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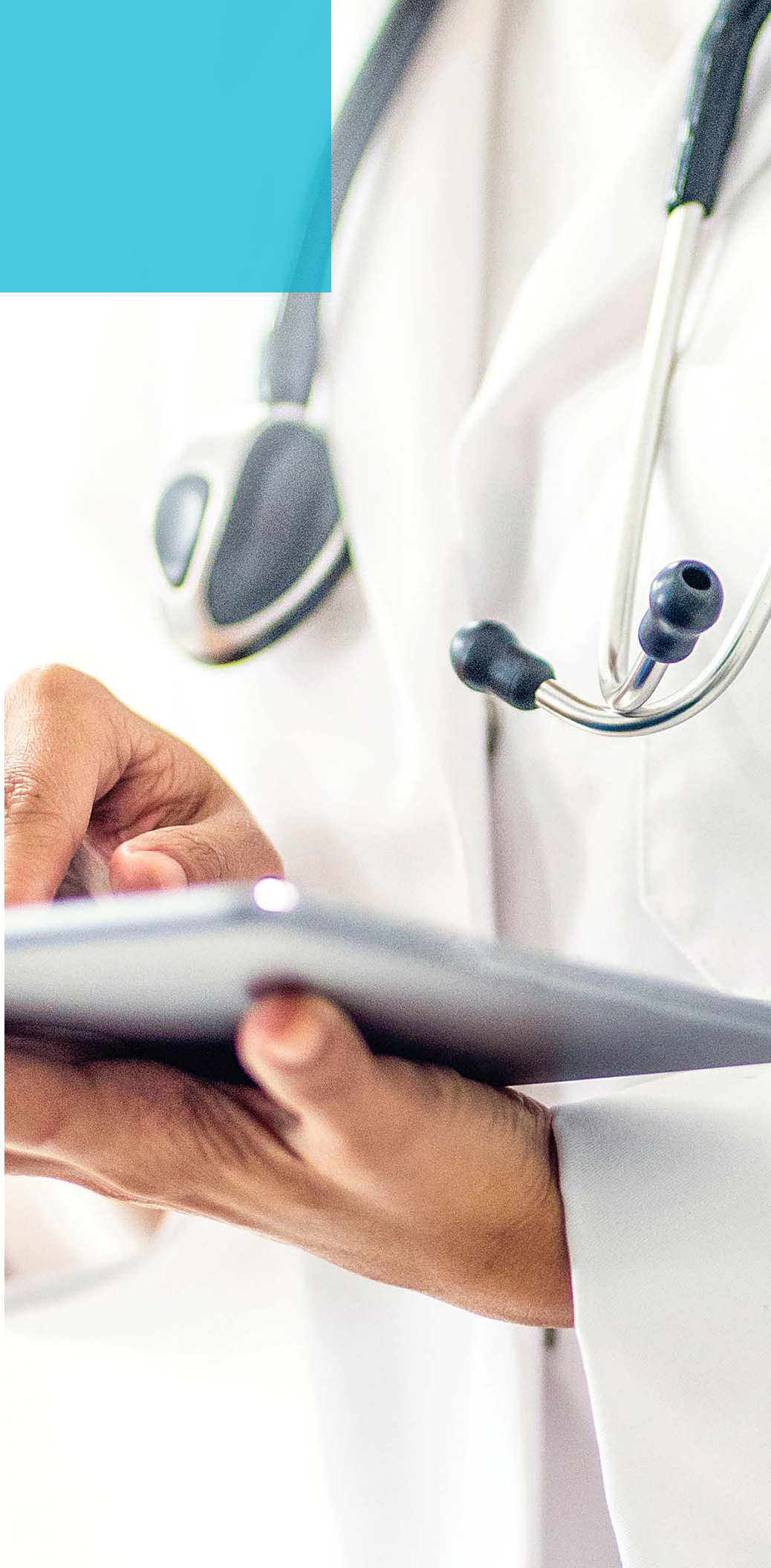
INSIDE THIS ISSUE

INSIDE



Dear Colleagues,

The current issue of *The Scope* has something for everyone. Elizabeth Ollinick, Esq., has written a very thoughtful and comprehensive piece about a subject that has been front and center these days, namely, artificial intelligence, or AI. The subject has created great excitement, and much anxiety, among us all, and it's fair to say that there are a lot more questions than answers. Still, I think that there are certain statements that can be made with certainty:

1. AI is here to stay, like it or not.
2. AI has the potential to be a great help in the diagnosis and treatment of certain conditions. This has already been shown in the diagnosis and treatment of lung and breast lesions.
3. AI recommendations will, rightly or not, have the potential to have a ring of certainty in medical malpractice suits.
4. AI will never replace, as a factor in treatment, the importance of a doctor knowing his patient well, including taking a thorough history and performing a thorough physical. Unfortunately, in these days of falling reimbursements and the demands of others, these elements are becoming less and less common.
5. AI is best seen as another tool at the physician's disposal in his/her treatment of the patient.

MLMIC, of course, is closely monitoring developments in this field, always with an eye for how we can protect and help our insureds. At this early stage, I feel I can safely make the following strong recommendation: If your diagnosis and/or treatment differ from what AI tells you, please document in your record the fact that you are aware of the difference and why you feel your diagnosis and/or treatment is best for the patient. This will document the thought process of a thoughtful and concerned physician and should help greatly at any trial.

Stay tuned!

In another vein, the Grieving Families Act is once again threatening us. As you know, it has passed the New York State Assembly and Senate, and it will once again be up to Governor Hochul to either sign, veto, or recommend modifications to the bill. The bill is only slightly different from the bill she vetoed last year. At that time, the Medical Society of the State of New York and a host of other organizations were successful in their efforts to have this harmful bill vetoed.

Since that time, I sense a certain lethargy has set in among us, and I urge you to call the governor's office to express your opposition to this bill. I did this, both last year and again this year. The call was warmly received by her office, and I urge you to make your own call. The number is (518) 474-8390. Press Option 3, then press Option 1 to leave a voicemail or Option 2 to speak with a person. It won't take long. Do it today.

Please continue to forward me your feedback on *The Scope* so that we may provide information that you feel to be most valuable.

Sincerely, your colleague,

John W. Lombardo, M.D., FACS
Chief Medical Officer, MLMIC Insurance Company
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Artificial Intelligence in Healthcare: Risks, Rewards, and the Unknown

Adopting emerging artificial intelligence (AI) technologies can create benefits for patients and providers, such as increased accuracy and safer, more efficient care, but these benefits are naturally accompanied by risk. Providers need to know how AI applications function and how the law will assign liability for injuries that may arise from them, but AI systems are still too new to have been challenged in medical malpractice lawsuits. Regulatory bodies like the Food and Drug Administration (FDA) are working to develop cohesive standards and compliance processes, but the advancement of AI technologies is exceeding regulatory bandwidth. In the absence of legal precedent and regulatory guidance, ongoing review of potential risks and proactive implementation of an adaptable risk management process can foster a strong defense against malpractice claims. This article discusses some foreseeable risks of using AI technologies in healthcare and suggests corresponding management strategies based on current information.

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Applications of AI in Healthcare

AI can be challenging to define with precision. In nontechnical terms, we can define AI as programs or machines performing tasks that once required human intelligence, such as problem-solving, reasoning, perception, learning, and exercising creativity.

Initial applications of AI in healthcare largely addressed administrative functions such as scheduling and billing but quickly moved into the clinical space. AI systems across the different health disciplines have various intended uses and audiences. AI is used to generate human-like responses, detect patterns that are useful for diagnostic insights, automate diagnostic processes, provide treatment recommendations, power remote-controlled robotic surgery, and support the development of personalized treatment protocols.

AI is now pushing past clinical decision-making support to directly interact with patients. For example, a recent study published in *JAMA Internal Medicine* and led by John W. Ayers, Ph.D., from the Qualcomm Institute at University of California San Diego compared written responses from physicians and those from ChatGPT to real-life health questions. A panel of licensed healthcare professionals preferred ChatGPT's responses 79% of the time and rated ChatGPT's responses as higher quality and more empathetic. The study is not conclusive but demonstrates how far AI is progressing into direct patient interaction.

Unresolved Risks

With widely reported AI successes in specialties like radiology, we can no longer credibly question whether AI technologies have a place in patient care. But there are still many unresolved risks that providers should consider when planning risk management strategies.

Faulty System Design

The increasing patient load and scarcity of healthcare providers is overwhelming the healthcare system. AI-based systems can reduce overload, but that goal should not come at the expense of provider well-being and patient safety. Patient safety requires the usability and reliability of new AI-technologies. Faulty system design, including poor usability and incomplete data input, can confuse and frustrate providers, leading to user error and patient harm. Incomplete or uninformed data input can cause medication errors, overdoses, and patient death. To mitigate these risks, end users must have a seat at the table early in the system development process, and organizations must deploy post-implementation provider support to ensure the safe adoption of all system functions and ease of user feedback.

Blind Judgment — The Black Box Conundrum

Transparent and interpretable AI models that offer decisional rationales to a clinician who proceeds to follow them should reduce the rate of malpractice actions. However, in many cases, AI clinical support technologies are "black box" AI models. This means the clinician can give the system input, such as an image, and the system can provide an output, such as a diagnosis, but the provider cannot see the rationale for the decision. Black box AI creates a number of risks.

Defending a provider's decision to follow or not follow an AI recommendation is difficult when the system offers no rationale to compare with the provider's judgment. The argument may be that the clinician's decisions were based on blind judgment. The absence of rationale can also complicate the informed consent process if the recommended treatment is informed by unexplainable AI output. Regulators and thought leaders are attempting to correct this issue by requiring AI developers to incorporate transparency into the AI decision-making process, but until those regulations are established, the risk of patient injury due to incorrect AI recommendations remains.

Cybersecurity Risks

HIPAA and HITECH are part of the common vernacular in the healthcare space, but those laws contemplate data breach caused by human intelligence, not artificial intelligence. In this age

of advanced healthcare technology, most patient information is no longer stored and accessed in provider-controlled environments. AI systems can create a complex flow of data that increases multiple-party use, storage, and access to electronic patient information. Multi-party access increases infrastructure vulnerability and opens providers to the risk of imputed liability for downstream breaches. Providers should identify all parties with downstream access and use appropriate contractual provisions to minimize the risk of imputed liability for third-party breach.

Bias

Bias presents another risk of using AI technology in healthcare. There are several ways bias can be introduced by AI, including relying on under-representative data or nonrepresentative data. AI systems learn from the data on which they are trained and can incorporate biases from that data. For instance, if the data available for an AI is primarily gathered from expensive wearables, the resulting AI systems will know less about patients from populations that cannot typically afford wearables. Treatment of those patients may be less effective, or even harmful.

Litigation Risks

What AI means for malpractice risk still largely remains to be seen and will evolve as acceptance of AI grows. The standard of care and allocation of responsibility are not yet clear.

Medical Malpractice

To establish a *prima facie* case of liability in a medical malpractice action, a plaintiff must prove that the provider deviated from accepted standards of medical practice and that such deviation proximately caused injuries. Currently, there are no established standards directing when and how a provider's judgment should be based on the "intelligence" of a machine, or at what point providers can or should "delegate" or defer to an AI recommendation.

There are several diagnostic modalities where studies have shown that the AI system appears to outperform experienced physicians. In fact, the number of FDA-approved, AI-enabled medical devices has been growing over the past few years.[1] There are also an increasing number of AI clinical decision support technologies that make medical treatment recommendations. Some providers will utilize these AI technologies, while others will not. The question will be which decision meets the standard of care. At what point do positive results in preliminary studies or FDA approval make those technologies the standard of care? Will failure to use them constitute a breach of duty?

> **In fact, the number of FDA-approved, AI-enabled medical devices has been growing over the past few years.[1]**

Vicarious Liability

Vicarious liability is the theory of imputed responsibility based on control and supervision. Health systems, hospitals, and practice groups can be held vicariously liable for the acts of their employees and affiliates. AI will introduce new complexity to the question of when a hospital or other institution offering healthcare can be vicariously liable for an injury caused by an individual provider's use or failure to use an AI technology.

In many cases, the institution, rather than the clinician, will select, install, and provide training for the AI technology. As a result, the institution may be directly or vicariously liable for any faults, including a decision not to make the latest AI capabilities available, deficiencies in the installation, and failure to properly train staff on the AI system. The hospital or other owner of the AI system may also face liability for issues related to the proper care and maintenance of the AI equipment.

Regulatory Determinants of Malpractice

In addition to case law, the regulatory status of AI in healthcare will be an important determinant of malpractice risks. However, at present, providers

[1] A list of AI/ML-enabled medical devices legally marketed in the United States as of October 2022 is available on the FDA website at **https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.**

have no cohesive regulatory framework to set parameters for the standard of care.

The FDA is actively regulating AI technologies that fit into the definition of a "medical device," but those regulations provide no guidance on the use of AI technology defined as Clinical Decision Support (CDS). The FDA considers an AI technology as a medical device if it is intended to treat, diagnose, mitigate, or prevent disease or other conditions. CDS is software that supports or provides recommendations to a healthcare professional who independently reviews and makes the decision.

> **This recognition may support an injured patient's argument that failure to question an AI clinical recommendation is a departure from the standard of care.**

Efforts are underway to address this regulatory gap at the macro level. This includes the Blueprint for an AI Bill of Rights published by the Biden Administration in October 2022. Providers can also look to emerging guidance from healthcare industry thought leaders, including the Coalition for Health AI (CHAI), which published its first version of the Blueprint for Trustworthy AI Implementation Guidance and Assurance for Healthcare in April 2023. The Blueprint recognizes that uncritical acceptance of an automated clinical recommendation is a known safety risk. This recognition may support an injured patient's argument that failure to question an AI clinical recommendation is a departure from the standard of care. But that argument may flip in the future. CHAI reported that its stakeholders are working to establish standards of AI output reliability. Once established, those reliability standards may flip the standard of care from critical review to unquestioned acceptance. Faced with this uncertainty, when feasible, providers should critically evaluate an AI recommendation and document their rationale for any rejection of it. If a rejected recommendation may have injurious consequences for a broader patient population, reporting the issue to an appropriate inhouse oversight committee will also be an important risk management strategy.

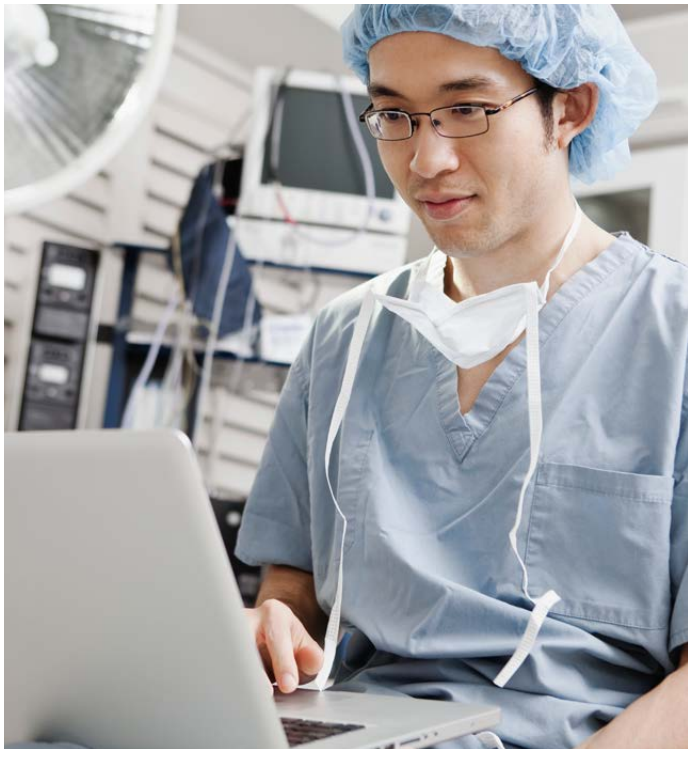
Risk Management Strategies

In the absence of a clear standard of care, and with minimal regulatory oversight of emerging AI medical technologies, providers must consider potential outcomes and proactively implement adaptable AI techology risk management strategies.

Start Early

Risk management related to AI technologies should start at the procurement phase with a proactive team approach. The team should include a representative end user and the IT professionals who will scope the cybersecurity risk, analyze compatibility with existing infrastructure, and own responsibility for updates and maintenance.

The team should be clear about the end user's objectives for the AI technology and ensure the vendor discloses any use limitations and potential



for data bias. Siloing information is a foreseeable risk of patient injury. Any vendor-disclosed limitations should be communicated to the end users. The team should also ensure that the technology is designed to maintain clinically relevant data acquired in a consistent manner.

Use the Contract To Allocate Risk

With the uncertainty over who will be liable for any patient injuries caused by the design and use of an AI technology or system, use contractual warranties, indemnities, and liability limitations to allocate risk. Where applicable, the contract should also require vendors to secure appropriate cybersecurity insurance to cover any indemnity obligations arising out of third-party access to the organization's IT infrastructure.

Given the risks and uncertainties, AI technology purchase agreements are often complex and usually one-sided. Providers should not shy away from contract negotiation and may want to employ experienced legal counsel to, at least, review the agreement and provide guidance for negotiation. For example, the contract may or may not require the provider to notify the manufacturer before disclosing metadata in response to discovery demands in a legal malpractice action. It will be important to understand whether this obligation exists, limit the obligation to the extent possible, and ensure compliance.

Training and Use

Inadequate end user training is a foreseeable risk and can result in vicarious liability. Organizations should require all providers, including new hires, to engage in training activities and demonstrate competency before engaging in clinical use, as well as require ongoing educational programs and in-services at appropriate intervals.

Oversight and Monitoring

Evidence of a comprehensive oversight and monitoring process can be used in defense to show a good-faith effort to ensure responsible use. Establish clear lines of operational control and unambiguous ownership of responsibility. Assign oversight responsibility to individuals who demonstrate appropriate expertise and experience. Develop comprehensive policies and procedures, including protocols for training and competencies, use of each application, updating and maintaining the technology, and communicating and addressing errors and unanticipated outcomes. Perform assessments to evaluate outputs on an ongoing basis. Remain alert for potential biases, and peer review errors and unexpected outcomes. Continuously evaluate security vulnerabilities and monitor the timeliness of system maintenance and technology updates. Include AI-related issues in event reporting procedures.

Conclusion

The use of AI in healthcare is outpacing the law. There is no clear legal precedent or cohesive regulatory framework to guide a defensible approach for the use and implementation of these emerging technologies. In the absence of legal guidance, providers should take a proactive approach to risk management, monitor the law on a consistent basis, and update policies and procedures as new legal precedent and regulations require.

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FROM THE BLOG

ECRI: Top 2023 Patient Safety Concerns

Last quarter, *The Scope* featured ECRI's #1 patient safety concern, **The Pediatric Mental Health Crisis**. This issue, we cover patient safety concerns #2 and 3.

#2 — Physical and Verbal Violence Against Healthcare Staff

MLMIC Insurance Company recognizes the seriousness of workplace violence in the healthcare setting and has identified this as a critical concern for our insureds. In this section, we'll take a deeper look at ECRI's #2 concern for **patient safety** in 2023.

What Is Workplace Violence?

Workplace violence can emanate from anywhere and affect anyone. Violence against healthcare workers can come from patients, family members, or staff. It can be in the form of physical or verbal abuse and, in most circumstances, stems from aggressive behaviors. Characteristics of aggressive behavior can include inappropriate comments, intimidation, bullying, lack of cooperation, threats, and profanity, as well as verbal or physical attacks. Violence against healthcare workers not only affects their psychological and physical well-being, but it also can lead to a lack of job motivation, compromised quality of care, increased risk for malpractice claims, and burn out.

Workplace Violence in the Healthcare Setting

Violence against healthcare workers has been on the rise over the last 5 years. **The World Health Organization** found that nurses, emergency room staff, and paramedics are at the highest risk for violence. According to a new survey from the **American College of Emergency Physicians**, more than 8 out of 10 emergency room physicians believe that the rate of violence in the emergency department has increased, with 45% saying it has greatly increased over the last 5 years. A recent survey of registered nurses revealed that 44% experienced physical violence and 68% experienced verbal abuse during the pandemic.

To curtail the amount of workplace violence against healthcare workers, MLMIC offers a variety of educational programs focusing on this issue. Our programs include strategies for addressing a disruptive patient, managing aggressive behaviors, discharging a patient from practice, and healthcare providers' responsibilities under New York's Safe Act. All of these programs can be tailored to your office practice, emergency department,

or in-patient setting and are offered at no additional cost to our insureds or any of our endorsed partners.

To read the full article, which includes risk management recommendations, please **click here.**

#3 — Clinician Needs in Times of Uncertainty Surrounding Maternal-Fetal Medicine

On June 24, 2022, the Supreme Court overruled Roe v. Wade, leaving individual states with the full power to regulate reproductive rights. ECRI recognized this issue as a significant concern for providers who practice in states that have either prohibited or limited access to abortion and listed it as their #3 concern for **patient safety** in 2023.

On June 23, 2023, Governor Hochul signed into law **Chapter 138 of the Laws of 2023.** This law provides certain legal protections for reproductive health service providers who provide legally protected health activities, including protection from extradition, arrest, and legal proceedings in other states relating to such services, and it restricts the use of evidence relating to the involvement of a party in providing legally protected care to persons located out of state. This law is effective as of June 23, 2023.

Since this law is newly enacted, it is important to recognize that its application will be subject to judicial interpretation. Accordingly, it is important to follow MLMIC for updates on this new law. In addition to **patient safety** and clinician concerns, there are other issues providers face when treating maternal-fetal patients. One of them is hypertension and preeclampsia.

The remainder of this blog will discuss the risk of hypertension and preeclampsia during pregnancy, share a brief analysis of obstetrical claims, and provide risk management tips to protect yourself from litigation.

To read the full article, which includes risk management recommendations, please **click here.**

MLMIC offers an array of educational programs addressing workplace violence, maternal-fetal medicine, **informed consent**, and documentation. To schedule an in-person or virtual program, contact Matthew Lamb, Esq., at **mlamb@mlmic.com** or **(518) 786-2762**.

MLMIC policyholders can reach our 24/7 emergency support services for questions regarding documentation or informed consent when treating the obstetrical patient by calling **(844) MMS-LAW1**. You can also submit a specific question by sending an email request **here.**

Tammie Smeltz is the Content Marketing Manager for MLMIC Insurance Company.

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CASE STUDY:

Proper Care Wins the Day at Trial

Initial Treatment: A 35-year-old married, unemployed female nurse with a history of smoking, depression, and cocaine addiction was originally seen at a MLMIC-insured hospital. At that time, deep vein thrombosis (DVT) of the right leg was diagnosed. The patient was placed on a regime of Coumadin and was advised to have her INR monitored by a hematologist. The following month, she was evaluated and diagnosed with unprovoked DVT as well as positive lupus anticoagulant and anticardiolipin antibodies and was advised she would require a lifelong regimen of Coumadin anticoagulation.

The patient returned to the hematologist 18 months later, at which time the physician discontinued the Coumadin and changed her regimen to a baby aspirin daily.

Complications Arise

Approximately 9 months later, the patient was transported via ambulance to our insured hospital's emergency department (ED) with pleuritic-type chest pain and apparent acute bronchitis. The ambulance call report noted the patient's complaints of flu-like symptoms and chest pain. The patient was alert and oriented with bilateral clear breath sounds. A physical examination was performed by an ED physician who noted the patient's complaints of pain upon inspiration, chest pain radiating to the right shoulder, and a history of fever of 101.8 degrees. She advised of her history of blood clots, which had been previously treated with Coumadin. In addition, she had a history of smoking but was noted to be well nourished and in no apparent distress despite her complaints.

A Di-Dimer test, used to rule out a blood clot, was elevated at 1,299. Normal limits are 68–500. An EKG revealed a normal sinus rhythm with a rate of 70 with no acute changes. A chest X-ray was ordered that revealed no acute pulmonary process and no focal consolidation, effusion, or pneumothorax. In addition, a bilateral Doppler of the lower extremities found no evidence of DVT. A CT scan of the chest with contrast revealed no pulmonary embolism, but a 5 mm nonspecific nodule in the upper right lobe and a mildly enlarged left hilar and azygoesophageal recess lymph node were noted.

A differential diagnosis included atypical chest pain, pleurisy, pneumonia, and pulmonary embolus. Based on the patient's history, examination, and diagnostic evaluation, there was no indication for emergency intervention or hospital admission and no indication of DVT or pulmonary embolism. The diagnosis was bronchitis from a bronchial infection with pleurisy.

The ED physician had a discussion with the patient and advised her to follow up with her private medical doctor in 1–2 days, and she was further advised that if the symptoms persisted or worsened, she should return to the ED. She was discharged with prescriptions for prednisone, Vicodin, and albuterol.

The patient returned to the ED 2 weeks later and complained of chest tightness and shortness of

breath, but no cough or fever. She advised of her prior ED visit, at which time she was diagnosed with bronchitis. The patient was seen by a physician's assistant, who found no sign of respiratory distress but heard wheezing in the left posterior base and noted complaints of pleuritic chest pain. The patient's labs were normal, her EKG showed no changes from the one done during the prior ER visit, and her chest X-ray was normal.

It was felt the patient was suffering from acute exacerbation of bronchitis with improvement, and she was treated with ipratropium, albuterol, and Decadron, which appeared to alleviate her symptoms. The PA discussed the case with the ED physician, who advised the patient of the need for follow up with her private physician. Of note, there was no physician signature on the ED record for this visit.

Four days later, the patient was brought by ambulance to another hospital with extreme shortness of breath and chest pain. A lower extremity Doppler found DVT of the right common femoral vein and right proximal superficial femoral vein. A CT angiogram revealed pulmonary emboli in the left upper lobe, right middle lobe, and right lower lobe. She was started on low-dose heparin at therapeutic dosing, a vascular surgery consult was requested, and an inferior vena cava (IVC) filter was placed. In addition, the patient was diagnosed with lymphedema and major depressive disorder and anxiety. She was discharged from the hospital 4 days later with instructions to follow up with her primary care physician for monitoring of Coumadin and INR.

The patient had subsequent admissions to this hospital for depression, anxiety, and suicidal ideation, which she attributed to the failure to diagnose the pulmonary embolism.

Lawsuit Filed

The patient brought a lawsuit against the MLMIC-insured hospital claiming that the hospital and its employees were negligent in failing to perform diagnostic tests, including CT scans and appropriate work-up, thus failing to diagnose and treat pulmonary embolism and DVT and misdiagnosing her condition as emphysema and bronchitis. As a result of this negligence, she claimed to have suffered a DVT and pulmonary embolism that required insertion of an IVC filter. In addition, she claimed this led to her depression and suicide attempt.

Expert Reviews

Reviews by an ED physician expert found that the standard of care was met during both ED visits. Radiology experts agreed that no evidence of DVT or PE was found on the studies, the ED work-up was thorough, and an array of tests aimed at diagnosing DVT and PE were normal. They felt that anticoagulation has its own risks and should be avoided when there are no clear indications to prescribe these medications.

In addition, an expert in pulmonology and critical care medicine felt that a pulmonary embolism was ruled out on the various studies. The patient was a smoker, obese, suffered from slight emphysema, and had a sedentary lifestyle, which were risk factors for pulmonary embolism and were appropriately ruled out.

The Trial

This case proceeded to trial with claims that, due to the plaintiff's known past medical history, the discontinuance of the anticoagulants, and the presented signs and symptoms, the defendant hospital failed to consider the possibility of an embolism in the ED. The patient's attorneys maintained their defense posture during the trial, which resulted in a verdict in favor of the hospital. The plaintiff did not pursue an appeal, and the case was closed with no payment made on behalf of the hospital.

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USE OF TECHNOLOGY **CHECKLIST**

THE USE OF COMPUTERS IN EXAMINATION ROOMS

The presence of laptops/tablets in examination rooms has become commonplace as more providers implement electronic health records. This method of documentation may place a barrier between the provider and the patient. Providers may miss nonverbal cues, and patients may perceive an electronic device as a hindrance to communication. In several recent medical malpractice cases, plaintiffs testified that the provider spent too much time entering information into the computer and not enough time listening. Utilizing effective communication skills to engage the patient while using a computer will enhance the integration of this technology into healthcare and improve the patient experience.

	YES	NO
1. The examination room has been analyzed for placement of the computer. It is positioned in a way that enhances provider/patient communication. The use of a cart on wheels is considered to position the computer so that the provider faces the patient.	☐	☐
2. Eye contact is established with the patient, and his/her concerns are listened to before using the computer. Providers look at the patient while they speak.	☐	☐
3. Reassurance is given to the patient by our providers that demonstrates they are listening to him/her.	☐	☐
4. The POISED[1] model is utilized: • **P** = Prepare for the visit. • **O** = Orient the patient to what you are doing. • **I** = Information gathering — allowing time for conversation. • **S** = Share what you are looking at on the screen with the patient. • **E** = Educate the patient, and reinforce the plan of action. • **D** = Debrief and assess the degree to which the patient understands the recommendations and plan. The "teach-back" method is used.	☐	☐
5. A print copy of the visit is provided to the patient, and a copy is retained in the patient's record (e.g., after-visit summary).	☐	☐
6. When computers remain in examination rooms, providers log off at the completion of the encounter to protect patient privacy.	☐	☐

The attorneys at Mercado May-Skinner are available to assist you in the proper use of technology. Contact Mercado May-Skinner in Syracuse at (315) 428-1380, Colonie at (518) 786-2880, and Long Island at (516) 794-7340, or call (877) 426-9555 toll-free.

1. Frankel Ph.D., JAMA Internal Medicine commentary, November 30, 2015.

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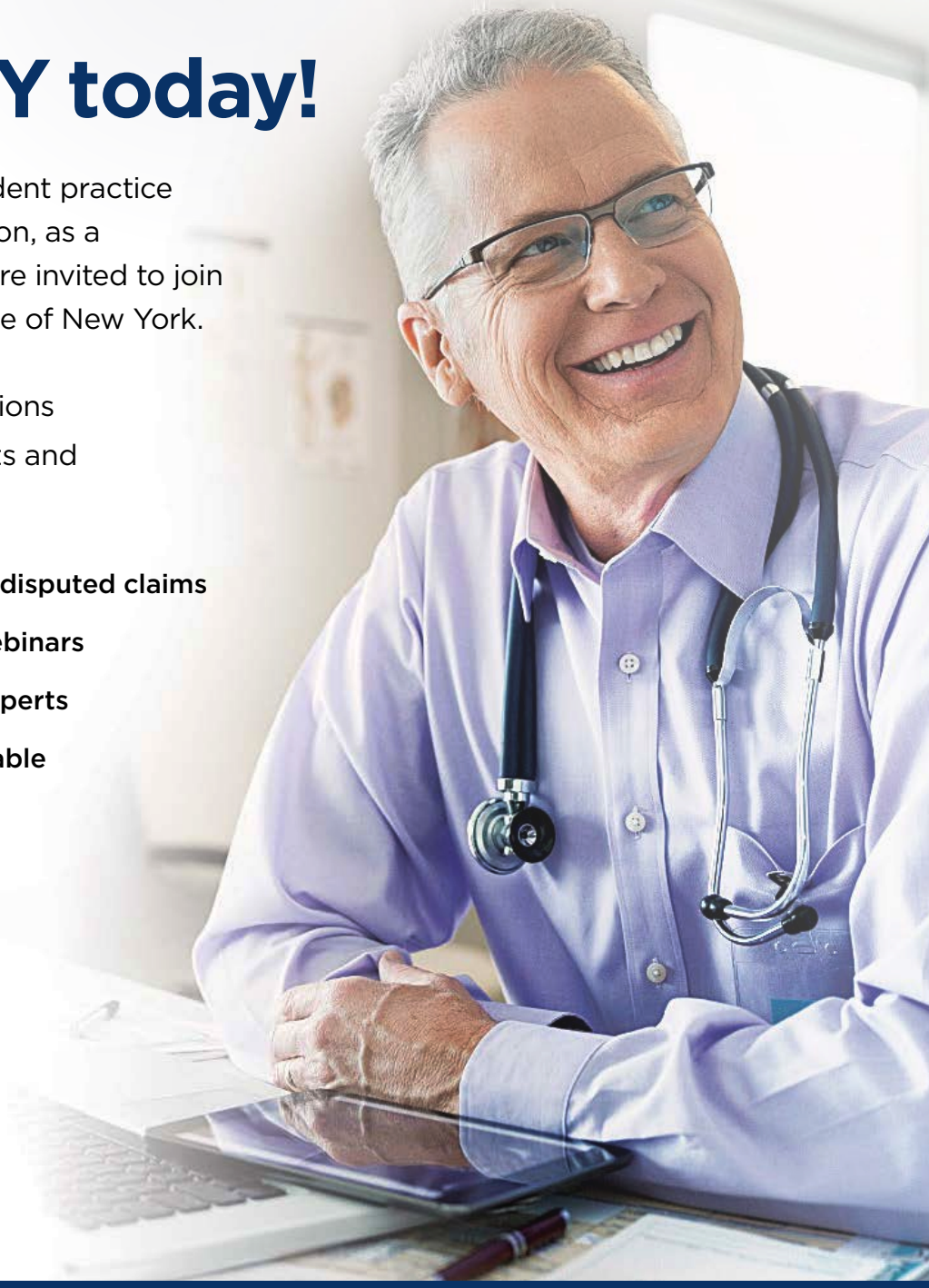

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