21st Century Cures Act Information Blocking Rule Withholding Clinical Notes

October 23, 2020

The 21st Century Cures Act (Cures Act) was enacted in 2016 to "accelerate the discovery, development, and delivery of 21st century cures, and for other purposes." Among the many requirements in the statute, the Cures Act includes a prohibition on "information blocking" which intends to increase interoperability of patient records amongst care providers through health information exchanges, to streamline availability of records to patients, and to facilitate patient directed transfers of their records to third parties such as researchers and health application developers.

Under the information blocking provisions, patients are provided test results and clinical notes automatically unless a specific exception applies. Healthcare providers may, on a case by case basis, determine that releasing information to a patient's MyChart account or through a health information exchange meets one of the exceptions. The expectation is that this will be rare and the determination should be supported by documentation in the note.

The criteria for the preventing harm exception or the privacy exception are as follows:

Preventing Harm Exception

On an individual case basis, it is determined that:

- 1. Withholding the information will substantially reduce a risk of harm to the patient or to another person; and
- 2. The information withheld is no broader than necessary to reduce the risk of harm; and
- 3. Releasing the information is reasonably likely to endanger the life or physical safety or cause substantial harm to the patient or another individual; and
- 4. The risk of harm must:
 - a. Arise from data that is known or reasonably suspected to be misidentified, mismatched, corrupt or otherwise erroneous; or
 - b. Determined by a licensed health care professional with a current or prior treating relationship with the patient to pose a substantial risk of harm to the life or physical safety of the patient or another individual, or in accordance with CGA Sec 17a-548, poses a substantial risk of severe deterioration in mental state.

As an example, the preventing harm exception may be applicable where the record to be withheld includes information on child or elder abuse or domestic violence and the information would be provided to the perpetrator of the abuse or where the record is known to include erroneous information that would be harmful to the patient or another person if disclosed.

Privacy Exception

On an individual case basis, it is determined that one of the following conditions is met:

1. The information to be released is subject to additional state or federal privacy laws requiring patient consent for the release and consent has not been obtained.

For example, substance abuse treatment, mental health, and HIV records require patient consent for release to anyone other than the patient under federal and state law. These records may be withheld from sharing through a health information exchange until patient consent is obtained.

- 2. The information may be withheld under the Privacy Rule. For example, when a research subject is participating in a blinded study, blinded information may be withheld as described in the study informed consent. Information also may be withheld if the information was developed in anticipation of civil, criminal, or administrative action or other proceedings.
- 3. The patient has requested and the University or Health System has agreed to a restriction in accordance with University or Health System policies on requesting restrictions on use and disclosure of protected health information.

To withhold a note from a patient, the "share w/ patient" button at the top of the note should be deselected and the reason for withholding indicated in the note.

