HIMSS

PREPARING FOR A WORLD OF NATIONAL NETWORKS AND FRAMEWORKS

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Introduction

The exchange of information in the American healthcare system has undergone an evolution in the last sixty years, mirroring the transformation of the healthcare delivery system itself. Moving from a largely siloed model of isolated individual providers to more large integrated delivery systems and somewhat more of a distributed and team-based model. The early paradigm of handwritten notes in paper charts has given way to electronic data capture and exchange. The advent of Electronic Health Records (EHR) marked a significant leap forward, offering a digitized version of a patient's medical record with interoperability ensuring that the information is accessible to an authorized interdisciplinary care team.

The overwhelming adoption of EHRs offers a digitized version of a patient's medical history and increases the availability and comprehensibility of this information. Interoperability enhances the accessiblity of patient information for interdisciplinary care teams across unafilliated healthcare organizations and other authorized healthcare constituents. Modern Certified EHR Technology (CEHRT) systems have highly structured machine readable discrete data formats that support national-scale interoperability. A patient´s critical health information can follow them across disparate implementations of the same brand or different brands of CEHRT from one healthcare environment to another, enabling continuity of care and reducing the risk of errors and duplicate treatments.

Today, we stand on the cusp of the next evolution in interoperable healthcare delivery through an Office of the National Coordinator for Health Information Technology (ONC) supported National Framework: the Trusted Exchange Framework and Common Agreement (TEFCA). TEFCA, through the designation of Qualified Health Information Networks (QHINS), aims to create a single ´on-ramp´ to nationwide connectivity, simplifying the process for patients, providers and authorized healthcare participants to share health information securely and efficiently. This framework represents the ambition to achieve a national interconnected health system.

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Interoperability Overview

Interoperability in Clinical Care

As EHRs were increasingly adopted and discrete machine-readable data documented therein,it became possible to exchange data across diverse healthcare provider organizations involved in caring for shared patients.

Safe, efficient, effective care requires communication across the patient's care team regardless of whether members of the team are within a single organization or across multiple organizations. For years faxes have been used to communicate, then eFaxes which could be received directly into a specific patient's EHR record. Faxes and eFaxes, as simply text, require extensive data entry on receipt to keep the patient's chart up to date. Not only is manual data entry burdensome and time consuming, it is also prone to data entry errors potentially leading to patient harm.

True, modern interoperability requires data documented in the sending EHR record to be recorded as discrete data, meaning that the data element that has been documented has an associated standardized machine-readable code. When the recipient EHR that has the capability to "read" the discrete data receives a document with coded data the recipient can either manually accept, or in some cases have the system automatically, incorporate this data into the patient record in the recipient system.

Interoperable discrete data not only improves safety, it also has the potential to dramatically decrease clinical burden and improve clinician, staff and patient satisfaction, Patients can avoid continually filling out identical forms for information when they go to a new caregiver as their prior data has been interoperably received by the new EHR and is already incorporated into the new provider's system. In addition, patients are not subjected to uncomfortable, costly duplicate testing.The Direct Protocol for sharing documents across Direct Networks based on clinical data architecture (CDA), was designed to "push" CDAs interoperably to the patient's care team across diverse certified EHRs that had adopted this capability. DirectTrustTM provides a trust framework for Direct Networks. As Direct is a "push" network, several national Networks have evolved to satisfy the need for "pull." They include eHealth Exchange, CommonWell, and all of the Carequality Framework Implementer Networks. Recently, Carequality has added push to their Framework.

Under TEFCA, QHINs will offer "push" and "pull" with a roadmap to national FHIR at scale. Initial QHIN- facilitated FHIR exchange will begin in 2024, with QHIN to QHIN exchange required beginning in 2026. Full end-to-end FHIR exchange is planned for a future phase.[1]

Clinicians can readily understand the utility of both "push" and "pull" use cases. A primary care physician (PCP) referring a patient to a specialist wants the specialist to have all the necessary

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[1] HIR Roadmap for TEFCA Exchange v2.0: FHIR® Roadmap for TEFCA Exchange (sequoiaproject.org)

information for the patient prior to, or at the time of, the encounter. The PCP "pushes" the information to the specialist.

Once the specialist has completed the consultation, the specialist "pushes" the consultation back to the PCP. The PCP can then easily reconcile the discrete data received from the specialist into the patient's EHR in the PCP's office.

A patient arrives in the emergency department (ED) in a facility where the patient has no prior medical records in their EHR system. The ED doctor queries to "pull" the patient's records into their EHR system to treat the patient safely and appropriately.

The above examples illustrate how both "push" and "pull" clinical use cases are essential for interoperability leading to safe, efficient, cost-effective healthcare.

History

The history of national HIT frameworks and networks intertwines with the evolution of the medical record. The medical record dates back to ancient times, and for centuries, medical records were used to capture medical practices and procedures for educational purposes, and eventually insurance and legal purposes. Frameworks and standards emerged to ensure quality and consistency in recordkeeping.

In the United States, it wasn't until the 20th century that the medical record was used to track a patient's condition, treatment, and progress. These early patient charts enabled communication across the clinical team caring for the patient within the organization and a tool for teaching and claim management. Eventually the electronic medical record (EMR) and electronic health record (EHR) emerged, and national frameworks and standards ultimately drove the adoption of technology which has generated a tsunami of invaluable data.

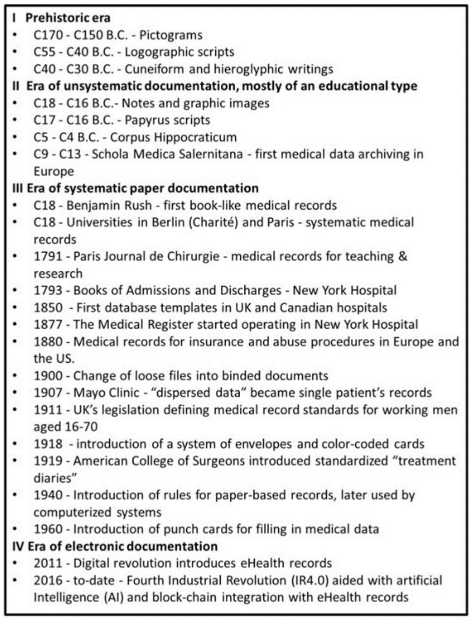
With increased data volume and access came the need for security. These real-time, patient-centered records made information available instantly and securely to authorized users; that is, until institutions needed to share the information outside their networks. Thus, the need for authorized Frameworks to certify, govern and require interoperability and data standards across their Networks. within the healthcare ecosystem grew. This is more critical now than ever, ensuring timely, secure access to relevant data, by the appropriate users, to help the healthcare system run efficiently and effectively. This section explores key milestones in the history and evolution of the governance models, Frameworks and standards guiding HIT in the United States. Please note that this section summarizes elements of the history of the United States healthcare system as we know it today at a very high level, omitting a number of key law and health policy milestones for purposes of brevity. For more information on the history of the United States healthcare system, please note the sources cited for this piece.

History of the Medical Record

The authors of Medical Records: A Historical Narrative have conducted fascinating, comprehensive research on the history of the medical record (Figure 1). Cave paintings of man injured by animal attacks, traced backed to 17,000 years ago, could arguably be considered the first medical records. Illustrations and basic words became the tools of medical knowledge transfer in ancient civilizations. Medical records as we define them today, were first written on papyrus by the ancient Egyptians, used for teaching.

A brief history of the medical record and modern medicine is incomplete without mention of Hippocrates of Kos (460–370 B.C.) who developed and curated clinical practices, treatments, and perspectives on foundational medical ethics, captured in the book Corpus Hippocraticum. Medical records advanced with the development of military medicine institutions, a cornerstone in the history of medical education. In the early 1720s, a military hospital in Berlin adopted the practice of daily patient rounding (checking on patients) whereby surgeons wrote notes concerning the patient's status and treatment plan in a journal. This demonstrates the evolution of the medical record from an archival document to a real-time tool for critical decision-making in patient treatment and care. Fast forward to the late 1700s, the New York Hospital established the Book of Admissions and the Book of Discharges, and the State of New York instituted a medical register and hospital rules, all tools to try formalized tracking of patients and setting of basic standards in recordkeeping focused on public health, population statistics, and financial data. While the tracking of standardized information on a patient's condition and treatment had evolved significantly at this point, the type of information collected was still limited: family history, patient's prior conditions, physical examination and labs results, and inquiry into eating and drug habits. The data collected on patients would also often include a physician's personal bias and perspective related to their own cultural and socio-economic stereotypes. As governance over medical record data expanded, national frameworks and standards were needed to ensure accuracy, timeliness and objectivity of data.

Figure 1. An Overview of the History of Medical Records.
("C" refers to Century)



I Prehistoric era
- C170 - C150 B.C. - Pictograms
- C55 - C40 B.C. - Logographic scripts
- C40 - C30 B.C. - Cuneiform and hieroglyphic writings

II Era of unsystematic documentation, mostly of an educational type
- C18 - C16 B.C.- Notes and graphic images
- C17 - C16 B.C. - Papyrus scripts
- C5 - C4 B.C. - Corpus Hippocraticum
- C9 - C13 - Schola Medica Salernitana - first medical data archiving in Europe

III Era of systematic paper documentation
- C18 - Benjamin Rush - first book-like medical records
- C18 - Universities in Berlin (Charité) and Paris - systematic medical records
- 1791 - Paris Journal de Chirurgie - medical records for teaching & research
- 1793 - Books of Admissions and Discharges - New York Hospital
- 1850 - First database templates in UK and Canadian hospitals
- 1877 - The Medical Register started operating in New York Hospital
- 1880 - Medical records for insurance and abuse procedures in Europe and the US.
- 1900 - Change of loose files into binded documents
- 1907 - Mayo Clinic - "dispersed data" became single patient's records
- 1911 - UK's legislation defining medical record standards for working men aged 16-70
- 1918 - introduction of a system of envelopes and color-coded cards
- 1919 - American College of Surgeons introduced standardized "treatment diaries"
- 1940 - Introduction of rules for paper-based records, later used by computerized systems
- 1960 - Introduction of punch cards for filling in medical data

IV Era of electronic documentation
- 2011 - Digital revolution introduces eHealth records
- 2016 - to-date - Fourth Industrial Revolution (IR4.0) aided with artificial Intelligence (AI) and block-chain integration with eHealth records

Figure Source: Medical Records: A Historical Narrative. Jacek Lorkowski and Mieczyslaw Pokorski. Biomedicines. 2022 Oct; 10(10): 259

Medical Record Governance, Frameworks, and Standards in the United States

In the United States, governance over medical records evolved with:

1. The expanded role of the hospital,
2. Global and domestic professional societies and trade organizations identifying the need for frameworks and standards setting, and
3. Creation of laws and health policies to drive health access, affordability and physician reimbursement.

Prior to the founding of the first government-funded hospital in 1751 (Pennsylvania Hospital), healthcare was delivered in a patient's home or the local physician's office. Hospitals were considered a harbor for the severely sick, elderly, and poor, and delivered charity care. Over time, however, hospitals became centers of routine medical care, surgery, and clinical research. With the expanded responsibilities of a hospital, in the late 1700s, institutions like New York Hospital formalized tracking patient identifiers, as well as basic financial and medical information. By the late 1800s, the Governor Council of the State of New York required patient case write-ups to be included as permanent records of a hospital as a means of archiving information for medical education purposes. Since 1880, medical records have been utilized for malpractice and social insurance reimbursement purposes. Table 1 summarizes the evolution of the data collected in medical records.

Table 1. Evolution of Medical Record and Patient Information Collected Between 1793 – 1990

Information Collected / Time Period	1793-1877	1877-1932	1932-1990
Statistical Reporting	✓	✓	✓
Educational Use by Students and Physicians	✓	✓	✓
Research (Case Reports and Clinical Studies)	✓	✓	✓
Retrospective Information on Patients	✓	✓	✓
Historical Information on Medical Practices	✓	✓	✓
Direct Patient Care Information		✓	✓
Financial and Billing			✓
Information for Reimbursement			✓
Quality Review of Record and Patient Care			✓
Legal Affairs for Determining Malpractice			✓
Public Health Research			✓
Social Services Document			✓
Document for Patient's Own Use			✓

The Evolution, Uses, and Present Problems of the Patient's Medical Record as Exemplified by the Records of the New York Hospital from 1793 to the Present. Trans. Am. Clin. Climatol. Assoc. Engle R.L., Jr. 1991; 102:182–189.

Professional and trade associations such as the American College of Surgeons led further data collection standardization among physicians in terms of the type and quality of information captured in records Information about mortality and morbidity were the primary focus. The origins of the International Classification of Disease (ICD) framework can be tied back to the International Statistical Congress of Brussels in 1853 which established the need for classifying causes of mortality. The International List of Causes of Death was adopted by the United States in 1898. It wasn't until 1948 when the World Health Organization (WHO) led the mortality and morbidity classification system, instituting the ICD framework. In 1962, the United States Public Health Service translated the ICD to manage medical records and surgical procedures. Subsequently, the United States expanded ICD codes (ICD-9-Clinical Modification, published by WHO in 1977) to cover inpatient, outpatient, and physician office (non-hospital) use, under the oversight of the National Center for Health Statistics, and eventually the Centers for Medicare and Medicaid Services. Decades later, ICD continued to expand with the publication of ICD 10 in 2009, providing even more detail on health conditions to support tracking of health care utilization and quality.

The 1960s marked a time of significant expansion of healthcare access and affordability with a focus on physician reimbursement. The American Medical Association (AMA) developed the Current Procedural Terminology (CPT) framework to create a common language to define medical services and procedures. The CPT and ICD frameworks combined to produce accurate reporting of diagnoses and services rendered. Capturing and archiving data did not evolve significantly until the arrival of computers, and the first computer technology leveraged physical punch cards which were then stored away securely. Healthcare was ripe for disruption with the advent of the modern computer.

Technological Innovation and the Emergence of the EMR and EHR

The first Electronic Medical Records (EMRs) and Electronic Health Records (EHRs) emerged in the 1960s, and by 1965 approximately 73 hospitals and clinical information projects and 28 projects for retrieval and storage of medical documents and other clinical information were in progress, according to HIMSS. It's important to note the differences between an EMR and EHR as described in Table 2.

Table 2. EHR Innovation in the 1960s and 1970s

Year	Institution	EMR and EHR Innovation
1960s	**Mayo Clinic**	One of the first major health systems to adopt an EHR.
1968	**Massachusetts General Hospital**	Researchers launched the Computer Stored Ambulatory Record project in 1968, which had modular design and accommodated flexible clinical vocabularies through vocabulary mapping.
1971	**El Camino Hospital**	Lockheed Corporation created a system for El Camino Hospital,featuring computerized physician order entry (CPOE) and allowing multiple, simultaneous users.
1972	**Regenstrief Institute**	Regenstrief Medical Record System is created, incorporating then nascent object-oriented programming principles to automate integration of structured, electronic clinical data from their sources, such aslaboratories and pharmacies. This is known as the first EMR.
Early 1970s	**Latter Day Saints Hospital**	The University of Utah, 3M, and Latter Day Saints Hospital deployed the Health Evaluation through Logical Processing system.
1970s	**Veterans Administration (Now Department of Veterans Affairs)**	The Veterans Administration begins work on the Decentralized Hospital Computer Program, the progenitor of the Veterans Health Information Systems and Technology Architecture, which innovated an enterprise-wide EHR system spanning hundreds of clinical settings across the country.

HIM Body of Knowledge, AHIMA, 2023

The cost of adopting emerging technology was high and few organizations implemented EMRs and EHRs except government institutions, research institutions and military health centers. By the 1970s, a number of institutions in the United States embarked on developing their own version of the EMR and EHR as seen in Table 3.

Table 2. Differences Between EHR and EMR

EHR (electronic health records)	**EMR (electronic medical records)**
A digital record of patient health information	A digital version of a chart
Streamlined sharing with other providers and labs, etc. of updated, real-time information	Not designed to be shared outside the individual practice
Allows a patient's medical information to move with them	Patient record does not easily travel outside the practice
Access to tools that providers can use for decision making	Mainly used by providers for diagnosis and treatment

Practice Fusion. 2023

The first computers available to corporations took up entire rooms, and the next generation of computer was roughly the size of a desk. By the 1970s, smaller desktop computers emerged which opened the floodgates for hospitals and physician practices to adopt technology more easily, enabling EHR adoption as well as improved billing and patient scheduling. As networking technologies allowed computers to interface with each other, interactions between hospitals, payers and service providers increased at an accelerated rate. This period of increased exchange of clinical, administrative, and financial data prompted both technology and adoption governance and frameworks:

- In the 1980s, Health Level 7 (HL7) protocol was founded to address data standardization issues as EHR development, new software capabilities and networking capabilities pushed forward. The precursor to HL7 was developed at the University of California at San Francisco (UCSF)
- Medical Center and first implemented in production in 1981. The "7" in HL7 refers to the seventh layer of the International Standards Organization (ISO)'s Open Systems Interconnection (OSI) reference model.
- In the 1980s the Master Patient Index was introduced which tracked basic intake, discharge and demographic data about patients, fueling the eventual creation of the Health Information Exchanges.
- By 1991, the Institute of Medicine (IOM) set a goal that all physicians would be using computers
- in their practice by 2000. This goal was set forth in the IOM publication "Computer-Based
- Patient Record: An Essential Technology for Health Care" which was the first piece to advocate for the promise and possibilities of the EMR. However, without the proper incentives and support for adoption, only 18% of physicians had adopted an EHR system.
- In 1993, the world wide web was made available i n the public domain.

- In 1996, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was established which required the creation of national standards to protect sensitive patient health information from being disclosed without a patient's consent.
- In 2004 President George W. Bush made an executive order to create the Office of the National Coordinator of Health Information Technology (ONC). This was a call for nationwide EHR use by 2014 and for every American to have an electronic health record.
- Centers for Medicare and Medicaid Services (CMS), recognizing the potential of EHRs, introduced the Meaningful Use (MU) Program in 2010 to incentivize healthcare providers and hospitals to adopt and use EHRs meaningfully. The MU requirements, rolled out in stages, outlined specific objectives that healthcare providers needed to achieve to qualify for financial incentives.

The period between 1960-2000 was marked by tremendous developments in patient care and technology adoption, but nothing could have prepared the United States' healthcare industry for the next 20 years of technological advancement, medical innovation, and law and health policy evolution. During this period, governance, frameworks, and standards became more critical than ever.

Health IT Governance, Frameworks, and Standards in the United States

The evolution of technology over the last 20 years has driven the transformational change of the United States healthcare industry from a "local, community-driven" and "paper-based" system to a "national, networked" system. Technology has enabled secure, real-time access and connectivity, promoting knowledge exchange across providers, pharmacies, public health organizations, and payers. Most importantly, technological evolution has ushered in an era of patient-driven healthcare, and healthcare consumerism; individuals are more informed and empowered by their healthcare information than any other time in history. The confluence of technology adoption, and information generation and exchange, has driven a critical need for governance, frameworks and standards to ensure data is accessible, accurate, secure and managed ethically. Thus, public and private sector organizations have worked diligently, in partnerships, to set fundamental, comprehensive expectations for HIT in the United States.

The establishment of the Office of the National Coordinator of Health Information Technology (ONC), within the Department of Health and Human Services (HHS) demonstrated the type of governance needed to create national standardization. The framework for a national certification requirement was the seminal public-private effort to set minimal standards of functionality, security and interoperability such as:

- Achieving interoperability among HIT applications
- Establishing criteria to certify HIT products meet national standards
- Ensuring the privacy and security of information
- Driving the creation of health information networks

In more recent years, the hallmarks of ONC's work to gain public-private alignment on standards include:

- The Fast Healthcare Interoperability Resources (FHIR) standard which supports coding for healthcare information exchange in an accessible, readable format,
- The United States Core Data for Interoperability (USCDI) standard driving EHR collection and exchange of discrete, machine-readable patient data,
- The Trusted Electronic Framework and Common Agreement (TEFCA) which governs, designates and regulates Qualified Health Information Networks (QHINs) and the QHINs Participants and Sub-participants. Under TEFCA the QHIN Networks will facilitate information exchange across the country. The first five QHINs were designated in December, 2023. They are eHealth Exchange, Epic Nexus, Health Gorilla, Konza and MedeAllies.

The ONC will continue to play a lead role in navigating the dynamic tension between the healthcare industry and the HHS Office of the Inspector General (OIG), concerning information exchange governance, law and policy. For example, in early 2024, HHS released a proposed rule establishing penalties for information blocking which is defined as a provider knowingly and unreasonably interfering with the access, exchange, or use of electronic health information except as required by law or covered by a regulatory exception. This proposed rule follows on the heels of a final rule to establish civil money penalties that apply to health IT developers of certified health IT, entities offering certified health IT, health information exchanges, and health information networks.

HHS recognizes a number of Standard-Setting Organizations (SSOs), Standards Development Organizations (SDOs), and Designated Standards Maintenance Organizations (DSMOs), focusing on developing, implementing and revising technical standards. These include the organizations listed in Table 4.

Table 4. Standard-Setting and Related Organizations Recognized by HHS

Category	Organizations
Advisory Groups	NCVHS – National Committee on Vital and Health Statistics WEDI – Workgroup for Electronic Data Interchange
Designated Authoring Entity for Operating Rules	CAQH CORE – Committee on Operating Rules for Information Exchange
Designated Standard Maintenance Organizations	ADA DeCC – Dental Content Committee of the American Dental Association ASC X12 – Accredited Standards Committee HL7 – Health Level Seven NCPDP – National Council for Prescription Drug Programs NUBC – National Uniform Billing Committee NUCC – National Uniform Claim Committee
Non-DSMO Standard-Setting Organizations	ANSI – American National Standards Institute EHNAC – Electronic Healthcare Network Accreditation Commission HIBCC – Health Industry Business Communications Council NACHA – The Electronic Payments Association NAIC – National Association of Insurance Commissioners NISO – National Information Standards Organization

CMS.gov, 2023.

Industry and trade organizations have played a vital role in the development and successful implementation and adoption of HIT standards across the country. These organizations boast knowledgeable leadership, engaged members at the institutional and individual level, and create aligned community that advance the promise of HIT in the United States.

- Founded in 1928, the American Health Information Management Association (AHIMA) focuses on the improvement of medical records. AHIMA's 51,000 members are dedicated to the effective management of personal health information needed to deliver quality healthcare to the public.
- Founded in 1961, the Healthcare Information and Management Systems Society (HIMSS) is the healthcare industry's membership organization exclusively focused on framing and leading healthcare public policy and industry practices through its advocacy, educational and professional development initiatives designed to promote information and management
- systems' contributions to ensuring quality patient care. HIMSS represents approximately 17,000 individual members and some 275 member corporations that employ more than 1 million people. HIMSS' vision is "to realize the full health potential of every human, everywhere. We're driven by our new mission: reform the global health ecosystem through the power of information and technology."
- Founded in 1991, the Workgroup for Electronic Data Interchange (WEDI) was formed to improve the efficiency of health data exchange. WEDI was named in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) legislation as an advisor to the Secretary of HHS. With a focus on advancing standards for electronic administrative transactions, promoting data privacy and security, WEDI has been instrumental in aligning the industry in an effort to harmonize administrative and clinical data.
- Founded in 2005, the Healthcare Information Technology Standards Panel (HITSP) is a public- private partnership designed to drive standards for interoperability across software applications. HITSP is sponsored by the American National Standards Institute (ANSI) in cooperation with strategic partners such as the Healthcare Information and Management Systems Society (HIMSS), and the Advanced Technology Institute (ATI), and HHS.

The fascinating history of the medical record demonstrates how the use of patient information evolved as a teaching tool, a means to treat disease, a way of predicting and preventing mortality, a resource to support healthcare quality, accessibility and affordability by informing malpractice cases, driving physician reimbursement, and guiding national metric reporting and scorecards. Thus, sustainable, flexible, proactively managed governance, frameworks and standards are essential to the future evolution of HIT.

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Interoperability Incentive Programs Overview

Incentive Programs

The Centers for Medicare and Medicaid Services (CMS) currently administers two programs to incentivize providers and hospitals to use electronic health records (EHRs) more effectively. Though borne of similar origins in the HITECH Act of 2009, the modern Promoting Interoperability Program, for hospitals and critical access hospitals (CAH), and the Merit-Based Incentive Payment System (MIPS) have evolved to support different goals. The Promoting Interoperability Program evolved from the original Meaningful Use program and incentivizes CAHs and acute care hospitals to continue deploying and using certified EHR technology (CEHRT). Meanwhile, the MIPS program focuses on collecting quality metrics and encourages eligible clinicians to demonstrate improvement in care quality, cost, clinical improvement activities, and promoting interoperability. Both programs offer incentives and disincentives and are designed to be budget neutral.

Medicare Merit-based Incentive Payment System (MIPS) and Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAH) (PIP)s – History & Current Status

History of Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals

The Promoting Interoperability Program, formerly the Electronic Health Record Incentive Program, is an initiative led by CMS. The central purpose of this program is to encourage the adoption and meaningful use of certified electronic health record technology by clinicians, hospitals, and CAHs.

The origins of PIP trace back to the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act (ARRA) of 2009. The HITECH Act established substantial financial incentives for eligible professionals and hospitals to demonstrate "meaningful use" of CEHRT. Initially, the EHR Incentive Program had three stages: Stage 1 focused on data capturing and sharing, Stage 2 emphasized advancing clinical processes, and Stage 3 aimed at achieving improved health outcomes. As the Meaningful Use program evolved, the requirements for demonstrating meaningful use were modified and expanded based on industry feedback and technological advancements, and CMS pursued the original Stage 3 goals through several new programs, including the EHR Incentive Program.

In 2018, CMS rebranded the initiative as the Promoting Interoperability Program to reflect broader health IT priorities and pivot from a structure that incentivized mere adoption to one that encouraged actual usage. PIP's renewed focus was ensuring that health information was accessible across the care continuum, empowering patients to access and control their health data, and leveraging technology to tackle the national opioid epidemic. PIP intends to advance the adoption of interoperable health IT systems and bolster EHR utilization across healthcare settings. Four main objectives underscore the program: ensuring secure patient access to their health information, fostering information exchange across care providers, allowing patients to exchange health information across platforms seamlessly, and integrating public health and clinical data systems. PIP offers financial incentives to eligible healthcare professionals, hospitals, and CAHs demonstrating meaningful use of CEHRT. In 2019, many of the goals of Stage 3 finally became mandatory for participants of the PIP. Of note regarding the forthcoming national networks operating under the TEFCA framework, the incorporation of support for the US Core Data for Interoperability (USCDI) was added to the CEHRT program via the rules promulgated to facilitate the 21st Century Cures Act. This enshrines the USCDI as the base data set for national exchange via TEFCA.

Current Status of PIP

In 2023, PIP requires eligible hospitals and CAHs to report on or attest to objectives and measures in the following four categories to be considered a meaningful EHR user and avoid a downward payment adjustment:

- Advancement of CEHRT functionality
- Burden reduction
- Advancing interoperability and
- Improving patient access to their health information.

As related to advancing interoperability, there are four key objectives with measures related to each:

- Electronic Prescribing
    - e-Prescribing
    - Query of Prescription Drug Monitoring Program (PDMP)
- Health Information Exchange
    - Support electronic referral loops by sending health information and support electronic referral loops by receiving and reconciling health information *or*
    - Health information exchange bi-directional exchange *or*
    - Enabling exchange Under TEFCA
- Provider to Patient Exchange
    - Provide patients with electronic access to their health information
- Public Health and Clinical Data Exchange
    - Report on the following:
        - Syndromic surveillance reporting
        - Immunization registry reporting
        - Electronic case reporting
        - Electronic reportable laboratory result reporting
- BONUS (report one)

  - Public Health registry reporting or
  - Clinical Data registry reporting

In addition, the following Attestation Measures are required for 2023. Some of which are related to Interoperability:

- Security Risk Analysis
- afer Guides Measure
- No Information Blocking
- ONC Direct Review
- ONC-ACB Review

And CEHRT Requirements:

- 2015 Edition Cures Update criteria
- 2015 Edition Cures Update functionality must be used as needed for a measure action to count in the numerator during the EHR reporting period chosen by the eligible hospital or CAH for a continuous 90-day period.

Additional PIP requirements include e-Clincal Quality Measures (eCQM) reporting.

https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs

https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs/medicare- medicaid- basics#:~:text=Beginning%20in%202011%2C%20the%20Promoting,meaningful%20use%20of%20certifie d%20electronic

For a CMS Webinar on this subject: https://www.youtube.ecordingcom/watch?v=zjHgN37ncsQ

History of MIPS

The Merit-based Incentive Payment System (MIPS) was instituted as a part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), representing a pivotal shift in the healthcare payment paradigm within the United States. Before this act, Medicare Part B reimbursement was structured under the Sustainable Growth Rate (SGR) formula, which had faced recurring criticism for its propensity to introduce periodic "payment cliffs" that often necessitated last-minute legislative fixes. MACRA sought to do away with the unstable SGR system and introduced two primary pathways for physician payment: Advanced Alternative Payment Models (APMs) and MIPS. The MIPS program incentives and disincentives and are designed to be budget neutral, shifting funds between providers without increasing the overall reimbursement available.

MIPS amalgamates three pre-existing quality reporting programs: the Physician Quality Reporting System (PQRS), the Value-based Payment Modifier (VBM), and parts of the Medicare Electronic Health Record incentive program. Instead of requiring providers to juggle multiple disparate systems, MIPS streamlined these into a single structure, consolidating the performance metrics into four domains: Quality, Cost, Promoting Interoperability, and Improvement Activities. MIPS scores healthcare providers in each area, with a composite performance score derived from these evaluations determining a positive, negative, or neutral adjustment to their Medicare Part B payments.

The primary purpose of MIPS is to transition the healthcare payment system from a volume-based, or fee for service model, to a value-based paradigm, incentivizing providers to deliver higher-quality and more efficient care. By linking payment adjustments to performance metrics, MIPS encourages clinicians to focus on activities that improve patient outcomes, advance the use of health information technology, and ensure cost-effective care. The overarching goal is to enhance patient care, foster innovation in delivery methods, and reduce overall costs to the Medicare program, ensuring its sustainability for future generations.

Current Status of MIPS

Under MACRA, for physicians to successfully participate in the Quality Payment Program (QPP), there are two tracks: MIPS and Advanced Alternative Payment Models (APMs). The APM path is designed for clinicians providing high-quality and high-value care and can focus on specific conditions, care episodes or patient populations. Clinicians participating in an APM who do not achieve Qualifying APM Participant (QP) or Partial QP status will be required to participate in MIPS. In addition to the two tracks in 2023, MIPS has three reporting options: Traditional MIPS, MIPS Value Pathways (MVPs) and APM Performance Pathway (APP). The MVP path offers clinicians subsets of measures and activities relating to a specific specialty or medical condition. The weighting and scoring of the four categories below vary depending on the pathway selected.

MIPS is a budget neutral program. The MIPS final score determines whether the clinician receives a positive, neutral or negative payment adjustment.

MIPS reporting in 2023 includes measures /activities data for the following three categories:

- Quality,
- Improvement Activities and
- Promoting interoperability.
- In addition, CMS collects and calculates data for Cost.

The Promoting Interoperability category requires a minimum of 90 continuous days, requires 2015 Edition Cures Update CEHRT and has four scored Objectives:

- Electronic Prescribing,
  - e-Prescribing
  - Query of prescription drug monitoring program (PDMP)
    - Schedule II, III and IV drugs
- Health Information Exchange,
  - Support electronic referral loops by sending health information and support electronic referral loops by receiving and reconciling health information or
  - Health information exchange bi-directional exchange or

  - Enabling exchange Under TEFCA - Attestation
- Provider to Patient Exchange and
  - Provide Patients electronic access to their health information
- Public Health and Clinical Data Exchange report to the following public health or clinical data registries
  - Immunization Registry Reporting
  - Electronic Case Reporting
    - For both above: Pre-production and validation or
    - Validated data production
  - Bonus point option to report one of the following public health agency or clinical data registry measures:
    - Public Health Registry reporting or
    - Clinical data registry reporting or
    - Syndromic Surveillance reporting

For information on the Quality, Improvement Activities and CMS Cost collection and calculation please see the CMS MIPS Resources below.

https://qpp.cms.gov/mips/traditional-mips

2023 MIPS Overview Webinar - YouTube

Payer-driven: HEDIS, NCQA, Payer-to-Payer Data Exchange

The interoperability and Patient Access rule released in 2020 required all payers to provide a standardized patient access API by 1 July 2021. In January 2024, CMS promulgated the Interoperability and Prior Authorization Final Rule which requires implementation of expanded patient access capability, new provider API access, new prior authorization APIs, and new payer-to-payer APIs by 1 January 2027.

The National Committee for Quality Assurance (NCQA) oversees the Healthcare Effectiveness Data and Information Set (HEDIS) measures. These NCQA-curated measures address a range of public health challenges, including heart disease, diabetes, cancer, and behavioral health. In collaboration with the Centers for Medicare & Medicaid Services (CMS), HEDIS measures are collected from Medicare Special Need Plans (SNPs). This data assists SNPs in pinpointing areas for improvement and in tracking the outcomes of their quality initiatives.

In a recent comment letter, NCQA addressed the move to digitize prior authorization, indicating that it could streamline patient and provider experiences. The adoption of digital methods may reduce administrative complexities inherent in prior authorization. NCQA supports CMS's directive for the full adoption of APIs by January 1, 2026, which is geared towards the enhancement of digital health data. This initiative is expected to accelerate the authorization processes and align healthcare with quality and value-based models. Additionally, NCQA highlights the potential benefits of integrating social risk data into healthcare practices.

NCQA also advises CMS to continue its incentives for standardized data exchange, such as those under TEFCA, to facilitate consistent quality measurement.

HEDIS and NCQA maintain annual reporting cycles with regularly updated standards. Concurrently, the industry is progressing with the phased introduction of standardized APIs and the payer-to-payer data exchange initiative. Standardized APIs define the protocols for software interactions. Within healthcare, they facilitate communication between varying systems, such as EHRs from distinct providers or disparate payer databases. This adoption is structured with phased compliance dates, allowing organizations to methodically adapt to these standards, mitigating disruptions. The payer-to-payer data exchange initiative underscores the importance of effective data sharing between insurance entities, particularly when patients transition between insurance providers. Efficient data transfer ensures continuity of care and minimizes repetitive procedures.

Reference

HEDIS & Performance Measurement

https://www.ncqa.org/comment-letter/ncqa-comments-on-cmss-advancing-interoperability-and- improving-prior-authorization-processes-proposed-rule/

https://www.cms.gov/priorities/key-initiatives/burden-reduction/faqs/payer-data-exchange

Information blocking (2021)

This practice involves limiting or restricting the exchange and use of electronic health information. The ONC (Office of the National Coordinator for Health IT) has set rules to prevent this practice, stating that healthcare providers, developers, health information exchanges, and health information networks are prohibited from engaging in information blocking. ONC's Cures Act Final Rule compliance dates have been set in various phases, with major compliance requirements effective since April 5, 2021.On June 27, 2023, the Department of Health and Human Services' Office of the Inspector General (HHS-OIG) released its final rule on information blocking penalties, grounded in the provisions of the 21st Century Cures Act. The rule sets forth penalties up to $1 million per violation but does not introduce new guidelines on information blocking. Instead, it references the existing regulations set by the Office of the National Coordinator for Health Information Technology (ONC).

Starting September 1, 2023, these penalties will be enforced. Notably, any violations before this date will not be penalized. The rule's focus is specific, targeting entities like health IT developers with certified technology, those offering such technology, and key players in data exchange like health information networks and exchanges. While this rule addresses penalties, it does not define disincentives for healthcare providers. This aspect is being addressed in a separate rule currently in development by the Department of Health and Human Services.

Reference:

ONC Cures Act Final Rule

https://www.federalregister.gov/documents/2023/07/03/2023-13851/grants-contracts-and-other- agreements-fraud-and-abuse-information-blocking-office-of-inspector

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=0955-AA05

Brief Summary: Structure of Interoperability Frameworks and Networks

Interoperability Methods

There are various methods of health information exchange which are often used in combination to best support the clinical use case:

1. Directed Exchange allows data to be "pushed" from one entity (e.g., out of a healthcare organizations EHR directly to another, e.g., to support transitions of care, referrals, discharges, care coordination, results delivery, Admission, Discharge and Transfer (ADT) Notification and public health reporting.)
2. Query-based exchange (a "pull") allows those seeking information to request this from a data holder, either the original source, such as a healthcare provider, through federated exchange, typically facilitated by a health information network (HIN), or from a centralized system, such as a regional HIE/HIO. Federated exchange is where the data stays in the system where it was originated and is pulled to another system across a Network. Non-Federated exchange is when data is moved from the originating system into a central data repository (CDR) where it is stored along with data from multiple other originating sources and this CDR is then queried for data. There are obvious privacy and security implications for this model.

Consumer Mediated Exchange leverages the individual's rights under HIPAA to access and obtain (View, Download and Transmit) a copy of their health information and share this information with others, if the consumer so desires.

National Interoperability Frameworks and Networks

In 2001, with the advent of electronic prescribing, proprietary Networks developed to connect prescribing providers, pharmacies and payers. In 2013, the CommonWell Health Alliance was developed, a vendor-led initiative to allow the exchange of data between users of several vendor EHR systems.

CommonWell is a Network where Protected Health Information (PHI) can be exchanged across organizations using member vendor systems, but only with the systems that are part of the CommonWell Alliance, and not others. During this period there was a proliferation of a number of private health information Networks to address market needs, however none of these Networks were under Frameworks.

With Network proliferation it became clear that there was a need for a Trust Framework to facilitate exchange across and between the range of evolving Networks. Trust Frameworks, which have developed in other industries, such as financial services and telecommunications, support cross-network data sharing and workflows. The first such Framework, started in 2011, was DirectTrustTM which governs and accredits interoperable Direct Networks called Health Information Service Providers or HISPs pushing Direct Secure Messages.

In 2014 the Carequality Interoperability Framework was founded, a Trusted Exchange Framework that governs Carequality Networks which are called Carequality Implementers.

Frameworks make it possible for healthcare to replicate the success other industries have achieved in breaking down barriers between many Networks, programs, and platforms.

Frameworks (DirectTrust, Carequality and TEFCA) provide certain characteristics for Networks to exchange PHI:

1. Networks and their endpoint participants must agree to a common set of data sharing policies and legal terms.
2. Technical standards by which exchange actually happens (Implementation Guides / SOPs).
3. Technical means of identifying trusted endpoints (directory/security).
4. A process for onboarding and monitoring to ensure networks and endpoint participants adhere to technical standards.
5. Governance to review & update all the above on a regular basis.

Trust Frameworks utilize agreements to define an Entity which acts as an intermediary (the Network) and clearly distinguish those Entities from the Network's "connections / participants" who typically do not contract directly with the Trust Framework.

It is important to note that interoperable exchanges do not cross Networks regulated by different Frameworks. For example, an organization sending a message via Direct will not be received through a Carequality Network into a recipient EHR.Both CommonWell and eHealth Exchange are Networks. Both have drawn to their Network different specific organization types. CommonWell has several EHR vendors and eHealth Exchange has many participating Health Information Exchanges (HIEs) and Government organizations. That being said, in order to be able to exchange outside their participating organizations they needed to become Carequality Implementers. For example: CommonWell participants can readily exchange with the EHR vendor healthcare organizations within Commonwell, but to exchange with non-CommonWell EHR vendors they would need to subscribe to Commonwell's Carequality Network as well.

Table 1. Networks and Frameworks

Network	Push/Pull	Consent	Trust Framework	Directory	Record Locator Service	Documents	Use Cases
QHINs cvAs of December 2023, the following are the TEFCA designated QHIN Networks: EHealth Exchange, Epic Nexus, Health Gorilla, Konza, MedAllies	Currently Pull Query only Push Future	Yes	TEFCA	QHIN Directory (Organization Level) FHIR Directory Future	All QHIN Networks need to have	IHE based C-CDA, Aggregated Record FHIR Resources Future	Initial Required IAS and Treatment Future: operationalize additional purposes of use in short order, including Public Health, Payment, and Healthcare Operations

Table 1. Cont.

Network	Push/Pull	Consent	Trust Framework	Directory	Record Locator Service	Documents	Use Cases
CarequalityTM Multiple Networks called “Carequality Implementers”	Massachusetts General Hospital	Yes	Carequality Trust Principles Agreement and Carequality Connected Agreement	Carequality Directory (Organization Level) FHIR Directory in Development	Yes	IHE based C-CDA, Aggregated Record FHIR Resources Future	Finding available patient data. Treatment Required with Live. Future: IAS, OBO, operationalize additional purposes of use in short order, including Public Health, Payment, and healthcare Operations, On Behalf Of (OBO)
CommonWellTM (*Also, a Carequality Implementer) Data Privacy and Security Policy and CommonWell Member Services Agreement	Query based Pull	Yes	Not a Framework	CommonWell Directory	Yes	IHE based C-CDA, Aggregated Record	Finding available patient data. Treatment Required with Live. Future: IAS, OBO, operationalize additional purposes of use in short order, including Public Health, Payment, and healthcare Operations, On Behalf Of (OBO)
Direct Multiple Vendor Networks called HISPS	Push	No for Provider to Provider,	Registration Authority, Certificate Authority, HISP Trust Framework, Federated Services Agreement	Direct Directory (Individual Level)	No, not required as Point to Point Push	IHE based C-CDA, Aggregated Record Also, sent information may be curated from sender to receiver	Transition of Care, ADT Alerts, Any Push Document Exchange
Regional/State HIE Multiple Via Participation Agreement (Business associates or their covered entities) HIE can produce an audit log	Pull Data received by Direct Networks or Queried via National Networks	Yes	Not a Framework	No	No RLS, Each HIE maintains own MPI and data clean up algorithms maintained by many HIEs	Aggregated Record for specified region	Finding available patient data and may have cleaning (e.g. Deduplication), sharing as needed with their membership ADT Panel Based Push Notification
eHealthExchange (*Also, a Carequality Implementer) DURSA Trust agreement	Pull	Yes	Not a Framework	EHE Network Directory & FHIR R4 (HAPI) directory	No RLS	IHE based C-CDA, Aggregated Record	Same as Carequality

HIM Body of Knowledge, AHIMA, 2023

Implementing Interoperability: General implementation Requirements and Considerations

IMPLEMENTATION, CHANGE MANAGEMENT, ADOPTION AND USAGE

Identify a Clinical Lead and your Organization’s Use Cases

As with all implementation projects it is recommended to identify a strong, well-respected and well-liked physician/clinician leader for the interoperability implementation project. Then, to identify yourorganization’s priority interoperability use cases. Examples may include querying for all external patient data for the roster of patients scheduled for encounters for the following day (a ″pull” use case) or sending patient data as a specialty referral is ordered and receiving the referral summary following the specialty encounter (“push” use cases).

Work with your EHR vendor

Once these use cases are identified it is recommended to then work with your EHR vendor to advise you regarding the technology and workflow options available. Your vendor might be able to recommend specific preferred Networks that they have agreements with. Make sure that the Network has access to all the Information you will require, preferably a Network that is part of a National Framework. In addition, your EHR vendor can advise you regarding the best practice role-based workflows in their software. Use this as a starting point to create role-based workflows specific to your organization with consideration taken of your staffing models and capabilities.

What’s in it for me? (WIFM)

Create end-user buy-in, and ultimate adoption of the project by engaging all involved in defining the role- based workflows and ensuring their understanding of the advantages for them of the new processes to their workload.

Create screenshot-based training materials for each of the steps of the role-based workflow and train all participants. Once the project is live, ensure that there is adequate support for the new end users during the initial implementation. Track metrics and provide additional training and support if the new processes are not being followed.

Materials for clear patient education, consent/decline and information about the organization’s data sharing of PHI must be created and obtaining patient consent or refusal needs to be included in the workflow process. Interoperability projects differ from most other implementations as they may involve working with external organizations for optimal implementations. For example, if you are implementing a specialty referral use case, the implementing organization would identify their prominent trading partners and potentially reach out to discuss the project and expectations, such as defining the timing expectations for the use case of patients referred to specialists. When a patient is referred to a specialist, the relevant data is pushed at the time of the consultation request and pushed back to the referring provider following the completion of the consultation. Track project success and reach out to trading partners for improvement if they are not achieving the agreed upon timelines or are falling back to old methods, e.g. Fax or eFax.

National Interoperability Requirements

Electronic Health Records (EHRs) are required to include data exchange as core product offerings due to Health IT Certification requirements from the Office of the National Coordinator for Health IT (ONC), information blocking rules in the 21st Century Cures Act, and value-based payment program trends.

Individuals and organizations interested in exchanging data beyond their walls should first review their technology vendor certification status.

IHE and HL7

Information exchange generally relies on Integrating the Healthcare Enterprise (IHE) profiles and Health Level 7 (HL7) document architecture. Both IHE and HL7 are composed of member organizations and advisory councils that review, maintain, and update standards widely accepted by health IT networks and vendors. IHE profiles describe critical workflows such as how to conduct cross-referencing of patient identifiers from multiple domains, audit trail and node authentication, and document discovery and retrieve. HL7 standards include structural specifications for Consolidated Clinical Document Architecture (C-CDA), messaging standards such as Version 2, and Fast Healthcare Interoperability Resources (FHIR).

A national network interaction (cross-gateway query) using IHE standards may follow the following steps:

1. ITI-55: XCPD, Patient Demographic Query
2. ITI-38: Document Request
3. ITI-39: Document Retrieval

FHIR

FHIR is a standard for Application Programming Interfaces (API) to represent and exchange health information. FHIR leverages existing concepts familiar to developers outside of healthcare to simplify application creation. It creates a set of resources that can be interacted with individually or in combination to satisfy use cases. These resources tend to be simple in construction which encourages exchange across a network. For example, the Patient resource includes a human readable summary and then a core set of structured data elements such as medical record number and name.

USCDI

The United States Core Data for Interoperability (USCDI) is a standardized set of health data classes and elements for nationwide interoperability. The data classes are aggregations of elements by a common theme or to support a specific use case. The data elements are individual pieces of data. For example, an organization may request Clinical Notes (the class) for follow-up care, and receive a consult note, discharge summary, history & physical, imaging narrative, lab report narrative, pathology report, procedure note, and progress note (the elements). Each element is further defined by relevant standards where applicable, such as Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) or Local Observation Identifiers Names and Codes (LOINC).

Additional References

https://www.ihe.net

https://www.hl7.org/

https://www.healthit.gov/

https://chpl.healthit.gov/

Looking Ahead

As we delve deeper into the future of healthcare interoperability and integration, we remain optimistic about fostering true national trusted and secure interoperability across all healthcare constituents.

The National Directory of Healthcare Providers and Services presents a promising avenue for streamlined healthcare service provisions, acting as a comprehensive catalog for stakeholders. Moreover, we hope the USCDI becomes a beacon of hope in standardizing health data. By refining the USCDI, we aim to ensure consistency and accuracy in health information across various platforms.

Sequoia's Data Usability Workgroup, as the name implies, is focused on clinician interoperability adoption and usage and enhanced patient care through ensuring that received data is trusted and usable by the recipient clinician or other healthcare constituent end user. This group has already created a Version 1 Implementation Guide and are working on Version 2.

The Sequoia Data Usability Taking Root Movement encourages the development of the Data Usability Implementation Guide within applicable HIT systems.

The Electronic Prior Authorization (ePA) processes also present areas ripe for exploration; by potentially streamlining these procedures, there might be enhanced patient care access and reduced administrative bottlenecks. Furthermore, we hope that the broader adoption of Application Programming Interfaces (APIs) represents a significant leap towards fluidity in information exchange, ensuring that health institutions might seamlessly integrate data, improving both patient and provider experiences.

While we celebrate the strides made, we remain mindful of the prevailing challenges. Barriers in electronic health data sharing, fragmented health information exchanges, and the evident gaps in health IT incentives underscore the work that lies ahead. A collective approach is pivotal, accentuated by our ambition to prioritize information dissemination, uphold technology standards, and ardently support health equity.

Together, we stand at the precipice of creating a robust, interconnected health IT infrastructure for future generations. The ONC supported TEFCA Framework with their designated QHIN Networks will truly be the "on-ramp" for next phase of national interoperability simplifying the process for patients, providers and authorized healthcare participants to share health information securely and efficiently. This framework represents the ambition to achieve a single national interconnected health system.

References

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