

21st Century Cures Frequently Asked Questions

What is information blocking?

Essentially, information blocking is any practice that physicians or health information technology developers use to make it more challenging for others to access, exchange or use electronic health information (EHI) when those other parties have a right to the information.

Formally, [45 CFR § 171.103](#) defines information blocking as a practice that:

1. Is likely to interfere with access, exchange or use of electronic health information; and
2. A health care provider knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.

Exceptions

The following list are the exceptions to information blocking, provided certain conditions are met. For additional information on any of the exceptions, see the Office of the National Coordinator for Health Information Technology's (ONC) [Information Blocking Exceptions](#).

1. Preventing harm to a patient or another person.
2. Protecting an individual's privacy.
3. Protecting the security of electronic health information (EHI).
4. Infeasibility.
5. Health IT performance (e.g., to operate properly, health IT must be maintained and sometimes taken offline).

The remaining exceptions involve procedures for fulfilling requests to access, exchange or use EHI.

6. Limiting the content of the response to a request or the way it is fulfilled.
7. Fees (due to the electronic nature of the records and the exception to fees in 45 CFR § 164.524(c)(4), this is unlikely to apply to health care providers).
8. Licensing interoperability elements for EHI to be accessed, exchanged or used.

What data must be accessible?

As part of the 21st Century Cures Act Final Rule, the United States Core Data for Interoperability (USCDI) was adopted for the initial definition of EHI. USCDI is "a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange," and it is intended to set "a foundation for broad sharing of electronic health information to support patient care."¹ This information may already be in your EHR system and includes, among others, the [following data elements](#) (note that clinical notes now must be accessible to patients):

- Patient information.

¹ The Office of the National Coordinator for Health Information Technology, [healthit.gov/cures/sites/default/files/cures/2020-03/USCDI.pdf](https://www.healthit.gov/cures/sites/default/files/cures/2020-03/USCDI.pdf).

- Vital signs.
- Medication list.
- Assessment and plan of treatment.
- Care team members.
- Clinical notes (except psychotherapy notes and information compiled in anticipation of a lawsuit or administrative hearing).
- Patient goals.
- Health concerns.
- Labs and medications.

Beginning Oct. 6, 2022, the definition of EHI will expand to include all HIPAA electronic designated data set.

Who must comply?

Health care providers (broadly defined) are included in the list of those that must comply, and that includes doctors of optometry. Other “health care providers” are hospitals, skilled nursing facilities, nursing facilities, home health entities or other long term care facilities, health care clinics, community mental health centers, emergency medical service providers, federally qualified health centers, group practices, pharmacists and pharmacies, laboratories, physicians, providers operated by, or under contract with, the Indian Health Service or by an Indian tribe, rural health clinics, ambulatory surgical centers, therapists, and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary of HHS.

Can I still use a fax machine to send information to other physicians?

By developing standards to create increased interoperability by electronic health records, the Department of Health and Human Services is working towards the goal of having increased communication between physicians and EHR systems. Before the regulations were finalized many assumed that HHS would prohibit the use of fax machines for sending health information all together. HHS chose not to specifically disallow the use of fax machines, so their use remains allowable.

Does this law help me to meet the requirements under the Fairness to Contact Lens Consumers Act (FCLCA) related to providing contact lens prescriptions to patients?

The FCLCA requires physicians to provide a copy of the contact lens prescription at the completion of the contact lens fitting process. In new rules finalized in June 2020, the Federal Trade Commission (FTC) indicated that doctors could provide prescriptions to patients electronically, if the patient provides consent to receive the prescription in a specific electronic format. In the rules, FTC noted that some options for providing the prescription electronically would be via patient portal, email or text message.

AOA has confirmed with FTC that providing patients access to their EHRs under the Cures Act would not preclude doctors from providing a patient with a copy of their contact lens prescription in every circumstance, but if certain stipulations are met, it could. Compliance would require that a copy of the patient’s contact lens prescription be in the clinical notes of the patient’s EHR, as well as having the patient consent to that specific means of electronic delivery of the prescription. The FTC further clarified that if the prescription is in the clinical notes, it would need to be in a format typically associated with a prescription to meet the FCLCA’s requirements (for example, it cannot just have the technical information of a prescription somewhere in the

notes and be considered compliant). However, keep in mind the FCLCA has other requirements, such as showing that the prescription was sent, received, or made accessible, downloadable and printable to the patient for at least three years, so compliance with the Cures Act is likely not a way to avoid dealing with the FCLCA's requirements. The spirit of the FCLCA is to increase prescription portability and providing patients with access to their patient record overall does not seem to be in the spirit of the law.

What if my practice uses only paper charts?

Practices may continue using paper charts, and if you do not use electronic records, the 21st Century Cures Act likely has little impact on your practice. The concern for doctors is not to be an "information blocker." As described in the definition above, information blocking relates only to *electronic* records. Since you are not using electronic health records, you wouldn't be information blocking or in violation of the Cures Act.

When does this take effect?

On Oct. 29, 2020, the compliance date for the information blocking provisions was extended from Nov. 2, 2020 to April 5, 2021, due to the COVID-19 pandemic.

What if I do not comply?

It isn't clear. Under the Cures Act, health care providers who engage in information blocking may be "referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary [of HHS] sets forth through notice and comment rulemaking."

What steps should I be taking now?

1. Evaluate how your practice currently handles its EHI.
2. Be aware that patients now have the right to clinical notes (and the other items listed above).
3. Contact your EHR vendor and ask how the company plans to comply with the new requirements of the Cures Act and confirm what information will be more (or newly) accessible

to patients. It is also worthwhile to see if the company is offering any training or other information for you and your staff to review.

4. Update NPPES with your digital contact information.
5. Provide information and training to your staff on the new requirements.

If you have questions, please contact askaoa@aoa.org.