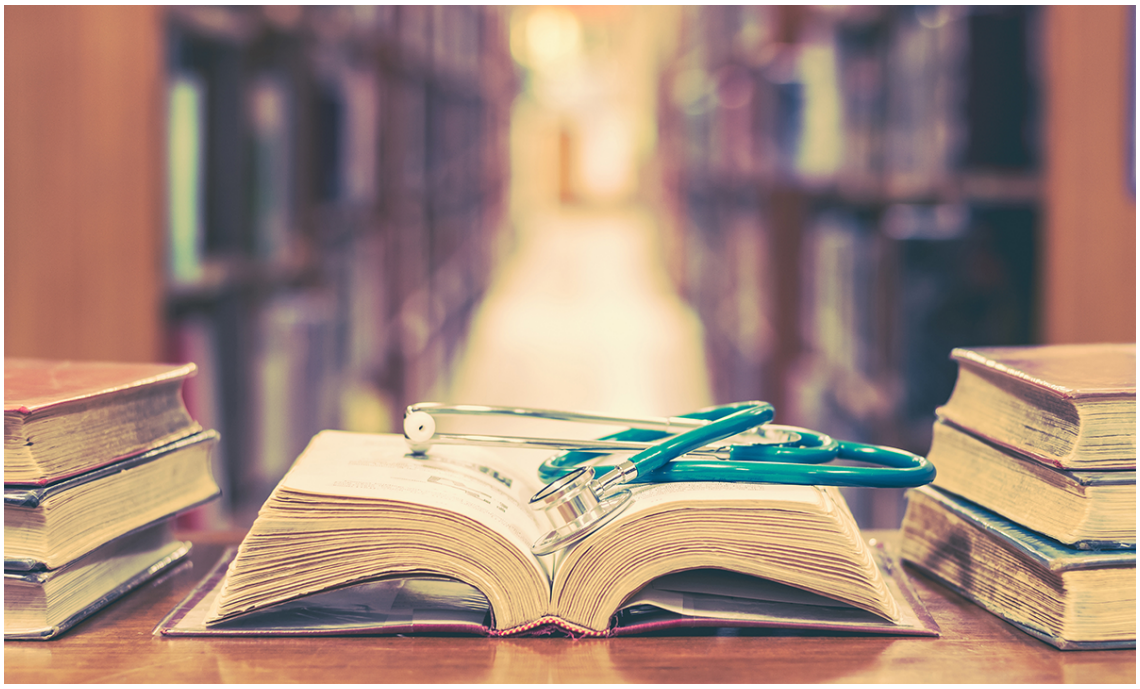
Covered Entity? Business Associate? Know the Difference and Your Obligations under HIPAA



By Justin Joy, JD, CIPP

No matter how small, every medical practice likely has multiple vendors upon whom the practice relies for its everyday operations. Larger medical practices may have arrangements with dozens of third parties providing an array of services ranging from administrative support to x-ray machine service. With the near ubiquity of electronic health record systems, medical practices are also increasingly connected to a variety of vendors providing information technology related services. While creating an ecosystem of vendors to enhance a medical practice's capacities and capabilities can provide several advantages, medical practices, as HIPAA covered entities, must also be mindful of HIPAA obligations and potential liabilities whenever a third party is involved in the transmission, creation, receipt, or storage of protected health information ("PHI").

Medical practices must be able to identify a business associate. In general terms, any third-party providing services to a covered entity that involve the use or disclosure of PHI is likely a business associate. Functions and activities such as claims administration, data processing, quality assurance, billing, and practice management; and services such as accounting, consulting, and legal may be provided by business associates. Again, the determinative consideration is whether the use or disclosure of PHI is necessary for the third party to provide services or perform functions and activities on behalf of the medical practice. Additionally, a covered entity may be a business associate of another covered entity. For example, if Covered Entity A is providing data analysis or quality assurance reviews utilizing PHI provided by Covered Entity B, Covered Entity A is likely a business associate of Covered Entity B and must adhere to the legal requirements addressed below. Furthermore, a business associate may utilize the services of a third-party subcontractor as part of its provision of services to a covered entity. This business associate–subcontractor arrangement is legally analogous to the covered entity–business associate arrangement.

Conversely, medical practices should be mindful of when a business associate relationship is not created with a third party, and, relatedly, when a business associate agreement is not required. In addition to potentially incurring unnecessary legal and administrative costs involved with drafting, negotiating, and executing documents, like any other contract, a business associate agreement imposes legal obligations on both parties which, if breached, could potentially lead to legal action. Many common activities and services involving third parties are not business associate arrangements. Perhaps most prevalent in medical practices is the disclosure of PHI from one medical practice to another for treatment purposes. Other common examples include service providers, such as electricians and janitorial services, whose functions do not involve disclosure of PHI, and disclosures to financial institutions for consumer transactions such as clearing checks and processing credit cards.[1] In instances when it is not clear whether a third party is a business associate, legal counsel should be consulted to assist in making the determination.

When it is determined that a business associate relationship exists between the covered entity and its business associate, satisfactory assurances in the form of a legally binding contract (business associate agreement) must be in place between the parties. A compliant business associate agreement must address a few respective obligations of the contracting parties. Categorically, the agreement between a covered entity and a business associate[2] must:

1. Describe the permitted and required uses of PHI by the business associate
2. Provide that the business associate will not use or further disclose the PHI other than as permitted or required by the contract or as required by law
3. Require the business associate to use appropriate safeguards to prevent a use or disclosure of the PHI other than as provided for by the contract -and-
4. Require that the business associate take other specified actions, the failure of which

may result in termination of the contract by the covered entity.

Beyond these categories, business associate agreements must contain numerous specified obligations. While business associates have some direct regulatory liability under HIPAA, ultimately it is the covered entity's legal obligation to obtain a signed compliant agreement from the business associate. SVMIC and OCR have published sample business associate agreement forms, however, given the potential liability arising from violations of these contracts, particularly in the event of a data breach, drafting and negotiating business associate agreements has become increasingly complicated.

Provisions pertaining to obligations such as breach notification requirements, indemnification, cyber insurance, and breach expense reimbursement are increasingly commonplace in these contracts. While simpler forms, such as the OCR sample form, may be appropriate in certain contexts, consideration should be given to consulting legal counsel pertaining to arrangements where the liability of either party may be significant based on the amount of access to provided PHI. Medical practices must be mindful that in the event of a breach, under the HIPAA Breach Notification Rule they, as covered entities, are ultimately responsible for providing notification to individuals, HHS, and in incidents involving 500 or more individuals, the media.[3] Perhaps more significantly, when it comes to answering questions and addressing concerns about a breach, patients will often look to the medical practice, as the entity to whom they provided their personal information, not the business associate, with whom they often have no direct relationship.

With the dramatic increase in cybersecurity risk in recent years, security incident notification provisions and breach notification provisions in business associate agreements have gained significant attention.[4] Among the numerous required provisions in any business associate agreement, a business associate must notify a covered entity of any use or disclosure of PHI not permitted by the contract. Specifically, under the Breach Notification Rule, a business associate must provide specific information to the covered entity within 60 calendar days of discovery of a breach by the business associate. The business associate agreement may provide a shorter timeframe for notification, as well as address other obligations of the business associate such as investigation cooperation and additional notification content. In the context of security incidents, under the HIPAA Security Rule, business associate agreements must also contain a provision for notification regarding any security incident (regardless whether the security incident results in a data breach) of which the business associate becomes aware. Given the broad definition of security incident under the HIPAA Security Rule and the open-ended security incident notification regulatory requirement, business associate agreements will often specify when and how business associates are to notify covered entities about security incidents.

Given the potentially significant legal liability associated with business associate arrangements, medical practices should keep an updated listing of active business associate relationships. Among other items, this listing should also include the nature of access the business associate has to the medical practice's PHI, as well as a contact

person at the business associate. Medical practices should also follow up after termination of a business associate agreement to confirm that any PHI in the possession of the business associate at agreement termination has been destroyed or returned, as required in the contract. Finally, medical practices should be mindful of their regulatory obligation to take action to cure a business associate's material violation of a contract, and if the violation has not been cured or cannot be cured, to terminate the agreement as necessary.

As the task of operating a medical practice of any size continues to grow in scope and complexity, other firms and companies increasingly play an essential part in achieving success. When the services of any third party involve PHI, however, medical practices must remain mindful of their obligations under HIPAA as well as the legal obligations contained in business associate agreements.

If you have questions about business associates, business associate agreements, security incidents involving business associates or other cybersecurity topics, or how to access to the resources available exclusively to SVMIC policyholders, call 800-342-2239 or email ContactSVMIC@svmic.com. Individuals in your organization such as your administrator, privacy or security officer, or information technology professional may benefit from this article and the other available resources to SVMIC policyholders and staff through their Vantage® account. If someone in your organization needs a Vantage account, they can sign up here. If you experience a cybersecurity incident, contact SVMIC as soon as possible by calling 800-342-2239 and ask to speak to the Claims department.

[1] The US Department of Health and Human Services Office for Civil Rights (OCR) has published guidance material on business associates, which includes numerous examples of business associate arrangements and arrangements that are not business associate arrangements. https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html (Of note, this guidance was partially superseded by the 2009 enactment of the Health Information Technology for Economic and Clinical Health (HITECH) Act. OCR has published guidance regarding the direct applicability of HIPAA regulations to business associates. https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html)

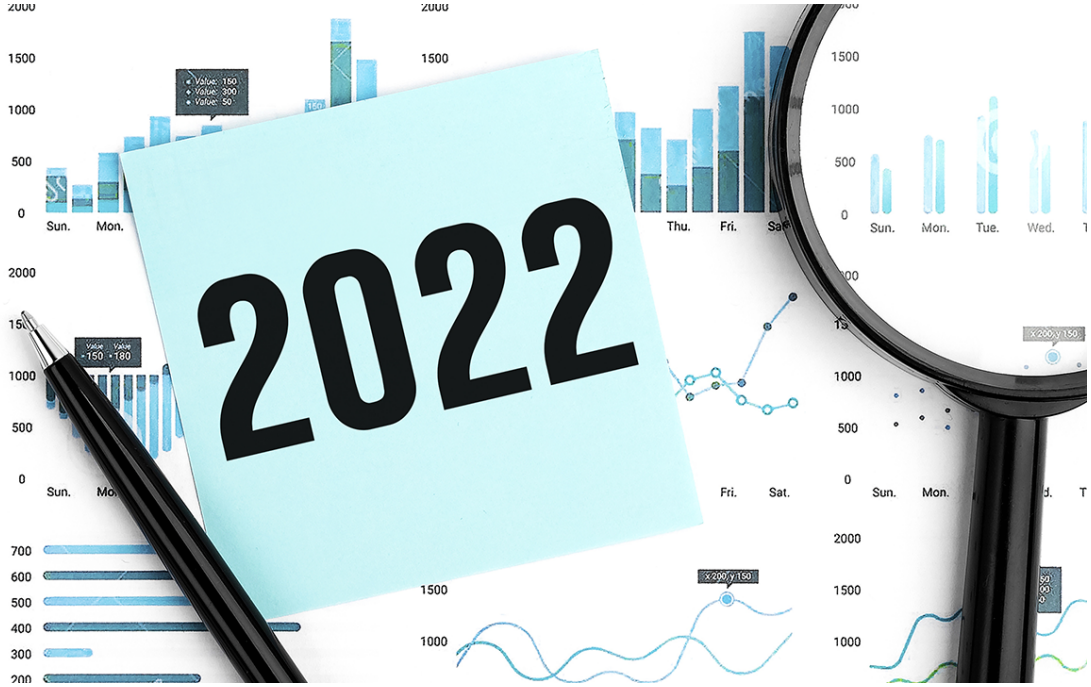
[2] Similarly, a business associate must obtain satisfactory assurances, in the form of a business associate-subcontractor agreement, from any subcontractors utilized when performing services on behalf of covered entities. The agreement between a business associate and a subcontractor is substantially similar to an agreement between a covered entity and a business associate.

[3] As addressed above, however, it is not uncommon for a covered entity to require in the business associate agreement that the business associate reimburse it for all costs associated with notifying individuals and other expenses involved with a breach. Additionally, in some cases, the business associate may be contractually required to provide notification on behalf of the covered entity. Such provisions however should be

drafted thoughtfully, as the covered entity will likely want involvement and input in that process.

[4] The difference between a security incident and a breach is addressed in a November 2021 Sentinel article. https://www.svmic.com/resources/newsletters/302/obligations-of-medical-practices-in-responding-to-data-security-incidents-not-just-data-breaches

Medicare Reimbursement Forecast for 2022



By Elizabeth Woodcock, MBA, FACMPE, CPC

Released on November 2, 2021, the final Medicare Physician Fee Schedule (PFS) revealed few surprises, given the foreshadowing of the previously issued proposed rule. However, it's still a hard pill to swallow. While the changes are issued by the Centers for Medicare & Medicaid Services (CMS), the impact is far-reaching as many commercial insurance companies use the Medicare PFS to set their rates.

The conversion factor drops to $33.5893 in 2022 from the current rate of $34.8931, representing a 3.7% decrease. The decline in reimbursement is across the board, impacting the Medicare rates for all professional services. Advocates have already begun lobbying Congress to infuse additional funding into the program to boost reimbursement. These efforts are likely to be successful, as the precedent was set in December 2020 when similar efforts were rewarded with additional funding days before the lower rate was set to start. The impact to all physician specialties ranged from -1 to +1%, with the exception of Vascular Surgery and Interventional Radiology, with a projected 5% decline.

The news was good for physician assistants, who were given the green light to directly bill for Medicare services. **The change, however, does not affect reimbursement or scope of practice.** The new policy may require completion of a new Medicare enrollment form. Another major policy impacts advanced practice providers (APP), with a refinement of the definition of split (or shared) visits. The billing provider is the physician or APP who performs the "substantive portion of the visit." The definition is evolving over the coming year, with CMS requiring a "FS" modifier to be appended to all split visits regardless of whether the billing provider is a physician or APP. Clarifications were also issued for critical care and teaching physician services.

Gastroenterologists welcomed a clarification about the coinsurance for routine colonoscopies that turn into diagnostic tests during the procedure. For 2022, the coinsurance will be 20%, but it is now scheduled to be reduced to 0% by 2030.

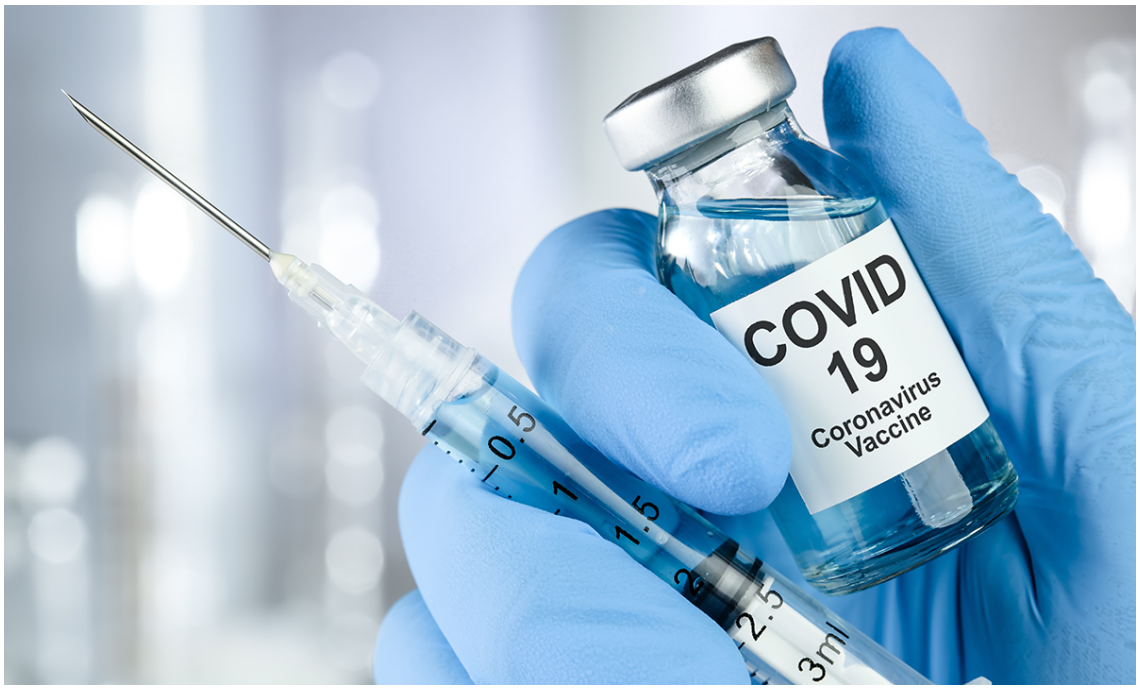
The government decided to delay the imposition of the Appropriate Use Criteria (AUC), thereby reducing the administrative burden for medical practices to comply with the rule. CMS determined that such treatment was not necessary for the Quality Payment Program (QPP), however. The threshold to avoid the penalty in 2022 was increased to 75 points for the Merit-based Incentive Payment System (MIPS), with the bar boosted to 89 points for the final year of the bonus associated with exceptional performance. Participants will contend with the cost category being enhanced to 30% of the score, based on a shift away from quality as required by statute. This represents a challenge, as the cost category operates behind the scenes. Many participants find it difficult to understand – and, perhaps, more importantly, to affect the score. Instead of requiring MIPS Value Pathways (MPVs), the government decided to convert them to voluntary reporting beginning in the new year. This voluntary participation will extend through 2027, with MVPs required the following year.

The government extended the services payable via telemedicine until the end of 2023 for Medicare beneficiaries. This extension incorporates payment for telemedicine services rendered for mental health care, to include the patient being at home and audio-only services. However, in-person visits are required periodically. Remote therapeutic monitoring (RTM) was added to the payment docket, with five new *CPT* codes (*98975*, 98976, 98977, 98980, 98981). These codes are similar to the remote physiological monitoring (RPM) codes, although RTM allows the patient to upload the data. This coverage contrasts with the existing RPM codes, which require the data to be

automatically transmitted to the provider from the device. New CPT codes were also added to the list of care management services, with four new codes for principal care management (99424, 99425, 99425, 99426).

For more detail, the 2,414-page ruling can be found here.

Risk Matters: COVID-19 Vaccines



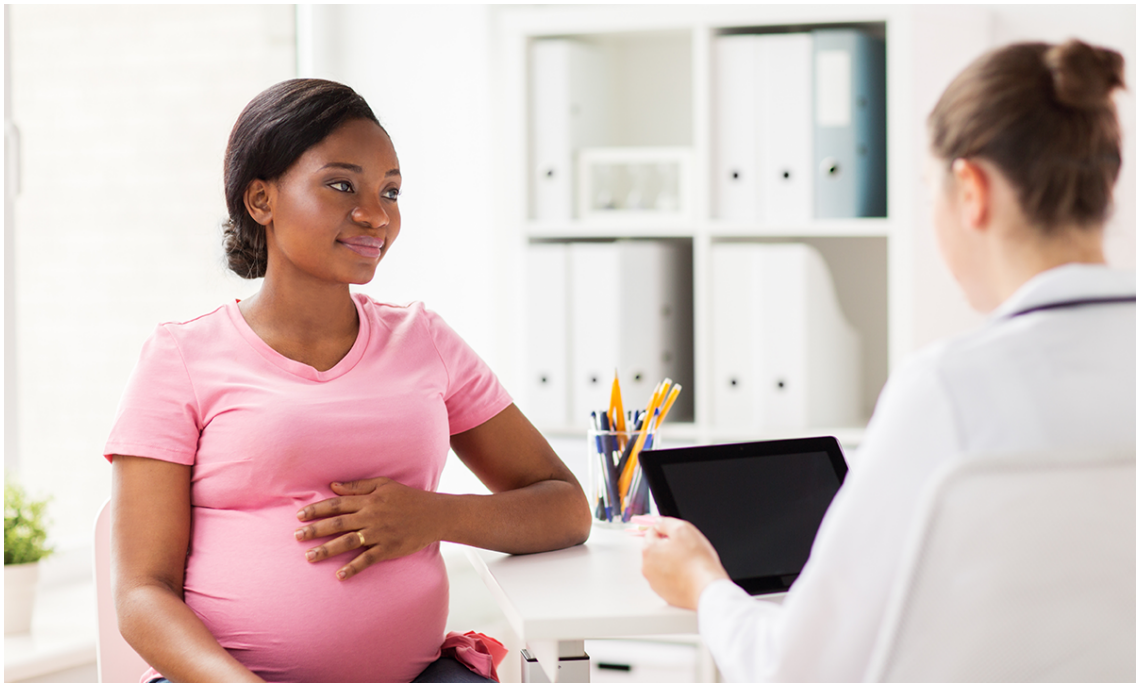
By Jeffrey A. Woods, JD

Ever since the U.S. Food and Drug Administration (FDA) authorized the emergency use of specific formulation (10 mcg/0.2 ml) of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine for children ages 5 through 11 years, reports of mix-ups with the Pfizer-BioNTech COVID-19 vaccine formulation intended for individuals 12 years and older (30 mcg/0.3 ml) have been pouring in.[1] For example, in December, a Tennessee mother was interviewed by a Nashville television news station because her 11-year-old child erroneously received the adult dosage of the Pfizer vaccine at a chain drug store.[2] She cautioned other parents to be on the lookout for potential COVID-19 vaccine errors and had filed a complaint with the Tennessee Board of Pharmacy. Of note, the mother in the story is a pharmacist. It is unknown what, if any, effect receiving the wrong vaccine/dosage will have on children, but practitioners should take precautions and have a protocol in place to avoid this type of mix-up. Although the Pfizer vaccine vials are similar, the vaccine vial for children ages 5 to 11 has an orange cap, and the vaccine vial for older patients has a purple cap.

[1] Institute for Safe Medication Practices (ISMP) - National Alert Network (NAN), Dec. 6, 2021

[2] Child receives adult-sized COVID-19 vaccine by mistake (newschannel5.com)

Tragic Outcomes Don’t Equal Bad Medicine



By John T. Ryman, JD

This case is a good example of circumstances we sometimes encounter where the outcome is tragic, although the medical care by our insured physician was appropriate and caused no harm. The magnitude of the injury fuels the pursuit of the lawsuit. A case like this will garner great sympathy for the patient from everyone involved, is a professional tragedy for the doctor, and creates significant anxiety about the risk of trial.

This patient’s outcome is unquestionably tragic. Eve* was a pregnant 22-year-old with a history of smoking and obesity as well as a family history of venous thrombosis. At 30 weeks' gestation she presented with placental abruption and fetal demise requiring an emergency cesarean section. On postoperative day five, she presented to the emergency department with chest pain and shortness of breath. On exam, a nurse and physician’s assistant both documented good pulses in all extremities. A chest CT angiogram was negative for pulmonary embolus. She was seen by her obstetrician and discharged. When she was seen in her obstetrician’s office the following day, Eve reported that her foot felt

like it was asleep. Her OB reported no lower extremity tenderness. If pulses were evaluated, it was not recorded. Two days later, Eve presented to the local emergency department complaining of left lower extremity pain. She was found to have 2+ pulses in her right foot and 1+ pulses in the left foot, with sensation and motor function. Her left lower extremity was cool despite good pulses in all extremities. There was discoloration on the plantar surface of her left foot. Eve was transferred to a higher-level facility. On presentation she was found to have a discolored left foot. Venous and arterial ultrasounds were negative for major vessel thrombosis. She was discharged but returned eight days later to the same hospital. At that time there were no pulses in her left foot. Our insured surgeon, Dr. Jones, was consulted. Since she had preserved motor function and sensation, and symptoms were not considered acute, Dr. Jones recommended intravenous anticoagulation with Heparin. The next morning Dr. Jones recommended arteriography and surgical intervention. Dr. Jones made an extensive attempt at removing arterial blood clots found throughout Eve's left leg but found no flow into the smaller arteries. Four days later he performed a below-the-knee amputation.

The patient filed suit against eight physicians alleging medical negligence. With respect to our insured, the plaintiff's experts were critical that Dr. Jones deviated from the standard of care by failing to use TPA as a first measure, that use of mechanical thrombectomy caused downstream embolization that made distal occlusions worse, and that Dr. Jones was not qualified and should have consulted an OB/GYN prior to further treatment.

The defense theme was that Dr. Jones considered administering TPA, but it was not appropriate to attempt given the timing and unresponsiveness to other interventions. Imaging showed that there was significant clotting that had been present for more than a week when Dr. Jones first saw the patient. During the procedure, Dr. Jones used a spider wire basket to catch embolization when he attempted to recanalize the proximal clot. He also used spot imaging during the procedure, before and after and found no evidence of downstream embolization. The unfortunate fact was that the patient's leg was not salvageable by the time she saw Dr. Jones and had not been salvageable for a significant period of time before his treatment. Of course, both the plaintiff and defendants had medical experts to support their positions.

It seemed that the medical care was appropriate, and the biggest risk was sympathy for the young plaintiff and the potential for a large verdict. The plaintiff would claim physical and emotional pain and suffering, and that the injury would limit her employment prospects. A juror would have to be pretty cold-blooded not to sympathize with this young woman.

The defense team obtained reviews of the care from multiple physician experts. The clear consensus was that Dr. Jones met the standard of care and exercised appropriate professional judgment. Further, by the time Dr. Jones was consulted there was nothing he could have done to prevent the unfortunate outcome. Dr. Jones was quite concerned about the case and at times waivered in his resolve to go to trial. His concerns were normal and common. However, his defense counsel helped him to choose the course of

proceeding through trial and defending his care. This turned out to be the right choice. We did not believe that this was a case of medical negligence by Dr. Jones and strongly supported him throughout the process. As part of our analysis, the case was reviewed and discussed thoroughly both in-house and with defense counsel. We were convinced that the care provided by Dr. Jones was appropriate and deserved to be defended, and further, that a jury would likely agree. Every case is unique, and they all involve risk, some more than others.

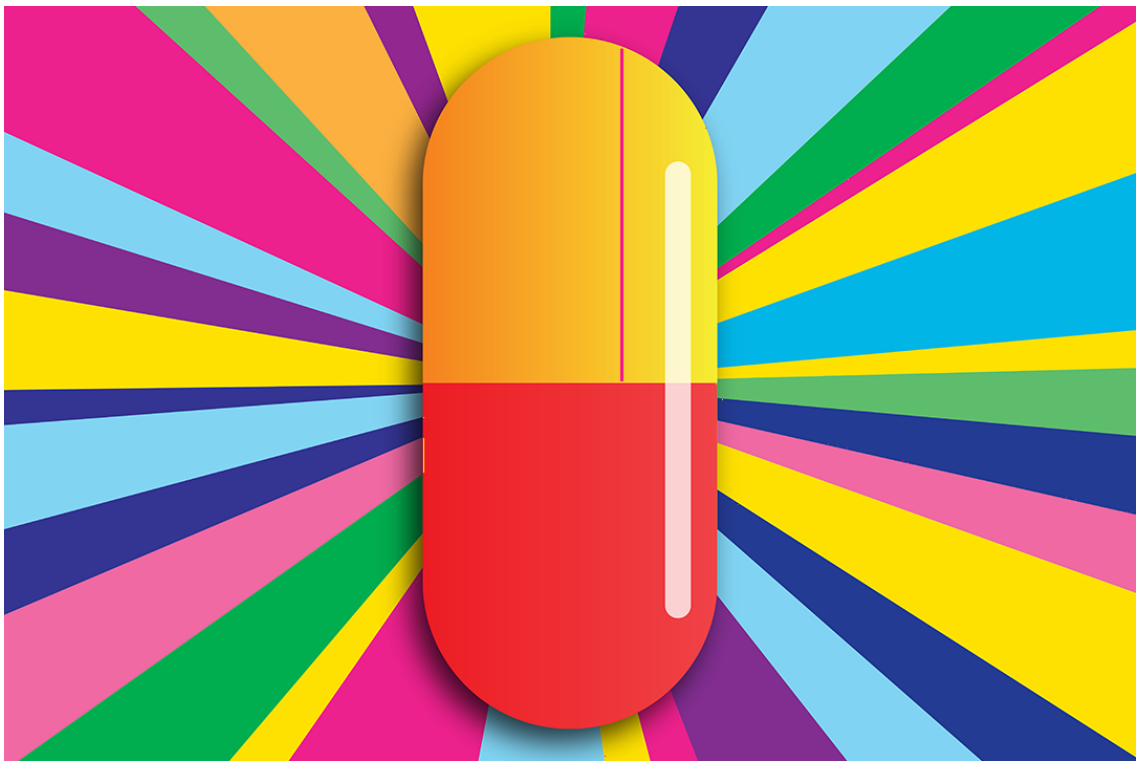
The case proceeded through a two-week trial. By the time the case was submitted to the jury for a decision only three defendants remained, including Dr. Jones. After two days of deliberations the jury had reached a verdict on two defendants but was at an impasse as to the third. The jurors presented a verdict in favor of Dr. Jones and one other defendant but were unable to reach a verdict as to the third defendant. The Court declared a mistrial. Defense counsel for Dr. Jones filed a Motion with the Court to enter judgment in favor of Dr. Jones notwithstanding the mistrial. The Court denied the Motion, and defense counsel subsequently filed a new Motion for judgment in favor of Dr. Jones, arguing that the jury found that Dr. Jones did not deviate from the standard of care, which is the threshold liability issue, and the jury's decision covered all issues against Dr. Jones. In response to this second Motion, the Court set aside the mistrial as to Dr. Jones and entered a defense verdict. Thus, the trial against Dr. Jones was successfully concluded.

As is often the case, the defendant doctor was the most important witness. Everyone else simply provided support. In his deposition and later at trial Dr. Jones was an excellent witness. He explained his medical decision-making in a simple and understandable way. He presented as a competent, caring physician, and a good teacher. In previous editions of this newsletter, we have addressed the challenges of a physician entering the courtroom arena. It is not an easy path. Dr. Jones entered, fought, and won.

Often, we have found, as we did in this example, that defending good medical care with a good doctor and experienced defense counsel is often a successful strategy. It is unfortunate that a tragic outcome will often lead to stressful litigation, but good medicine can be effectively defended through trial when the defendant physician and defense counsel work closely together, supported in their efforts by SVMIC.

*The names have been changed as a courtesy to the persons involved.

Notice of New Tennessee Rule: Chapter 1145-01 Commissioner's Controlled Substance Monitoring Database



By Julie Loomis, RN, JD

The Tennessee Controlled Substance Monitoring Database (CSMD) rules have been amended effective January 26, 2022. The amendment **requires** that **all healthcare practitioners**, unless otherwise exempted, **check the CSMD prior to issuing a Schedule II amphetamine**, at the beginning of a new episode of treatment[1]; prior to the issuance of each new prescription for the first ninety (90) days of a new episode of treatment; and at least every 6 months during that course of treatment.

This rule change means that Schedule II amphetamines constitute a third class of drugs triggering a check (opioids and benzodiazepines being the two current classes) and is the result of the CSMD Committee's determination that Schedule II amphetamines demonstrate a high potential for abuse. As with opioids and benzodiazepines, an authorized healthcare practitioner's delegate may check the controlled substance database on behalf of the healthcare practitioner who is prescribing Schedule II amphetamines.

The rule amendment also increases the list of mandatory fields for pharmacy and prescriber dispenser reporting information to the CSMD.

This table provides the links for each state's Prescription Drug Monitoring Program (PDMP/CSMD) information.

Alabama	**https://www.alabamapublichealth.gov/PDMP/**
Arkansas	**https://www.healthy.arkansas.gov/programs-services/topics/prescription-mo**
Georgia	**https://dph.georgia.gov/pdmp**
Indiana	**https://www.in.gov/bitterpill/prescribing-resources/inspect/**
Kentucky	**https://chfs.ky.gov/agencies/os/oig/dai/deppb/Pages/kasper.aspx**
Mississippi	**https://pmp.mbp.ms.gov/laws-regulations/**
Missouri	**https://missouri.pmpaware.net/identities/new**
North Carolina	**https://www.ncdhhs.gov/divisions/mental-health-developmental-disabilities-a carolina-drug-control-unit/nc-controlled-substances-reporting-system**
Oklahoma	**https://www.obndd.ok.gov/registration-pmp/pmp**

South Carolina	https://scdhec.gov/sites/default/files/media/document/PMPLaw_0.pdf
Tennessee	https://www.tn.gov/health/health-program-areas/health-professional-boards/
Texas	https://www.pharmacy.texas.gov/PMP/
Virginia	https://www.dhp.virginia.gov/PractitionerResources/PrescriptionMonitoringP

As always, SVMIC is here for you and happy to answer any questions you may have by email at ContactSVMIC@svmic.com or 800.342.2239. You may also contact the licensure board in your state for additional information.

[1] A “new episode of treatment” means a prescription for a controlled substance that has not been prescribed by that healthcare practitioner within the previous six (6) months.