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HHS releases final interoperability and information blocking rules aimed at giving patients more access to personalized health information in a standardized format

Mandates payers, providers, and health IT adopt APIs and promote data exchange

Today (March 9), the Department of Health and Human Services (HHS) finalized two data sharing rules aimed at making it easier for patients to access their clinical and claims information from providers and insurers, as instructed by the bipartisan 21st Century Cures Act. The rules are part of President Trump's MyHealthEData initiative, designed to empower patients to make better health care decisions in part through enhanced access and control of their personal health information (PHI). The final rule from the Centers for Medicare and Medicaid Services (CMS) requires CMS-regulated payers to adopt standards-based application programming interfaces (APIs) that allow patients to easily access their claims and encounter information while also requiring hospitals to send electronic admissions, discharge, and transfer notifications certain providers. The companion Office of the National Coordinator for Health Information Technology (ONC) final rule requires health IT vendors to make patient data downloadable using a common data sharing standard and specific API criterion, and outlines what will constitute "information blocking."

HHS Secretary Alex Azar called the rules "the start of a new chapter in how patients experience American healthcare, opening up countless new opportunities for them to improve their own health, find the providers that meet their needs, and drive quality through greater coordination." Don Rucker, National Coordinator for Health Information Technology, said that the rules will "give patients' control of their electronic health information which will drive a growing patient-facing healthcare IT economy, and allow apps to provide patient-specific price and product transparency" and CMS Administrator Seema Verma said "the days of patients being kept in the dark are over," adding that HHS is now "holding payers to a higher standard while protecting patient privacy through secure access to their health information."

Since the release of the proposed rules last February, the rules highlighted a rift between health care industry stakeholders who came out in force against the rule - flagging concerns over a perceived lack of guardrails on data sharing - with those who called for swift release of the rule and voiced strong support for efforts to put health record information in the hands of patients. In particular, electronic health records (EHR) giant Epic, along with a group of partner hospital systems, voiced their disapproval and argued that the rules will increase health care costs and result in patients losing control of their data. Those voicing support for the rule include EHR vendor Cerner, along with the Carin Alliance - a private sector collaboration made up of major health insurers, providers, health IT companies - and tech giants including Apple and Microsoft.

- View [ONC final rule](#) and [additional information](#)
- View [CMS final rule](#) and [fact sheet](#)

CMS Interoperability and Patient Access final rule

The CMS Interoperability and Patient Access final rule requires CMS-regulated payers, specifically MA organizations, Medicaid Fee-for-Service (FFS) programs, Medicaid managed care plans, CHIP FFS programs and managed care entities, and Qualified Health Plan issuers on Federally-facilitated Exchanges, to implement and maintain a secure, standards-

based “Patient Access API” that allows patients to easily access claims and encounter information, as well as a defined set of clinical information through third-party applications beginning January 1, 2021. The rule also requires:

- **Payer-to-Payer Data Exchange:** CMS-regulated payers are required to exchange certain patient clinical data at the patient’s request, allowing the patient to take their information with them as they move from payer to payer. Payers are required to implement a process for this data exchange beginning January 1, 2022.
- **Provider Directory API:** CMS-regulated payers are required to make provider directory information publicly available via a standards-based API.
- **Admission, Discharge, and Transfer Event Notifications:** CMS is modifying Conditions of Participation to require hospitals to send electronic patient event notifications of a patient's admission, discharge, and/or transfer to another healthcare facility or community provider, applicable 6 months after publication of this rule.
- **Public Reporting and Information Blocking:** Beginning in late 2020, CMS will publicly report eligible clinicians, hospitals, and critical access hospitals that may be information blocking based on how they attested to certain “Promoting Interoperability Program” requirements.
- **Digital Contact Information:** CMS will begin publicly reporting in late 2020 those providers who do not list or update their digital contact information in the National Plan and Provider Enumeration System.
- **Increasing the Frequency of Federal-State Data Exchanges:** The rule updates requirements for states to exchange certain enrollee data for individuals dually eligible for Medicare and Medicaid from monthly to daily exchange to improve the dual eligible beneficiary experience, starting April 1, 2022.

ONC Cures Act Final Rule

The ONC final rule updates certification requirements for health IT developers and establishes new provisions to ensure that providers using certified health IT have the ability to communicate about health IT usability, user experience, interoperability, and security. It also outlines reasonable and necessary activities that do not constitute “information blocking,” which was banned by the 21st Century Cures Act of 2016. Key provisions include:

- **Updates to the 2015 Edition Certification Criteria:** The rule includes adoption of the United States Core Data for Interoperability (USCDI) as a standardized set of health data classes and data elements to promote nationwide, interoperable health information exchange. The USCDI includes “clinical notes,” allergies, and medications among other clinical data and demographic data to support patient matching across care settings. It also outlines new API certification criterion, including the use of the Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard Release 4 and other specifications. Other certification updates include those to electronic prescribing, clinical quality measures, and electronic health information export.
- **Conditions and Maintenance of Certification Requirements:** The rule adopts the information blocking Condition of Certification requirement, which prohibits any health IT developer from taking any action that constitutes information blocking; requires health IT developers to publish APIs that allow health information be accessed, exchanged, and used without special effort; requires health IT developers successfully test the real world use of health IT for interoperability; along with other attestation and reporting requirements.
- **Information Blocking:** The rule identifies eight reasonable and necessary activities as exceptions to the information blocking definition, which apply to certain activities that are likely to interfere with, prevent, or materially discourage the access, exchange, or use of EHI.

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