Protecting Patient Data in the Electronic Age: Updating 42 CFR Part 2

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Adoption of Electronic Health Records (EHRs) is now nearly universal in hospitals in the United States.[1] Primary care practices are not far behind with 87% having adopted an EHR, most of which are certified EHRs.[2] Behavioral health providers are far behind, but catching up with 79% of mental health agencies using an EHR in 2014[3] and 53% of substance use disorder specialty treatment agencies using an EHR in 2015.[4] While most primary care and hospital programs report that they cannot or do not transmit data to or from behavioral health organizations electronically (11% of physician offices, 28% of hospitals),[5] in the near future integration of behavioral health into the healthcare system will become the standard and sharing of electronic data on patients to improve care will become an expectation.

It is against this backdrop that Substance Abuse and Mental Health Services Administration (SAMHSA) undertook updating the rules regarding confidentiality of patient records for the treatment of substance use disorders. The law, 42 U.S.C. §290dd-2 Confidentiality of Records, generally referred to as 42 CFR part 2, or part 2 was enacted in the early 1970s. The last time the rules were substantially changed was in 1987. The rules did not envision a time when records were maintained electronically, would be transferred via the internet, and when treatment for substance use disorders would be a routine part of care in primary care settings. Primary care providers, integrated health systems and payers who manage part 2 data along with other health data have long complained that the 1987 regulations made operating integrated care difficult as records needed to be maintained separately from other health records and could not be submitted to Health Information Exchanges (HIEs) because the consent provisions of the law.

In 2014, SAMHSA held a listening session to solicit feedback about what needed to be changed to update the rules to function in the near future where patient information is shared electronically amongst providers. Approximately 1,800 people participated either in person or via phone and we received 112 verbal and 635 written comments. Based on the listening session, SAMHSA wrote proposed changes to the rules and published a Notice of Proposed Rulemaking (NPRM) in the Federal Register in February of 2016. Comments were due by April 11, 2016. SAMHSA received 376 comments.

After reviewing the written comments and working with other divisions in the Department of Health and Human Services (HHS) and other parts of the federal government, SAMHSA published the final rule on January 18, 2017 with a scheduled effective date of February 17, 2017. By executive order of the President, the rule is under review and its effective date is delayed until at least March 20, 2017.

The final rule as published on January 18, 2017 has several changes that are important for clinicians to know and understand. The most important of these is changes to the requirements for consent to share records. The new rule allows for a general designation in the "to whom" section of the consent form. For example, a patient could now sign consent for "all my treating providers" and XYZ Health Information Exchange (HIE) so that records that include part 2 information could be shared via an HIE with anyone that treats that patient as are other types of health information. Patients may sign a general release in a primary care setting prior to receiving care for a substance use disorder and may not know that unless they change their designation, that information about their treatment for a substance use disorder can be included in all of their health records. Counselors who work with patients who have substance use disorders should make sure that their patients understand what they are signing when they sign a release of information for confidential records and the pros and cons of using a general designation.

Because we did not change the rule in terms of using a general designation in the "from whom" section of the consent form, patients could sign a consent that basically says information could be shared "to all my providers" "from all my providers." While such consent will facilitate electronic data exchange, the patient should have a full understanding of what that means. If a patient uses the general designation in the "to whom" section of the consent form under the new rules, they have a right to request and receive a list of who accessed the information about their substance use disorder treatment. Programs may not use the general designation for the "to whom" section of the consent until the system of care in which the information is being shared is capable of providing the list of disclosures. Also, the consent must specify what type of information can be shared and for what purposes it can be shared. It is important for clinicians to help patients make good choices about their options. For consent to release records to individuals and entities other than health care organizations, the release must be specific to the individual or entity. The rules do not allow for the use of a general designation outside of the healthcare system. For example, for a part 2 program to provide information to a probation officer, the consent must specify the probation officer by name.

Another provision that may be of interest to clinicians is that programs must have in place formal policies and procedures to protect the security of records. The policy and procedure must specify mechanisms by which the organization protects against unauthorized disclosure or use of patient identifying information in both paper and electronic records. The security of records provision includes language regarding how records should be disposed of in the event that a program is closed or merged into another organization. Since so much data is now held "in the cloud," specific processes for purging electronic records that may be dispersed in multiple places is now necessary to ensure confidentiality.

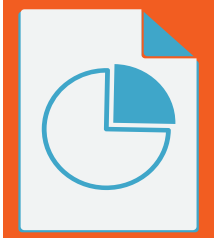
The new rules clarify that the prohibition on re-disclosing records only applies to part 2 information that would be directly linked to an identifiable individual. For organizations that receive information from a part 2 program and incorporate that information into the electronic medical record, the entire record does not fall under part prohibitions on re-disclosure. Only the information that links the specific patient to the part 2 data is prohibited from re-disclosure. So, for example, a healthcare

system that had part 2 data incorporated into its EHR would be able to release information about part 2 services if the data was de-identified, or it could re-release information about the patient if the part 2 data was removed. All of these releases would be subject to other laws such as the Health Insurance Portability and Accountability Act. Depending on the receiving organization and the purpose of the disclosure, general consent may allow for re-disclosure. The prohibition on re-disclosure provisions assume the patient has not consented to re-disclosure.

There are a number of provisions in the new rules that make accessing and sharing data for research and audit and evaluation purposes easier. Based on comments submitted in response to the NPRM, we went further than we had originally proposed in terms of allowing part 2 data to be linked to other datasets for the purposes of research. At the same time, we also clarified how the researcher needed to maintain and dispose of confidential records. We also clarified that part 2 data could not be shared with law enforcement agencies even for the purposes of data linkages for research.

We clarified that the audit and evaluation exception to consent included audits for the Children's Health Insurance Program and for evaluation at the Accountable Care Organization (ACO) or similar system level when those activities are required by funders for payment decisions. This was done by clarifying that the Centers for Medicare & Medicaid Services *or its agents* could conduct audits and evaluations. In addition, on the same day the Final Rule was published, we also issued a Supplemental Notice of Proposed Rulemaking (SNPRM) to address an issue that was raised in comments but not addressed in the initial NPRM. The use of contractors to conduct a variety of activities by health systems (not just individual providers) led to concerns that essential functions could not be conducted by contractors if part 2 data is in the record. Part 2 programs may use a qualified services organization agreement (QSOA) to allow contractors to perform essential business functions, but the QSOA provision was written to support only the part 2 program. A large health system, an ACO or some other entity to which the part 2 program might belong or which might be a lawful holder of part 2 data, and which might conduct activities related to payment and operations via contractors cannot use the QSOA provision. For example, a part 2 program might, with an appropriate consent, provide information to a managed care company for the purposes of payment. If the managed care company used a contractor to conduct any of their operations such as data analysis for rate setting, under the current regulation it is not clear that they are allowed to share the part 2 data with the contractor. The SNPRM proposes clarifying the parameters of sharing data with contractors when the organization that is sharing the data is not a part 2 program. Comments on the SNPRM were accepted through February 17, 2017.

With all of these changes to increase data sharing, it is important to remember the reason the confidentiality law was originally passed. The law was designed to protect people who sought treatment from being at higher risk of prosecution than people who did not seek treatment. It is important to remember that as long as there is illegal drug use, people who have drug use disorders are at risk for prosecution for breaking the law. If the protections provided by 42 CFR part 2 are removed, then their medical records can be used as evidence against them. Similarly, even people with alcohol use disorders could have their medical records used to prosecute them for other offenses if their records were available to law enforcement.



The changes made in the rules published in January are an attempt to allow for data sharing within the healthcare system so that patient care may be improved by being integrated, and to improve research by ensuring that data about a patient's substance use and treatment for substance use disorders is not a missing variable in research studies. We retained protection from use of part 2 information about a patient for the purposes of prosecution and prohibitions on sharing the data with law enforcement agencies. It is up to treatment agencies and clinicians to help patients understand the risks and rewards of greater sharing within the healthcare system. While improved care might be an outcome, the risk of accidental unauthorized release is increased as the data is more widely shared. Patients will need to be informed of their right to request a list of to whom their information is provided if they sign a general consent. In this era of big data, it behooves everyone to better understand and consider with whom we share personal information whether it is regarding health care, our activities, our location or our consumer habits. The new rules allow for, but do not require, broader sharing of information about treatment for substance use disorders. Look to the SAMHSA website for future guidance about implementing the new rule and sample consent forms that you may consider using.

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