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Interoperability and Prior Authorization Proposed Rule

BACKGROUND: THE PUSH TOWARDS INTEROPERABILITY

On December 10th, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator (ONC) proposed a rule that, if finalized, would place new requirements on state Medicaid and CHIP fee-for-service programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs). The rule focuses on improving the exchange of health information among payers, providers, and patients by increasing access to patient-specific payer data and by streamlining the prior authorization process to reduce provider burden.

Throughout 2020, the federal government has advanced a regulatory campaign aimed at expanding the electronic exchange of healthcare data among payers, providers and patients using standardized and public application programming interfaces (APIs), and by setting new conditions for mandatory data exchange. Much of this regulation implements provisions regarding interoperability, patient access and data blocking contained in the 21st Century Cures Act.

- On March 9th, CMS finalized the Interoperability and Patient Access final rule, under its authority to regulate Medicare Advantage (MA), Medicaid, CHIP, and QHP issuers on the FFEs. The rule is described in additional detail below.
- On March 9th, ONC finalized a rule focused on preventing data blocking by health technology companies and providers.
- On October 28th, CMS released a Transparency in Coverage final rule to require health insurers to make negotiated price information publicly available for plan years on or after January 1, 2022, and to make cost-sharing liability tools available to enrollees available starting in 2023.
- On October 29th, CMS published an interim final rule implementing price transparency requirements for hospitals to show negotiated payer rates, and extended the effective dates for these requirements, now beginning April 5, 2021.

These policies, as well as any future iterations, will play a key role in shaping patients' access to health information, as well as the level of burden faced by both payers and providers, and their ability to manage the flow of health care information. The current proposed rule, which builds primarily on the March Interoperability and Patient Access final rule, is available here. Comments must be received by January 4th, 2021.

MARCH 2020 INTEROPERABILITY AND PATIENT ACCESS FINAL RULE

Patient Access API, Provider Director API, and API Access Exceptions

The March final rule established that MA organizations, Medicaid and CHIP managed care plans, state Medicaid programs, and QHPs on the FFEs are required to implement and maintain two standards-based APIs: a Patient Access API and A Provider Directory API. Through the Patient Access API, payers are required to allow third-party applications to retrieve claims, encounters, and clinical/laboratory data.

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Through the Provider Directory API, payers are required to make standardized information about their providers (e.g., names, addresses, phone numbers, etc.) available on a public-facing endpoint on their websites. QHPs are excluded from the Provider Directory API requirement. Both the Patient Access and the Provider Directory APIs must be fully implemented by January 1st, 2021. The rule also identifies a limited number of exceptions to the API requirements. For instance, a payer could deny access if it reasonably determined that allowing an app to connect or remain connected to an API would present an unacceptable level of risk to the security of PHI on the payer's systems. Generally, however, payers may not restrict third party access to an API.

Other Provisions

The rule also establishes a payer-to-payer data exchange. All states will be required to participate in a daily exchange of buy-in data, in which they send data in the form of a Medicare Modernization Act file, and receive responses from CMS on a daily basis. The rule also has implications for the Merit-based Incentive Payment System and the National Plan and Provider Enumeration System. Finally, the rule requires that hospitals, psychiatric hospitals, and critical access hospitals that utilize an electronic medical records system or electronic administrative system demonstrate that their systems meet certain criteria related to admission, discharge, and/or transfer notifications. Sachs Policy Group created a more in-depth summary of the Interoperability and Patient Access final rule, available here.

DECEMBER 2020 ACCESS AND PRIOR AUTHORIZATION PROPOSED RULE

The December 10th proposed rule would create new health care data and prior authorization requirements for Medicaid and CHIP managed care plans, state Medicaid and CHIP fee-for-service programs, and QHP issuers of the FFEs. This rule, however, would not affect MA plans or employer group plans. Building on the Interoperability and Patient Access final rule, it would establish a new set of Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) standard-based APIs and other requirements. These policies are proposed to take effect on January 1st, 2023.

Plan-to-Plan Sharing

The rule would require the use of a FHIR-based API for the exchange of certain patient health information. The Interoperability and Patient Access final rule merely encouraged the use of a FHIR-based API, while this rule would actually require that standard. This rule also builds on the previous rule by requiring impacted payers to exchange claims and encounter data, a sub-set of clinical data as defined in the U.S. Core Data for Interoperability (USCDI) version 1, and information about pending and active prior authorization decisions.

CMS' intent here is twofold. The agency has stated it wants to make it easier for patients to take their health information with them as they move from one plan to another. However, CMS also hopes that this will speed up prior authorization determinations and eliminate repeated determinations processes. CMS is specifically seeking comment on whether the agency should limit plans from requiring patients to undergo repeat evaluations without first reviewing the medical records and notes of the previous payer, which would presumably be made available through the Payer-to-Payer API.

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Plan-to-Provider Sharing

CMS is also proposing to require that payers build and maintain a Provider Access API for plan-to-provider data sharing of the same claims and encounter data, the sub-set of clinical data defined in the USCDI version 1, and pending and active prior authorization decisions as the Payer-to-Payer API. The Provider Access API would be able to process both individual patient requests and groups of patients using the HL7 FHIR Bulk Data Access, or Flat FHIR, specification.

Plan-to-Member Sharing

This rule would build on the Patient Access API introduced in the Interoperability and Patient Access final rule. Starting January 1st, 2023, CMS would require payers to also include information about the patient's pending and active prior authorization decisions in the Patient Access API. CMS hopes that this will better inform patients about that process and how it might impact their care. The rule would also establish process for third-party application developers to attest to certain privacy policy provisions prior to retrieving data via the payer's Patient Access API.

Lastly, the rule would require plans to report quarterly metrics about patient use of the Patient Access API to CMS in order for the agency to assess the impact the API is having on patients. Specifically, CMS would have plans report the total number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app, and the number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app more than once.

Prior Authorization Provisions

The proposed rule also has a major focus on relieving provider, patient, and plan burden by moving aspects of documentation and prior authorization to APIs. The agency seeks to shift the prior authorization process away from the fax and telephone. The first API, the Document Requirement Lookup Service API, would be integrated with a provider's electronic health record and allow providers to locate prior authorization requirements for each specific payer from within the provider's workflow. The second API, the Prior Authorization Support API, would send prior authorization requests and receive responses electronically within existing workflows.

In addition to requiring the implementation of these two APIs, CMS would also require that plans send prior authorization decisions within 72 hours for urgent requests and 7 calendar days for standard requests (although this would not apply to QHP issuers on the FFEs). Finally, CMS would require plans to include specific reasons for a denial when denying a prior authorization request, and publicly report data about their prior authorization process (i.e., the percent of prior authorization requests approved vs. denied, or average time between submission and determination).

The prior authorization provisions of the rule set what the agency hopes to be a uniform standard to prior authorization, in order to reduce administrative costs and provider burden and burnout. In a press release, CMS Administrator Seema Verma stated that, "If just a quarter of providers took advantage of the new electronic solutions that this proposal would make available, the proposed rule would save between 1 and 5 billion dollars over the next ten years."