

THE FEDERAL 21st Century CURES ACT AND WHAT IT MEANS TO MASSACHUSETTS' PSYCHIATRISTS

AKA Interoperability and Information Blocking of Medical Records

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The 21st Century Cures Act (Cures Act), signed into federal law in December 2016, is a wide ranging law covering a wide swath of the medical scientific and care provision landscape with the goal of accelerating the pace of medical scientific discovery and improving patient care. From the perspective of patient care delivery, the law is designed to assist doctors and hospitals in improving the quality of care, specifically by leveraging electronic health care system use and development and empowering patients through improved access to their electronic health information.

There has been a recent publication of federal rules around this law which have generated a lot of concern and questions about provisions regarding "Information Blocking". Importantly, this law does not fundamentally change what is already the case; that patients have the right to their medical records, including psychiatric records, and our notes should be written with the realization that patients may one day look at them. Let's dive in.

Cures Act Final Rules

Several final rules (1) emanating from the Cures Act were published in May 2020 addressing two principle goals. The first goal is to make patient records available to clinicians and patients alike in a manner that requires no special effort on the part of the patient or the clinician. The vision is that modern technology such as Apps on a smart phone and electronic health record platforms can be used for data requests. Patients will be able to access their electronic health information easily and inexpensively in a fully automated, low cost manner using an app of their choice. There is nothing in this act which mandates use of an electronic health record by individual providers, although Medicare incentivizes use of electronic health records.

Another goal of the newly released final rules, this one by Health and Human Services Health Information Technology office (also known as Office of the National Coordinator- ONC) (2) aims to prevent so-called "Information Blocking". Information Blocking is a practice that deliberately or materially restricts or delays authorized access to patient records. The law is primarily aimed at software developers and other information technology professionals and disallows the purposeful development of features to block patients from having ready access to their medical records as described above. Developers need to comply with defined IT components by Feb 2021, which is a push back from an earlier deadline of Nov 2020.

The rules about information blocking also apply to holders of clinical records, which includes psychiatrists. The Cures Act requires that you do not interfere with the lawful release of medical or psychiatric records. It defines exceptions to record release rules which are not considered Information Blocking. Some of them are recognizable from other statutes. Examples include an exception for preventing harm, e.g. withholding information for patient safety reasons; an exception for protecting privacy, e.g. content is revealed that would violate the privacy of a third party; and an exception for temporary interruptions in service, e.g. a power outage of IT system maintenance, among others. Per MPS Counsel Jim Hilliard, "If there are to be delays due to unforeseen circumstances, notification should

be conveyed to the requesting party immediately to avoid a complaint, and as long as the request is properly before you and your records system is designed to function in as expeditious manner as is reasonable under the circumstances, you will be OK. As always, the important thing to remember when you have been asked to release psychiatric records to someone other than the patient, is that you either have a proper release, signed by the patient or the patient's duly appointed representative, or you have a duly authorized court order, or the release is mandated by a statute. In these cases the records should be provided as soon as possible."

Confidentiality of and Definition of Psychiatric Records in Federal and State Law

For the purposes of transfer of medical record information HIPAA federal law defines a "designated record set". HIPAA does not include psychotherapy notes as part of the designated record set. It defines psychotherapy notes as notes that a mental health professional takes during a "conversation" with a patient. HIPAA dictates that psychotherapy notes are kept separate from the designated record set. HIPAA also does not allow the provider to make most disclosures about psychotherapy notes without the patient's authorization and does not allow for automatic patient access to psychotherapy notes.

In contrast Massachusetts General Law MGL Chapter 112 section 12CC, which supersedes federal HIPAA law, defines psychotherapy records as the entirety of a psychotherapist's record. (The law confusedly uses the term psychotherapy to refer to a broad array of mental health treatment including psychiatric treatment.) It allows a patient access to their own "psychotherapy" record, but also allows the psychotherapist the discretion of providing the patient with a "summary" in lieu of the entire record if the psychotherapist in the reasonable exercise of their judgement believes providing the entire record would adversely affect the patient's wellbeing. This is similar to the patient safety exception provided by the 21st Century CURES Act as described above. In such a case however, the psychotherapist shall make the entire record available to either the patient's attorney, with the patient's consent, or to such other psychotherapist as designated by the patient. The CURES act has a further Content and Manner Exception which states: "It will not be information blocking for an actor to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request ...provided certain conditions are met." The decision as to whether the conditions were met will be left to interpretation and challenge by ONC. This is often the case for new law. It gets sorted out in time through complaints and litigation. Attorney Hilliard's advice is to follow the MA statute and release a psychotherapy patient's record in its entirety to the patient unless you believe that releasing the entire record would adversely affect the patient's wellbeing and in such case only release a summary. He notes that in his experience when psychiatrists have not maintained two separate records per the HIPAA defined practice, when releasing records some psychiatrists have simply redacted the "conversation" references which belong in a separate psychotherapy note per HIPAA.

The 21st Century Cures ACT is mandating use of a new standard record set for called the United States Core Data for Interoperability (USCDI) to be used in the development of electronic transfer capability. The USCDI includes "progress notes" and makes no distinction between progress notes and psychotherapy notes. This lack of distinction has already been a part of the practice life of many psychiatrists who operate in hospital or other medical based systems. But some hospital based system in MA are already moving to make automatic access to patient progress notes a deliverable for every patient visit. This practice appears to exceed the mandates of the 21st Century Cures Act law which are based on patient request, but this raises the issue of sensitive material in mental health notes in this context. Advocates for transparency in medicine, including a group called Open Notes, founded at Beth Israel Deaconess Medical Center, argue that transparent notes create more trust and engagement between provider and patient, allow for patient reflection and oversight of their care, reduce errors, and promote person- centered communication, among other benefits. 3

The Bottom Line for MA Psychiatrists

The CURES Act does not give the patient access to records they did not already have a right to under MA law. Patients have a right to their medical record, including their psychiatric notes, with very limited exception. Privacy protections for psychotherapy notes remain in place, and they should not be released without written permission from the patient. Those who have electronic systems that can transmit information electronically, primarily health care systems with IT departments, now have rules to develop faster capability and standardized electronic information platforms, for the transfer of electronic health information to both patients and other providers. Progress notes should be written judiciously as always, noting that some content covered in psychotherapy should either not be included or should be maintained in a separate note. Enlisting the patient's involvement in note writing and review is a growing movement in response to anticipated increased patient access to routine progress notes. Future Business Associates Agreements (BAAs) between users of electronic health record systems and electronic health record companies will likely have language to address compliance with the CURES Act. As with the case for all major laws, future guidance and common practice will be defined by inquiries, complaints and litigation, so it will be interesting to see in the next few years, how patient record access evolves.

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1 <https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet>

2 [Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule](#)

3 <https://www.opennotes.org/>