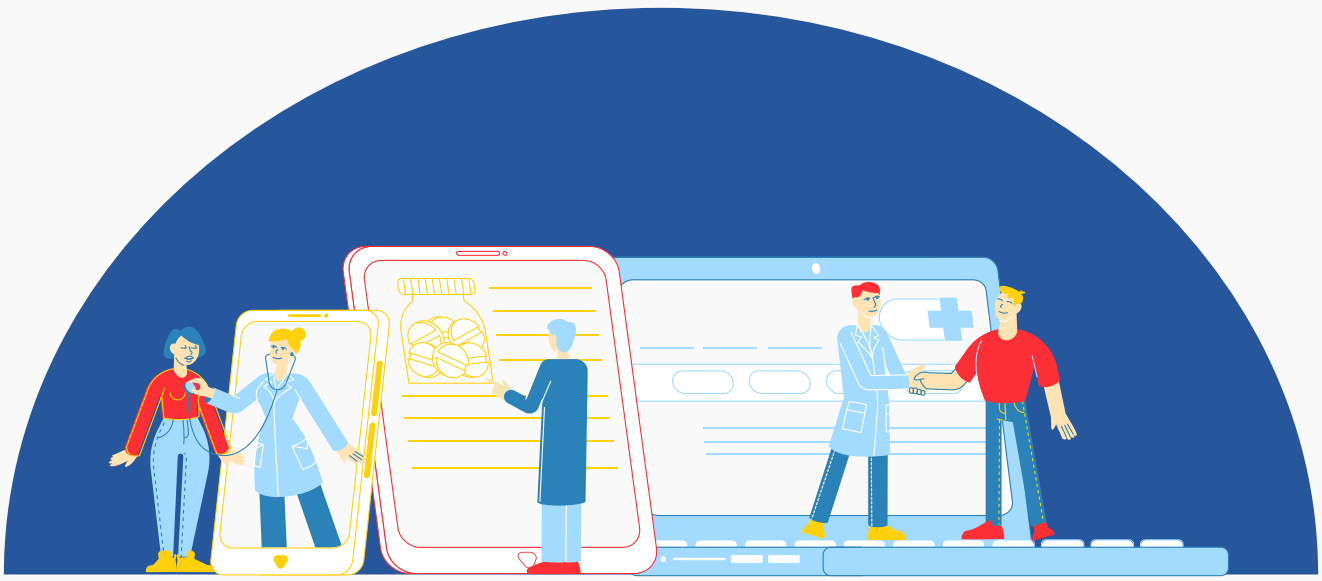
White paper

DAMO CONSULTING

Interoperability and Patient Access

The CMS final rule: what it is, who gets impacted, and how to plan for the future

This paper contains a detailed summary of the Interoperability and Patient Access Final Rule and the 21st Century Cures Act, along with technical and implementation standards. The paper explains how the ruling impacts healthcare enterprises and technology firms and provides a planning guide for implementation of the requirements.



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Authors

PADDY PADMANABHAN

Paddy Padmanabhan is the CEO of Damo Consulting, and co-author of the book ***Healthcare Digital Transformation: How Consumerism, Technology and Pandemic are Accelerating the Future (Aug 2020)***.

paddy@damoconsulting.net

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JOYOTI GOSWAMI

Dr. Joyoti Goswami is a Principal Consultant at Damo Consulting who works closely with our technology and healthcare provider clients.

joyoti@damoconsulting.net

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Executive Summary

Historically, nuances of a patient's healthcare journey have been locked in multiple silos within electronic health records and payer systems, both being the custodians of patient data. A patient visiting various providers has his or her health record stored into individual EMRs of the providers as well as in the claims and encounter data of payer systems. With the final ruling, the patient can now get medical records on their smartphones using any application of choice. All their health information from labs, prescription data, past medical history, and data from continuous monitoring devices like Fitbit can now be available on the screens of their phones. Undoubtedly, this will create a high level of empowered and engaged patients. The success of healthcare facilities in the post-COVID world, therefore, depends on the interoperability of healthcare information and making it available to all stakeholders across the healthcare continuum, with the patient being at the center of all data exchange transactions. In the end, it is all beneficial for the patients who are more engaged and a partner in their healthcare decisions.

The MyHealthEData initiative was announced at the HIMSS 2018 conference, following which the Office of the National Coordinator (ONC) and CMS released the Interoperability and Patient Access Final Regulation on May 1, 2020. The regulation implements the key provisions of the 21st Century Cures Act and empowers patients with control of their own healthcare records. The deadline to implement the final rule is early- to mid-2021. There is a list of infrastructure and technology updates that payers, providers, and Health IT vendors need to implement to comply with the ruling.

For payers, the first milestone is in January 2021, which gives them less than six months to put their action plan together. The CMS has announced a temporary policy of relaxed enforcement due to the COVID-19 crisis which may extend to July 2021. Nevertheless, the payers must have the technical infrastructure in place to share patient claims, encounters, and clinical data stored in their databases in a format that can be easily consumed by third-party developers and applications. The data must be made available in FHIR compliant APIs (Application Programming Interfaces), and USCDI prescribed vocabulary standards along with a robust patient authentication and identification standard.

For providers, including the healthcare systems, the ruling is relatively more straightforward with most of the technical implementation burden being on the EMR systems, payer systems, and other technology vendors. Provider organizations only need to attest to not blocking information and providing digital contact information to NPPES online records.

The technology vendors must conform to the vocabulary standards and attest to the technical and implementation standards. In this paper, using Damo's ICEA™ framework, we have highlighted the applicable impact of the ruling on each of the four types of technology providers.

This paper explains how the CMS Interoperability Rule impacts healthcare enterprises and technology firms, and provides a roadmap to plan for the future.

Introduction

The healthcare regulatory landscape in the United States has been continually evolving ever since the HITECH Act proposed the meaningful use of interoperable electronic health records throughout the healthcare delivery system. Healthcare providers using an electronic medical record system has increased from 20% in 2004 to more than 86% in 2017. There have been many regulatory norms and quality reporting measures to protect the interest of the patients and reduce costs across the care continuum. The electronic medical record systems have been at the center stage for all the reporting to happen. There has been improved documentation of patient health records but most of this information has been locked with the technology providers or the payers. Patients have had little or no ownership of their data.

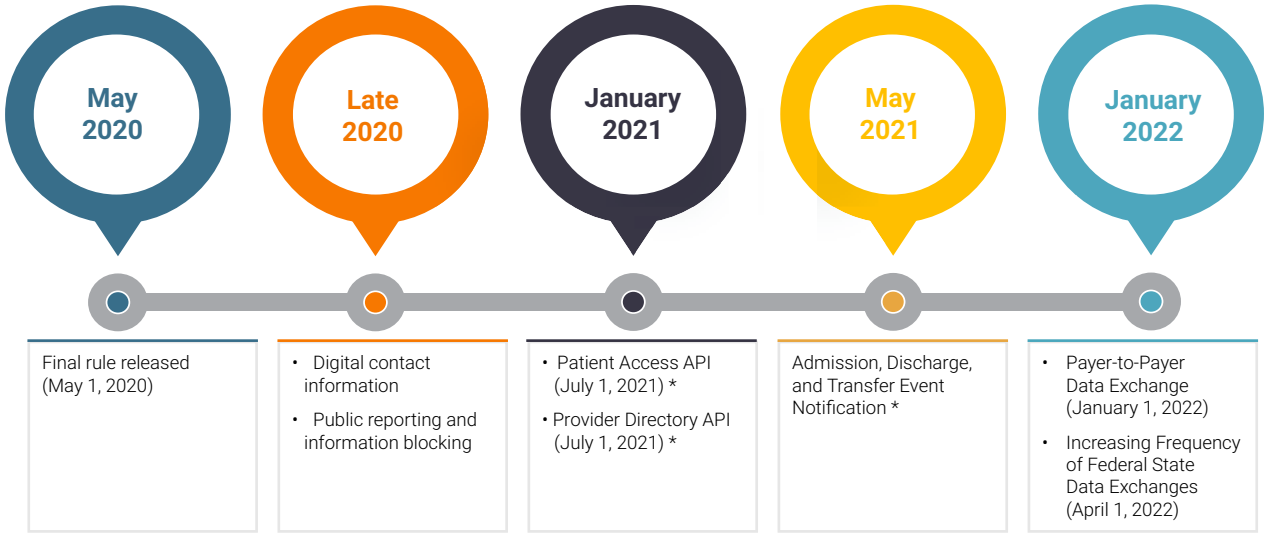
Given this background, the CMS announced the MyHealthEData initiative to empower patients to give them control of their healthcare information. This will allow patients to share their data with other providers and access it on any device or application of their choice. The Interoperability and Patient Access rule will support the regulations of the MyHealthEData initiative and 21st Century Cures Act within a defined timeline.

The information required for completing the compliance parameters, however, is exhaustive and scattered in multiple sources. This paper will help organizations to identify their essential requirements and implementation strategies to help them define their roadmap.

The Final CMS RULE

Interoperability and Patient Access: Timeline and What it Means For Patients, Providers, and Payers

The final CMS rule for Interoperability and Patient Access empowers patients by giving them access to their health information when they need it, on any device or application of their choice, and in a way, they can best use it.



* In view of the COVID-19 crisis, CMS has extended the implementation timeline for the proposals by six months.This timeline has been updated accordingly.

What It Means For: Patients, Providers, and Payers

The new ruling empowers **patients**. The major onus of updating technology infrastructure to publish the APIs is on the **payers**. **Providers** must attest to "not blocking information" and updating their digital contact information. The update to ADT electronic patient event notifications will be facilitated by the EMR vendors.

Patients

- Access their own data at no additional cost
- Share and decide how their data will be used
- Access health information from any device or application of their choice
- Ensure security and privacy of the data

Providers

- Digital contact information on NPPES portal
- Public reporting of information blocking
- ADT electronic patient event notifications

Payers

- Publish patient access API
- Publish provider directory API
- Exchange data set to another plan or to recipient as identified by the enrollee
- Participate in a trusted exchange network
- Increase the frequency of federal-state data exchange to submit data to CMS daily

What The Final Ruling Means For Different Healthcare IT Providers (ICEA™ Framework)

For healthcare technology providers, the new ruling comes with increased opportunities in terms of innovations and increased technological enhancements of existing infrastructure vendors.

Innovators

Point solutions: "we have a whole new way of doing it":

E.g. Digital health startups

- Compliance to the FHIR integration framework and USCDI data standards

Custodians

Systems of record: "we have the data and the workflow":

E.g. EHR vendors

- Make available open access FHIR APIs with USCDI vocabulary compliance
- Patients to get electronic access to their data at no additional cost

Enablers

Platforms: "rent it, build on it":

E.g. Health cloud platforms

- Provide development environment with FHIR APIs, security and identity management, PHI/HIPAA, and other tools

Arbitrageurs

Resources: "cheaper, faster, better":

E.g. Consulting firms

- Consulting firms with good knowledge of healthcare domain and technology – EMR data standards and FHIR APIs

The Rule

The Interoperability and Patient Access rule has been framed in consultation with a group of stakeholders led by the White House Office of American Innovation. The rule implements the provisions of the 21st Century Cures Act to advance interoperability; support the access, exchange, and use of electronic health information (EHI); and address occurrences of information blocking. The rule is primarily useful for healthcare IT developers to develop new products and maintain the certification of existing products.

Stakeholders

HHS has finalized the technical and content standards of the ONC 21st Century Cures Act final rule, which has been adopted by CMS. NIH is actively funding the FHIR related research and development. Organizations involved in the finalization of the rule:

- CMS (The Centers for Medicare & Medicaid Services)
- HHS (Department of Health and Human Services)
- ONC (Office of the National Coordinator)
- NIH (National Institutes of Health) and
- VA (Veteran Affairs)

Inclusions and Exclusions

The CMS is authorized to regulate the policies of this rule on the following payers:

- Medicare Advantage (MA)
- Medicare and Medicaid
- Children's Health Insurance Program (CHIP)
- Qualified Health Plan (QHP) issuers on the federally-facilitated exchanges (FFEs)

The following payer groups are excluded from the Interoperability regulations:

- Stand-alone dental plans (SADPs)
- QHP issuers only offering QHPs in the Federally-facilitated Small Business Health Options Program Exchanges (FF-SHOPs)
- State-based Exchanges on the Federal platform (SBE-FPs)

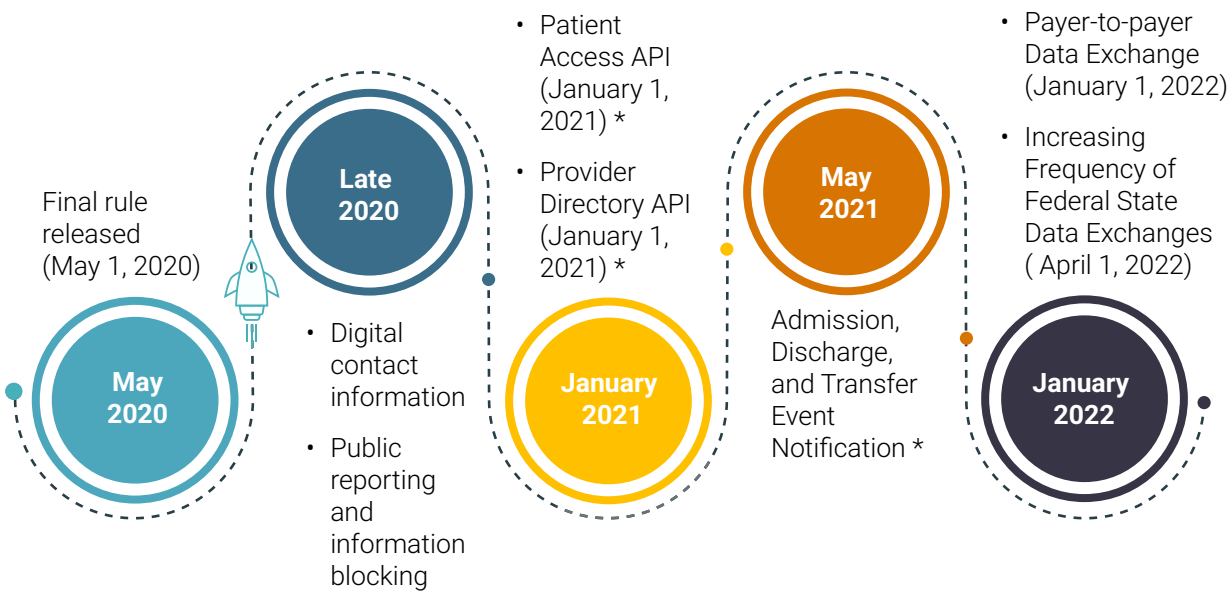
Outcomes

As an outcome of this ruling:

- The Meaningful Use Programs and the QPP (Quality Payment Program) will have an increased focus on interoperability
- QPP (MIPS MACRA) that leads to interoperability will be prioritized
- Information blocking will be discouraged and reported on a public website

The Interoperability and Patient Access final rule empowers patients by giving them access to their health information when they need it and, on any device or application of their choice and in a way, they can best use it.

Figure 1: Timelines for the implementation of the interoperability and patient access ruling



** In-view of the COVID-19 crisis, CMS has extended the implementation timelines for these proposals by six months*

Source: (Centers for Medicare & Medicaid Services, 2020)

Key Terminologies

Following is a list of key terms to help understand the ruling:

MyHealthEData: This is an initiative launched to empower patients to have control over their health records from any device or application of their choice. Patients can have electronic access to their healthcare records using the Blue Button API.

Blue Button 2.0: This is a standards-based FHIR API that enables beneficiaries to connect their claims data to the applications, services, and research programs they trust. It uses the OAuth 2.0 standard for beneficiary authorization. This standards-based FHIR API has been developed by CMS and contains four years of Medicare Part A, B, and D data for 53 million Medicare beneficiaries. Developers can integrate with the Blue Button API to develop applications containing a variety of beneficiary health data such as:

- Type of Medicare coverage
- Drug prescriptions
- Primary care treatment
- Cost of treatments in the past

21st Century Cures Act: This act is designed to give patients, healthcare providers, and the healthcare industry to adopt standardized APIs to allow individuals to securely access structured and/or unstructured electronic health information at no additional cost. The rule also implements provisions to discourage information blocking. The health IT certification criteria and the ONC Health IT Certification Program has been updated.

Good to Know!

Major Highlights of 21st Century Cures Act

1. Deregulatory actions for previous rulemakings: A few certification criteria and randomized surveillance have been removed that will reduce the burden for health IT developers, providers, and other stakeholders.
2. Some certification criteria have been updated to include:
    a. Adoption of the USCDI as a terminology standard.
    b. Electronic prescribing (e-Rx): Update to NCPDP SCRIPT standard version for certification to the electronic prescribing criterion of the current part D e-Rx and medication history.
    c. Clinical quality measures (CQM) report: Health IT modules will now support the CMS QRDA implementation guides (IGs).
    d. Electronic health information (EHI) export: To provide a means to export the entire EHI, a certified health IT product to support single-page EHI export and for patient EHI export when a health care provider is switching health IT systems.
    e. Application programming interfaces (API): FHIR Standard Release and advance interoperability of API-enabled "read" services for single and multiple patients.
    f. Privacy and security transparency attestations: To identify whether certified health IT supports encrypting authentication credentials and/or multi-factor authentication (MFA).
    g. Security tags and consent management: Data segmentation for privacy (DS4P) for creating and receiving summary records with security tagging in the Consolidated Clinical Document Architecture (C-CDA documents).
    h. Modifications to the ONC Health IT certification program: There have been updates to the certification criteria, and the requirements have been broadened beyond the Medicare and Medicaid EHR incentive programs, which has now been renamed to Promoting Interoperability (PI).
4. Health IT for the care continuum. This includes:
    a. The National Coordinator to encourage and recognize the voluntary certification of health IT for use in medical specialties and sites of service where more technological advancement or integration is needed.
    b. Outlines a provision related to the voluntary certification of health IT for use by pediatric health providers to support the health of children.
5. Conditions and maintenance of the certification program: The "Conditions of Certification" and "Maintenance of Certification" rules that have been defined for health IT developers and certified Health IT modules prohibits them from any Information Blocking, they would also need to attest for the same if needed. A developer must, through an API, "provide access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws."

Source: (The Office of the National Coordinator for Health Information Technology, 2019)

Technical Standards

HHS has finalized the technical standards in the ONC's 21st Century Cures Act final rule for payers and developers to use:

Fast Healthcare Interoperability Resources (FHIR) Standards for APIs

FHIR Release 4.0.1 resources define the content and structure of core health data, which can be used by developers to build standardized applications. FHIR is the missing link between the EMR and various apps and IoT devices. ONC requires the APIs to make common clinical data sets specified by USCDI, such as the patient's problem list, medication list, and others, available via the API. As a part of this standard, existing technologies will have to map their current data feeds to FHIR resources for which a mapping tool is available. A FHIR resource contains a set of structured data items as defined by the resource type. A target FHIR server can register the client with a defined set of FHIR resources.

SMART IG / OAuth 2.0

(Secure authorization of third-party apps using the OAuth 2.0 standard)

This standard is used by app developers to access FHIR resources by requesting access tokens from OAuth 2.0 compliant servers.

App developers can access FHIR resources by requesting access tokens from OAuth 2.0 compliant FHIR authorization servers that have defined scopes of access. HL7 FHIR has defined the SMART App Launch Framework that can connect third-party applications to Electronic Health Record data. This framework supports apps for use by patients and providers to launch either stand-alone or from a portal. The profile defines a method through which an app requests authorization to access a FHIR resource, and then uses that authorization to retrieve the resource. Synchronization of patient context and HIPAA compliance are out of scope for this profile. The OpenID Connect framework addresses this.

OpenID Connect

The identity layer on top of the OAuth 2.0 protocol enables clients to verify the identity of the end-user based on the authentication performed by an authorization server, as well as to obtain basic profile information about the end-user in an interoperable and REST-like manner.

OpenID Connect implements authentication as an extension to the OAuth 2.0 authorization process.

Content and Vocabulary Standards

USCDI: US Core Data for Interoperability (USCDI) is a standard data set. It is the foundation for sharing electronic health care information needed for the API FHIR interface.

For example, allergies and intolerances are a data class which includes three data elements that must be mapped to the data standards indicated below.

Example data class: allergies and intolerance	
Data Elements	**Vocabulary Standards**
Substance (Medication)	RxNorm™ and The Unified Code of Units for Measure (UCUM™)
Substance (Drug Class)	SNOMED™ International
Reaction	SNOMED™ International

Table 1: Example USCDI data class for allergies and corresponding vocbulary standards

Following are the mandatory 16 data classes with their component elements and respective vocabulary standards defined for content sharing.

Figure 2: United States Core Data for Interoperability (USCDI) Data

Source: HealthIt.gov (United States Core Data for Interoperability, 2020)

Implementation Standards

The policies of the interoperability rule have different implementation roadmaps for payers and providers. A high level of the implementation guidelines for each segment is described briefly below for each of the policies:

Policies Applicable to Payers

It may become challenging for most payers to move to the FHIR API R4 world. Most payers have online portals for their members and must upgrade themselves by moving to FHIR APIs so that beneficiaries can access data through apps. Below are the policies that apply to payers:

Patient Access API: Payers are required to make a patient's claims and encounter data available via the Patient Access API. Using the HL7 FHIR resources, the Patient Access API should have at a minimum the following data points and should be available within one business day after it is received:

- Adjudicated claims ((including provider remittances and enrollee cost-sharing)
- Encounter data
- Clinical data: This is the data that is maintained by the payer and includes the 16 data classes that are included in USCDI Version 1.
- Laboratory data
- Drug Benefit data

The CARIN Blue Button® Framework and Common Payer Consumer Data Set (CPCDS), provides a set of resources that payers can display to consumers via a FHIR API.

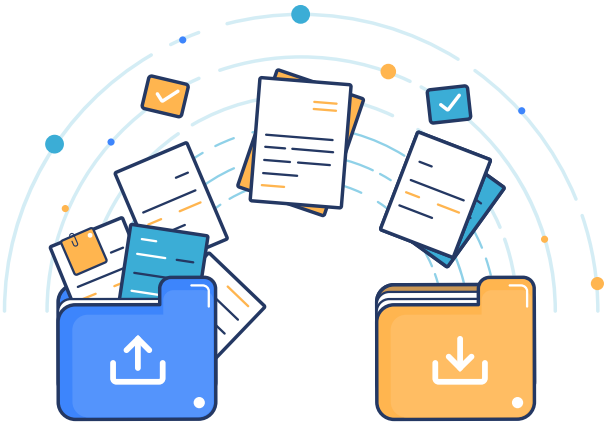
Provider Directory API: Under this rule, payers are required to make the provider information available on the payer's website by using the Provider Directory API.

The DaVinci PDEX Payer Network Implementation guide defines a standard FHIR based API that can enable third party applications through which consumers and providers can query the contents of a payer's network to identify providers that can address their health care needs.

While provider directories are readily available with multiple sources, including the hospital listing all its physicians, the focus of this API is the payer-provider directory. This API provides information specific to the practitioner and includes provider name, NPI, specialty, insurances accepted, hospital affiliations, gender, languages spoken by the practitioner, and locations at which the provider is available.

Payer-to-Payer Data Exchange: Payers should have the provision to exchange data sets of up to five years to another plan that the enrollee wants to move. This process must be implemented by January 1. 2022. The DaVinci Payer Data Exchange project (PDex) defines a FHIR interface to a health insurer's drug formulary information for patients and consumers.

This implementation covers the exchange of claims-based information and clinical information using the clinical resources based on FHIR R4. The clinical data is inclusive of the elements defined in the USCDI version 1 data set. This implementation will ensure that the new payer has complete records if the patient has changed plans. It will also allow providers to request data from the plan and third-party application exchange.



Source: Designed by pikisuperstar / Freepik

Increasing Frequency of Federal-State Data Exchanges: States are required to implement the daily exchange of data starting April 1, 2022. Currently, the data exchanges happen monthly, which will now be changed to daily exchange. The daily exchange will benefit beneficiaries who have dual eligibility (e.g., both Medicare and Medicaid) to get access to appropriate services and billed the first time, eventually leading to less waste. The increased data exchange will need both sending and receiving responses from CMS daily. In the post-COVID world, this is an important policy which will help to track, trace and monitor patients requiring isolation.

Participate in Trusted Exchange Network: A "Trust Framework" can verify the security and identity of participants on both ends of the communication channel and share health information freely. Payers in CMS programs should be able to participate in a trusted exchange network that allows them to join any health information network they choose. Information can securely flow across payers and providers throughout the healthcare system.

Policies Applicable to Providers

Public Reporting and Information Blocking: This refers to a practice by a healthcare provider, health IT developer, HIE, or HIN to do anything that is likely to interfere with access, exchange, or use of EHI. CMS will publicly report eligible clinicians, hospitals, and critical access hospitals (CAHs) that may be blocking information based on how they attested to certain Promoting Interoperability Program requirements. The attestation requirements consist of three statements about a provider's use of CEHRT to which a provider needs to attest in the affirmative. This information will be available on the profile pages of the providers, hospitals, and CAHs on a public website. It will help patients choose providers who have attested to Promoting Interoperability.

Digital Contact Information: Providers will have to update their digital contact information as a direct address, and/or FHIR API endpoint. CMS has updated the National Plan and Provider Enumeration System (NPPES) to capture digital contact information for individuals and facilities. CMS will publicly report the names and NPIs of providers who do not have their digital contact information stored in the NPPES. NPPES has also added a public API that can be used to obtain contact information stored in the database.

Admission, Discharge, and Transfer Event Notifications: Hospitals and CAHs need to send electronic patient event notifications of a patient's admission, discharge, and/or transfer to another healthcare facility or another community provider or practitioner. An electronic patient event notification message is triggered when there is a change in the ADT status of the patient either directly to the designated provider or through an HIE. Hospitals not part of an HIE will have to develop and maintain this functionality. The receiving provider or facility of the notification will be able to reach out to the patient and deliver timely follow-up care.

Following the pandemic, sharing ADT information to subsequent caregivers of a patient at the time of discharge will help in better contact tracing and follow-up of COVID positive patients.

Implementation Strategies for Technology Firms: ICEA™ Framework[1]

What the final ruling means for the different types of technology providers in the healthcare IT market

Innovators	Custodians	Enablers	Arbitrageurs
These are digital health startups, technology firms, and app developers. A world of opportunity opens for them as they can now create technology solutions for various market needs due to the availability of patient data that was till now locked down in EMRs. Technologies will need to be updated to FHIR.	EMR vendors have long been the custodians of data. Most of the leading EMR vendors have dedicated developer portals with APIs available in their sandboxes that can enable technology vendor companies to create applications.	Many cloud platforms focus on healthcare environments that provide standards compliant code and plugins to facilitate development. Microsoft and Google are two of the leading platform providers that have the FHIR API environment along with security measures to enable deployment in a SaaS or PaaS model quickly.	Consulting firms with a strong knowledge of technology and healthcare domain can reap in the benefits by offering niche consulting services to stakeholders to fill in the gaps and provider expertise to solve business challenges.

The Damo ICEA™ framework classifies technology providers into four categories based on a set of attributes. The framework is a useful guide for healthcare IT executives and their technology providers to understand the competitive positioning of various vendor types in the health IT market.

The four categories in the Damo ICEA™ Framework and how they are impacted by the CMS final ruling[2]:

- The **innovators** and digital technology solution vendors need to update their product strategy to take advantage of this entirely new world of data that has now been made accessible. Personal Health devices and remote monitoring sensors can create personalized data solutions for patients using the advantage of the data stored with the custodians, aka EMRs and payers.
- The **custodians** of the data are the EMRs and payer systems. Many of the legacy systems are still on an HL7 2.x version. They will need to upgrade to FHIR to comply with the ADT electronic notification of patient transition events to the primary care physician.
- The **enablers** are the technology platform vendors that are enabling the interoperability ruling by providing hosted solutions on the cloud that can help health plans to comply with toolsets and easy to configure interfaces. These are hosted platforms that provide the infrastructure to create exportable data extracts and convert them to the FHIR formats in custom data lakes.
- The **arbitrageurs** or consultants have a primary role to play by converting the data sets to the recommended FHIR and USCDI vocabulary standards. Understanding all the nuances of the interoperability ruling and knowing where to start is the first step towards a successful implementation.

1 From the book Healthcare Digital Transformation: How Consumerism, Technology and Pandemic are Accelerating the Future by Edward Marx and Paddy Padmanabhan, (publisher Taylor & Francis, 2021)

2 Padmanabhan, P. (2017). The Big Unlock: Harnessing Data and Growing Digital Health Businesses in a Value-Based Care. Archway Publishing (17 November 2017)

Implementation Strategies for Healthcare Enterprises

Organizations that are directly affected by the Interoperability and Patient Access rule include:

- Payers
- Provider Organizations, including hospitals and health systems
- EMR, LIS, RIS, and other core health IT technology vendors
- Digital health startups such as device manufacturers and health app developers

Payers

Following are the steps to follow for a successful implementation of the rule:

Current state assessment

The current state assessment will list out existing data packets for capturing claims, diagnoses, procedures, member details, and coverage data along with the current HL7 version being used. It will also check for inconsistencies in the vocabulary standards defined by USCDI.

Identifying and mapping the gaps

a. Mapping to FHIR Resources: The data elements identified must be mapped to FHIR resources, details of which are available in the CARIN Blue Button framework.

b. Mapping to the USCDI Vocabulary standards: Once the FHIR resources have been finalized, the healthcare database content must be mapped to the defined USCDI vocabulary standards. This step can be an extensive exercise for organizations that are just setting up their EMR systems. Organizations already using EMRs are likely to have the USCDI standards in place, and only the gaps identified must be addressed.

Hosting and orchestration

a. Use API gateway or platform: A healthcare platform customized to healthcare database content and data standards with custom plugins may ease the implementation process. Payers must host the APIs on a platform so that they are easily accessible to developers. Payers must create rules and policies to define this access.

b. Enable security and identity standards: Security and identity standards have been defined in the HL7 FHIR SMART app launch framework and OpenID Connect. Payers must set up the authorization and identity process for third-party apps using OAuth secure tokens and add an identity layer above it.

Testing

Before publishing the APIs, testing to validate the availability of all required data fields with the required authentication and identity protocols should be in place. End to end process testing as well as component-level testing will be needed to validate compliance.

Documentation

Complete documentation of the usage of the APIs and a sandbox environment with de-identified sample data must be made available by payer organizations.

Healthcare Providers

There are three policies applicable to providers that must be implemented:

Digital Contact Information

Healthcare enterprises or healthcare providers must update their digital contact information i.e. names and NPIs on the NPPES site at https://nppes.cms.hhs.gov/ . Enterprises are encouraged to include FHIR endpoint information in NPPES, when they have the information.

Admission, Discharge, and Transfer Event Notifications

Using a certified EHR system ensures compliance to this policy for healthcare providers. ADT messages include a patient's basic demographic information and may include additional detailed information such as clinical status and care received from the sending provider. For a hospital that currently has an EHR system, this capability can be demonstrated by showing that the EHR system

- Is fully operational in accordance with the regulations regarding the exchange of Patient Health Information (PHI)
- Utilizes standard content and vocabularies ,
- Sends notifications of minimum PHI (patient's name, treating practitioner name, sending institution name, and, if not prohibited by other applicable law, patient diagnosis), and
- Sends notifications directly, or through an intermediary that facilitates exchange of health information at any care transition event.

Healthcare facilities must make sure that the EMR they use support all the above

Public Reporting and Information Blocking

Provider organizations must submit a "no" response to any of the three prevention of information blocking statements. These statements include:

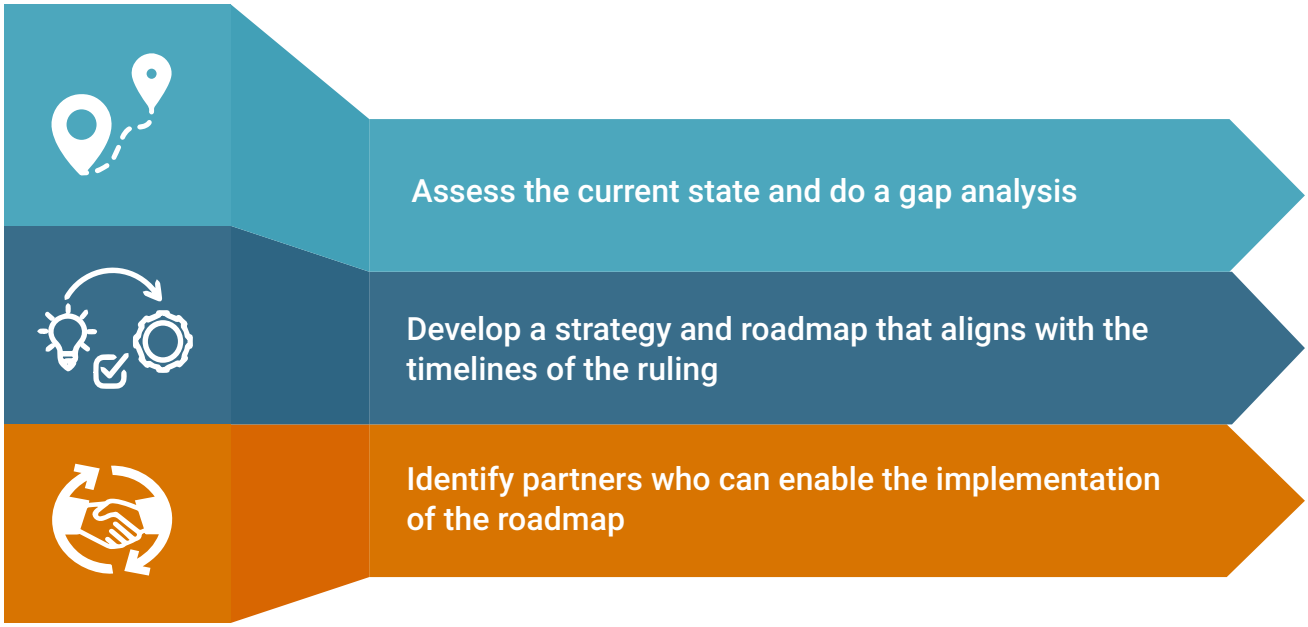
- Prevention of information blocking attestations
- ONC direct review attestations
- Completion of the security risk analysis measure in 2020.

The prevention of information blocking attestation statements are tied to the MIPS Promoting Interoperability performance category score. Eligible clinicians have 25% of the MIPS performance category scores tied to Promoting Interoperability. MIPS eligible clinicians must collect their data in EHR technology with 2015 edition functionality. In addition to the above attestations, there are six required measures that must be reported. The objectives of the six measures include e-prescribing, health information exchange, provider to patient exchange, and public health & clinical data exchange (Details of these measures are beyond the scope of this paper.) Provider organizations can send their EHRs CMS identification code from the certified Health IT product list available at https://chpl.healthit.gov/#/search

Conclusion

The CMS has described this rule as the first step towards interoperability. The rule is likely to change the way medicine is practiced. Along with the COVID pandemic, telehealth is an accepted norm and is now completely reimbursable. With interoperability in place, there will be a leap in more engaged and empowered patients. The power to make informed choices will rest with the patients and physicians will have all the needed information at their fingertips to provide better care.

To summarize:



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USA
Damo Consulting Inc., 1000 Jorie Blvd #200, Oak Brook, IL 60523, Phone: (630) 928-1111, Ext. 204

INDIA
No 60, Ferns Residency, K. Narayanapura, Kothanur, Bangalore – 560077, (Regd. address)

Website: www.damoconsulting.net

Email: info@damoconsulting.net