Administration releases final rules on interoperability with compliance deadlines beginning in 2021

As of May 5, 2020

The Department of Health and Human Services (HHS) on May 1, 2020, published revised final rules on interoperability and information blocking after initially releasing final rules on March 9, 2020. Notably, the final rules codify proposals that put the sharing of health information squarely in the hands of individuals, reinforcing a more consumer-centric approach to health care. As further evidence of this view, the agencies emphasize that a number of provisions of the final rules are intended to support individuals' movement among different payers and providers.

In the revised final rules, the Centers for Medicare and Medicaid Services (CMS) formally updated the compliance deadline for the Medicare conditions of participation for hospitals, while accompanying guidance provided by CMS and the Office of the National Coordinator for Health Information Technology (ONC) outlined how the agencies would exercise enforcement discretion beyond the compliance deadlines adopted in the final rules.

Under the revised final rules, the deadline for hospitals to send automated electronic notifications is pushed back an additional six months to May 1, 2021 (12 months after publication in the Federal Register, rather than six months after publication in the Federal Register). Similarly, CMS announced six months of enforcement discretion for requirements for plans participating in CMS programs to make available certain information via open application programming interfaces (APIs), and the ONC announced three months of enforcement discretion beyond the compliance deadlines adopted in its final rule on interoperability and information blocking.

In the most notable departure from the proposed rules, CMS did not finalize a requirement for payers and providers to participate in a trusted health exchange. CMS cited the absence of a final Common Agreement under the Trusted Exchange Framework and Common Agreement (TEFCA) as a key factor in the decision.

In addition to the final rules from CMS and ONC, the HHS Office of Inspector General also released a proposed rule to create new civil monetary penalty authorities to enforce the ONC's information blocking provisions. This marks the beginning of the rulemaking process to enforce these provisions.

The revised final rules provide clarity for health plans, hospitals, health IT developers and other industry stakeholders as they navigate new regulatory requirements and operating pressures arising from the response to the COVID-19 public health emergency. To that end, the release of the final rules delivered less flexibility than many health care stakeholders had expected, underscoring the degree of importance the Administration is placing on access to and shareability of health care data.

Trade associations representing hospitals have not released public comments on the revised final rules or the Administration's announcement of enforcement discretion. America's Health Insurance Plans on April 21, 2020 (the date the revised final rules were released) voiced skepticism that six months of enforcement discretion will be sufficient for plans to meet the rules' requirements but raised concerns that existing health care privacy protections will not be adequate under the interoperability final rules.

The final rules should be taken in the context of the broader health care agenda enacted by Congress. The interoperability requirements are shaped in part by provisions of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 and are intended to provide key enabling capabilities for risk-based and coordinated care payment models. The rules' information blocking provisions similarly are anchored in MACRA and were further refined by provisions of the 21st Century Cures Act, enacted in 2016. Keeping in mind that both MACRA and the 21st Century Cures Act were passed with strong bipartisan support, it becomes clear how important interoperability is to the shared national goals of controlling health care cost growth, coordinating care more effectively, and making it easier for individuals to make more informed health care decisions. In addition to interoperability, the Trump administration has called for increased price transparency within the health care system to assist patients in making choices about their care armed with new pricing data and online tools.

Overview

Summaries and analysis of key provisions of the CMS final rule on interoperability are provided below. While the final rule includes additional provisions on electronic contact information for providers and state coordination of data for dual eligibles, among other provisions, this article focuses on the provisions of the final CMS rule that present the most significant strategic planning opportunities and compliance obligations for payers, hospitals, and other health care stakeholders.

An overview of provisions of the ONC final rule on interoperability and information blocking that most directly affect health care providers and payers also is included.

Application Programming Interfaces (APIs)

The Administration's efforts to support individuals' access to health information in an easily shareable format centers on the use of standards-based application programming interfaces (APIs) that are accessible to third-party applications and developers. CMS intends for APIs to provide "a simple and easy electronic way to request, receive, and share data they want and need, including with a third party" with a goal of making it easier for individuals to move between health care providers.

The final rule builds upon CMS' experience with the Blue Button 2.0 approach by requiring payers participating in CMS programs to implement, test, and monitor an open, standards-based application programming interface (API) to make patient claims and other health information available to patients through third-party applications of the individual's choice.

Importantly, the API requirements are being adopted as conditions of contract for payers participating in government programs, including Medicare Advantage, Medicaid managed care and the health insurance Exchanges established under the Affordable Care Act (ACA). Thus, payers will be required to comply with the final rule in order to be eligible to participate in CMS programs.

In the preamble to the final rule, CMS emphasizes that the final rules outline the minimum data that must be made available via APIs. Payers have the option of including more information via Patient Access APIs, Provider Directory APIs, or using other available standards.

The final rule adopts the Fast Healthcare Interoperability Resources (FHIR) release 4.0.1 (as finalized by the ONC in its final rule on interoperability and information blocking) as the foundational standards for APIs.

Patient Access APIs

Under the final rule, CMS payers will be required to make available claims and clinical information via a Patient Access API as an initial move in CMS's larger effort to support easy access to a more complete longitudinal view of an individual's health experience. In the preamble to the final rule, CMS explains that although more than 95% of hospitals and 75% of office-based clinicians currently use certified health IT, the current "siloed nature of health care data prevents physicians, pharmaceutical companies, manufacturers, and payers from accessing and interpreting important data sets, instead, encouraging each group to make decisions based upon a part of the information, rather than the whole."

Applicability

The Patient Access API requirement applies to:
• *Medicare Advantage*
• *Medicaid*: state Fee-for-service (FFS) programs and managed care plans,
• *Children's Health Insurance Program* FFS programs and managed care entities
• *Insurance Exchanges established under the Affordable Care Act (ACA)*: Qualified Health Plans (QHPs) run by the federal government (federally facilitated Exchanges, or FFEs)

Scope of data

The information required to be made accessible under the open API will include:
• Adjudicated claims (including cost)
• Encounters with capitated providers
• Provider remittances
• Enrollee cost-sharing
• Clinical data (including laboratory results, where available) maintained by the payer
• Formularies or preferred drug lists (except for Exchange plans offered on federally-facilitated Exchanges)

The final rules adopt a definition of "maintain" with regard to clinical data to mean the payer has access to the data, control over the data, and authority to make the data available through the API.

The data must be provided in the form of the U.S. Core Data for Interoperability version 1 data set (adopted in the final rule on interoperability and information blocking from the ONC). In a matter of critical importance for payers' compliance preparations, the requirement to make claims and encounter data available via an API applies to all data maintained by the payer for dates of service on or after January 1, 2016.

The final rule clarifies that MA plans will be required to make available via APIs claims data, encounter data, and clinical data for supplemental benefits, including dental benefits, as well as for standard benefits.

In addition, Medicaid managed care plans are required to include any data from subcontractors and providers compensated by the plan for services. Examples of such providers include behavioral health organizations, dental management organizations, and pharmacy benefit managers. Medicaid managed care plans will have to include all claims and encounter data, regardless of whether it is adjudicated or generated by the managed care plan itself, a subcontractor, or a provider compensated on the basis of capitation payments.

Timeliness

The rules will require CMS payers to make the claims data available via APIs within one business day of a claim being adjudicated and for clinical data to be made available within one business day of the encounter data being received by the plan.

While CMS is adopting time limits for plans to make available claims and encounter data via APIs, the agency emphasizes that it will not seek to adopt regulations standardizing contracts between payers and providers; CMS leaves it to payers to determine whether to include time requirements for submission of claims and encounter data in contracts with providers.

Privacy and security

In a change from the proposed rule, CMS adopted a provision that allows CMS payers subject to the Patient Access API requirement to request that third-party apps attest to having certain information included in their privacy policy and inform individuals about this attestation to help make them aware of the privacy risks associated with their choices.

The final rules do not alter existing responsibilities to protect personal health information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) privacy rules or other laws that currently are applicable.

CMS finalized a deadline of January 1, 2021, for the Provider Access API requirement. CMS will exercise enforcement discretion for six months, beginning enforcement of the requirements on July 1, 2021.

Provider Directory APIs

In a modification from the proposed rule, CMS will only require payers to provide information on provider directories via a public facing Provider Directory API. The proposed rule considered requiring payers to provide such information via a Patient Access API, as well as a Provider Directory API.

While MA organizations, state Medicaid programs and Exchange plans currently are required to make information available about their provider networks, CMS explains the requirement for a Provider Directory API accessible to enrollees and prospective enrollees could support the development of third-party apps "that would pull in current information about available providers to meet enrollees' current needs." CMS also states that the availability of provider directory information via APIs also could support "innovation in applications or other services that help enrollees to more easily compare provider networks while they are considering their options for changing health plans."

The Provider Directory API must be accessible via a public-facing digital endpoint on the payer's website to ensure public discovery and access.

Applicability

The Provider Directory API requirement applies to:
- *Medicare Advantage*
- *Medicaid*: state Fee-for-service (FFS) programs and managed care plans,
- *CHIP:* FFS programs and managed care entities

The requirement for provider directories and formularies would not apply to QHP issuers in FFEs because such issuers already are subject to a similar requirement.

Scope of data

At minimum, the Provider Directory API must include provider names, addresses, phone numbers and specialties.

For MA plans that include Part D prescription drug coverage, the Provider Directory API also must include pharmacy directory data: pharmacy name, address, phone number, number of pharmacies in the network, and mix (i.e., the type of pharmacy, such as "retail pharmacy").

Timeliness

Payers are required to make updates available within 30 calendar days of receiving the information or an update to the provider directory information. The 30-day standard also applies to pharmacy information for MA-PD Plans.

Compliance deadline

CMS finalized a deadline of January 1, 2021, for the Provider Directory API requirement. CMS will exercise enforcement discretion for six months, beginning enforcement of the requirements on July 1, 2021.

Payer-to-payer data exchange

In an effort to support patient-directed coordination of care, CMS is finalizing a requirement for a payer-to-payer data exchange. Importantly, CMS puts the individual member at the center of this data exchange in that plans must undertake the exchange subject to the approval of and at the direction of a current or former member.

CMS intends for the policy to support better care coordination at the payer level and reduced provider burden by supporting an individual's access to and ability to share more complete health information.

Applicability

The payer-to-payer data exchange requirement applies to:
- Medicare Advantage organizations
- Medicaid managed care plans
- CHIP managed care entities
- QHPs offered on federally-facilitated Exchanges

Medicaid and CHIP state agencies are not subject to this requirement.

Scope of data

CMS is finalizing a requirement for payers to maintain a process for the electronic exchange of, at minimum, the data classes and elements included in the USCDI content and vocabulary standard. Payers will be required to share data they maintain for dates of service on or after January 1, 2016.

While CMS will require a payer to incorporate data received from another payer under this policy into the enrollee's record, a payer is required only to send the data received from another payer under this policy in the electronic form and format it was received.

Under this requirement, payers will need to prepare an initial historical set of data for sharing with other payers.

Compliance deadline

CMS finalized a compliance deadline of January 1, 2022.

Conditions of Participation for hospitals and critical access hospitals – Electronic notifications

The final rule also modifies the Conditions of Participation (CoPs) for Medicare by requiring hospitals, including psychiatric hospitals and critical access hospitals (CAHs), to send electronic patient event notifications of patient's admission, discharge, and or transfer to another health care facility or another health care provider. The requirement applies specifically to hospitals with EHR systems that support such notification capabilities.

Applicability

The requirement to send electronic notifications applies to hospitals that currently have EHR systems with the technical capacity to generate information for electronic patient event notifications, defined as an EHR system that uses the ADT messaging standard Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1).

CMS notes that this standard is referenced by certification criteria related to transferring information to immunization registries and transmission of laboratory results to public health agencies. Adoption of certified health IT that meets these criteria has been required for any hospital seeking to qualify for the Promoting Interoperability Program (formerly called the Meaningful Use program).

Thus, the new condition of participation in effect applies to hospitals that have participated in the Promoting Interoperability Program.

Scope of data

CMS will require hospitals to provide, at minimum, the patient's basic personal or demographic information, as well as the name of the sending hospital. CMS emphasizes that this requirement is intended to "set a minimum floor" for electronic notifications, recognizing that there is "significant variation" in how hospitals use HL7 2.5.1 messages.

The rules will require hospitals to send notifications to a patient's established primary care practitioner (or established primary care practice group or entity) or any other practitioner (or practice group or entity) identified by the patient as primarily responsible for his or her care. In addition, hospitals will be required to send notifications to all applicable post-acute care (PAC) providers or suppliers, meaning PAC services providers and suppliers with whom the patient has an established care relationship prior to admission or to whom the patient is being transferred or referred.

Importantly, CMS is not adopting a requirement for hospitals to use a specific standard or format to deliver patient event notifications. Similarly, CMS is not requiring hospitals to use a specific technology to send patient event notifications, giving hospitals options for transmitting the notifications. CMS provides the example of a hospital partnering with an intermediary to deliver notifications to external providers, while using features internal to a shared EHR system to transmit information to providers that are part of the same organization.

When a notification must be sent

Under the new conditions of participation, CMS will require hospitals to send a notification when:
* A patient is registered in a hospital emergency department (ED), if applicable
* A patient is admitted as an inpatient, regardless of whether the patient is admitted from an ED, from an observation stay, or as a direct admission from home, their practitioner's office, or as a transfer from another facility
* A patient's discharge or transfer from the hospital, either from the ED or an observational stay or an inpatient services unit

The rules clarify that hospitals will not be expected to send notifications in cases where:
* A hospital is not able to identify a primary care provider for a patient
* The patient has not identified a provider to whom they would like information sent
* There is no applicable post-acute care provider or supplier

Compliance deadline

Citing the COVID-19 public health emergency, CMS adopted an applicability date of 12 months after finalization of the rule for hospitals, including psychiatric hospitals, and critical access hospitals. Thus, hospitals will face a May 1, 2021, compliance date for the conditions of participation.

ONC Final Rule on Interoperability and Information Blocking

The final rule aims at supporting interoperability activities by adopting certain technical updates and new standards for health IT certification and Patient APIs and clarifying the exceptions to the prohibition on information blocking.

This ONC final rule is focused on implementing key provisions of the 21st Century Cures Act. The final rule identifies and finalizes the reasonable and necessary activities that do not constitute information blocking while also establishing new rules to prevent information blocking practices. The final rule also requires electronic health records to provide the clinical data necessary (including core data classes and elements) to promote new business models of care.

The final rule also makes several changes to the existing 2015 Edition Health IT Certification Criteria and establishes standardized application programming interfaces (APIs) requirements to support patient access and control of their health data. The aim of this provision is to allow patients to securely and easily obtain and use their health data from their provider's Medicare record for free using a smartphone app of their choosing.

Applicability

The information blocking provisions associated with this rule apply to health care providers, health IT developers, health information exchanges, and health information networks. While many of the technical updates to the 2015 Edition Health IT Certification Criteria will be immediately applicable to health IT developers, it will be important for hospitals and health systems to understand what changes have been made and to make sure they are utilizing certified open APIs. In addition, future updates to the Promoting Interoperability programs for hospitals and clinicians could reflect the updated certification criteria for health IT and require hospitals and care providers to demonstrate use of the new capabilities.

Compliance dates

While ONC did not formally delay the compliance deadlines, the agency announced that it would exercise three months of enforcement discretion following the final rule's official compliance deadlines. Importantly, the first of the compliance deadlines will begin six months after the publication of the final rule (i.e., November 1, 2020), translating to enforcement for the first provisions beginning February 1, 2021.

Compliance deadlines will continue across a 36-month period.

Conclusion

While the final rules mark a significant move toward greater interoperability, the Administration emphasizes that these rules are a first phase on interoperability and that future rulemaking could expand current requirements. The final rules can be expected to have significant interactions with the development of future payment models, approaches to measuring quality, and price transparency efforts.

As health care stakeholders digest this new wave of requirements, they would be well advised to keep the broader context in mind: there is ongoing support by policy makers to create a truly interoperable health care system and further regulation is likely to follow. Decisions that payers, providers, health IT developers and other stakeholders make under the current framework in many cases will serve as the foundation of a larger interoperability program that will need to be aligned with future regulations, a changing marketplace, and consumer demand.

Contacts:

Anne Phelps
US Health Care Regulatory Leader
Principal | Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
annephelps@deloitte.com

Ryan DeMerlis
Senior Manager | Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
rdemrlis@deloitte.com

Lindsay Wisdom
Manager | Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
lwisdom@deloitte.com

Daniel Esquibel
Senior Manager | Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
desquibel@deloitte.com

Adam Lowry
Senior Manager | Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
alowry@deloitte.com