21st-Century Cures Act

Frequently Asked Questions

The "open notes" and transparency provisions of the 21st-Century Cures Act ("Cures Act") have raised several questions and concerns for health care providers. Although there are yet to be solid answers to all the questions, many answers have become available to date.

To whom does the Cures Act apply?

To the three categories of "actors" defined by the Office of National Coordinator for Health Information Technology (ONC). These include the following:

- *Health Care Provider*
  A hospital; nursing facility; home health entity or other long-term care facility; health care clinic; community mental health center; renal dialysis facility; blood center; ambulatory surgical center; emergency medical services provider; federally qualified health center; group practice; pharmacy; pharmacist; laboratory; physician; practitioner; provider operated by or under a contract with the Indian Health Service or an Indian tribe, tribal organization, or urban Indian organization; rural health clinic; covered entity under 42 U.S.C. § 256b; ambulatory surgical center; therapist; and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the U.S. Department of Health & Human Services (HHS) Secretary. Essentially, a health care provider is any person or facility that creates or generates electronic health information (EHI) on patients.
- *Health Information Network or Health Information Exchange*
  Health information network or health information exchange refers to an individual or entity that determines, controls, or holds the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of technology or services for the access to, exchange, or use of EHI
  - among more than two unaffiliated individuals or entities (other than those to which this definition applies) that are enabled to exchange with each other; and
  - that is for the purpose of treatment, payment, or health care operation, as such terms are defined in 45 CFR § 164.501, regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164.
- *Health IT Developer of Certified Health IT*
  A health IT developer of certified health IT is any individual or entity, other than a health care provider, that self-develops health IT for personal use, that develops or offers health information technology (as defined in 42 U.S.C. § 300jj[5]) and has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules voluntarily certified through a health information technology program kept or recognized by the National Coordinator according to 42 U.S.C. § 300jj-11(c)(5).

When was the effective date of the Cures Act?

Although passed in 2016, the Cures Act did not become effective until April 5, 2021. The first attestation of compliance is April 5, 2022.

What are the Cures Act Requirements?

The Cures Act generally allows patients/families/guardians (hereinafter, collectively referred to as "patient") to access, exchange, or use electronic health information (EHI). For the American public, the final rule promotes innovation in the health care technology ecosystem to deliver better information more conveniently to patients and clinicians. It also promotes transparency, utilizing modern computers, smartphones, and software to allow the American public to regain visibility in the services, quality, and costs of health care.

At what point in the episode of care must EHI be made available to the patient?

Draft clinical notes and laboratory results pending confirmation are examples of data points that may not be appropriate to disclose or exchange with the patient until finalization. However, if such data is used to make health care decisions about an individual, then it would fall within the "designated record set" and therefore within the definition of EHI. To the extent that a data point falls within the definition of EHI, practices likely to interfere with legally permissible access, exchange, or use of that EHI may implicate the information blocking definition.

A designated record falls under the following definitions:

(1) A group of records maintained by or for a covered entity that includes
(i) patient medical and billing records maintained by a covered health care provider;
(ii) the enrollment, payment, claims adjudication, case, or medical management record systems maintained by or for a health plan; or
(iii) those used, partly or fully, by or for the covered entity to make decisions about patients.

For purposes of this paragraph, the term *record* means any item, collection, or grouping of data that include protected health information and is maintained, collected, used, or disseminated by or for a covered entity (45 CFR § 164.501).

The patient does not have real-time access to their EHI. The EHI must be at a certain stage of completion before it can be accessible.

What materials are required to be accessible?

There are eight mandatory categories of clinical notes that must be made available to the patient:

- Consultation notes
- Discharge summary notes
- History and physical examination notes
- Imaging narratives
- Lab report narratives

- Pathology report narratives
- Procedure notes
- Progress notes

The level of detail required in disclosed notes has not been finalized. It is likely true that the above categories can be manipulated for safety. For example, rules require the disclosure of EHI. However, the name of the nurse who wrote the progress note is not EHI. The name of the provider must be disclosed, but disclosing the names of those who took the X-ray, drew the patient's blood, or hung the IV line is not necessary to convey the essence of the information to the patient. Additionally, crude, unflattering, or defamatory language should never be in a medical record revealed to the patient. In short, the record revealed to the patient should be concise, accurate, and factual.

Until October 6, 2022, EHI's scope for the information blocking definition purposes remains limited to the information represented by data classes and elements within the United States Core Data for Interoperability (USCDI). Therefore, until that date, *only* the notes that map the eight types specified in the "Clinical Notes" data class within the USCDI will be *required* in response to a request for legally permissible access, exchange, or use of EHI. However, actors (health care providers, health IT developers of certified health IT, and health information networks or health information exchanges) should keep in mind that none of the eight clinical note types currently represented within the USCDI are limited based on the specialty of the professional who authors them.

A USCDI "data class" is an aggregation of data elements by a common theme or use case. A USCDI "data element" is the most granular level at which a piece of data is exchanged. For example, "date of birth" is a whole data element rather than its constituent day, month, or year because the date of birth is the unit of exchange.

What are "blocking" provisions?

Blocking provisions impede or preclude a patient's access to their EHI. However, there are many valid reasons for blocking a patient's access to EHI listed as exemptions to the access requirements.

What are information blocking practices?

Practices considered blocking include the following:

- Practices that restrict authorized access, exchange, or use under applicable state or federal law of information for treatment and other permitted purposes, including transitions among certified health information technologies (health IT)
- Implementing health IT in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using EHI
- Implementing health IT in ways that are likely to
    - restrict access, exchange, or use of EHI with respect to exporting complete information sets or in transitioning between health IT systems; or

- lead to fraud, waste, abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health IT

What are the exemptions to the rule requiring access?

One of the primary exemptions to the rule requiring access is in the case of psychotherapy notes. "Psychotherapy notes means notes recorded (in any medium) by . . . a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session, and that are separated from the rest of the individual's medical record. Psychotherapy notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date."

Another exemption to the blocking requirement surrounds notes compiled in reasonable anticipation of or use in a civil, criminal, or administrative action or proceeding. These should qualify as "work products" to be protected.

Other exemptions to the rule requiring access include the following:

- *Preventing Harm Exemption*
  It will not be considered information blocking if an actor engages in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met.

- *Privacy Exemption*
  It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI to protect an individual's privacy, provided certain conditions are met.

- *Security Exemption*
  It will not be information blocking if an actor interferes with the access, exchange, or use of EHI to protect EHI security, provided certain conditions are met.

- *Infeasibility Exemption*
  It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, provided certain conditions are met.

- *Health IT Performance Exemption*
  It will not be information blocking if an actor takes reasonable and necessary measures to make health IT temporarily unavailable or degrade the health IT's performance for the benefit of its overall performance, provided certain conditions are met.

- *Content and Manner Exemption*
  It will not be information blocking if an actor limits the content of its response or the manner in which it fulfills a request to access, exchange, or use EHI, provided certain conditions are met.

- *Fees Exemption*
  It will not be information blocking if an actor charges fees, including those that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met. This is true only to the extent that they comply with the "Fees Exemption" (45 CFR § 171.302). For example, if the fees to export or convert data from technology were not agreed to in writing at the time the technology was acquired, then the "Fees Exemption" would not be available, and such fees may implicate the information blocking definition unless another exemption applies.

- *Licensing Exemption*
  It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met.

How is unlawful information blocking reported?

Anyone who believes they may have experienced or observed information blocking by any health care provider, health IT developer of certified health IT, health information network, or health information exchange is encouraged to share their concerns with ONC through the Information Blocking Portal on ONC's website, HealthIT.gov. Reports can be made anonymously and ONC will begin its investigation within two (2) business days.

Must a health care provider use certified health IT?

The information blocking regulations do not require actors to have or use certified health IT under the ONC Health IT Certification Program. Actors subject to information blocking regulations are not required to immediately upgrade their certified health IT (as of April 5, 2021) if they are also participating in a separate regulatory program that requires the use of certified health IT, such as CMS's Promoting Interoperability Programs.

Is a business associate subject to the Cures Act?

In some instances, a business associate will be an actor under the information blocking regulation in 45 CFR part 171 and, in other situations, may not. Any individual or entity that meets any definition of an "actor" in the Cures Act is subject to the information blocking regulation in 45 CFR part 171, regardless of whether they are also a HIPAA-covered entity (CE) or business associate (BA).

How is the Cures Act enforced?

Enforcement of the information blocking regulations depends upon the individual or entity that is the subject of an enforcement action or actor. For health IT developers and health information

networks/HIEs, the HHS Office of the Inspector General is presently engaged in rulemaking to establish enforcement dates. Currently, for health care providers, HHS must engage in future rulemaking to establish appropriate disincentives as directed by the Cures Act.

After April 5, 2021, any actor's agreements, arrangements, or contracts are subject to and may implicate the information blocking regulations. Consequently, all health care providers should review their contracts and agreements for health care portals and electronic medical records to ensure compliance with the Cures Act. Because many health care providers are not also IT experts, each vendor who supplies software or products that may affect EHI handling should submit a statement affirming or certifying the product's compliance with the Cures Act.