CMS Interoperability and Patient Access Rule

The Centers for Medicare & Medicaid Services (CMS) issued a final rule on patient access to data and interoperability (CMS NPRM). Concurrently, the Office of the National Coordinator for Health Information Technology (ONC) released its final rule implementing provisions of the 21st Century Cures Act (Cures) related to electronic health information (EHI) blocking, interoperability and the ONC Certification Program. In addition to promoting patient access and price transparency, these rules will impact interoperability and the way data is exchanged between patients, health providers, payers, technology developers, and other health care stakeholders. Together, they represent a major push by the Administration to remove all barriers it has identified as impeding patient access to data, and to greatly expand access for payers and third-party companies.

CMS Final Rule on Advancing Interoperability and Patient Access to Health Data

The CMS Final Rule requires all health plans subject to CMS authority to make certain clinical, claims, and coverage information available to patients and their personal representatives accessible through an open application programming interface (API). Impacted payers include the Medicare Fee-for-Service (FFS) Program; state Medicaid and CHIP FFS Programs; Medicare Advantage (MA) Organizations; Medicaid and CHIP Managed Care plans/entities (managed care organizations (MCOs), prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs)); and qualified health plan (QHP) issuers in Federally-facilitated Exchanges (FFEs) (collectively, Impacted Payers). While most of the rule's provisions apply to the Impacted Payers, a few apply to clinicians and hospitals, including critical access hospitals (CAHs).

Provisions applicable to Impacted Payers

Patient Access to Data Through Open APIs. CMS is requiring Impacted Payers to implement, test, and monitor standards-based HL7® FHIR®-based APIs that allow patients to access a wide variety of clinical and claims information through third-party applications (apps) of their choosing. Beginning January 1, 2021, Impacted Payers must provide access to adjudicated claims (including provider remittances and enrollee cost-sharing); encounters with capitated providers; clinical data maintained by the Impacted Payer, including laboratory results; as well as formularies or preferred drug lists for all impacted payers except QHP issuers on the FFEs. The AMA commented that CMS should also require prior authorization information to be made available through an API. While CMS did not adopt that recommendation for inclusion in this rule, it did clarify that because step therapy is a utilization management procedure, it is included among the types of information MA-PDs must make available about Part D drugs through the API. The Impacted Payer must make available any and all such data it has dating back to January 1, 2016. New information must be made available within one business day after the Impacted Entity receives the data or processes the claim.

Provider Directory API. MA organizations, Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities must make standardized information about their provider networks available through a Provider Directory API by January 1, 2021. CMS solicited feedback on whether it should extend this requirement to QHP issuers on the FFEs (we said yes), but CMS declined to do so. The Provider Directory API must be accessible via a public-facing digital endpoint on the Impacted Payer's website to ensure public discovery and access. At a minimum, Impacted Payers must make available via

the Provider Directory API provider names, addresses, phone numbers, and specialties. For MA organizations that offer MA-PD plans, they must also make available, at a minimum, pharmacy directory data, including the pharmacy name, address, phone number, number of pharmacies in the network, and mix (specifically the type of pharmacy, such as "retail pharmacy"). All directory information must be made available to current and prospective enrollees and the public through the Provider Directory API within 30 calendar days of a payer receiving provider directory information or an update to the provider directory information.

Payer to Payer Exchange. Beginning January 1, 2022, upon a beneficiary's request, MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs must coordinate care between payers by exchanging, at a minimum, data in the United States Core Data for Interoperability (USCDI). This data includes information about diagnoses, procedures, tests and providers seen. A payer must, if asked by the beneficiary, forward his or her information, dating back to January 1, 2016, to a new plan or other entity designated by the beneficiary for up to 5 years after the beneficiary has disenrolled with the plan. CMS also finalized a provision that a payer is only obligated to share data received from another payer in the electronic form and format it was received, which is intended to reduce burden on payers.

Care Coordination Through Trusted Exchange Networks. CMS proposed, but did not finalize, a requirement that certain Impacted Payers participate in trust networks to improve interoperability. Many commenters, including the AMA, noted that ONC has not yet finalized the Trusted Exchange Framework and Common Agreement (TEFCA), a set of policies and procedures for interoperable exchange to which CMS could eventually align this trusted exchange participation requirement; CMS agreed that it would be premature to require TEFCA participation at this time.

Improving the Dual Eligible Experience by Increasing Frequency of Federal-State Data Exchanges. CMS finalized its proposal to update the frequency with which states are required to exchange "buy-in" data on dually eligible beneficiaries. By April 1, 2022, all states must shift from a monthly exchange with CMS to a daily exchange in an attempt to improve benefit coordination for the dual-eligible population.

Provisions applicable to providers

Public Reporting and Prevention of Information Blocking. Beginning in late 2020, and starting with data collected for the 2019 performance year data, CMS will publicly report a "no" response from clinicians, hospitals, and CAHs to any of the three attestation statements regarding the prevention of information blocking in the Promoting Interoperability Programs in the Quality Payment Program (QPP) and Medicare FFS. Physician responses will be posted on Physician Compare; hospital and CAH responses will be posted on a publicly available CMS website.

Provider Digital Contact Information. As required by Cures, the National Plan and Provider Enumeration System (NPPES) includes fields for one or more pieces of digital contact information that can be used to facilitate secure sharing of health information. To ensure that the NPPES is updated with this information, CMS finalized its proposal to publicly report the names and National Provider Identifiers (NPIs) of those providers who have not added digital contact information to their entries in the NPPES system beginning in late 2020.

Revisions to the Conditions of Participation (CoPs) for Hospitals and Critical Access Hospitals. CMS finalized its proposal to create a new condition of participation for hospitals and CAHs requiring them to electronically send "patient event notifications" when a patient is admitted, discharged, or transferred (ADT) to a patient's health care providers. The requirement would be limited to only those Medicare- and Medicaid-participating hospitals and CAHs that possess EHRs systems with the technical

capacity to generate information for electronic patient event notifications. It would, however, impose a new set of requirements related to the use of EHRs outside of the Promoting Interoperability program. CMS revised its final regulatory text to state that the sharing may only occur to the extent permissible under applicable federal and state law and regulations, and only as consistent with the patient's expressed privacy preferences.

Optional Privacy Attestations for Payer APIs

The AMA and many other stakeholders commented on concerns related to how apps may use the information beneficiaries access using the new Patient Access API. We noted in particular that bad actors could use apps to profit from an individual's information in ways that the individual did not authorize or understand and that the downstream consequences of data being used in this way may ultimately erode a patient's privacy and willingness to disclose information to his or her physician. We recommended that CMS require the API to alert patients as to whether an app had a model privacy notice, whether the app was designed with best privacy practices in mind, and whether the app utilizes best practices for privacy while sharing data. While CMS acknowledged and agreed with many of the concerns raised by the AMA and other stakeholders, it frequently noted that patients could simply choose to not use apps if they had concerns over the privacy of their health information. It did finalize its proposal requiring Impacted Payers to make educational materials about privacy available to its beneficiaries. This guidance is not yet available, but we will review it when it becomes public. CMS also states that Impacted Payers are "encouraged, but are not required, to request third-party apps attest to having certain privacy and security provisions included in their privacy policy prior to providing the app access to the payer's API." CMS used as an example the question of whether an app has a plain-language, publicly available privacy statement shared with the patient prior to the patient authorizing the app to receive his or her information and stated that Impacted Payers can look to industry best practices for provisions to include in their attestation request that best meet the needs of their patient population. If an Impacted Payer chooses to request third-party apps provide this attestation, it must request it of all apps that seek to obtain data.