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Using mental health records for research

By Salvatore G. Rotella, Jr., Esq.

Editor's note: Mr. Rotella is an attorney and a member of the law firm of Cozen O'Connor. He may be reached by telephone at 215/665-3729.

The Health Insurance Portability and Accountability Act's Privacy Rule (the Privacy Rule) strikes a balance between restricting the unauthorized disclosure of medical records and permitting health care providers to operate effectively, including participation in research studies. Specifically, the Privacy Rule takes into account that getting patient authorization for a disclosure can be problematic for researchers who do not interact directly with their research subjects. Health services researchers, for example, typically analyze large amounts of patient data to reach evidence-based conclusions about ways to improve the quality and efficiency of health care services.

State laws and, to some extent, the Privacy Rule itself afford significant additional protection to records of mental health treatment. As a result, the careful balance between ensuring confidentiality and fostering studies to improve health care can shift dramatically in the case of research involving mental health records. Pennsylvania offers a good test case jurisdiction for understanding how to navigate the often complex overlay of federal and state laws governing a provider's disclosure of mental health records to an independent researcher.

Federal law: The Privacy Rule

The Privacy Rule sets a floor as to a provider's obligation to maintain the confidentiality of all protected health information (PHI). It generally allows disclosure of a patient's PHI only: for treatment, payment, or operations; with a valid authorization from the patient; or under certain other, limited circumstances. One of these other circumstances is for research purposes.[1]

As a threshold matter, the Privacy Rule's research provision applies only if a research undertaking's "primary purpose" is to obtain "generalizable knowledge." Accordingly, providers can customarily review patient records for quality assessment and improvement purposes without worrying about the restrictions on unauthorized disclosure, because such reviews constitute health care operations, not research.

Research-related disclosure of medical records in general. If a provider is participating in an effort to obtain "generalizable knowledge," it may disclose records that contain PHI only with a valid patient authorization or under the following scenarios:

First, the provider may de-identify the records, so that they no longer constitute PHI. This process entails either removing 18 separate indentifiers or having a qualified statistician determine that there is minimal risk that the intended recipient could use the information to identify the subject, either alone or in combination with other reasonably available information.[2]

Second, the provider may create a so-called "Limited Data Set," which involves removing certain identifiers from the records and entering into a data use agreement with the researcher who will receive the data.[3]

Third, the provider may obtain a waiver of the patient authorization requirement, for the specific research use at issue, from an appropriate Institutional Review Board (IRB) or Privacy Board.[4]

Fourth, a provider may disclose records for activities preparatory to research, such as for the researcher to prepare a research protocol.[5]

As a practical matter, the Department of Health and Human Services (HHS) has issued guidance clarifying that a researcher who is the intended recipient of a covered entity's de-identified records can also be the person to de-identify the records.[6] This is so because the process of creating de-identified health information from PHI is itself deemed a health care operation, and not part of the research project. Especially in the case of health services research involving large databases of patient information, the fact that the researcher can undertake the de-identification may well allow a provider to participate in an independent research project that would otherwise be out of the question because of the significant resources the provider would have had to devote to itself de-identifying the patient records before disclosing them to the researcher. Because the HHS guidance on this issue contemplates that the researcher will be a "business associate," it makes sense for a provider to enter into a business associate agreement with any researcher to whom it provides PHI to be de-identified and used for research purposes.

Finally, if a provider discloses PHI without a valid authorization, it must further ensure that it both limits the PHI disclosed to the "minimum amount necessary" to accomplish the research purpose and is prepared to provide an accounting of its disclosures to the relevant patients.[7] Notably, the regulations reasonably allow a provider to rely on the researcher's request as one that, by definition, seeks the minimum necessary PHI to achieve the researcher's purpose in cases involving a

properly documented IRB or Privacy Board waiver, a review preparatory to research, or research on decedents' PHI.[8]

Research-related disclosure of mental health records. Notwithstanding the other mechanisms generally allowing disclosure of PHI to a researcher absent patient consent, federal law permits a provider to make such a disclosure of so-called "psychotherapy notes" only with a valid patient authorization;[9] and this remains the case even if the notes have been de-identified.

The Privacy Rule defines psychotherapy notes as notes of a private counseling session taken by a mental health professional. The term encompasses only such notes kept separately from the rest of the patient's medical record, and the definition explicitly excludes treatment-related information, such as medication prescription and monitoring, counseling session start and stop times, and any summary of the patient's symptoms, prognosis, and progress to date.[10] Consistent with this narrow definition, HHS has observed that information critical to the treatment of a patient is normally maintained in the medical record, and thus, by definition, separate and apart from psychotherapy notes. According to HHS, the regulations provide additional protection to psychotherapy notes precisely because they are usually of little value to anyone (presumably including a researcher) not present at the counseling session.[11]

State law: The Pennsylvania Mental Health Procedures Act

Pennsylvania's Mental Health Procedures Act (MHPA or "the Act") presents a much more formidable obstacle than does the Privacy Rule to researchers seeking access to records of mental health treatment. Rather than focusing only on psychotherapy notes, Section 111 of the MHPA provides that "[a]ll documents concerning persons in treatment shall be kept confidential and, without the person's written consent, may not be released or their contents disclosed to anyone" except those engaged in providing treatment, to the county administrator in connection with emergency examinations, to a court in connection with proceedings authorized by the MHPA, and pursuant to federal rules when treatment is undertaken in a federal agency.[12] Regulations promulgated by the Pennsylvania Department of Public Welfare (DPW) that implement the Act add some additional permissible disclosures, but likewise do not include researchers among those enumerated third parties to whom an entity may potentially release or disclose mental health records without written consent from the patient.[13]

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The scope of the MHPA.
The MHPA's virtual blanket prohibition on the disclosure of mental health records without patient consent applies directly to all involuntary treatment and voluntary inpatient treatment of mentally ill persons, and, effectively, to voluntary outpatient treatment provided in a facility as well. In addition to stating that the Act "establishes rights and procedures for all involuntary treatment of mentally ill persons whether inpatient or outpatient, and for all voluntary inpatient treatment of mentally ill persons," the MHPA's "scope" provision defines the term "facility" broadly to include, among other things, community mental health centers.[14] DPW's implementing regulations, in turn, provide that the agency's rules regarding the confidentiality of mental health records—including the nonconsensual release of patient information regulation that parallels Section 111 of the Act—more generally apply to records of persons receiving mental health services from any "facility."[15] In addition to making its MHPA confidentiality regulations apply to facilities that treat voluntary outpatients, DPW also makes compliance with those regulations an express condition of licensure for both psychiatric outpatient clinics and partial hospitalization facilities.[16]

An argument could be made that to be consistent with the statute, the DPW regulations should be interpreted to apply only to records in a facility that are also records within the scope of the MHPA itself—i.e., records of inpatient or involuntary treatment. To be safe, however, providers should assume that Pennsylvania law permits the disclosure (to a researcher or otherwise) of records of voluntary outpatient mental health treatment provided in a "facility" only to the same limited extent it permits disclosures of records of mental health treatment provided to inpatients or on an involuntary basis.[17]

Permissible disclosures under the MHPA.
Because the MHPA provides even greater privacy protection with respect to the disclosure of mental health records than does the Privacy Rule, the federal rule does not preempt the state rule in this respect.[18] That means that Pennsylvania providers can only disclose mental health records covered by the MHPA as permitted by Section 111 and its implementing regulations. And under those state rules, a provider can only disclose such a record to a researcher if the patient consents in writing.

Two final, practical issues are worth noting: First, it is possible to comply with both the DPW-required elements of a written consent pursuant to Section 111 of the MHPA and the Privacy Rule's mandate that a valid patient authorization include certain core elements and required statements, be written in plain language, and that the individual authorizing the disclosure receive a copy of the signed authorization.[19] As a result, a provider should ensure that the "written consent" it obtains prior to disclosing records to a researcher under the MHPA also meets all of these requirements of a valid Privacy Rule authorization.

Second, because de-identified records do not constitute PHI, the Privacy Rule would allow a provider to disclose de-identified mental health records (other than psychotherapy notes) without an authorization. The MHPA, by contrast, seems to prohibit the disclosure even of de-identified records absent patient consent. While this approach may seem overly restrictive, it is consistent with the rest of the MHPA, as well as with how the courts and DPW have interpreted the Act.

Like the Privacy Rule, for example, the MHPA makes allowances for a facility to undertake internal quality assessment and improvement. While the federal rule permits a provider to use patient-identified records for these efforts, the state law permits such reviews only on the express condition that the provider does not identify individual patients.[20]

Federal and state courts interpreting the MHPA have likewise consistently found that, unless one of the four exceptions set forth in Section 111 applies, the Act "absolutely forbids [the] disclosure" of documents concerning persons receiving mental health treatment without the patient's written consent. *Hahnemann Univ. Hosp. v. Edgar*, 74 F.3d 456, 465 (3d Cir. 1996). See also *Pearson v. Miller*, 211 F.3d 57, 70 (3d Cir. 2000) (finding that "[i]t is settled under Pennsylvania law that the MHPA gives rise to an 'absolute confidentiality privilege' covering documents related to the treatment of mental health problems"); *Zane v. Friends Hosp.*, 836 A.2d 25, 32 (Pa. 2003) ("The terms of [Section 111] are eminently clear and unmistakable and the core meaning of this confidentiality section of the Mental Health Procedures Act is without doubt—there shall be no disclosure of the treatment documents to anyone.") Significantly, the courts have adopted this strict interpretation of the provision even in cases in which doing so meant denying the victim of a violent crime access to potentially key evidence. See, e.g., *Zane*, 575 Pa. at 251 (denying female hospital patient access to mental health treatment records of a male patient who had kidnapped and sexually assaulted her); *Hahnemann*, 74 F.3d at 465 (prohibiting lower court from requiring the hospital to allow the court to examine mental health records of two hospital patients who raped a female patient).

DPW has taken the position, finally, at least in the labor and employment contexts, that the MHPA prohibits the disclosure even of de-identified records of mental health treat-

ment, on the theory that although de-identified, they still constitute "documents concerning persons in treatment."

Conclusion

Special federal and state confidentiality protections present significant challenges to research involving records of mental health treatment. Under the federal Privacy Rule, providers can generally disclose to researchers de-identified records and limited data sets without patient authorization. They can also disclose complete records containing PHI for reviews preparatory to research or pursuant to a waiver of the patient authorization requirement by an IRB or Privacy Board. Only the patient, however, can authorize disclosure of psychotherapy notes within a record.

State laws often impose even greater confidentiality measures with respect to mental health records, and thus are not preempted by the Privacy Rule. Providers must take care to adhere to these local rules as well. In Pennsylvania, for example, many mental health records are subject to the strict provisions of the MHPA and its implementing regulations. Under that regulatory scheme, a provider cannot disclose any documents concerning mental health treatment, probably even including records that have been de-identified, without the patient's written consent.

Ultimately, a second look at both what laws apply and what those laws permit is always wise when confronting issues involving the disclosure of mental health records. ■

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1 45 C.F.R. § 164.512(i).
2 45 C.F.R. § 164.514(a)-(c).
3 45 C.F.R. § 164.514(e).
4 45 C.F.R. § 164.512(i)(1)(i) & (i)(2).
5 45 C.F.R. § 164.512(i)(1)(ii). The regulations also allow for research based on an existing patient consent that predated the applicable compliance date of the Privacy Rule and for research involving decedents' PHI. See 45 C.F.R. §§ 164.532(c) & 164.512(i)(1)(iii).
6 See HHS' "Health Services Research and the HIPAA Privacy Rule" at pp. 9-11 and 45 C.F.R. § 164.502(d)(1).
7 45 C.F.R. §§ 164.502(b) & 164.514(d) (minimum necessary); 45 C.F.R. § 164.528 (accounting for disclosures).
8 45 C.F.R. § 164.514(d)(3)(iii)(D).
9 45 C.F.R. § 164.508(a)(2).
10 45 C.F.R. § 164.501.
11 See 65 Fed. Reg. 82462, 82623 (December 28, 2000).
12 50 Pa. Stat. Ann. § 7111 ("confidentiality of records").
13 55 Pa. Code § 5100.32 ("nonconsensual release of information").
14 50 Pa. Stat. Ann. § 7103 ("scope of act).
15 55 Pa. Code §§ 5100.31 ("scope and policy").
16 55 Pa. Code §§ 5200.41(c) & 5210.26(d).
17 The Privacy Rule provisions (discussed in Section 1) would appear to govern the disclosure by a Pennsylvania provider to a researcher of a mental health record not covered by the MHPA, such as a record of voluntary outpatient treatment not provided in a facility.
18 45 C.F.R. § 160.202(b).
19 Compare 55 Pa. Code § 5100.34(f) (DPW required elements for consent form) with 45 C.F.R. § 164.508(c) (Privacy Rule authorization elements).
20 50 Pa. Stat. Ann. § 7111(a).

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