

Open Notes Mandate Starts Now



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In May 2020, the Office of the National Coordinator for Health Information Technology (ONC) published the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule*, which is designed to provide patients and providers secure access to health information. This implementation ruling follows the 2016 passage of the law titled – “21st Century Cures Act.” The law – and subsequent ruling about its application -- contained many terms, but one key provision – electronic health information (EHI) blocking – was scheduled to launch last fall. With only days until the new standards went into effect, the US Department of Health and Human Services (HHS) extended the mandate to April 5, 2021, citing challenges related to COVID.

That day has come, and it’s time to gear up for compliance with the new rules.

The so-called “open notes” mandate dictates that physicians must be able to make eight types of clinical notes data available to patients upon request (see SIDEBAR). Clinical notes are defined as “Composed of both structured (i.e., obtained via pick-list and/or check the box) and unstructured (free text) data. A clinical note may include the history, Review

of Systems (ROS), physical data, assessment, diagnosis, plan of care and evaluation of plan, patient teaching and other relevant data points.” Clinical notes are one of 16 data classes in the United States Core Data for Interoperability (USCDI) Version One. (See <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>.) The USCDI list identifies the data elements that must be incorporated in the response to a patient’s request to use, access, or exchange the information. If the data elements were not captured, they do not have to be reported.

The government’s latest efforts build upon the requirement to allow access to patient records mandated under the 2000 HIPAA Privacy Rule. HIPAA established a patient’s right to access, inspect and obtain a copy of their health records. The government subsequently passed the 2009 HITECH Act that launched the EHR Incentive Program to encourage adoption. Further, the Act directed HHS to adopt certification standards for electronic health record systems, including methods for access. For participating physicians, the program’s “meaningful use” criteria necessitated granting records’ access to patients.

Although physicians could purchase portals to comply with the program’s meaningful use measures, EHR vendors were not required to extend the functionality to support data exchange or interoperability. Indeed, the blocking of the capability was so ubiquitous that “gag clauses” were often integrated in EHR system contracts. So, patients could garner access to these closed ecosystems but little more. Vendors were not the only ones blocking information, however. The ruling names three categories of “actors” subject to the new rules: certified health IT developers, health information exchanges and health information networks (HIEs/HINs), and health care providers.

Under the ONC’s new ruling, which was opposed by EHR system vendors, “actors” are prohibited from information blocking practices that have become the norm; instead, systems, networks and providers must open their doors to clinical data sharing.

To comply, data exchange must be performed on a standard information highway – HL7 FHIR (Release 4) – and transacted at no cost to the patient. Because this data standard supports smartphone apps, many experts expect a proliferation of companies to focus on this new access point.

Of course, this translates into patients’ ability to access their records, including your clinical notes. The new rule focuses on your response to patients’ requests, not broad availability. For example, HHS professes:

While the information blocking regulations do not require actors [to include health care providers] to proactively make electronic health information (EHI) available, once a request to access, exchange or use EHI is made, actors must timely respond to the request (for example, from a patient for their test results). Delays or other unnecessary impediments could implicate the information blocking provisions. In practice, this could mean a patient would be able to access EHI such as test results in parallel to the availability of the test results to the ordering clinician.

For more information, see: <https://www.healthit.gov/curesrule/resources/information-blocking-faqs>.

The government has outlined exceptions, including prevention of risk or harm to patients, privacy and security, and infeasibility. However, “routinely time-delaying” data availability does not fall under the exception, according to the Final Rule.

While it may be frustrating to learn about another complex rule with which to comply, the ruling will benefit some physicians. Vendors can no longer charge excessive fees for restricting access to patients’ data, for example, a significant challenge that often occurs when physician practices decide to switch electronic health record (EHR) systems. Further, vendors are prohibited from implementing tactics that delay access to data. Experts surmise that the ruling will also extend to prohibit the all-too-common practice of vendors requiring expensive upgrades to add on patient-facing communication platforms such as patient portals. In sum, there may be corollary benefits to physicians.

The government’s new stance on access to data is not going away. The ruling is consistent with the government’s overall health care technology strategic plan, just released in the fall. (<https://www.healthit.gov/topic/2020-2025-federal-health-it-strategic-plan>) Accessibility of health information is a key principle of the new plan; it may be an opportune time to determine if and how the “open notes” mandate will impact your practice.

Required Patient Data Available for Clinical Notes:

- Consultation note
- Discharge summary note
- History and physical
- Imaging narrative
- Laboratory report narrative
- Pathology report narrative
- Procedure note
- Progress note

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