CHANGE HEALTHCARE REGULATORY AND STANDARDS UPDATE

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Change Healthcare Accreditations and Certifications

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Timeline

2021

2022

2023

01/21/2021

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

07/13/2021

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

01/24/2022

RFI for ePA (electronic pre-authorization)

Q2 2022

X12 and CAQH CORE submit recommendations to NCVHS

07/28/2022

USCDI v3 published

12/13/2022

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

12/21/2022

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

01/18-19/2023

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

03/13/2023

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

03/21/2023

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

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Section 1

ASC X12N SUBCOMMITTEE VERSION 8020™ FINALIZATION



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 <u>Annual Release</u>
 <u>Cycle</u>, 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 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 (8371)
- 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



Recommendation for Federal Adoption

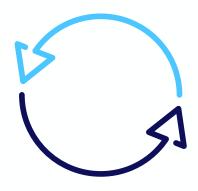


- In June 2020, X12 submitted its initial recommendation to NCVHS:
 - Claim Submission / Remittance Advice (June 2022)
 - 008020X323 | Health Care Claim: Professional (837)
 - 008020X324 | Health Care Claim: Institutional (837)
 - 008020X325 | Health Care Claim: Dental (837)
 - 008020X322 | Health Care Claim Payment/Advice (835)
- Via the regulatory process, the National Committee on Vital and Health Statistics (NCVHS)—advisory body to HHS— held a hearing on January 18th, 2023, to solicit industry feedback regarding the recommendations.
- The NCVHS is then expected to make its recommendations to HHS based on the January 2023 hearing feedback.

More info at: x12.org/news-and-events/x12-recommendations-to-ncvhs & https://ncvhs.hhs.gov/meetings/standards-subcommittee-hearing/



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.



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.
- Change Healthcare is also participating in the X12 Proof of Concept pilot program.
- 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.



Section 2

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 feefor-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).

Comments must be submitted no later than 5 p.m. on March 13, 2023.

Link to the federal register proposed rule publication: https://www.federalregister.gov/documents/2022/12/13/2022-26479/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability

Link to the CMS fact sheet: https://www.cms.gov/newsroom/fact-sheets/advancing-interoperability-and-improving-prior-authorization-processes-proposed-rule-cms-0057-p-fact



Section 3

Administrative Simplification: Attachments NPRM



Attachments—Overview



Notice of Proposed Rulemaking published on December 21, 2022

- The Administrative Simplification provisions under the ACA include adoption of transaction standards and operating rules for attachments.
- Electronic attachments are electronic transactions that support the transmission of clinical documentation for claims and prior authorizations that require additional clinical information in order to adjudicate, such as:
 - Health Care Claim: (837)
 - Health Care Services Review Request and Response (278)

From the NPRM Executive Summary:

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



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

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

The proposed rule would:

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

Comments must be submitted no later than 5 p.m. on March 21, 2023

Link to the federal register proposed rule publication: https://www.federalregister.gov/documents/2022/12/21/2022-27437/administrative-simplification-adoption-of-standards-for-health-care-attachments-transactions-and

Link to the CMS fact sheet: https://www.cms.gov/newsroom/fact-sheets/administrative-simplification-adoption-standards-health-care-attachments-transactions-and-electronic



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

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

Attachments related:

- X12N 275 Additional Information to Support a Health Care Claim or Encounter (006020X314), September 2014; IBR approved for § 162.2002(d).
- X12N 275 Additional Information to Support a Health Care Services Review (006020X316), August 2021; IBR approved for § 162.2002(c).
- X12N 277 Health Care Claim Request for Additional Information (006020X313), September 2014; IBR approved for § 162.2002(e).
- HL7 CDA R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 March 2017; IBR approved for§162.2002(a).
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1,
 Volume 1— Introductory Material, June 2019 with Errata; IBR approved for §162.2002(b).
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1,
 Volume 2 Templates and Supporting Material, June 2019 with Errata; IBR approved for §162.2002(b).

Attachment Type Value Set:

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

Prior Authorization Related:

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



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 4

CAQH® CORE OPERATING RULES



CAQH® CORE Operating Rule Restructure

CAQH® CORE has restructured its operating rules from **phased**-based rule sets to a **business transaction**-based model.

- All operating rules, including those adopted under federal regulation, have been assigned new rule numbers and have been repurposed to eliminate references to phases.
- There were no substantive content changes to any rules.

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



CAQH® CORE 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.

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.

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

Operating Rules	X12® TR3	Rules Define
Patient Attribution (Value-Based	X12/005010X279A1 (270/271) X12/005010X318 (834)	Single patient attribution requirements for the Health Care Eligibility Benefit Inquiry and Response (270/271).
Payment)		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).



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).



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 <u>CORE Voluntary Certification</u> (Clearinghouses tab).
- Additional information regarding the Change Healthcare operating rules program can be found on www.hipaasimplified.com.



Section 5

CMS COMPLIANCE REVIEW PROGRAM

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 <u>Change Healthcare Accreditations and Certifications</u> 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



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

Section 6

FEDERAL POLICY AND REGULATIONS

PRICE TRANSPARENCY



PRICE TRANSPARENCY REQUIREMENTS FOR HOSPITALS FINAL RULE

Price Transparency Requirements for Hospitals

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

Below is a summary of major provisions:

- Defines a "hospital," "items and services," and five types of "standard charges" that hospitals are required to make public. Federally owned/operated facilities are deemed to have met all requirements.
- Establishes requirements for making public a machine-readable file for all items and services provided by the hospital.
- Establishes requirements for making public 300 "shoppable" services that are displayed and packaged in a
 consumer-friendly manner, plus a policy to deem hospitals that offer internet-based price-estimator tools as
 having met this requirement.
- Establishes methods for monitoring, and actions that would address, hospital noncompliance.

More information on the rule can be found here.



TRANSPARENCY IN COVERAGE FINAL RULE

Transparency in Coverage Final Rule

On Nov. 12, 2020, the <u>Transparency in Coverage</u> 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 <u>August 2021 CMS FAQ</u> (questions 1-4).



NO SURPRISES ACT



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 <u>guidance document</u> entitled "FAQS About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49."



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, coinsurance, 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 innetwork cost-sharing rates.



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.



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.

<u>Federal Register Link</u>

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.

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.

<u>Federal Register Link</u>

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.



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.

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
- TrueViewTM

- AEOB Workflow (new)
- Communication EOB and ID Cards
- ConnectCenter
- Authorization and COB

Please reach out to your account representative for more information.

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.

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.

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.

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.



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-ofnetwork 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.



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.



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.



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.



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.

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.

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.

Section 7

HIPAA Privacy Rule NPRM



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

On December 10, 2020, the Office for Civil Rights (OCR) provided <u>advance notice</u> 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 <u>published in the Federal Register</u> with a comment window due date of March 22, 2021. On March 9, 2021, OCR announced a <u>45-day extension of the public comment period</u> extending the comment window due date to May 6. 1,436 comments were submitted during the public comment window.



Section 8

ONC CERTIFICATION AND INFORMATION BLOCKING RULE

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).



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.



ONC Cures Act Final Rule—Additional Information

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



Section 9

CHANGE HEALTHCARE ACCREDITATIONS AND CERTIFICATIONS

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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