

UNPACKING THE 21ST CENTURY CURES ACT

The 21st Century Cures Act is a complex piece of legislation encompassing multiple spheres where medicine and technology intersect. Here, we provide an overview of its most noteworthy facets for physician practices; TMA also maintains a resource page on the law within the Health Information Technology (HIT) section of its website (www.texmed.org/21stCCA).

INTEROPERABILITY PROVISIONS

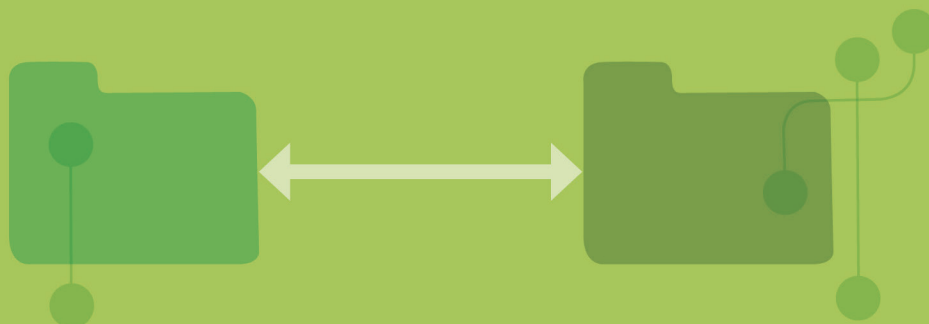
What they do: On March 9, 2020, the Office of the National Coordinator for Health Information Technology (ONC) released a final rule focused largely on interoperability – in this case, the ability for health information technology systems like electronic health records (EHRs) to operate in concert with one another so EHI can be shared easily among physicians and others.

How physicians are impacted: Per HealthIT.gov, the final rule updated requirements for EHR developers participating in the ONC Health IT Certification Program and adopted the U.S. Core Data for Interoperability (USCDI), which “sets a new baseline for interoperability and includes ‘clinical notes’ among other data important for clinical care.”

Within USCDI, for example, are data classes like demographics, and data elements or pieces of information like a first name or last name – the idea being, that if all certified EHR systems use the same data classes and data elements for classifying information, it will be much easier to share that data across systems.

Compliance and possible penalties: Vendors seeking certification for their EHR systems must comply with ONC guidelines, including the adoption of USCDI and enabling patients to access certain EHI online. Physicians participating in Medicare’s Merit-Based Incentive Payment System (MIPS) and Medicare accountable care organizations (ACOs) must use certified EHR technology (CEHRT) to report or face related payment penalties.

Also, using CEHRT can help physicians to avoid information blocking, as a certified system should improve interoperability with other health IT systems and facilitate a patient’s access to their EHI, making it easier for physicians to timely respond to request for EHI.



INFORMATION BLOCKING PROVISIONS

What they do: As of April 5, 2021, with implementation occurring in phases, physicians (and other health care professionals) are prohibited from engaging in information blocking of certain electronic health information (EHI), with some exceptions detailed in a March 2021 TMA white paper on the legislation (www.texmed.org/21stCCAWhitepaper; available on the TMA site for members, log in required for access).

How physicians are impacted: Information-blocking provisions require that a physician give a patient prompt electronic access to significant portions of the patient's EHI upon request, unless an exception applies. EHI includes:

- Discharge summaries
- History and physicals
- Progress notes
- Consult notes
- Imaging reports
- Laboratory reports
- Pathology reports
- Procedure notes

Compliance and possible penalties: The consequences for information blocking conduct are detailed in two sets of regulations. The first is geared toward health IT developers, entities offering certified health IT, health information exchanges, and health information networks.

Per the U.S. Department of Health and Human Services Office of Inspector General's (OIG's) June 2023 final rule, if an individual or entity in one of those four categories is found to have committed information blocking – following a process that begins with OIG receiving an information blocking complaint – it can result in up to a \$1 million penalty (adjusted annually for inflation) per violation (tma.tips/InfoBlockingRules). The amount of the penalty depends on several factors, including the nature and extent of the information blocking and any resulting harm (including, where applicable, the number of patients and providers affected and the duration of the information blocking).

The second is for physicians and other health care providers. As of July 31, 2024, physicians participating in MIPS who are found to have committed information blocking can receive a zero score in the promoting interoperability category – which makes up 25% of the MIPS score that determines their payment. MIPS penalties can range up to 9% of Medicare fee-for-service payment. The OIG rule does not apply to Medicare Advantage programs.

ACO physicians in the Medicare Shared Savings Program (MSSP) found in violation may be ruled ineligible to participate in the program for at least one year, though that disincentive can be mitigated by several factors (such as time since the information blocking occurred, the physician's diligence in identifying and correcting the problem, and any past incidents of information blocking).

