidance for the voluntary reporting by group health plans to State All Payer Claims Databases of medical claims, pharmacy claims, dental claims, and eligibility and provider files that are collected from private and public payers.

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No Surprises Act—Section Breakdown (Summary)

Section 116. Protecting patients and improving the accuracy of provider-directory information.

- Requires plans and issuers to establish a database and verification process to ensure up-to-date directories of their in-network providers and facilities, available to patients online, or within one business day of a telephone inquiry.
- Patients that relied on incorrect provider-network information would only be subject to in-network cost-sharing amounts.
- Plans and issuers are required to disclose patient protections against balance billing.

Section 117. Advisory committee on ground ambulance and patient billing.

- Requires the secretaries to establish an advisory committee for reviewing options to improve disclosure of charges and fees for ground ambulance services to inform consumers of insurance options and protect consumers from balance billing.
- Requires a report on recommendations from the advisory committee no later than 180 days after the committee's first meeting.

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HIPAA Privacy Rule NPRM

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Notice of Proposed Rule (NPRM) to Modify the HIPAA Privacy Rule

On December 10, 2020, the Office for Civil Rights (OCR) provided advance notice of a proposed rule to modify the HIPAA Privacy Rule to support individuals' engagement in their care, remove barriers to coordinated care, and reduce regulatory burdens on the health care industry.

The proposed changes to the HIPAA Privacy Rule include:

- Strengthening individuals' rights to access their own health information, including electronic information.
- Improving information sharing for care coordination and case management for individuals.
- Facilitating greater family and caregiver involvement in the care of individuals experiencing emergencies or health crises.
- Enhancing flexibilities for disclosures in emergency or threatening circumstances, such as the opioid and COVID-19 public health emergencies.
- Reducing administrative burdens on HIPAA-covered health care providers and health plans, while continuing to protect individuals' health information privacy interests.

On January 21, 2021, the proposed rule was formally published in the Federal Register with a comment window due date of March 22, 2021. On March 9, 2021, OCR announced a 45-day extension of the public comment period extending the comment window due date to May 6. 1,436 comments were submitted during the public comment window.

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ONC CERTIFICATION AND INFORMATION BLOCKING RULE

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21st Century Cures Act

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

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Overview of ONC's Regulation

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

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ONC Cures Act Final Rule—Additional Information

Available at: https://www.healthit.gov/curesrule/

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REDUCING PROVIDER AND PATIENT BURDEN BY IMPROVING PRIOR AUTHORIZATION

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CMS NPRM to Address Prior Authorization

On December 10, 2020, CMS provided advance notice of a proposed rule to place new requirements on Medicaid and CHIP-managed care plans, state Medicaid and CHIP fee-for-service programs, and qualified health plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs) to improve the electronic exchange of health care data and streamline processes related to prior authorization.

This rule has been withdrawn.

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ONC RFI for Electronic Prior Authorization

On January 24, 2022 the Office of the National Coordinator for Health IT (ONC), Health and Human Services (HHS), published a "Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria."

The department was seeking input from the public regarding electronic prior authorization standards, implementation specifications, and certification criteria that could be adopted within the ONC Health IT Certification Program. Responses will be used to inform potential future rulemaking.

Comments were accepted through March 25, 2022.

Federal Register Link

Press Release

More Information

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Section 6

CHANGE HEALTHCARE ACCREDITATIONS AND CERTIFICATIONS

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Change Healthcare Accreditations and Certifications

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

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