

Empowering Patients Through Information Sharing: Cures Act Compliance Series

November 2021/Cures Act Overview Q & A

The following questions were submitted by participants before and during the November 10 webinar and November 17 Ask the Experts sessions. The answers provided are for informational purposes only; they do not, and are not intended to, constitute legal advice. Only your attorney can provide assurances regarding the application of this information to your particular circumstances.

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Access

Q: Are providers using EHRs required to give patients electronic access (i.e., use of patient portal)?

A: Yes, the Cures Act requires that agencies provide electronic access to their records. Typically the primary methods for this access are via a portal and/or third-party application.

Q: How proactive does a health care organization need to be about providing *electronic* access? We don't get a lot of requests that I am aware of for specifically electronic access. Is it sufficient to (for example) be prepared to put records on a flash drive and give that to the patient if requested, or do we need to have something like a portal or third-party software enabled and affirmatively offer access to all patients, even if they aren't specifically requesting electronic access to their records?

A: Per the Cures Act, electronic access should be offered proactively to patients via an electronic method, even if the patients do not utilize its features. The act prescribes that the records must be available in the method that patients request; preparing a portal in advance can help prevent delays when requests are made.

Q: Can we set policies that state we provide electronic information to patients only via patient portal, CD, API, etc. (restricted to the options available to us) and be compliant in the ONC's eyes? Or do you have to have a policy that you provide it however the patient wishes to receive the electronic information?

A: Although there are considerations around licensing and method of delivery, you still need to be prepared to provide records via various methods and cannot have a policy that proactively limits a method or methods of delivery.

Q: As a point of clarification, once a patient registers for a portal account, that's considered a request for records and we are obligated to post all diagnostic results, clinical notes, etc. to keep their record up to date?

A: Yes, offering patients their records upon completion is a requirement of the Cures Act, and thus the records need to be available continually on an up-to-date basis.

Q: How quickly do notes need to be completed by providers to stay in compliance with immediate access requirements for Cures? Are we required to have the progress note immediately on the patient portal once the provider finishes it? Or is it acceptable to be able to share as soon as the patient calls and requests it?

A: The Cures Act final rule itself does not have any rules around the timing of completion of records; the rules are prescriptive around the timing of delivery once the records have been completed, which are addressed in other questions. However, there are other considerations and laws, such as Medicare Timely Filing, that need to be considered.

Q: Does the entire progress note in its original form need to be available or is it acceptable to have portions of the note available on the portal? For example our patient portal for Medent allows patients to view any Dx codes, recommendations from provider, labs ordered, etc. But it does not list the HPI, CC, or exam portion of the note.

A: Yes, the entirety of the record must be made available to your patients. This includes the full chart notes and results as well as billing and financial information.

Q: Are there limits to what patients can request? They might have eight years of records.

A: There are no limits as to what they can request, as long as it falls within the limits of other HIM retention laws. With this in mind, there are considerations on timing if a record is not currently contained within an electronic format. In this case, upon request, the recommendation is to utilize the Content and Manner exception to allow for the delay in digitization and delivery of older records.

Q: How do the requirements for timely access to electronic records impact the release of records on paper? is the turnaround time for giving patients a paper copy of their EMR records upon request shortened? Do they need to be released immediately on request?

A: The Cures Act is primarily focused on the delivery of records via electronic format; however, the ONC has clarified that the delivery of any records is impacted, as information blocking extends to any method of delivery, including paper. With this in mind, there are considerations around content and manner, as converting the record into paper or onto a USB or CD does require time to complete.

Content

Q: Is it ok to keep certain data (lab tests, diagnoses procedures) off of the patient portal for certain types of visits (e.g., adolescent family planning visit, or pregnancy test visit)?

A: On the whole, it is not appropriate to withhold entire categories of data from being shared, outside of psychotherapy notes, due to the broad nature of the information blocking this constitutes. Specific scenarios and use cases, such as pregnancy tests, will need to be identified on a case-by-case basis to determine if they fall under the Privacy and/or Preventing Harm exceptions.

Q: Patients who are 13-17 – what do you do regarding releasing their information?

A: Patients aged 13-17 are considered their own entities and are entitled to have access to their own records; however, sharing of records with their parents or guardians is more complicated. The recommended action plan would require the patient to sign a consent for their parent/guardian to access the record. We plan to host a more in-depth review of this specific scenario later in the series.

Q: How is sensitive information handled – alcohol, substance use, mental health records?

A: In these cases, 42 CFR Part 2 still takes priority under the Privacy exception in how others may access the records; however, these records are still considered part of the designated record set that should be available to patients themselves.

Q: I was under the impression that mental health records can be requested by the patient for continuum of care but should not be given directly to the patient.

A: This is correct specifically for psychotherapy notes; however, most types of behavioral health documentation do need to be shared with the patient via a portal or other method.

Q: If we receive results or diagnoses (cancer diagnoses example or cancer result, or even a urology progress note consult) – if it comes into our electronic medical record – do we need to provide the result to the patient regardless of whether the other place also provides them an electronic copy of the result?

A: In the strictest sense, no, you only need to provide access to records generated by your organization, including the results of orders that may have been resulted off site (such as labs drawn on-site but completed by an outside agency). The vague nature of the definition of the designated record set does bring this into question, as it includes any documentation that assisted in making a decision about an individual. This is a determination that would need to be made with internal counsel as to how your organization will interpret this rule.

Q: Is there is a New York State law requiring counseling to patients receiving results of HIV tests? Can we hold HIV test results until we contact the patient by phone and talk with them about their results? This seems like a state law exception, and a preventing harm exception.

A: Although most results are required to be sent to the patient immediately upon result completion, this use case does bring an added layer of complexity. It's possible that receipt of HIV results prior to a provider consult could be easily argued to fall under the Preventing Harm exception, and thus would be acceptable to delay. We will review the exceptions in greater depth in January.

Mechanics

Q: If I understand correctly, HIPAA states we must have a signed records release, but the Cures Act states that this may be considered information blocking. Which takes precedence?

A: If a patient is requesting their own records, a release is not required; however, if they are requesting another individual's records (or are requesting on behalf of them), a consent is required. Requiring a patient to sign a consent for their own records can be viewed as a violation of the information blocking rules.

Q: Does a patient have to sign a release to get their own information via a portal they have already enrolled in?

A: No, a patient does not need to sign a release to receive their own records. In fact, requiring a release could be construed as a violation of information blocking rules.

Q: When requesting a copy of their medical records is anyone using a device like USB and are they using encryption?

A: The most common methodology for release records is via a portal, a third-party application or a Health Information Exchange. Providing records on USB devices is also an acceptable method. While it is always advisable to encrypt PHI/ePHI, when giving the patient their record via USB, it is not expressly required. It is best to validate that patients are aware that once the records are in their possession, the health center is no longer responsible for the security of the records.

Q: Would we have to provide the USB or just be able to put the files on a USB that the patient provides?

A: You are not required to provide a USB; however due to concerns of connecting a foreign device to your network, it is inadvisable to accept USB devices from patients. It is still acceptable to charge fees for receiving records, including fees for the USB itself.

Q: If a patient gives us their own USB, are we still require to have patient sign a Release Form?

A: A patient is not required to sign a consent for their own records on USB; if someone is requesting another person's records, a release would be necessary. It is recommended to include documentation along with delivery of the USB indicating that the security of their records once they leave your possession is up to the patient.

Q: I've had specialists require I pay for copies of my medical records. Is that still permitted under the Cures Act?

A: Yes, it is still permitted to charge for fees, however there is verbiage in the Final Rule that aims to reduce and eliminate any excessive or undue fees.

Q: Is there guidance available around developing policies and procedures?

A: When performing a review of accuracy and completeness of policies and procedures (P&Ps), it is best to start with updating currently developed P&Ps, then determine any gaps that must be addressed. The [compliance library compiled by Helen Oscislawski](#) has several helpful resources, and accounts are available through CHCANYS (contact Amy Freiman at Afreiman@chcanys.org for details). We will discuss this topic in greater detail in February and March.

Q: Is there is an assessment checklist that my organization could use to help us determine what needs to created or enhanced?

A: A checklist is being developed in conjunction with the Empowering Patients Education Series and will be available in early 2022.

Q: I am using a template info blocking policy given to me by my law firm, it is mainly a list of the exceptions available under the info blocking rule. I am going to take my privacy policy section on Access to Patient Information (which was written with HIPAA in mind), and replacing the section on Grounds for Denying Patient Access with the new info blocking policy language. Are there other sections of my privacy policy (which is 78 pages) that I need to update for info blocking? Related to this is what HIPAA privacy rule procedures/policy would need to be changed to comply with info blocking rules.

A: The largest changes that have come about from the Cures Act that should be evaluated are regarding method of access, timing and the full availability of the records. These would be the primary areas of focus and review.

EHR/EMR Vendors

Q: In light of the Act, should we have BAAs attest to compliance with it?

A: It is always recommended to ensure that data privacy is included in BAAs with vendors and partners, both existing and future. When seeking a new vendor partner, validate that the platform has a certified health IT designation.

Q: If you find an EMR vendor is in violation of the Cures Act or feel they do not provide a compliant workflow, how do you report them to ONC? Do we ask the vendor to be compliant first and explain why?

A: You are more likely to see faster progress reaching out directly to your EMR vendor, however if you do not feel the vendor is being responsive, you can reach out to report violations to the ONC directly via [this portal](#).

Q: Is Medent taking any steps to comply with the Cures Act?

A: For EMR-specific questions, please reach out to us directly, and we will engage directly with a SME on that EMR (email hccn@chcanys.org).

Other

Q: What are some examples of non-designated record set info, maybe patient complaints, potential HIPAA violations, fully paid (not sent to third-party biller) services, etc.?

A: Due to the currently vague description of the designated record set, it is difficult to know exactly what should or should not be included. The examples in the question of patient complaints and HIPAA violations will most likely not be included. Non-billable encounters, such as health education is more likely to be included, as they can guide the clinical decision-making of a patient's care plan.

Q: What should be done if a patient points out a typo or mistake in their records? Can you change the record after the fact without getting into any trouble?

A: It is encouraged to update the record to correct the mistakes that are found within the record via an addendum, as to not violate any other medical record rules.