

CHANGE HEALTHCARE REGULATORY AND STANDARDS UPDATE

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CHANGE
HEALTHCARE

Timeline

2016-2017	2018	2019	2020+
<p>9/1/2016 X12N v7030™ public comment cycles begin.</p> <p>12/13/2016 Public law 21st Century Cures Act enacted.</p> <p>1/1/2017 MACRA Final Rule.</p>	<p>4/1/2018 Transition period HICN to MBI begins.</p>	<p>3/3/2019 21st Century Cure Act Rulemaking begins with publication of ONC and CMS NPRMs on Interoperability, Patient Access, Information Blocking. Comment period ended 5/3/2019.</p> <p>3/28/2019 CMS launches Compliance Review Program for Health Plans and Clearinghouses.</p>	<p>4/10/2019 CMS launches Compliance Review Provider Pilot Program.</p> <p>12/31/2019 HICN (SSN) – MBI transition period ends. Entities must support MBI only.</p>
			<p>Ongoing 2019 Initial Review and Comment, plus second Review and Comment for draft X12 7030 TR3s.</p> <p>Anticipated 2019 Attachments Regulation with 6020 278 and Acknowledgments expected Q4 2018.</p>
			<p>Anticipated X12 to recommend adoption of version 7030 of named HIPAA transactions.</p>

← 4/1/2018 through 12/31/2019 Entities must support both HICN and MBI →

← X12N v7030™ Staggered Public Comment →

Withdrawals	
<p>12/19/2018 Proposed Rule to Rescind Health Plan Identifier (HPID) Proposed Rule to rescind Health Plan Identifier Regulation of 2012. Comment period ended 02/19/2018.</p>	<p>Withdrawn-Certification Regulation Health Plan Eligibility, Claim Status, EFT, ERA, Health Plan Claims, Enrollment, Attachments, Premium Payment, Referral; Penalty fees</p>

Section 1

CMS NEW MEDICARE CARD PROJECT

CMS New Medicare Card Project – the transition is here

- △ All new Medicare cards have been issued.
- △ The CMS transition from HICN to MBI in electronic transactions and on print claim forms began **April 1, 2018** and extends through **December 31, 2019**, after which Medicare will accept MBI only (with some exceptions).

★ Change Healthcare is successfully receiving, processing, and routing transactions containing MBI. ★

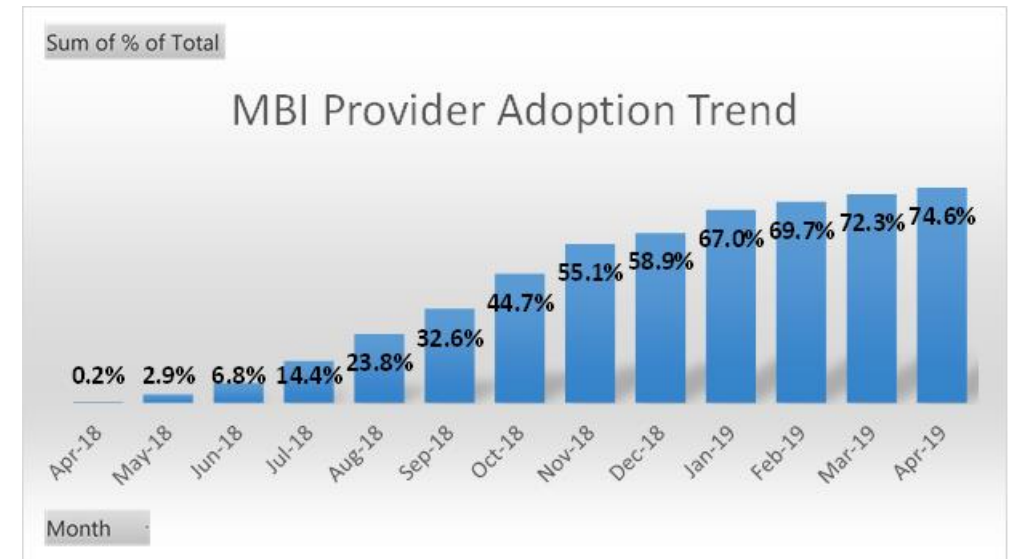
See www.hipaasimplified.com for [additional information](#).

Important Dates

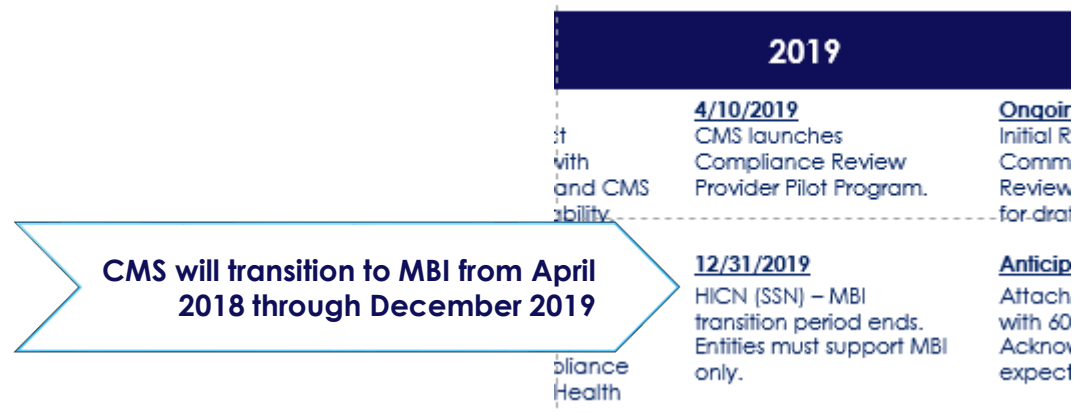
- **June 1, 2018** – CMS MBI Lookup tool became available to providers via their MAC (see CMS [letter](#) to providers). Patient MBIs can be obtained using the patient's Social Security number, first and last names, and date of birth.
- **October 1, 2018** – CMS began returning the MBI on the Claim Payment/Advice (835) as a Corrected Identifier, when a HICN has been submitted on the claim.
- **January 1, 2020** – MBI must be used in all transactions and print forms.

MBI provider adoption trend

- △ Change Healthcare has been tracking provider use and adoption of the Medicare Beneficiary Identifier (MBI) in Medicare claim transactions flowing through our network to the MACs.
- △ The chart to the right shows the trend and percentage of Medicare claim transactions of total that included an MBI for part A and B claims to all MACs.
- △ Change Healthcare's metrics of **69.7%** for February closely align with those reported in the March 14, 2019 MLNConnects newsletter: "For the week ending March 1, providers submitted **67%** of fee-for-service claims with the MBI".



CMS New Medicare Card Project – background



- △ The Medicare Access and CHIP Reauthorization Act (MACRA) mandates the removal of the Social Security number-based Health Insurance Claim Number (HICN) from Medicare cards.
- △ As a result, the Centers for Medicare & Medicare Services (CMS) has initiated their New Medicaid Card Project wherein all beneficiary Medicare cards will be reissued with the new Medicare Beneficiary Identifier (MBI), and all Medicare systems will be remediated to accept and process the new identifier.
- △ The primary goal of the New Medicare Card Project is to decrease Medicare beneficiaries' vulnerability to identify theft and fraud by removing the HICN from all Medicare ID cards and systems and replacing it with a randomly-generated MBI.

Regulatory roadmap – transition to MBI

- △ CMS is conducting a phased issuance of new ID cards which will include the MBI.
- △ **All systems, applications, and operational processes must be able to accept, process, and transmit both the HCIN and MBI from April 1, 2018 through December 31, 2019.**
- △ During the transition period:
 - CMS will accept, use for processing, and return to stakeholders either the MBI or HICN. CMS will return the same beneficiary number submitted on the incoming transaction.
 - CMS will return a message segment (MSG) in the eligibility transaction when the beneficiary has been mailed their MBI card. Providers may also ask patients if they have received their new card with their assigned MBI.
 - For claims submitted using the HCIN identifier, CMS will return the MBI on the remittance advice starting October 2018.
 - CMS recommends that providers use the beneficiary's MBI in transactions once the beneficiary has received their new card.
- △ All systems and processes must use only the MBI beginning January 1, 2020. There may be limited exceptions for use of the HICN after transition, such as appeals, adjustments, and other scenarios.

MAILING NOW
**New Medicare cards
with new numbers.**
Are you ready?
#NewCardNewNumber
LEARN MORE

Technical and operational readiness



- △ Change Healthcare has completed our internal remediation and operational readiness program in preparation for the issuance and support of new Medicare numbers (MBIs).
- △ All Change Healthcare systems and solutions now accept, process, and transmit either the old Medicare number (HICN) or the new Medicare number (MBI) within applicable health care transactions.
- △ As directed by CMS, the MBI will utilize the same data elements as the current CMS HICN.
- △ Change Healthcare trading partners that support transaction workflows involving Medicare, Medicaid, or Medicare supplemental plans should research and identify needed technical or operational remediation within their applications and organizations.

Additional information

- △ CMS is working with state Medicaid agencies who display the HICN on their Medicaid cards as well as the Railroad Retirement Board who issues their own cards.
- △ All new cards have been issued.
- △ CMS is conducting intensive education and outreach to beneficiaries and their agents, providers, advocacy groups, caregivers, states and territories, key stakeholders, vendors, and other partners.
- △ CMS will monitor impact to providers and other industry stakeholders throughout the transition.
- △ More information is available at <https://www.cms.gov/medicare/new-medicare-card/nmc-home.html>.
- △ For Change Healthcare's HIPAA Simplified overview, [click here](#).

Watch Change Healthcare's [HIPAA Simplified](#) site for updates.

Section 2

ASC X12N VERSION 7030™ PUBLIC REVIEW AND COMMENT PERIOD

X12N version 7030™ – public review and comment



The public review and comment cycles for version 7030™ of the X12N Type 3 Technical Reports (TR3s) began in the fall of 2016. These public review and comment periods allow the health care industry the opportunity to review the proposed changes and provide feedback on the next published version of the healthcare administrative transactions.

- △ Cycle 6, for the Health Care Eligibility Benefits Inquiry and Response (270/271), was completed on November 16, 2018, after a 120 day public review and comment period. Released for review with this TR3 was a new companion TR2 document **Code Value Usage in Eligibility Benefit Inquiry and Subsequent Response**, which instructs on proper usage of external code sets.
- △ Five additional initial review cycles, comprising 17 TR3s (both HIPAA-adopted and non-mandated), have also been completed.
- △ Based on industry comments received during initial reviews, some TR3s will undergo a second public review and commenting period.

X12N version 7030™ – key facts



The public review and comment cycles for version 7030™ of the X12N Type 3 Technical Reports (TR3s) began in late 2016.

- △ Public comment periods for the TR3s are being held in staggered cycles.
- △ Public comment periods will be held for all 7030 TR3s, including transactions not mandated under HIPAA.
- △ A staggered approach allows for more focused reviews and hopefully, increased participation from the industry.

X12N version 7030™ – timeline



Initial Review Cycles - Upcoming

Cycle 7 TBA

- Health Care Request for Additional Information (277RFI)
- Additional Information to Support a Health Care Claim or Encounter (275)
- Additional Information to Support a Health Care Services Review (275)
- Application Reporting for Insurance (824)

For X12's Summary of the status of version 7030 public comment periods, see:

<http://www.x12.org/announcements/x12-announcement-2018-tr3-public-review-timeline-revision-9.cfm>

Second Public Comment and Reviews

Review of changes stemming from first public review

Upcoming (TBA)

- Health Care Claim Status Request and Response (276/277)
- Health Care Claim Acknowledgment (277CA)
- Health Care Claims (837P/I/D)
- Health Care Services Request for Review and Response (278RR), Review Inquiry and Response (278IR), and Notification and Acknowledgment (278NA).

Closed: April 1 through May 15, 2018

- Payroll Deducted and Other Group Premium Payment for Insurance Products (820)
- Health Insurance Exchange Related Payment (820)
- Health Care Claim Payment/Advice 835

X12N version 7030™ – timeline



Initial Review Cycles - Complete

Cycle 1

September 1 through October 31, 2016

- Payroll Deducted and Other Group Premium Payment for Insurance Products (820)
- Health Insurance Exchange Related Payments (820)
- Benefit Enrollment and Maintenance (834)
- Health Insurance Exchange: Enrollment (834)

Cycle 2

October 1 through November 30, 2016

- Health Care Claim Status Request and Response (276/277)
- Health Care Claim Acknowledgment (277CA)
- Health Care Claim Pending Status Information (277P)
- Implementation Acknowledgment for Health Care Insurance (999)

Cycle 3

November 1, 2016 through January 30, 2017

- Health Care Claim Payment/Advice (835)

Cycle 4

February 1 through June 1, 2017

- Health Care Claim: Professional (837P)
- Health Care Claim: Institutional (837I)
- Health Care Claim: Dental (837D)
- Health Care Service: Data Reporting (837R)

Cycle 5

September 1 through January 31, 2018

- 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)

Cycle 6

July 16 through November 16, 2018

- Health Care Eligibility Benefits Inquiry and Response (270/271)
- Code Value Usage in Eligibility Benefit Inquiry and Subsequent Response (TR2)

X12N version 7030™ Informational Forums



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

X12N version 7030™ – participation



For updates to the public comment period timeline, watch: www.x12.org.

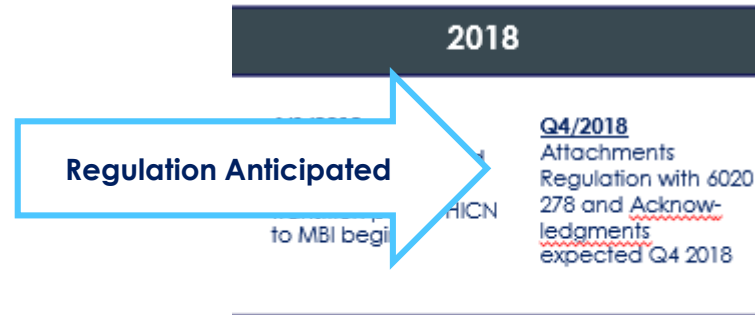
Change Healthcare Encourages Your Participation

- △ Change Healthcare is actively participating in the v7030™ Public Review and Comment process and we encourage all entities to participate.
- △ See the Change Healthcare Version 7030™ Customer Communication and Version 7030™ FAQs on www.hipaasimplified.com.
- △ To view and comment on the TR3s, go to forums.x12.org.

Section 3

ATTACHMENTS NPRM

Attachments – Timeline



- △ The Administrative Simplification provisions under the ACA include adoption of transaction standards and operating rules for Attachments.
- △ Electronic Attachments are electronic transactions that support healthcare transactions 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 expected in December 2018, per the Unified Agenda of Regulatory and Deregulatory Actions ([RIN 0938-AT38](#)).**

Attachments – Publications

△ HL7 Publications:

- [HL7 CDA® R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 Standard for Trial Use](#)
- [HL7 CDA ® Release 2 Implementation Guide: Exchange of C-CDA Based Documents; Periodontal Attachment, Release 1](#)
- [HL7 CDA® R2 Implementation Guide: Orthodontic Attachment, Release 1 – US Realm \(draft\)](#)

△ X12, HL7, and the Workgroup for Electronic Data Interchange (WEDI) White Paper:

- [Guidance on Implementation of Standard Electronic Attachments for Healthcare Transactions](#), provides guidance on the implementation of standard electronic attachments for healthcare transactions.

Attachments – Recommendations

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

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

To see the NCVHS Letter to the Secretary – Recommendations for the Electronic Health Care Attachment Standard, click [here](#).

Additional Regulatory Action in Attachments NPRM



△ The upcoming Attachments Regulation is expected to propose the following:

- X12 Version 6020 of the Health Care Services Request for Review and Response (278), replacing the 005010X217 TR3 currently under adoption.
- Acknowledgments transaction standards for the health care claim status, enrollment and disenrollment in a health plan, health plan premium payments, coordination of benefits, referral certification and authorization, and health care attachments transactions
- Acknowledgement transaction standards and operating rules for the eligibility and benefits (270/271), health care claim status (276/277), and health care electronic funds transfers (EFT) and remittance advice transactions (835).

Attachments – Regulatory Roadmap



- NCVHS hearing was held on February 16, 2016.
- NCVHS Letter of Recommendation sent to HHS on July 5, 2016.
- Unified Agenda ([RIN 0938-AT38](#)) indicated that a proposed rule was expected in December 2018, with Public Comment Period.
- Proposed Rule to include adoption of X12 Version 6020 Health Care Services Request for Review and Response (278) as well as X12 Health Care Acknowledgments.
- Final Rule to follow with an implementation period and compliance date of up to two years following final rule publication.

Section 4

NCVHS DRAFT RECOMMENDATIONS PREDICTABILITY ROADMAP

History

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

*See [Roadmap Narrative](#)

Next steps

- △ **October-November 2018:** Industry stakeholders reviewed the **Draft Recommendations for the Predictability Roadmap**.
- △ **December 13-14, 2018:** The NCVHS Standards Subcommittee conducted a [hearing](#) to hear testimony on these recommendations.
- △ **December 2018 through January 2019:** The Standards Subcommittee incorporates feedback from comments and testimony.
- △ **February 6-7, 2019:** The full NCVHS will consider the revised draft recommendations. Meeting transcripts and other materials are available at <https://ncvhs.hhs.gov/meetings-meeting/>.
- △ **TBA:** NCVHS will release letter of recommendation to HHS based on review and final Committee vote.

Resources

[Draft Recommendations for the Predictability Roadmap](#), October 2018

[Improving Health Care System Efficiency by Accelerating the Update, Adoption, and Use of Administrative Standards and Operating Rules: A Brief History and Draft Recommendations](#) (Roadmap Narrative), September, 2018

[NCVHS Hearing December 12-13, 2018](#)

Section 5

MEDICARE ACCESS AND CHIP REAUTHORIZATION ACT OF 2015 (MACRA)

About MACRA



- △ On April 16, 2015, the [Medicare Access and CHIP Reauthorization Act](#) (MACRA) was enacted into public law. The [MACRA](#) amends the Social Security Act making changes to how Medicare pays those who provide care to Medicare beneficiaries and extends the CHIP program.
- △ Includes provisions for CMS to remove Social Security numbers (SSNs) from Health Care Insurance Numbers (HICNs) and Medicare Claims Numbers (MCNs). See [CMS New Medicare Card Project \(SSNRI\)](#).
- △ Required that CMS establish a classification code set for [physician-patient relationships](#).
- △ On November 4, 2016, the [MACRA Final Rule with Comment](#) was published in the Federal Register. The rule establishes a unified framework called the [CMS Quality Payment Program](#) that rewards the quality and value of care in one of two ways:
 - Merit-based Payment System (MIPS),
 - [MIPS Overview](#)
 - Advanced Alternative Payment Models (APMs)
 - [APMs Overview](#)
 - Quality Payment Program Participation Status Tool
 - [QPP Participation Status](#)
- △ More information on the Quality Payment Program can be found in the [Quality Payment Program Resource Library](#)

Section 6

21st CENTURY CURES ACT

About the 21st Century Cures Act

- △ On December 13, 2016, the [21st Century Cures Act](#) was enacted into public law “to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.”
- △ The legislation includes 18 sections under 3 divisions:
 - DIVISION A—21ST CENTURY CURES
 - TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE; TITLE II—DISCOVERY; TITLE III—DEVELOPMENT; TITLE IV—DELIVERY; TITLE V—SAVINGS
 - DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS
 - TITLE VI—STRENGTHENING LEADERSHIP AND ACCOUNTABILITY; TITLE VII—ENSURING MENTAL AND SUBSTANCE USE DISORDERS PREVENTION, TREATMENT, AND RECOVERY PROGRAMS KEEP PACE WITH SCIENCE AND TECHNOLOGY; TITLE VIII—SUPPORTING STATE PREVENTION ACTIVITIES AND RESPONSES TO MENTAL HEALTH AND SUBSTANCE USE DISORDER NEEDS; TITLE IX—PROMOTING ACCESS TO MENTAL HEALTH AND SUBSTANCE USE DISORDER CARE; TITLE X—STRENGTHENING MENTAL AND SUBSTANCE USE DISORDER CARE FOR CHILDREN AND ADOLESCENTS; TITLE XI—COMPASSIONATE COMMUNICATION ON HIPAA; TITLE XII—MEDICAID MENTAL HEALTH COVERAGE; TITLE XIII—MENTAL HEALTH PARITY; TITLE XIV—MENTAL HEALTH AND SAFE COMMUNITIES
 - DIVISION C—INCREASING CHOICE, ACCESS, AND QUALITY IN HEALTH CARE FOR AMERICANS
 - TITLE XV—PROVISIONS RELATING TO MEDICARE PART A; TITLE XVI—PROVISIONS RELATING TO MEDICARE PART B; TITLE XVII—OTHER MEDICARE PROVISIONS; TITLE XVIII—OTHER PROVISIONS

21st Century Cures Act – Title IV-Delivery (focused breakdown)

- △ **Sec. 4001. Assisting doctors and hospitals in improving quality of care for patients**
- △ **Sec. 4002. Transparent reporting on usability, security, and functionality**
- △ **Sec. 4003. Interoperability**
- △ **Sec. 4004. Information blocking**
- △ **Sec. 4005. Leveraging electronic health records to improve patient care**
- △ **Sec. 4006. Empowering patients and improving patient access to their electronic health information**
- △ **Sec. 4007. GAO study on patient matching**
- △ **Sec. 4008. GAO study on patient access to health information**
- △ Sec. 4009. Improving Medicare local coverage determinations
- △ Sec. 4010. Medicare pharmaceutical and technology ombudsman
- △ Sec. 4011. Medicare site-of-service price transparency
- △ Sec. 4012. Telehealth services in Medicare

Title IV-Delivery - Section 4001

Assisting doctors and hospitals in improving quality of care for patients

- △ 4001 (a) Amends the HITECH Act to require HHS to establish a goal, develop a strategy, and make recommendations to reduce regulatory or administrative burdens relating to the use of EHRs
- △ 4001 (b) ONC must encourage, keep, or recognize the voluntary certification of health IT for use in medical specialties. HHS must solicit stakeholder input and make criteria recommendations, adopt certification criteria, and support voluntary certification to support health IT for pediatric health providers
- △ 4001 (c) HHS must publish attestation statistics for the Medicare and Medicaid EHR Incentive Programs to assist in informing standards adoption and related practices
 - CMS is renaming the EHR Incentive Programs to the [Promoting Interoperability \(PI\) Programs](#)

Title IV-Delivery - Section 4002

Transparent reporting on usability, security, and functionality

- △ 4002(a) Requires HHS, through notice and comment rulemaking, to require as a condition and maintenance of certification, that the HIT developer or entity “does not take any action that constitutes information blocking” (as defined in Section 3022(a) of the Public Health Service Act, as amended), or “any other action that may inhibit the appropriate exchange, access, and use of electronic health information”
 - HealthIT.gov [Usability and Provider Burden](#) page & [Strategy on Reducing Burden](#) draft
- △ 4002(b) A health care provider whose adopted health IT is decertified is exempted from the application of a payment adjustment
- △ 4002(c) HHS must support the convening of stakeholders to develop reporting criteria

Title IV-Delivery - Section 4003

Interoperability

△ 4003(a) Defines Interoperability:

- △ The term 'interoperability', with respect to health information technology, means such health information technology that:
- A. Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user
 - B. Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law
 - C. Does not constitute information blocking as defined in section 3022(a) of the Public Health Service Act (PHSA) as amended

Title IV-Delivery - Section 4003

Interoperability (continued)

△ 4003(b) directs the National Coordinator to convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement (TEFCA) for exchange between health information networks.

- [A User's Guide to Understanding the Trusted Exchange Framework](#) (ONC HealthIT.gov)

- Timeline:



Title IV-Delivery - Section 4003

Interoperability (continued)

- △ 4003(c) requires that HHS establish an index of digital contact information for health professionals, health facilities, and others to encourage the exchange of health information
 - The [Center for Program Integrity](#) (CPI) in CMS will be responsible for implementing the provision. CPI is working with ONC on implementation of the provision.
- △ 4003(e) replaces the Health IT Policy Committee and the Health IT Standards Committee with the Health IT Advisory Committee (HITAC)
 - The ONC must periodically convene the HITAC to report on priority uses of health IT and standards and implementation specifications that support the implementation of a health information technology infrastructure that advances the electronic access, exchange, and use of health information.

[ONC 2018 Report to Congress](#)

Title IV-Delivery - Section 4003

Interoperability (continued)

- △ On April 19, 2019, ONC released Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA).
- △ The TEFCA outlines a common set of principles, terms, and conditions to support the development of a Common Agreement that would help enable a nationwide exchange of electronic health information (EHI) across disparate health information networks (HINs).

[Trusted Exchange Framework and Common Agreement \(TEFCA\) Draft 2](#)

- △ For more information, including a user's guide and market-specific information sheets, see <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>.

Title IV-Delivery - Section 4004

Information blocking

△ 4004(a) defines information blocking as a practice that:

- A. “except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.”
- B. “(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or (ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.”

Title IV-Delivery - Section 4004

Information blocking (continued)

- △ 4004(b) The Inspector General of HHS is authorized to investigate claims of information blocking
 - A health information technology developer or other entity offering certified health information technology, or a health information exchange or network, may be penalized for engaging in information blocking, up to \$1M per violation.
 - Providers determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking.
- △ 4004(d) The National Coordinator must implement a standardized process for the public to submit reports on claims of information blocking

Title IV-Delivery - Sections 4005 & 4006

Leveraging electronic health records to improve patient care

- △ 4005(a) To be certified, electronic health records must be capable of transmitting to, and where applicable, receiving and accepting data from, registries certified by the ONC
- △ 4005(c) HHS must report on best practices and current trends provided by patient safety organizations to improve the integration of health IT into clinical practice

Empowering patients and improving patient access to their electronic health information

- △ 4006(a) instructs HHS to:
 - Encourage partnerships between health information exchanges and health care providers, health plans, and others with the goal of offering patients access to their electronic health information
 - Issue guidance to health information exchanges on best practices
 - Educate providers on leveraging health information exchanges
 - Promote policies to facilitate patient communication with providers and others, given patient consent
 - Update education on accessing and exchanging personal health information
 - Develop and prioritize standards, implementation specifications, and certification criteria required to support patient access to electronic health information and usability

Title IV-Delivery - Section 4007

GAO Study on Patient Matching

- △ 4007(a) instructs the Comptroller General to conduct a study to review ONC HIT and other relevant stakeholder policies and activities to ensure appropriate patient matching to protect patient privacy and security of electronic health records (EHR) and the exchange of electronic patient information.
- △ 4007(b) outlines areas of concentration to evaluate current methods used for patient matching and taking steps to improve matching.
- △ 4007(c) requires a report concerning the findings of the study be reported to Congress.
 - The report “**Approaches and Challenges to Electronically Matching Patients' Records across Providers**” was published on January 19, 2019.
 - Web link @ <https://www.gao.gov/products/GAO-19-197>
 - [Full Report](#)

Title IV-Delivery - Section 4008

GAO Study on Patient Access to Health Information

- △ 4008(a) instructs the Comptroller General to conduct a study to review patient access to their own protected health information, including barriers to such patient access and complications or difficulties providers experience in providing access to patients.
- △ 4008(b) outlines areas of concentration to consider.
- △ 4008(c) requires a report concerning the findings of the study be reported to Congress.
 - The report “**Fees and Challenges Associated with Patients’ Access**” was published on May 14, 2018.
 - Web link @ <https://www.gao.gov/products/GAO-18-386>
 - [Full Report](#)

Section 7

PROPOSED RULES SUPPORTING PROVISIONS OF THE 21st CENTURY CURES ACT

CMS and ONC Issue Proposed Rules

- △ On February 11, 2019, the U.S. Department of Health and Human Services (HHS) proposed new rules to support seamless and secure access, exchange, and use of electronic health information. The rules, issued by the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC), would increase choice and competition while fostering innovation that promotes patient access to and control over their health information. The proposed ONC rule would require that patient electronic access to this electronic health information (EHI) be made available at no cost.
 - ❑ CMS Fact Sheet - <https://go.cms.gov/2E3dp5v>
 - ❑ ONC Fact Sheet - <https://bit.ly/2TJyRSG>
 - ❑ HHS Press Release - <https://bit.ly/2GCqggO>
 - ❑ Public comments will be accepted through **June 3, 2019** (extended from original deadline of May 3, 2019).
- △ In addition to the policy proposals, CMS released two Requests for Information (RFIs) to obtain feedback on interoperability and health information technology (health IT) adoption in Post-Acute Care (PAC) settings, and the role of patient matching in interoperability and improved patient care.

NPRMs Published in the Federal Register

- △ [CMS-9115-P / RIN 0938-AT79](#) - Medicare and Medicaid Programs: Patient Protection and Affordable Care Act; [Interoperability and Patient Access](#) for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers
- △ [ONC RIN 0955-AA01](#) - 21st Century Cures Act: [Interoperability, Information Blocking, and the ONC Health IT Certification Program](#).

Click on the links above to review the NPRMs as published in the Federal Register.

Associated CMS RFIs

The following Requests for Information (RFIs) are also included in **CMS-9115-P / RIN 0938-AT79**:

- △ **Interoperability and Health Information Technology (Health IT) Adoption in Post-Acute Care (PAC) Settings**
 - See NPRM Section XI. Request for Information on Advancing Interoperability Across the Care Continuum
- △ **The Role of Patient Matching in Interoperability and Improved Patient Care**
 - See NPRM Section XIII. Request for Information on Policies To Improve Patient Matching
 - Specifically there are 7 questions posed in part B. Solicitation of Comments.

Section 8

OPERATING RULES

Change Healthcare operating rules readiness



Change Healthcare clearinghouse services **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.HIPAAimplified.com.

Operating Rules – Phase IV revisions

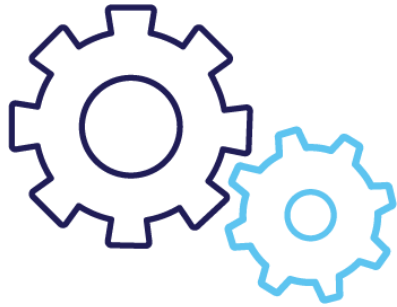
- △ In September 2015, CAQH CORE via their voting process, approved the Phase IV Operating Rules for voluntary certification.
- △ The Phase IV rules define infrastructure, connectivity, and companion guide requirements for Health Care Claims (837), Health Care Services Review – Request for Review and Response (278), Benefit Enrollment and Maintenance (834), and Premium Payment (820) transactions.
- △ In April 2019, CAQH CORE announced the formation of a workgroup to revise Rule 452 Health Care Services Review-Request for Review and Response Infrastructure Rule.
- △ The purpose of this workgroup is, in response to industry interest, to evaluate opportunities to strengthen Rule 453 to include a response time requirement for a final preauthorization determination.
- △ Meetings are scheduled through August 2019. Contact CAQH CORE at core@caqh.org for additional information.

Phase V Operating Rules



- △ CAQH CORE has completed development of the Phase V rules for the Prior Authorization transaction (005010X217 278 Health Care Request for Review and Response), which is a HIPAA adopted transaction.
- △ Rules address data content requirements for the 278 as well as proprietary web portal prior authorization form standardization.
- △ Phase V Operating Rules were approved by member ballot in April, 2019.

Phase IV and V Operating Rules – regulatory roadmap



- On July 6, 2016, NCVHS sent a letter to the HHS secretary recommending that the Phase IV Operating Rules not be adopted under regulatory mandate and supporting voluntary industry adoption.
- Recommendations also included; addressing inconsistencies in authentication and connectivity requirements, regulatory adoption of the acknowledgement standard as HIPAA-mandated, and transaction-specific findings and recommendations.
- To see the NCVHS Letter to the Secretary – Recommendations for the Proposed Phase IV Operating Rules, click [here](#).
- No regulatory action has occurred surrounding Phase V rules.

Future operating rule development - attachments



- In their April 24, 2019 webinar *Delivering Value through Electronic Healthcare Attachments*, CAQH CORE presented their Attachments initiative.
- The ACA mandated the development of operating rules for Attachments.
- In 2018 CAQH CORE launched an environmental scan of the industry relating to attachments.
- CAQH CORE published a white paper on May 7, 2019, entitled [CAQH CORE Report on Attachments: A Bridge to a Fully Automated Future to Share Medical Documentation](#), which captures the results of their environmental scan and identifies five rule opportunity areas.
- Operating rule development will begin following HHS Attachment rulemaking.

HEALTH PLAN IDENTIFIER (HPID)

Health Plan Identifier – timeline



- △ On 12/19/18, HHS published a Proposed Rule, entitled [Administrative Simplification: Rescinding the Adoption of the Standard Unique Health Plan Identifier and Other Entity Identifier](#), which would rescind the Health Plan Identifier (HPID) regulation issued on September 5, 2012.
- △ The original Final Rule, entitled **Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier** (45 CFR Part 162):
 - Adopted the HPID as the standard unique identifier for health plans,
 - Defined the terms "Controlling health plan" (CHP) and "Subhealth plan" (SHP),
 - Required all covered entities to use an HPID whenever a covered entity identifies a health plan in a covered transaction.
 - Adopted a data element serving as an "other entity identifier" (OEID) for entities that are not health plans, individuals, or health care providers.
- △ HHS will accept comments on the proposed rule through 2/19/19. Change Healthcare continues to support the near-unanimous industry consensus to rescind the HPID regulation.

Section 11

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. Of the ten volunteer organizations meeting the criteria for participation, four clearing houses and one health plan completed the pilot.

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

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

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

Section 11

CHANGE HEALTHCARE ACCREDITATIONS & CERTIFICATIONS

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.
- Visit the Change Healthcare [Viewpoints blog post](#) for additional information.
- [Certificate of Completion](#)

Change Healthcare Accreditations & Certifications

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

Click [HERE](#) for more information.

CHANGE HEALTHCARE