An overview of the impact of recent amendments to the HIPAA Privacy Rule: Compliance deadlines and key changes for healthcare providers

By Justin Joy, JD, CIPP

For the first time in over a decade, substantive changes have been made to the HIPAA Privacy Rule. The HIPAA Privacy Rule To Support Reproductive Health Care Privacy became effective on June 25, 2024. Although the compliance deadlines for this new rule are months (or longer) away, providers should begin assessing how they are going to comply with the new requirements. Several of the changes will significantly impact medical practices that provide reproductive health care services or offer substance use disorder treatment, and a smaller number of changes will affect all HIPAA covered entities.

When is compliance with these changes required?

While all the changes implemented by the new regulations are now effective, the deadline

for compliance varies depending on how the amendments impact a particular medical practice. Any practice generating or maintaining reproductive health care records, which is discussed in more detail below, must comply with certain aspects of the new rule by December 23, 2024. For all other practices, including those that may provide substance use disorder treatment, there is more time to prepare, as the compliance date for those regulations is not until February 16, 2026. However, because the new rules are now in effect, medical practices should have a planned timeline for revising policies and procedures, creating forms, and perhaps even implementing new technology to support the new or revised regulations. Of course, there is no need to wait until the compliance deadlines to implement these changes.

Changes impacting all providers

For all practices, the notice of privacy practices (NPP) form will need to be revised to include a statement like the one required on protected health information (PHI) disclosure authorization forms, adequate to put patients on notice of the potential that any PHI disclosed according to the Privacy Rule is subject to redisclosure by the recipient and no longer protected by HIPAA. Additionally, as discussed in more detail below, providers must also modify their NPP to address prohibitions on uses and disclosures of reproductive health care records and when valid attestations are now required. Finally, any providers creating or maintaining substance use disorder treatment records should review the information below pertaining to required NPP content changes.

Changes impacting providers creating or maintaining reproductive health care records

The Privacy Rule now includes new provisions regarding reproductive health care records. According to the new rule, reproductive health care is "health care that affects the health of an individual in all matters related to the reproductive system and its functions and processes."[1] Importantly, this definition is not expressly limited to gynecology or obstetrics, and could encompass various healthcare settings, such as urology and primary care. Furthermore, for Privacy Rule applicability, the scope of reproductive health care information is effectively expanded further to include activities like expressing interest in, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, administering, authorizing, providing coverage for, approving, counseling about, assisting, or taking any action to engage in reproductive health care.[2] For instance, this could potentially include a patient seeking advice on contraception, a doctor performing a hysterectomy, or a clinic providing information on fertility treatments. This means that any healthcare provider or organization with records related to these types of activities must be aware of these new obligations.

The new rule specifies that a HIPAA covered entity cannot use or disclose protected health information for the following activities:

1. Conducting a criminal, civil, or administrative investigation into any individual for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

2. Imposing criminal, civil, or administrative liability on any individual for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.
3. Identifying any individual for the purposes described in (1) or (2) above.

The above prohibitions on sharing PHI exists when the covered entity or business associate has reasonably determined that one or more of the following conditions exist:

1. The reproductive health care is lawful under the state law in which it is provided and the circumstances in which it is provided.
2. The reproductive health care is protected, required, or authorized by federal law, including the United States Constitution, under the circumstances in which it is provided, regardless of the state in which it is provided.
3. The covered entity has no actual knowledge the health care provided by another person was unlawful, nor has the covered entity been supplied with information by the person making the request to demonstrate that the care provided by another was unlawful.

A new mechanism is introduced with these new rules. For the first time, the HIPAA Privacy Rule requires an attestation for specific uses and disclosures of protected health information to individuals or organizations outside of covered entities or business associates. There are many specific requirements for an attestation to be valid, but in summary, an attestation must accompany any request to disclose reproductive health care PHI for health oversight activities, judicial and administrative proceedings such as in response to subpoenas, law enforcement purposes, or to coroners and medical examiners.[3] The attestation must be free of any errors, written in plain language, and include specific information such as a description of the requested information, the name of the person or organization who are requested to make the use or disclosure, the name of the person or organization to whom the covered entity is to make the requested use or disclosure, and a clear statement that the request is not being made for a purpose prohibited under the amended Privacy Rule. The attestation must also include a warning about potential criminal penalties for unauthorized disclosure of health information. The attestation must be signed and dated by the person requesting the information, and if signed by a representative, the representative's authority must be provided. For example, unless accompanied by a valid attestation, no PHI potentially related to reproductive health care may be disclosed in response to a medical records subpoena, which are commonly issued in lawsuits involving personal injuries.[4] Conversely, reproductive health care records requested by another provider for treatment purposes are not required to have an attestation.[5]

Changes impacting providers creating or maintaining substance use disorder treatment records

The updated HIPAA rule introduces significant changes for providers who create or maintain records related to substance use disorder (SUD) treatment. These regulations apply to any covered entity maintaining SUD records subject to federal confidentiality protection, namely 42 CFR Part 2 (Part 2), regardless of whether the records were created

by the medical practice or the records were received from another organization. It's important to note that many changes to Part 2 have also been made. While those recent changes are beyond the scope of this article, the Privacy Rule amendments address some of the corresponding modifications in the Part 2 regulations. A goal of the new HIPAA provisions is to align the confidentiality rules in Part 2 with the HIPAA Privacy Rule to facilitate the disclosure of SUD records, especially for treatment purposes.

One significant change is the provision of a notice of privacy practices to individuals whose records are related to SUD treatment. These individuals are now entitled to receive information about the uses and disclosure of their SUD records. New content requirements for NPP apply to covered entities maintaining SUD records protected by federal confidentiality laws. If a use or disclosure is prohibited or limited by another applicable law, such as Part 2, the description of how the information is used or disclosed, including restrictions on those uses and disclosures, must align with the more stringent law. The description for each purpose for which SUD records may be used or disclosed must include enough detail to inform individuals about permitted or required uses and disclosures as defined in this subpart and other applicable laws, such as Part 2.

If the medical practice receives SUD treatment records from providers subject to Part 2, or receives testimony relaying the content of such records, notice shall be provided in the NPP that such information will not be used or disclosed in civil, criminal, administrative, or legislative proceedings against the patient unless the patient gives written consent, or a court order with a proper subpoena after notice and an opportunity to be heard is provided to the individual or the holder of the record, as provided in the Part 2 regulations. Additionally, if a covered entity intends to participate in fundraising using SUD records subject to Part 2, notice must be provided in the NPP that individuals must be allowed to opt out of receiving fundraising communications.

All HIPAA covered entities are impacted to some degree by the recent amendments to the Privacy Rule, which became effective in June 2024. The degree of policy and operational modifications required, as well as the deadline for complying with the regulatory changes, will depend in large part on the nature of services your medical practice provides to patients, as well as the type of records maintained by your medical practice. Now is the time to assess, based on the unique operations of your medical practice, what is needed to comply, as well as to develop a plan for meeting the applicable compliance deadlines.

If you have questions about HIPAA, cybersecurity, or access to these resources, call 800-342-2239 or email ContactSVMIC@svmic.com.

If you experience a cybersecurity or other HIPAA related incident, contact SVMIC as soon as possible by calling 800-342-2239 and ask to speak with the Claims department.

Other individuals in your organization may benefit from these articles and resources, such as your administrator, privacy or security officer, or information technology professional. They can sign up for a Vantage account here.

[1]. 45 CFR § 160.103.

[2]. 45 CFR § 164.502(a)(5)(iii).

[3]. 45 CFR § 164.509.

[4]. Unless contrary guidance is released, any medical practice that maintains PHI potentially related to reproductive health care should consider requiring a valid attestation for any use or disclosure requiring one. Otherwise, every time such a request is received, the medical practice would have to do a page-by-page review to determine whether or not there are any reproductive health care records in the designated record set for an individual whose records are requested by means which require an accompanying valid attestation.

[5]. Regardless whether or not an attestation is required for a particular use or disclosure scenario, the new general prohibitions on improper uses and disclosures of reproductive health care information applies in any use of disclosure circumstances.

Risk Matters: Shadows

By Jeffrey A. Woods, JD

We are often asked our position on allowing students or other non-employees to "shadow" physicians, providers, or staff in a medical practice or other clinical environment. Shadowing allows individuals to observe the day-to-day activities of a medical practice, giving them a realistic view of what a career in medicine entails which can help them to make informed decisions about pursuing a medical career. Permitting someone to shadow within the practice is a kind gesture, but often as the saying goes, "no good deed goes unpunished." There are liability risks associated with allowing untrained, unlicensed persons to observe and/or assist in patient care, especially if the shadow is a minor.

Some areas of risk are:

Confidentiality and privacy: Generally, under the HIPAA Privacy Rule, the physician or practice ("covered entity") must develop and implement written privacy policies and train all workforce members under the direct control of the entity "whether they are paid or not" (which includes volunteers and shadows). High school and college students may not understand or appreciate state and federal privacy laws, and there is an increased risk

they will discuss their experiences with family and friends. Ensuring that shadows understand and comply with HIPAA and other privacy regulations is the responsibility of the physician and/or practice.

Under no circumstance do we recommend a person under the age of majority be permitted to shadow, work, or volunteer in a healthcare environment. Legally, minors lack the capacity to enter into contracts and typically cannot be held responsible for violating the terms of an agreement such as a HIPAA acknowledgement form. Even students who appear to be the most trustworthy, intelligent, and mature can have a moment of indiscretion resulting in liability for the physician/practice.

Disruption of Clinical Workflow: Shadows can sometimes be disruptive to the workflow of healthcare providers, especially if they require too much attention from staff during busy periods. We are also aware of instances where a staff member or the person assigned to supervise the student focuses more on the interaction with the student than on the patient or job at hand.

Hands-On Experience: The purpose of shadowing is observational learning. It is often a temptation for the supervisor to permit the shadow to engage in patient care. Unless they are students enrolled in an accredited medical school or nursing program which expressly authorizes limited participation in direct patient care on credentialed procedures, shadows should never engage in patient care even if under the supervision and instruction of a physician.

Liability Issues: The presence of a student or other non-employee in a clinical setting can raise liability concerns, particularly if an error, accident, or misunderstanding occurs. Examples include:

- improper delegation of tasks
- failure of the physician/provider to obtain the patient's consent to have an untrained, non-employee shadow present
- injury to the shadow while on the premises of the practice either by a piece of equipment, slip-and-fall, or attack by a patient.

Before allowing a student or non-employee to shadow, the physician or practice manager should confirm with the practice's liability insurance carriers, including SVMIC, whether coverage extends to these individuals.

Based upon the risks outlined above, it is our recommendation that physicians and other healthcare providers should only permit adults who are actively enrolled in an accredited medical school or nursing program to "shadow" them. These types of accredited programs typically have adequate liability insurance for their students and delineate in writing those specific tasks the student is credentialed to perform. These students are exposed to privacy and confidentiality concerns as part of their education and understand the importance of HIPAA. Students should be required to sign a Confidentiality Agreement with the practice. The patient should be told at the outset of the student's role, and patient permission should be obtained and documented.

Introducing The Shield Summit

By Meghan Clark, MA

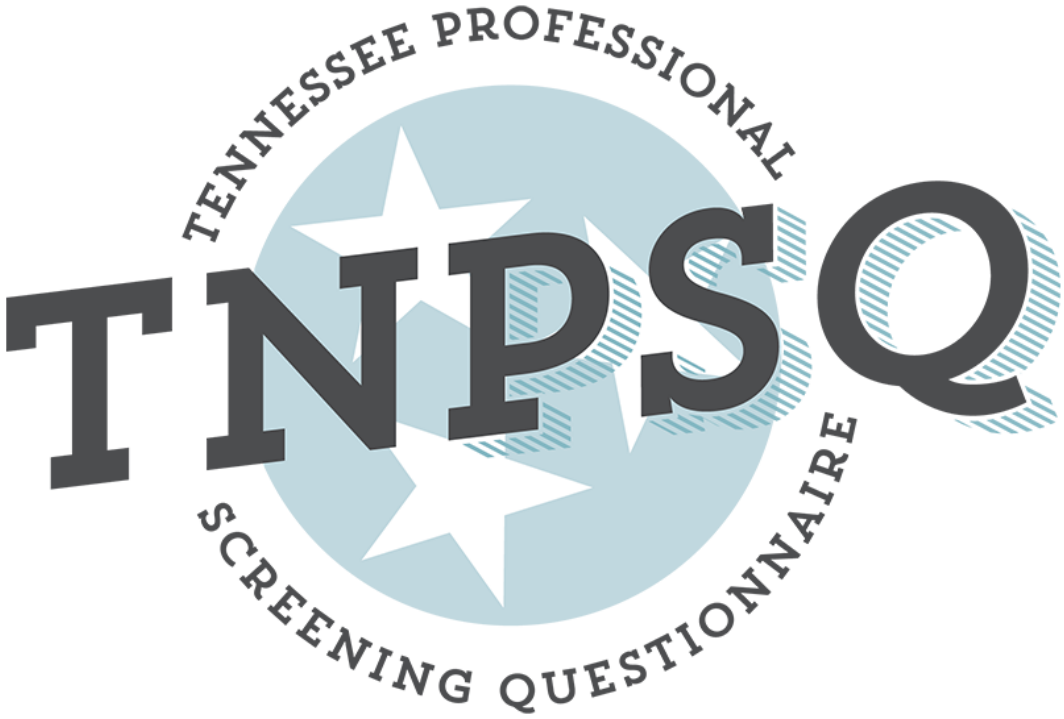
When you took the Hippocratic Oath and promised to “first, do no harm”, you embraced a life of servitude and dedication to the care of others. However, at that early stage of your career, you may not have anticipated the effort required to balance all the additional challenges that a life in medicine may bring to your doorstep.

SVMIC has always been an advocate for physicians**.** For nearly 5 decades, SVMIC has been educating physicians and their staff on a wide variety of topics in various formats. For the first time in the company’s educational journey, SVMIC is offering The Shield Summit.

Recognizing that a career in medicine extends beyond practicing medicine and caring for patients, The Shield Summit is designed with the physician and their spouse or partner in mind. While exceptional patient care is at the core of practicing medicine, the work of a physician encompasses so much more. Managing a successful practice can present unique challenges for a physician, including the ongoing effort to balance work and family life, the worry about potential lawsuits and avoiding risk, the leadership roles you assume—whether by choice or not—, your reputation within the community, delivering quality care, and countless other responsibilities. The Shield Summit will provide an opportunity to escape for a few days with your loved one to one of the most exciting cities in the Southeast, to network with other physicians and their spouses, and dig deep into things you might not get an opportunity to focus on in your day-to-day. With panel discussions featuring physicians and their spouses sharing insights on a life in medicine, presentations from physicians who have survived a medical malpractice lawsuit, DiSC* analysis to help you better understand and refine your leadership style, and several sessions dedicated to the business side of medicine, you will certainly leave The Shield Summit with new connections and new tools to support your personal growth in the practice of medicine.

SVMIC's commitment to protect physicians includes offering educational opportunities, fostering safe and collaborative learning spaces, and building a community to support physicians who are invested in their personal and professional development, as well as the development of their partners. The Shield Summit is exactly that. Earn up to 10.5 CME credits and join us on October 18-19, 2024. We look forward to meeting you there!

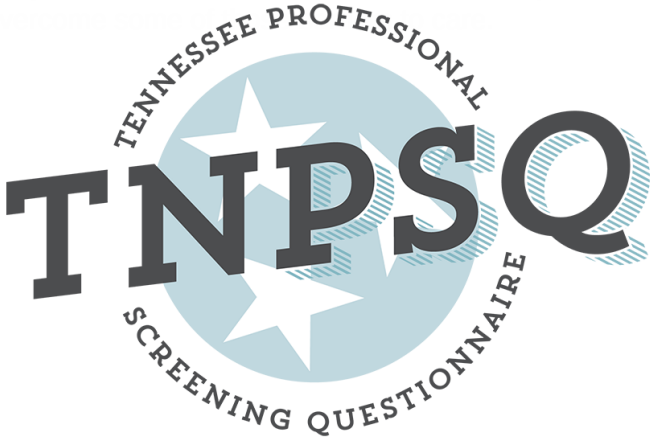
Free, Anonymous Screening Tool Addresses TN Health Professional Mental Health Concerns



By Michael Baron, MD, MPH, DFASAM, FAPA

Increased mental health concerns among health professionals was deemed a public health crisis even before the pandemic; post-COVID conditions have intensified longstanding challenges and contributed to worsening problems, including compassion fatigue, depression, anxiety, substance use disorders, and suicidal thoughts. Burnout among these professionals has reached crisis levels, according to the Centers for Disease Control.

Physicians at every level, including students, residents, and fellows, battle fear, stigma, and other barriers to seeking mental health care. We are pleased to let you know about a [illegible] al community that will help [illegible]



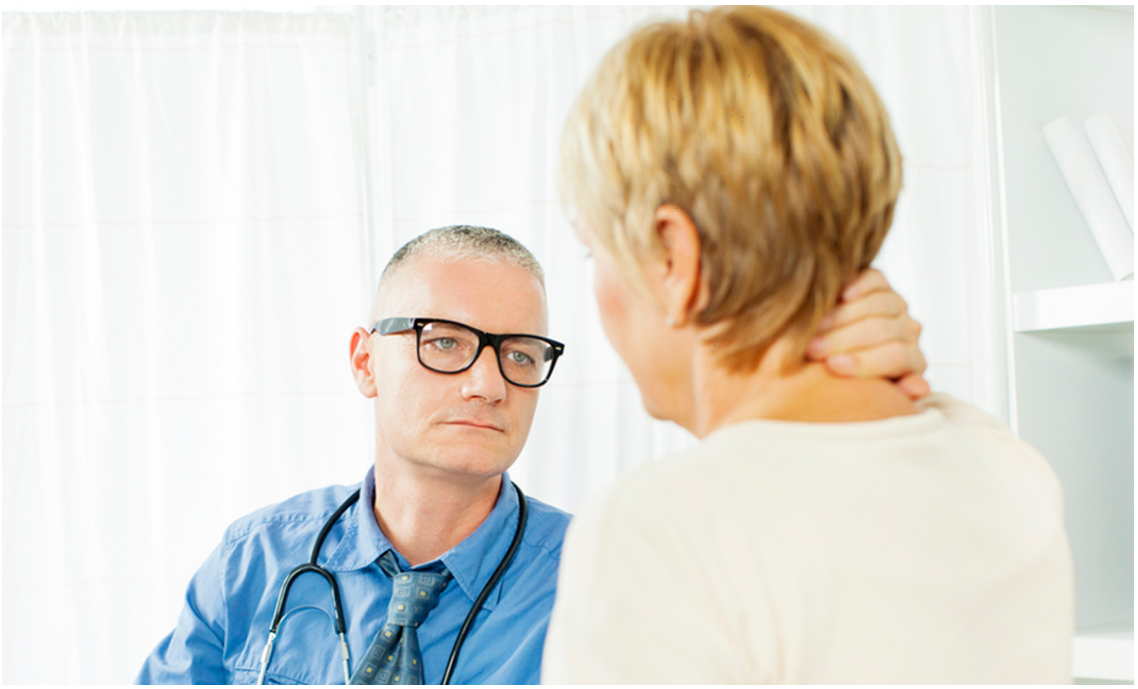
The Tennessee Professional Screening Questionnaire (TN-PSQ) is a free, online resource provided by the Tennessee Medical Foundation that allows you to anonymously:

- Take a brief questionnaire for stress, depression, and other mental health conditions
- Receive a personal response from a program counselor
- Exchange messages with the counselor, ask questions, receive recommendations and support for connecting with available mental health services.

Completing the online questionnaire and making use of this service is completely voluntary. ***Your identity will not be known to SVMIC or to the TN-PSQ counselor unless you decide to share it.***

SVMIC is committed to supporting our community to maintain optimal wellness. If you have any questions about this service, please contact Brenda Williams-Denbo at brendaw@e-tmf.org or 615-467-6411.

Allegations of Profit over Patients



By J. Baugh, JD, CPA

A physician faced a medical malpractice lawsuit after administering injections that allegedly failed to alleviate a patient's chronic pain. The patient, who sought relief from persistent discomfort, not only claimed the treatments were ineffective, but she also claimed the treatments were given simply so the physician could make money. This lawsuit underscored the complexities and risks associated with pain management therapies, raising important questions about the standard of care and the responsibilities of healthcare providers in ensuring patient well-being. This case serves as a poignant reminder of the challenges in achieving successful pain relief for patients.

Fran Spicer[1], a 40-year-old female patient, was referred to Dr. Andy Qualls, an interventional neurologist, by her PCP for pain in her neck that was radiating into her shoulders and arms and for pain in the median and ulnar nerves in both of her arms. Dr. Qualls diagnosed Ms. Spicer with lumbar radiculopathy. He also treated her with numerous injections over the course of several years, with the injections being given in her back, neck, legs and arms. Dr. Qualls' records showed that Ms. Spicer experienced good results from the injections and that she was pleased with the pain management provided

by Dr. Qualls. Despite this, Ms. Spicer filed a lawsuit against Dr. Qualls alleging that he performed unnecessary and excessive procedures on Ms. Spicer for Dr. Qualls' own monetary gain and that Dr. Qualls' actions fell below the standard of care.

Defense counsel made a couple of interesting observations after reviewing Ms. Spicer's medical records. First, it appeared that subsequent providers were critical of Dr. Qualls's "chronic" injection therapy. Second, Ms. Spicer contended that subsequent providers determined that her median and ulnar nerve issues were mild and did not equate to the pain she was experiencing. Ms. Spicer later had to have a triple level anterior cervical diskectomy at C3-4, C4-5, and C5-6 with cage insertion, which Ms. Spicer suggested could have been diagnosed by Dr. Qualls at the outset of his care. Ms. Spicer contended that Dr. Qualls was "masking" this issue so he could make money off the injections. Criticisms from subsequent providers make it difficult to defend a physician's care, and that was true with Dr. Qualls' care in this case.

If a physician decides to treat a patient for a chronic condition, it is helpful in the defense of a case for the physician to document the reasons for repeatedly treating the chronic condition with the same method of treatment, such as Dr. Qualls' decision to treat Ms. Spicer's chronic pain with continued injections. In this case, Ms. Spicer's attorneys were able to locate expert witnesses that said Dr. Qualls should have changed his method of treatment at some point, such as referring Ms. Spicer to a surgeon, rather than continuing with the injections. Documenting the reasons for continuing to treat chronic pain with injections rather than referring the patient to a surgeon would have helped not only with a standard of care defense, but it would have also helped rebut the allegation that Dr. Qualls continued to give the injections as a money-making enterprise. If a jury were to believe that the reason for continuing the injections was only to make money, it could cause a jury to think he was only interested in hiimself and not inerested in helping Ms. Spicer.

There were additional issues unrelated to Dr. Qualls' treatment that negatively impacted the defense of this case. The first issue was the history that Dr. Qualls had with medical board licensure proceedings. Regardless of the facts that lead to the medical board taking action against Dr. Qualls' medical license, disclosure of a negative licensure proceeding would have made the defense of this case more difficult. Whether this type of information will be admitted into evidence at trial is a decision that is solely within the court's discretion. Some courts will rule that licensure proceedings that are not related to the instant case are irrelevant and are therefore inadmissible during the trial, meaning the jury would not be informed that a licensure board took any action against the defendant. However, some courts will allow information about licensure proceedings to be admitted into evidence and allow the jury to decide whether that information should be considered in determining whether the defendant's treatment in the instant case fell below the standard of care. A second issue was the fact that Dr. Qualls closed his practice and moved back to his country of origin after the lawsuit was filed. SVMIC's policy states that an insured has a duty to cooperate with the defense of a claim. However, Dr. Qualls left the country with no indication that he would ever return for a deposition or a trial, making it even more evident that defending Dr. Qualls' care in this case would be difficult.

The decision to settle a claim usually is not made based on one single fact or issue in a case. The decision to settle is usually made based on several factors, which was true with the case that Ms. Spicer filed against Dr. Qualls. She claimed the injections Dr. Qualls provided were unnecessary and were given only for money-making purposes, surgery rather than injections ultimately provided the relief from the pain she was experiencing, Dr. Qualls had previous licensure board issues that may have been admitted into evidence at trial, and Dr. Qualls chose to leave the country wihtout giving any assurances that he would return. It may have been possible to overcome any one of these factors, but the combination of factors appeared to be too much to overcome, and the parties agreed to a settlement in this case.

[1] Names have been changed.
