LEGAL ADVICE FOR HEALTH PLANS

HEALTH LAW ALERT
May 1, 2020

Final Interoperability and Patient Access Rule Published

Enrollee Claims, Other Information to be Available for Download via APIs
Rule to be Enforced Beginning July 1, 2021

Today, the Centers for Medicare and Medicaid Services (CMS) formally[1] published the final Interoperability and Patient Access Rule, in which the agency adopted standards for certain health plans to make significant amounts of an enrollee's protected health information available to the enrollee through mobile phone Apps and other, similar devices (the "**Patient Access API**"). The Rule will also require affected health plans to make provider directory information available in a similar manner (the "**Provider Directory API**") as well as to exchange an enrollee's data with another health plan upon request by the enrollee (the "**Payer-to-Payer Data Exchange**"). Although the Rule requires health plans to make the Patient Access API and Provider Directory API available by January 1, 2021, CMS concurrently announced that, due to the COVID-19 public health emergency, it would exercise its enforcement discretion "to adopt a temporary policy of relaxed enforcement in connection to implementation of the [Rule]," so that (practically speaking) health plans must implement the Patient Access and Provider Directory APIs by July 1, 2021.

The Interoperability and Patient Access Rule will apply only to specific lines of business. Specifically, the Rule will apply to the following "**Covered Health Plans**":

- Medicare Advantage Organizations (MAOs);
- Qualified Health Plan (QHP) Issuers on Federally Facilitated Exchanges (except with respect to the Provider Directory API);
- Medicaid Managed Care Plans;
- CHIP Managed Care Plans; and
- State Medicaid and CHIP Agencies.

An "API" is an "Application Programming Interface," which (in this context) is a portal that Covered Health Plans must make available to the public through which data in

[1] CMS ***informally*** published the Rule on its website on March 9th; the Rule was again ***informally*** published on the Federal Register's "Public Inspection" website on April 21st. A Rule is not formally published—and the publication has no legal effect—until it is published in the Federal Register itself.

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standardized format can be obtained "through the use of common technologies and without special effort from the enrollee." Applications ("Apps") designed for use on an enrollee's mobile phone (or similar device) would then be able to access the enrollee's claims and other data through the API. CMS believes that the APIs will permit enrollees to "select third-party applications [*e.g.*, mobile phone Apps] to compile and leverage their electronic health information to help them manage their health and engage in a more fully informed way in their health care."

The final Interoperability and Patient Access Rule is published at 85 *Federal Register* 25520 (click here). The CMS announcement relating to its enforcement discretion (as well as other information about the Rule) is available here.

Patient Access API

Covered Health Plans are required to implement and maintain a Patient Access API, which permits third-party Apps to access an enrollee's claims (including encounter data from capitated and similar arrangements with providers). Covered Health Plans must also include certain clinical data (such as lab tests). While the Rule does not require Plans to collect this data if they do not already have it, clinical data that a Covered Health Plan does maintain must be provided through the Patient Access API. Covered Health Plans must make the data available through the Patient Access API to Apps selected by enrollees. The data must be provided in standardized format, using standards applicable to electronic transactions in the HIPAA Transactions and Code Sets Rule (45 C.F.R. Part 162) and the United States Core Data for Interoperability standard (USCDI), which was developed for providers' Electronic Medical Records.

An enrollee must request the disclosures in a manner that allows the Covered Health Plan to comply with HIPAA. Nevertheless, the Apps that receive a patient's protected health information will not be subject to HIPAA. The only restrictions on an App's use and disclosure of a patient's protected health information will be self-imposed, through the terms and conditions and privacy policies that the App elects to adopt. Covered Health Plans will, however, be required to provide to enrollees educational materials that address how they can protected their personal information and "factors to consider in selecting an [App]." A Covered Health Plan generally cannot refuse to allow an App to obtain enrollees' protected health information through its API, unless it can demonstrate that such access "present[s] an unacceptable level of risk to the security of . . . protected health information on the [Covered Health Plan's] systems."

Once the Patient Access API is operational, Covered Health Plans will be required to make adjudicated claims available to Apps within one business day after the claim is adjudicated and encounter data available to Apps within one business day after the data is received from the provider. The claims and other data that must be provided through the API include data for dates of service on or after January 1, 2016. Medicare Advantage Prescription Drug Plans and Medicaid/CHIP Managed Care Organizations must include data for adjudicated prescription drug claims, formulary data, and utilization management information.

Provider Directory API

Covered Health Plans must make an API available to the general public that supplies "a complete and accurate directory" of the Plan's network of participating providers. (QHP Issuers on a Federally Facilitated Exchange are not required to comply with this requirement, as they already have similar obligations in place.) The provider directory information must include provider names, addresses, phone numbers, and specialties and the Covered Health Plan must update information within 30 days of any change.

Payer-to-Payer Data Exchange

Beginning on January 1, 2022, health plans will be required to exchange data with other health plans upon request by an enrollee. Specifically, Covered Health Plans will be required to disclose to another health plan the data classes and data elements established in the USCDI standard (the standard for providers' Electronic Medical Records), including data with a date of service on or after January 1, 2016. Covered Health Plans must receive such information from another health plan and "incorporate" the information into its records.

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