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Editor's Corner

AHRMNY's Risk Management Journal (RMJ) is the official journal of The Association for Healthcare Risk Management of New York, Inc. (AHRMNY) and is published several times a year.

RMJ's Mission Statement: To enhance the quality of healthcare delivery through education, research, professional practice, and analysis specific to risk management issues.

This journal contains articles on a wide variety of subjects related to risk management, patient safety, insurance, quality improvement, medicine, healthcare law, government regulation, as well as other relevant information of interest to risk managers. The articles are usually written by AHRMNY members, so the journal serves as an opportunity for members to showcase their writing talents.

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Article Requirements: Maximum article length 3,500 words. Photos should be high-resolution JPEGs (at least 300 dpi); AHRMNY will not publish articles promoting products or services.

The information presented in AHRMNY RISK MANAGEMENT JOURNAL is for educational purposes only.

Questions or comments to editors may be sent to ahrmny@gmail.com

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PRESIDENT'S MESSAGE



Dear Members,

I am excited and grateful for the amazing opportunity to be leading such an amazing, successful, innovative, and compassionate group of professionals this year. I look forward to working with all of you to continue to build this incredible organization.

First, I wanted to thank Dylan Braverman, who lead AHRMNY to a very successful 2019-2020 term. Dylan was an excellent mentor to me and to so many others. I greatly appreciated the support he has shown in me.

Dylan's term started off with a very well attended and successful ASHRM Conference Party in Baltimore. Dylan also put together an extremely successful Veteran's Day Educational Conference and a sold-out CPHRM Prep Review Class in January 2020.

I really want to thank our sponsors, who mean so much to us. Their generosity and participation help make our educational conferences, webinars, events, and social activities possible. As a result, I want to personally thank our 2020 Sponsors. Gold Sponsors: The Doctors Company and EmPRO Insurance and our Silver Sponsors: Fumuso, Kelly, Swart, Farrell, Polin & Christensen; MedPro Group, Phalanx Healthcare Solutions, and SafeQual. Our 2021 Sponsors: EmPRO Insurance, COVERS, Resolute Systems, LLC, The Doctors Company, Healthcare Risk Advisors, and Vigorito Barber, Patterson, Nichols & Porter.

Our Education Series for the 2020-2021 Term began with six (6) successful webinars. On September 23, 2020-Telehealth: Regulatory Landscape Prior to and During the COVID 19 Pandemic, October 20, 2020-Insights in Organizational Risk Assessment, a collaborative event on October 26, 2020-Catholic Health Services of Long Island's Response to the Covid-19 Pandemic, November 6, 2020-The Future of Post-Pandemic Long Term Care, and on December 10, 2020-Moral Injury & Personal Resiliency, and our most recent virtual symposium: "Covid-19 Pandemic in 2021: An Update on Key Advances in Patient Management & Disease Prevention. If you missed any of these webinars, I encourage you to order the video recording which is free to current AHRMNY members.

The education committee is planning new webinars for 2021 as in-person conferences are still not advisable at this time. Stay tuned for announcements soon.

I am encouraging all of our members to get involved. If you are interested in joining a committee, please reach out to me or President-Elect, Robert Marshall. Contact Linda Foy to submit an article for this journal and please contact Lesli Giglio if you would like to become a sponsor.

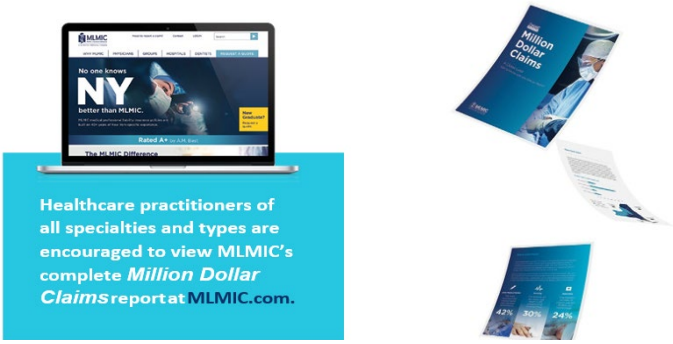
Yours truly,

Michael

Million Dollar Claims – A Closer Look

By Anne Heintz, Joyce McCormack, and Kate Palella

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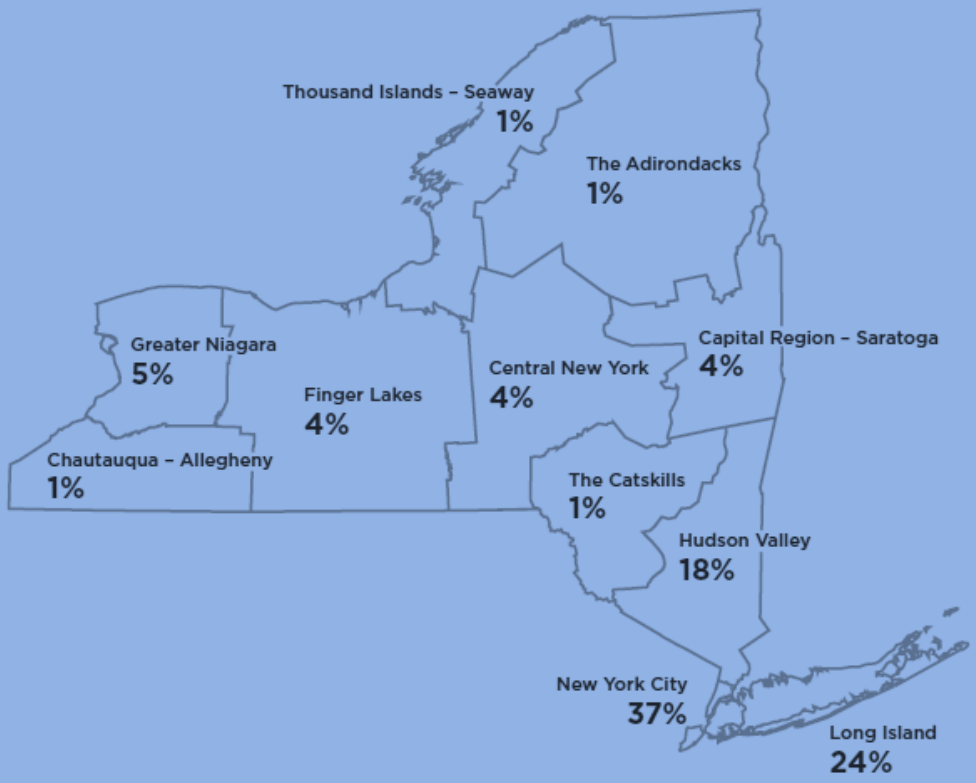
As part of MLMIC Insurance Company's ongoing efforts to provide our insureds with information to improve patient safety, MLMIC is pleased to announce that our Risk Management staff have performed an analysis of our closed medical professional liability (MPL) claims occurring over a five-year period that resulted in payment of $1 million or more: Million Dollar Claims – A Closer Look.

This detailed examination will provide valuable insights for our policyholders into the leading causes of loss that contribute to significant payment amounts. This first issue of MLMIC's new publication, The Scope, will focus on the topic of diagnostic errors, one of the foremost causes of loss identified in our analysis of million dollar MPL cases.

Million Dollar Claims

The graphic below illustrates the geographic distribution of claims that resulted in a payout of $1 million or more.

More than 1 in 3 of these claims originated in the southern part of New York State.



Diagnostic Errors Explored

The detailed examination of closed medical professional liability (MPL) claims presented in MLMIC Insurance Company's Million Claims – A Closer Look found an allegation of error in diagnosis in more than 1 in 3 (35%) of the MPL claims reviewed in our analysis. This result mirrors the findings of others who have studied the root causes of litigation in healthcare. For example, nearly one quarter of closed claims and lawsuits reported to the Medical Professional Liability Association's Data Sharing Project between 2008 and 2017 cited diagnostic error as the primary allegation.[1] Additionally, ERCI's "Top Ten Patient Safety Concerns" for 2020 listed errors in diagnosis as its number one concern.[2] Diagnostic error has been on ECRI's Top Ten list for several years.

Although often considered underreported, diagnostic error is relatively common, occurring in anywhere from 5% to 20% of emergency department, inpatient and ambulatory visits.

Diagnostic error can occur in any medical specialty. For example, our data reveals cancer diagnoses were missed, delayed or misidentified in 6 out of 10 of the cases where a diagnostic error was identified. These MPL claims were filed against many specialties. Our data also demonstrated that diagnostic error resulted in patient death in 34% of all instances.

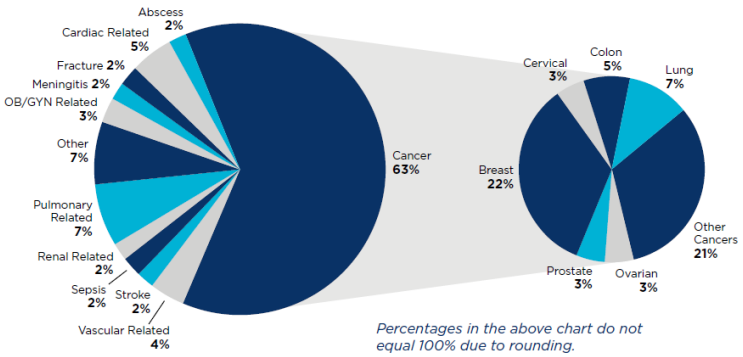
Many factors have been identified as contributing to diagnostic errors, including faulty recognition of symptoms and the failure to act upon a concern raised by another member of the healthcare team.

Communication failures such as inadequate handoffs and the failure to establish clear lines of responsibility among caregivers are also frequently associated with cases of diagnostic error.

"Human" issues such as distractions and excessive workload, interruptions, fatigue and technology problems can also influence a physician's ability to diagnose correctly. All of these issues can have a significant impact on patient outcomes, and, unfortunately, often result in malpractice claims against the providers of care.

The extensive study of diagnostic errors has revealed that many errors are the result of process breakdowns during the physician-patient encounter involving individual and system-related factors. Diagnostic errors are commonly associated with history taking, physical examination, ordering of diagnostic tests, interpretation of test results, referrals and consultations, and appropriate follow-up on outstanding studies, test results and consultations.

Diagnostic Error: A Breakdown by Type



Diagnostic errors are commonly associated with the following:



Researchers have extensively examined the causes of diagnostic error and identified that many principles from the field of cognitive psychology apply to their analysis. The findings from the study of diagnostic error have demonstrated that how individuals process information influences decision making during the diagnostic process and can contribute to errors. A provisional diagnosis or a plan of care that is predicated on a cognitive bias may negatively impact decision making and adversely affect outcomes.

Providing healthcare professionals with knowledge regarding the influence of cognitive bias in healthcare will enhance their ability to recognize potential pitfalls and reduce the risk of an MPL claim. It has been shown that clinicians frequently use "heuristics" (mental shortcuts or "rules of thumb") when making a provisional diagnosis, especially when a patient presents with common symptoms. For experienced physicians, heuristics are fast and effective, and generally lead to accurate decision making. However, they can have a negative influence on a clinician's decisions by introducing bias.

Cognitive Influences That Contribute to Diagnostic Errors

BIAS	DEFINITION
Affective	Also called visceral bias; emotional influences can induce thinking errors, including the feelings physicians have about their patients, both positive and negative.
Anchoring	Narrow focus on a single feature in a patient's presentation to support a diagnostic hypothesis, even if other concurrent features or subsequent information refutes the hypothesis.
Availability	The tendency to think that things that come to mind immediately are more likely or more common.
Blind obedience	Inappropriate deference to the recommendations of authority, either by direct superiors or by expert consultants, even in the absence of a sound rationale.
Confirmation	The tendency to search for evidence to support an initial diagnostic impression, and the tendency not to search for, or even to ignore, evidence that refutes it.
Diagnostic momentum	The tendency of a diagnostic label to become propagated by multiple intermediaries (patients, physicians, nurses, other team members) over time; what might have begun as a possible "working diagnosis" becomes "definite."
Framing effect	The susceptibility of diagnosticians to be disproportionately influenced by how a problem is described, by whom it is described, or even by the environment where an encounter takes place.
Hindsight bias	Knowing the outcome of an event influences the perception and memory of what actually occurred; in analyzing diagnostic errors, this can compromise learning by creating illusions of the participants' cognitive abilities, with potential for both underestimation and overestimation of what the participants knew (or could have known).
Overconfidence	The tendency to think one knows more than one does, especially in physicians who might place faith in opinions without gathering the necessary supporting evidence.
Premature closure	Making a diagnosis before it has been fully verified.

One of the most prevalent types of cognitive bias is "anchoring." This occurs when a physician locks on to one symptom or piece of information in the patient's initial presentation and discounts subsequent information that may be critical to finding the right diagnosis. "Anchoring" may be seriously compounded by "confirmation bias," which is the tendency to seek out or interpret data in a way that confirms an initial diagnosis. If a physician has a diagnosis in mind, he/she may be more likely to ask questions, test for, and recognize signs and symptoms that support this diagnosis, and dismiss more definitive evidence that might refute it. The case study in this issue of The Scope provides a warning on the dangers of anchoring.

Biases in decision making may also result in "premature closure," which accounts for a large proportion of diagnostic errors. This occurs when the physician fails to consider reasonable alternatives after an initial diagnosis is made.

Strategies to Reduce Diagnostic Error

- Document all clinical decision- making processes using evidence-based practice and justify any deviations from the established standard of care.
- Promptly obtain test results and consults and modify diagnoses and plans of care as indicated.

- Consult with collaborating and/or supervising physicians on all cases of difficult or delayed diagnoses.
- Refer unstable and/or undiagnosed patients with acute symptoms to emergency services.
- Request second opinions and consults as indicated.
- Communicate any changes in diagnoses among all providers of a given patient.
- Enhance clinical skills and reasoning by understanding the sources of cognitive error.
- Recognize any potential diagnostic or cultural biases that may negatively impact care.

Diagnostic error can occur as the result of numerous factors that influence individual healthcare practitioners. Recognizing the risks associated with these factors and deploying strategies to mitigate their potential impact on the processes associated with healthcare delivery will improve the safety of patient care while lessening the potential for significant exposure to litigation. In future issues of The Scope, MLMIC will present other risk management topics that impact healthcare liability and offer strategies to reduce those liability risks.

To review the entire report *Million Dollar Claims – A Closer Look*, please visit our website, MLMIC.com.

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COVID-19 Immunity Laws: The Interaction Between the PREP Act and New York Public Health Law Article 30-D

By Andrew S. Kaufman, Steven D. Weiner, and Mario C. Giannettino

Federal and State governments have responded to the coronavirus pandemic with a series of laws, newly enacted or otherwise triggered, which are designed to help mobilize both the public and private sector response to COVID-19. For healthcare practitioners, two of the most significant legislative enactments are the Public Readiness and Emergency Preparedness Act (PREP Act) and the amendment to the New York Public Health Law Article 30-d. These statutes both acknowledge the extraordinary services and sacrifices our health care practitioners have been providing in this time of great need and extend liability immunity to providers responding to the COVID-19 crisis. However, insurers and risk managers alike must recognize that despite the seeming breadth of these statutes, neither the PREP Act nor NY PHL Article 30-D provide blanket immunity. Moreover, to date the Courts have struggled with application of these two statutes and by and large have not extended immunity coverage to providers.

A. PREP Act

The PREP Act[1] was enacted in 2005 and is designed to incentivize the expeditious production of vital medical equipment and other products during a public health crisis. However, the PREP Act has rarely been invoked and never before on such a widespread scale as has been seen with COVID-19. Whether a particular loss will trigger immunity under the PREP Act revolves around two central questions: whether the actor is a "covered person" and whether the claim is related to a "covered countermeasure".[2] Immunity rules apply only if the answer to the foregoing questions is "yes."

What are Covered Countermeasures and Who are Covered Persons: Many questions have been raised by providers encountering the PREP Act for the first time as they emergently respond to the COVID-19 pandemic. As a result, the Federal Government issued an Advisory Opinion (the "Opinion") on April 14, 2020 that was designed to offer some clarity to the healthcare industry and individuals regarding: (1) what constitutes a Covered Countermeasure; and (2) who/what qualifies as a Covered Person.

- "Covered Countermeasures" are defined by the PREP Act to include "qualified pandemic or epidemic product[s]"; security countermeasures; drugs, biologics, or devices that are cleared by the Food and Drug Administration (FDA) or authorized for emergency use. The Act was also amended to cover certain protective masks[3].
- "Qualified pandemic products" are drugs, biologics or devices that satisfy two conditions: (1) they address a pandemic disease in one of a number of specified ways; and (2) the FDA has approved or cleared the drug, biologic, or device or authorized it for emergency use.

In order to qualify for the protections under the PREP Act, a qualified pandemic product must fall into one of the three following categories[4]:

1. The product is manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or to limit the harm such pandemic or epidemic might otherwise cause;
2. The product is manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described above; or
3. The product or technology is intended to enhance the use or effect of a drug, biological product or device.

Additionally, to invoke the available immunity under the PREP Act, the product must fall under FDA approval or clearance or research[5] or emergency use authorization.[6] If these conditions are not met, a provider will not be able to invoke the immunity provisions of the PREP Act.

"Covered Countermeasures" include products, therapeutics, diagnostic tests, medical devices, and personal protective equipment (PPE) used to treat, diagnose, cure, prevent, or mitigate COVID–19.[7] Favorably, as part of the Opinion, HHS promulgated a non-exhaustive list of covered countermeasure products.[8]

"Covered Person(s)" are specifically defined by the Act as:

- The United States;
- A person or entity that is a manufacturer, distributor or a program planner of a countermeasure;
- A qualified person who prescribed, administered, or dispensed such countermeasure; or
- An official, agent, or employee of a person or entity of the above[9].

The definition of the term "qualified person" is likely of most interest to healthcare providers. It encompasses, in part, a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed.[10] Healthcare providers could also trigger potential PREP Act coverage as a "program planner;" meaning that they are involved in planning, administering or supervising programs for distribution of a countermeasure.

Significantly, an entity or person who otherwise meets the requirements for PREP Act immunity will not lose that

immunity—even if the entity or person is not a covered person—if that entity or person reasonably could have believed, under the current, emergent circumstances, that such entity or person was a covered person.[11]

PREP Act immunity is broad but it is not absolute – the Act only applies to claims for personal injury or damage to property but does not apply to enforcement actions brought by the federal government or claims under federal law for equitable relief. Also, Congress specifically excluded from the PREP Act's immunity provision the sole exception when a covered person proximately causes death or serious physical injury to another person through willful misconduct.[12] A serious physical injury must be life threatening, permanently impair a body function, permanently damage a body structure, or require medical intervention to avoid such permanent impairment or damage. Willful misconduct requires that the covered person acted (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit. Injured persons must prove willful misconduct by clear and convincing evidence, a higher standard than in a typical civil case.

Preemption: Where a provider is a covered entity which provides a covered countermeasure, the immunity provisions extended under the PREP Act preempt traditional state law tort claims. For example, in Parker v. St. Lawrence County Public Health Department, 102 A.D.3d 140 (2012), the Appellate Division of the New York Supreme Court upheld PREP Act protections for a county that conducted a school-based vaccination clinic in response to the H1N1 outbreak. A nurse employed by St. Lawrence County inadvertently vaccinated a kindergartener in the absence of parental informed consent. The child's mother filed suit, arguing that the County had committed a battery. The County moved to dismiss the Complaint on the basis that the claim was preempted under the PREP Act. The lower court denied the defendant's motion to dismiss, resulting in appeal by the County.

The appellate court reversed, finding that the federal PREP Act preempted the claims under state law and that the breadth of liability immunity provided under the PREP Act precluded the plaintiff's claims.

Other courts have not been as willing to apply PREP Act liability. For example, in Casabianca v Mount Sinai Medical Center, 2014 WL 10413521, No. 112790/2010 a State Court found the PREP Act was inapplicable when a hospital limited access to which patients would receive an H1N1 vaccine during a time of shortage. The Court found that the PREP Act "consistently speaks of administering or using the countermeasure" and therefore the "the vaccine must be administered to or used by a patient." Thus, the decision to withhold the vaccine removed the hospital's acts from covered countermeasure immunity.

Throughout the pandemic, Courts have grappled with applying the PREP Act to COVID-19 personal injury litigation claims. In the majority of COVID-19 lawsuits filed to date in state courts, defendants have attempted to remove the matters to Federal Court on the basis that the PREP Act is a complete preemption statute in that it provides an exclusive federal jurisdiction for the litigation of such claims. Courts have not been persuaded. For instance, a District Court in New Jersey determined that the PREP Act required actual administration of a countermeasure and therefore, claims where the plaintiff alleged that the healthcare provider did not actually provide PPE, testing, or mitigation measures, would not trigger the immunity provision. The New Jersey Court also determined that the PREP Act did not provide complete preemption of state law tort claims.

Despite filing multiple Advisory Opinions as to the scope of the PREP Act, including a statement that even the non-use of a countermeasure can constitute "administration" the United States Government only recently filed legal papers in a lawsuit as to how the PREP Act should be interpreted by the Federal Courts. In the foregoing matter, pending in Tennessee District Court, the U.S. Government emphasized that the PREP Act is a complete preemption statute. As of this writing, the legal battles concerning the scope of the PREP Act continue.

Other PREP Act Considerations: Suits alleging an exception to immunity for covered persons can only be brought before a three-judge panel in the United States District Court for the District of Columbia; to prevail, a plaintiff must establish, by clear and convincing evidence, that the willful misconduct proximately caused death or serious injury.[13] In the event that there is compensation for injuries, the PREP Act authorized a "Covered Countermeasures Process Fund" to compensate eligible individuals. The regulations implementing the Fund are found in 42 CFR Part 110.

Critically, PREP Act claims have not been insulated from challenges in state court and alleging the PREP Act as an affirmative defense will not trigger federal court jurisdiction. To date, the question whether the PREP Act applies has largely revolved on if the pleadings allege state law tort causes of action and if so, Courts have followed the "well-pleaded complaint rule" (i.e., the Complaint intends what it says and the absence of any reference of a failure to provide a countermeasure is because countermeasures are not implicated). Moreover, as diversity jurisdiction seldom exists in medical malpractice litigation, the Federal Courts have seen no reason to remove PREP Act cases at the pleading stage. As of this writing, other than the U.S. Government's recent filing in Tennessee, there has not been an actual Court decision that

holds that the PREP Act raises an exclusively federal question. In the cases filed to date, the decisions have hinged on the fact that the complaints did not discuss any improper use of a countermeasure that led to an injury. Rather, the complaints asserted standard claims of negligence, such as poor staffing, infection control measures and failure to adhere to CDC and CMS guidelines. In none of the matters did the defendant show at the initial pleading stage that they actually administered a covered countermeasure. Yet, none of the Federal court actions held that the PREP Act per se was inapplicable. Instead, the Courts opined that the defendant's potential entitlement to a PREP Act defense was for the determination of the state courts.

However, over the past few months the Federal Government has repeatedly emphasized that the PREP Act should be interpreted broadly and that it is of paramount importance that cases involving the PREP Act be treated uniformly in the Federal Court system. The Department of Health and Human Services has even gone on record to say that if there is a question about whether the PREP Act has been triggered, the Federal Courts should permit discovery on this threshold issue. It is now up to the Courts to determine if they will follow the Government's expansive interpretation of the PREP Act.

B. New York Public Health Law Article 30-D

In its initial form the protection afforded by New York's amendment to Public Heath Law 30-D was arguably more expansive than the PREP Act. While the PREP Act requires a causal connection with a "Covered Countermeasure", the New York law granted health care facilities and professionals "immunity from any liability, civil or criminal, for any harm or damages alleged to have been sustained as a result of an act or omission in the course of arranging for or providing health care services" as long as the following three conditions were met:

- The health care facility or health care professional is arranging for or providing health care services pursuant to a COVID-19 emergency rule or otherwise in accordance with applicable law;
- The act or omission occurs in the course of arranging for or providing health care services and the treatment of the individual is impacted by the health care facility's or health care professional's decisions or activities in response to or as a result of the COVID-19 outbreak and in support of the state's directives; and
- The health care facility or health care professional is arranging for or providing health care services in good faith.

However, the New York Legislature recently partially repealed the statute by changing the definition of services eligible for immunity protections by removing "prevention" of COVID-19 from the definition of health care services, and removing immunity protections for a facility or professional "arranging for" health care services. The new law also clarifies that immunity applies to the assessment or care of an individual with a confirmed or suspected case of COVID-19. Favorably, the revisions to the law are not retroactive.

Another significant difference between the PREP Act and New York law is that while the PREP Act's exception to immunity does not extend to 'willful misconduct,' the New York immunity is not available for actions arising from "willful or intentional criminal misconduct, gross negligence, reckless misconduct or intentional infliction of harm."[14] Despite the partial repeal of the New York statute, and of critical importance during a time where healthcare staff is spread thin, the Public Health Law retained key language that that "acts or omissions or decisions resulting from a resource or staffing shortage shall not be considered to be willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm".[15]

What is a Health Care Facility: The statute defines a health care facility as a hospital, nursing home, or other facility licensed under Article 28 of the Public Health Law; a facility licensed under Article 16 of the Mental Hygiene Law, which governs providers of services for individuals with developmental disabilities; a facility licensed under Article 31 of the Mental Hygiene Law, which governs providers of services for the mentally disabled; or a facility under a COVID-19 emergency rule.

Who is a Health Care Professional: A health care professional includes individuals licensed or authorized under the articles of the New York Education law governing: physicians; physician assistants; specialist assistants; pharmacists; nurses; midwives; psychologists; social workers; mental health practitioners; respiratory therapists and respiratory therapy technicians; and clinical laboratory technologists, histological technicians, and cytotechnologists. Also included in the legislation are nursing attendants or certified nurse aides, including an individual who is providing care as part of an approved nursing attendant or certified nurse aide training program; an individual licensed or certified under article thirty of this chapter to provide emergency medical services; a home care services worker under Section 3600 of the Public Health Law; an individual providing health care services within the scope of authority permitted by a COVID-19 emergency rule; or a health care facility administrator, executive, supervisor, board member, trustee or other person responsible for directing, supervising or managing a health care facility and its personnel or other individual in a comparable role.

The legislation further grants volunteer organizations "immunity from any liability, civil or criminal, for any harm or damages irrespective of the cause of such harm or damage occurring in or at its facility or facilities arising from the state's

response and activities under the COVID-19 emergency declaration and in accordance with any applicable COVID-19 rule." The immunity does not apply if "it is established that such harm or damages were caused by the willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm by the volunteer organization."[16]

C. What Potential Acts May Be Outside the Scope of Immunity?

Under the PREP Act, the key is whether the covered person's activity was in furtherance of a covered countermeasure. If not, immunity will not attach. The immunity of the PREP Act does not protect a provider from a claim that the provider neglected the proper care and treatment of a non-COVID-19 patient. There is nothing in the PREP Act to suggest that it protects health care institutions from failure to obtain protected countermeasures on a prophylactic basis in anticipation of COVID-19 cases. In such scenarios, the provider must show that the non-use of a countermeasure was part of a deliberative planning process (i.e., prioritizing the administration of a vaccine to one person as opposed to another individual in circumstances where there was a shortage of available vaccines).

Under the New York statute, there is no immunity with respect to the threshold question of whether the provider was, inter alia, grossly negligent or demonstrated willful misconduct. We anticipate that lawsuits will be filed alleging such claims which will require the judiciary to opine on the issue of whether the conduct triggers the immunity in the first place. Thus, there is a potential that courts may allow discovery on this preliminary issue and foreclose an outright motion to dismiss. We also anticipate attempts to certify class action lawsuits arguing that systemic infection control problems existed at the healthcare facility prior to the COVID-19 outbreak and that the failure to correct those deficiencies amounts to gross negligence or willful misconduct which ought not to be covered by the immunity law.

We also envision efforts to circumvent immunity, including claims of chronic, deficient staffing practices prior to COVID-19, and arguments that the immunity law should not protect facilities that failed to properly address these shortcomings and as a result, lacked the capacity to appropriately address manpower needs during the COVID-19 crisis. Employment claims filed by staff for the failure to procure adequate PPE inventory in advance and plan for potential PPE shortages also may loom on the horizon. We also anticipate claims on behalf of bereaved family members in connection with the improper storage and disposal of bodies as the number of deaths during the pandemic has drawn media and state scrutiny as has the failure to apprise family members of the status of such efforts. Neither the PREP Act nor the New York State immunity law forecloses regulatory exposure or penalties for failing to document compliance with CDC or CMS Infection Control guidelines which are changing rapidly. Long term care facilities may also be particularly vulnerable to suits, especially those alleging that the number of deaths associated with a given facility was wholly disproportionate to their number of beds and geographic location which suggests a reckless disregard for taking the recommended measures to properly seek to limit the scope of the outbreak.

The immunities provided by the PREP Act and Article 30 of the NY State Public Health Law serve as models for other jurisdictions and provide much needed legal clarity for those dedicated healthcare professionals who have bravely put themselves at risk in caring for patients. Regardless of the public's seeming admiration for our healthcare workers during this time of great uncertainty and anxiety, the healthcare community must nonetheless anticipate the opportunistic lawsuits that will certainly be filed in the months/years to come related to COVID-19 and recognize the potential liability gaps exist despite the seemingly favorable scope of immunity provided at the federal and state levels.

Please contact the undersigned if you have any questions.

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Andrew S. Kaufman is a founding partner of the law firm of Kaufman, Borgeest & Ryan, LLP.



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MEMBER SPOTLIGHT

Join us in congratulating the following AHRMNY members for volunteering to share their achievements featured in this edition's MEMBER Spotlight

Denise Neal, RN, BSN, MJ, CPHRM, FASHRM - AWAC Services Company



Denise Neal is an Assistant Vice President of the Risk Management Group at AWAC Services Company, a member company of Allied World. Denise recently achieved her FASHRM designation and was recognized at the business meeting during ASHRM's virtual annual conference.

Lisa Oberting, RN, MSN, CPHRM - St. Charles Hospital



Lisa Oberting joined St. Charles Hospital, part of the Catholic Health Services of Long Island in January 2020 as a member of the senior leadership team as the Director of Risk Management and Privacy Officer. Prior to joining CHSLI, Lisa practiced nursing for 35 years, most recently as a Corporate Risk Manager for a regional health system. Having held the CPHRM designation since 2016, Lisa looks forward to playing an active role in achieving the healthcare organization's risk prevention and patient safety goals.

Bonnie Boone - Arthur J. Gallagher



Bonnie was recognized in Insurance Business America's (IBA) Annual Hall of Fame. In this 4th Annual special edition, 26 of the industry's most dedicated and inspiring leaders were selected who have contributed more than 35 years to improving the lives of their clients and colleagues. Bonnie is a producer and Executive Vice President for Arthur J. Gallagher's Risk Management Practice Group. Her expertise includes captives, physicians, hospitals, long-term care, and managed care.

Click here to read Bonnie's full acknowledgment in IBA, page 34

Carolyn Reinach Wolf, Esq. - Abrams Fensterman, LLP



Carolyn Reinach Wolf is an Executive Partner in the law firm of Abrams Fensterman, LLP and Director of the Firm's unique Mental Health Law practice which she created over 25 years ago. The firm's practice is dedicated to serving individuals and families struggling with serious mental illness and/or alcohol/drug addiction. Carolyn published articles on her blog in Psychology Today on topics relevant to the COVID-19 health crisis and how it impacts mental health professionals and their patients. Notably, the June 29, 2020 article titled: "Liability Concerns When Practitioners Return to the Office" stresses the importance of planning ahead to ensure compliance with state and federal guidelines and minimizing exposure to legal liability.

Law Every Trial Attorney Should Know Before Leaving Home

By Shawn P. Kelly

The following is a compendium of recent significant cases that all of us should be aware of and which can have a very significant impact on the manner in which we evaluate the very complex cases that come across our desks each day. Certainly, the trial attorney and the claim professional should be conversant with the decisions and the rationale of the courts in the manner in which these decisions were made.

CASE NO. 1

Crucial Summary Judgment Decision by the Appellate Division
O'Toole v. Goodman, 170 A.D.3d 615

This is a very important decision just decided by the Appellate Division, First Department and reported prominently in the NYLJ. In this case the court determined that the bariatric surgeon was not responsible for post-op care of the patient which was a duty he did not assume as the patient's surgeon. Moreover, the opinion cites to the seminal decision on this point, Burtman v. Brown, 97 AD3d 156, and it makes the crucial distinction that it is necessary for the plaintiff to establish the existence of a duty on behalf of the physician which is not an appropriate subject for expert opinion. Invariably, plaintiff counsel attempts to "blur" the distinction between a physician who is consulted for a specific purpose/expertise and then attempts to pin the sins of the subsequent treating physicians on the original physician. We see this in boilerplate bills of particulars and expert disclosures where there is no true appreciation of the division of responsibility/expertise among the various named defendants. This decision along with the Burtman decision should trigger a motion to dismiss the overbroad allegations or, if applicable, a motion for summary judgement. Better still a motion to the court to limit the expected testimony from the plaintiff's expert to the specific care rendered by the physician. Remember, the court needs to rule on this limitation of testimony as a matter of law not the plaintiff's expert who typically would be all too willing to lump all the defendants together.

In order to reach any discussion about deviation from accepted medical practice in a medical malpractice case, it is necessary first to establish the existence of a duty. Whether a defendant doctor owes a plaintiff a duty of care is a question for the court. It is generally not an appropriate subject for expert opinion. Burtman v. Brown, supra.

CASE NO. 2

Vicarious Liability of a Hospital
Smith v. St. Barnabas Hospital, 145 A.D.3d 596

This very recent Appellate Division, First Department case restates an important principle that can often be overlooked in motion practice when one seeks to extricate a hospital from liability which is premised on vicarious liability. In this case, two (2) individually named physicians had been awarded summary judgment and the clever or not so clever plaintiff attorney sought to impose liability against the hospital on a theory of vicarious liability for their acts or omissions. Even assuming there might be a valid claim against the hospital on the principle of apparent agency once the individually named physicians were dismissed from the case any vicarious claim would no longer be valid.

The resourceful plaintiff attorney in this case then attempted to allege negligence on other employees of the hospital but the court scrutinized the reports of the plaintiff's medical expert who failed to allege negligence as against any other employees of the hospital and thus properly dismissed the case as against the hospital.

The court cited an old leading case Escobar v. New York Hospital, 111 A.D.2d 128, which held similarly but there is dicta suggesting the if properly pleaded once the individually named physicians are no longer a party the plaintiff could still pursue his claim against other employees for their independent acts. That continues to be good law.

All too often this distinction is overlooked by the court but in the case referenced herein the court took the initiative to ferret out the actual claims as alleged in the medical reports of plaintiff's expert and arrived at the correct conclusion.

CASE NO. 3

Medical Malpractice and Bad Faith – Appellate Division Third Department
HPIC v. Parentis, 165 A.D.3d 1558

I don't think I am overstating the concern by stating if there was ever a case that must be read carefully this is that case that was recently decided by the Appellate Division, Third Department. It involves a "bad faith" claim by a physician and

his erstwhile patient who presumably by means of an assignment of rights joined together to sue the physician's primary malpractice insurer, MLMIC, and his excess insurer, HPIC.

The dynamics of the decision making by defense counsel, the primary insurer (from field representative to claim handler to claims manager to the VP of claims) and on to the claims manager of the excess insurer and ultimately to the CEO of the excess insurer read like a John Grisham novel with the clock ticking to the extent that definite decisions had to have been made all within 46 minutes as the jurors were deliberating.

Basic Facts

Albany County case where the plaintiff suffered an ankle injury which eventually led to an above-the-knee amputation (details of the medical care not discussed in the opinion) and ultimately the jury awarded the plaintiff $8.6 million as against one of two named defendant orthopedic surgeons both insured by MLMIC. The jury exonerated the other orthopedic surgeon. This award was affirmed by the Appellate Division.

Confronted with a substantial excess award over and above his malpractice coverage of $2.3 million, the physician and the plaintiff joined forces and sued the two malpractice insurers alleging bad faith essentially alleging that the insurers' conduct constituted a gross disregard of the insured's interests. As the opinion sets forth, these cases lift the veil off the carrier's claim file which is often marked as exhibit #1, warts and all, in the bad faith litigation. Confidential in-house expert reviews become front and center and are scrutinized by the court and jury. Depositions are conducted of the claims examiner, the claims manager and in the case of HPIC, the CEO of the company. Confidential e-mails, telephone messages and confidential attorney written evaluations of the strengths and weaknesses of the defense are also front and center and subject to scrutiny. Often the assigned defense attorney is also deposed within the context of the bad faith action. ***Your insured becomes your adversary!***

Back to the Case

In this case the defense produced a qualified orthopedic expert to defend the care but as noted the jury rejected the defense. After the jury was deliberating for only about an hour, they sent out an ominous note at 2:44 p.m. requesting a read back on the life care plan expenses of the plaintiff. Following a read back of the testimony the jury resumed deliberations at 2:56 p.m. At that point defense counsel immediately sprung into action informing both his client, the physician, and MLMIC of this most troubling development.

Defense counsel dutifully secured the written consent of his client to settle. The MLMIC field representative was present in the courthouse and immediately communication was established with the claims examiner who then promptly notified his claims supervisor and later with MLMIC's Vice-President of Claims. The MLMIC Vice President directed that the excess insurer be made aware that MLMIC was prepared to pay the full extent of its policy ($1.3 million) but that it would also take the full extent of the HPIC's policy ($1 million) to settle the case. It is critical to be aware that at this time the plaintiff attorney had finally agreed to accept $2.3 million in full settlement of all claims. It should also be noted that at no time prior to trial had the defense made any offer to settle.

Critical Issue

The following is probably the critical aspect of the case. According to the decision, HPIC's Vice-President of Claims at 3:22 p.m. while the jury was still deliberating was contacted by the MLMIC claims examiner by e-mail of these trial developments. What information was actually conveyed during a telephone conversation between MLMIC's claims examiner and the Vice President of claims for HPIC is in dispute. The MLMIC representative states he communicated the fact that MLMIC was offering its policy to settle the case and that "the ball is in her court." Everyone agrees and the law is clear that the excess insurer has no duty to participate in settlement negotiations unless and until the full extent of the primary policy has been tendered. HPIC's Vice President of claims testified that she did not learn that the insured had signed a consent to settle UNTIL AFTER THE JURY VERDICT!!! AND MAINTAINED SHE WAS NEVER INFORMED THAT MLMIC HAD OFFERED THEIR POLICY!! Consequently, no offer was made by HPIC and the jury returned a verdict at 3:42 p.m. awarding the plaintiff $8.6 million, a sum which I am sure has significantly increased by the awarding of interest over several years while this bad faith litigation has been pending.

The Law

The court correctly cited the leading Court of Appeals decision in this area, Pavia v. State Farm, which was decided in 1993 and which could not have been a more potent and advantageous decision for the defense and for insurance carriers in defending claims of bad faith. The operative language from Pavia is recited in the opinion but suffice it to say under Pavia "the insured must show that "the insurer's conduct constituted a "gross disregard" of the insured's interests-that is, a deliberate or reckless failure to place on equal footing the interests of its insured with its own interests when considering a settlement offer." This is and has been an incredibly high bar for the plaintiff to establish in bad faith litigation. Before Pavia it was routine for plaintiff attorneys to send bad faith letters on seemingly every case and similarly

demand that the policy be offered in an unrealistic time period of 30 days or so. Such time-honored demands have largely disappeared after Pavia. The court also cites Smith v. General Accident, another Court of Appeals decision, that mandates the insurer notify its insured of settlement negotiations and, believe it or not, the insured's right to contribute towards an eventual settlement. See the below excerpt from the Smith decision.

> 1 It is well settled that an insurer may be held liable for damages to its insured for the bad faith refusal of a settlement offer (Soto v. State Farm Ins. Co., 83 NY2d 718; Pavia v. State Farm Mut. Auto. Ins. Co., 82 NY2d 445). This stems from the [*653] general principle that a covenant of good faith and fair dealing is implied in all contracts, including insurance policies, as well as a recognition of the control an insurer maintains over claims against an insured (Pavia v. State Farm [****10] Mut. Auto. Ins. Co., supra; Gordon v. Nationwide Mut. Ins. Co., 30 NY2d 427). When confronted with a settlement offer within the policy limits, an inherent conflict arises between the insurer's desire to settle the claim for as little as [**171] [***270] possible, and the insured's desire to avoid personal liability in excess of the policy limits. HN2 In order to establish bad faith in failing to settle a claim, the insured must show that "the insurer's conduct constituted a 'gross disregard' of the insured's interests--that is, a deliberate or reckless failure to place on equal footing the interests of its insured with its own interests when considering a settlement offer" (Pavia v. State Farm Mut. Auto. Ins. Co., supra, 82 NY2d, at 453). The issue here is whether the failure of the insurer to keep its insured informed of settlement negotiations can constitute some evidence of bad faith, as the trial court instructed the jury. We hold that it can.

Analysis

First and foremost, it is hoped that this decision will be appealed to the Court of Appeals. Otherwise, since a unanimous Appellate Division found questions of fact it will be remanded back to the trial court for trial. In the interim without question plaintiff attorneys will be citing this decision and issuing bad faith letters with greater frequency especially when the nature and the extent of the injury suggests a jury exposure that exceeds the available insurance coverage. This decision may have a tendency to unnerve the insureds who will likely have a greater incentive to seek personal counsel to advocate on their behalf that the case be settled within their policy limits in order to extinguish the potential for any personal exposure. Although not necessarily a new concern the notion that confidential in-house reviews by medical experts and the opinions of assigned counsel (not to mention in-house e-mails) may be discoverable may have a chilling effect on usual practices. Despite the above, the protective and comforting language of Pavia remains the law of the New York State and has continued vitality.

CASE NO. 4

Punitive Damages Award in a Medical Malpractice Action – MUST READ
Gomez v. Cabatic, 159 A.D.3d 62 (2d Dept. 2018)

This is simply an incredibly important decision by the Appellate Division, Second Department that should be the lead case discussed in any Risk Management seminar this year. The decision is a valuable lesson especially concerning the discussion about the legal threshold for an award for punitive damages as recited by the United States Supreme Court in the State Farm decision cited herein. The article is a little thin on the facts of the underlying case and they will be amplified somewhat here but all should take the time to read the actual decision. Due to the momentous holding and the potential implications decided by the lower court the Medical Society of the State of New York (MSSNY) filed an amicus or "friend of the court" brief seeking to stave off punitive damages. Although my opinion is irrelevant especially now that it is a reportable case with precedential implications it nevertheless seemed unduly harsh and I thought there were other remedies available to the court. I spoke to one of the interested parties involved in the case and learned that the pediatric endocrinologist who was found to have altered her records left the USA all together after the appeal and returned to her native Philippines and her professional liability insurer ultimately paid a reported $900,000 to settle all claims. This presumably included the claim for punitive damages which was subsumed in the settlement or simply discontinued.

What was most unsettling was the jury award for punitive damages of $7.5 million which was reduced by the trial judge to $1.2 million and later further reduced by the appellate court to $500,000. Punitive damages we all know is something that the public policy of New York disallows an insurer from paying as against public policy. Post-trial aside from the humiliation of such an award with its attendant publicity, the defendant is later questioned under oath by the plaintiff attorney about her assets, bank accounts and other sundry financial dealing to determine what might be recoverable.

Basic Facts

The case involved the wrongful death of a 6-year-old girl and it was alleged the peds endocrinologist Dr. Mercado failed to diagnose Type 1 diabetes that led to ketoacidosis and death. There were essentially 3 office visits which were as follows:

10/31/09	First office visit to the peds endocrinologist.
11/14/09	Second office visit.
12/9/09	Third and last office visit. Defendant Mercado wrote the child was to return for follow up "TCB in 4 weeks."
1/21/10	Child complained of being tired and not feeling well and received a note from the school RN.
1/22/10	Mom takes child to the hospital (not named in action).
1/24/10	Child is pronounced and autopsy recites "attributable to bilateral cerebellar tonsillar herniation 2* to cerebral edema following diabetic ketoacidosis."

The defendant Mercado testified at her Examination Before Trial that she prepared a two-page typed record of the first OV of 10/30/09.

On 2/26/10 defendant Mercado wrote a letter to the referring pediatrician thanking her for the referral and attached a consult note unaware that the child had died a month ago.

Late February she received a letter from plaintiff attorney asking her for her chart (**View those letters with caution!!**). After receiving this letter from the attorney, she destroys the original (scribbly) notes which had memorialized the two subsequent office visits of 11/4/09 and 12/09/09. She testified, "After typing up I throw them out." 4 months later - meaning the handwritten scribbly notes- that had now been replaced by a typed report which she sent to the attorney.

Mom testified after 12/12/09 office visit defendant Mercado told her to return in two months for a follow up visit and she produced an appointment card from the defendant's office that had a follow up appointment for 2/13/10. Remember her office chart said "TCB in 4 weeks." ***NO EXPLANATION PROVIDED FOR THE DISCREPANCY OF THE TIMING OF THE RETURN VISIT.***

Plaintiff contends: Mercado destroyed the handwritten (scribbly) records after receiving letter from plaintiff attorney and such was evidence of a malicious intent warranting the imposition of punitive damages.

Defendant contends: She had reasonable excuse for destroying handwritten notes for the 11/4 and 12/9 office visits since she used them to prepare the typed report of the visits.

Important discrepancies: Typed report adds "no polyuria, no polydipsia" both indicia of DM and also added ACANTHOS NIGRICANS (insulin resistance) but such had not appeared on the handwritten record.

Court Rationale: Punitive damages may be awarded for conduct that shows a high degree of immorality and indifference to civil obligations. The purpose of punitive damages is not to compensate the estate but to punish the defendant, Dr. Mercado, for malicious acts and, therefore, to discourage Dr. Mercado and other doctors from acting in a similar way."

Lesson: No surprise here that the integrity and completeness of office records and hospital records are of critical importance. With the advent of EMR this dilemma may not be as acute but be prepared that aggressive plaintiffs' counsel will continue to scrutinize the exchange of all such records and may create "false issues" concerning them which will lead to bogus and unnecessary discovery. A mere claim of punitive damages in the complaint will instill fear and apprehension in the lives of well-intentioned physicians who may be inclined to consult with personal counsel and who will place unnecessary demands on insurance carriers to settle the underlying case so as to avoid the specter of personal liability.

CASE NO. 5

Audit Trail and Meta Data – The Bane of the Medical Malpractice Defense Bar
Vargas v. Lee, 170 A.D.3d 1073

This decision is clearly must reading for anyone representing a hospital or a physician practice that uses EMR which now is ubiquitous throughout the industry.

This case involves a recent decision from the Appellate Division, Second Department, Vargas v. Lee, which mandated that the defense produce the audit trail regarding relevant portions of the plaintiff's medical record. Plaintiff bar association literature have widely reported that the audit trail and meta data have unearthed instances where, for example, an anesthesiologist has charted soon after induction that the extubation was uneventful long before the patient was extubated when in fact the patient later experienced hypoxic episodes that was anything but uneventful. Additionally, there have been reported instances when a radiologist reviewed a CT scan for less than 3 minutes while interpreting a study but when sued years later goes back to the CT and spends some 30 minutes (10x as much time) in what will be argued was for defensive purposes rather than clinical reasons. The timing of each interaction with the EMR is clearly timed and not easily refuted.

The burden on defense counsel and risk management to facilitate these requests should also not be overlooked as many such demands will unquestionably be "fishing expeditions" and will be labor intensive. Discovery on this issue alone will be contentious. In Vargas, an affidavit by the hospital's vice president of information technology stating that to compile such information would be "time-consuming" was found to be conclusory and inadequate to show that the requested production would be unduly onerous. To oppose such demands counsel for the defense must be specific in demonstrating to the court specifically the terrible burden imposed on the hospital staff to comply and must show how the demand is not calculated to lead to any relevant or material evidence that could not be obtained through less intrusive means.

CASE NO. 6

Pasek v. Catholic Health System, Inc. – 2020 NY Slip Op 04652

This is a very important recent case out of the Fourth Department for three reasons which I will briefly summarize. The best thing about the case is that it is precedent for dismissing those allegations in a bill of particulars that are not specifically addressed in the plaintiff's expert affidavit which is submitted in an effort to oppose/defeat defendant's motion for summary judgment. For instance, it is routine for the plaintiff to allege at times pages of allegations in the B/P of deviations (at times it could be 100 or more such deviations) and this case should be cited in an effort to dismiss such superfluous allegations which will have the effect of significantly narrowing the issues.

In the case cited above the patient suffered a hypoxic event as he was being transported from the ICU to the OR when the tubing on his extra corporeal membrane oxygenation (ECMO) system became dislodged leading to brain damage. The anesthesiologist who was involved to some extent in the transport moved for summary judgment and it was denied as to that specific claim regarding the transport. Also alleged against the anesthesiologist were numerous other serious allegations including his alleged failure to properly diagnose, consult, test, examine as well criticism directed to his pre-op and post-op treatment. Since all of those allegations were not specifically addressed by the plaintiff's expert affidavit those claims were deemed abandoned and dismissed. *Just think how that defense strategy has now narrowed the contested issues and at the same significantly shortened the length of the trial*.

Secondly, in moving for summary judgment, the defendant anesthesiologist relied upon his own affidavit in refuting all of the allegations of negligence/malpractice which the court characterized as "detailed, specific and factual in nature." Although not utilizing an independent expert for a summary judgment motion may be risky and I would not ordinarily recommend it in this instance it was sufficient to dismiss all but one central claim.

Thirdly, seemingly present in virtually every medical malpractice case, the plaintiff harps about record keeping and invariably offers proof that the failure to document is a deviation. However, as is often the defense argument, the failure to document is seldom the proximate cause of any injury. This appellate court realized that holding that the alleged documentation error could not have been the proximate cause and dismissed outright that deviation.

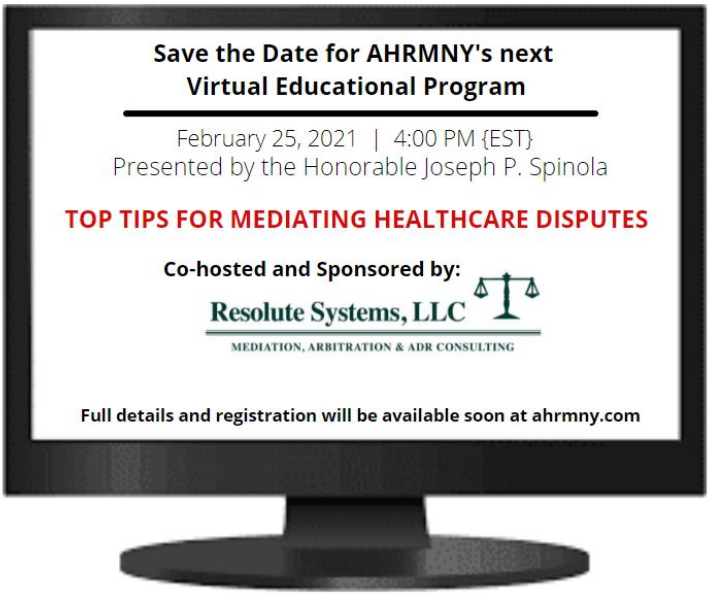
Great case that needs to go in everyone's trial folder.

About the Author



Shawn P. Kelly is the senior Partner of Kelly, Rode & Kelly LLP which was founded in 1956 and which has offices in Mineola, NY and Riverhead, NY. Mr. Kelly is a graduate of the University of Notre Dame who thereafter went on to receive his JD degree from St. John's Law School. His practice involves defending physicians, hospitals, nursing home facilities, and other health care providers which he has been doing for 40 years. He has lectured widely on matters of Risk management, Trial Tactics, and Evidence. He is a former chairperson of the Trial Lawyer's Section of the Nassau-Suffolk Bar Association.

In the year 2000 Shawn was inducted as a Fellow of The American College of Trial Lawyers (ACTL) in Washington, D.C. and has served over the years on committees of that organization. He has been awarded the "Super Lawyer" distinction each year from 2008-2020.



Remote Mental Hygiene Hearings During the COVID-19 Pandemic

By Preethi Swamy and David Bohrer

In March 2020, as the COVID-19 pandemic led to a shutdown of New York City, the New York State Unified Court System quickly halted all non-essential court matters. In addition to prioritizing certain criminal and family court matters as essential, the courts also placed an emphasis on mental hygiene proceedings, including applications for the involuntary retention of psychiatric patients, medication over objection, and Assisted Outpatient Treatment (AOT). This led to swift and collective efforts by the court system, behavioral health treatment facilities, their attorneys, Mental Hygiene Legal Service (MHLS) attorneys, and health care advocacy organizations such as the Greater New York Hospital Association, to develop an effective plan for the electronic filing of mental hygiene matters and remote mental hygiene hearings. Since March 2020, mental hygiene applications in New York City have primarily been filed electronically and all hearings have been conducted remotely. NYC Health + Hospitals, the nation's largest public health care system with 11 acute care facilities and more than 1,000 psychiatric beds across the system, has successfully adapted to and embraced this change. While the transition to remote video hearings has posed challenges, the overall benefits of remote video hearings have become apparent to NYC Health + Hospitals. Similar gains have been voiced by other health care systems throughout New York City and its surrounding area as well. Given the marked advantages to both patients and the facilities, there is a clear justification to use electronic filing and conduct remote video hearings post-pandemic.

Electronic Filing

Historically, New York courts have required that mental hygiene applications be filed in person. Even as other types of court matters have transitioned to electronic filing over the past several years, mental hygiene matters have remained one of the exceptions. During the pandemic, most of the New York State Supreme Courts have permitted electronic filing for mental hygiene matters. This process has proven to be advantageous as the use of electronic filing has greatly simplified the process of submitting mental hygiene petitions to the court. The pre-pandemic process of filing mental hygiene papers required facilities to obtain original signatures and then to contact a process server to file the papers in person. Due to strict court filing deadlines, the process servers were often racing to the courthouse to file these petitions in person. With the advent of electronic filing, there is no longer a need to go through this cumbersome process with challenging timeframes. The use of electronic filing has proven to be a streamlined process which saves all parties a significant amount of time and expense.

Litigating Mental Hygiene Hearings

The switch to conducting remote mental hygiene hearings has been a smooth one. The courts located throughout New York City initially used Skype for Business as its platform for remote hearings and have now transitioned to Microsoft Teams. In most instances, the judge, attorneys, and court staff appear remotely while the patient and treating psychiatrist appear in the hospital "courtroom". Overall, the technology has worked very well and the hearings have proceeded in an orderly and timely fashion. As to be expected, there have been some minor technological issues resulting from either a slow WiFi connection by one of the participants or a non-functioning webcam. However, these instances have been few and far between and, for the most part, these technological issues occurred at the beginning of this process and have since been eliminated or minimized over time.

The use of remote technology has also required a greater focus on witness preparation. There is no longer an opportunity for the facility's attorney to have a face-to-face preparation session with the treating psychiatrist in court. All planning must be done in advance. This includes taking the necessary steps to ensure that any anticipated evidence will be accepted by the court at the hearing. For example, medical records are typically offered into evidence during mental hygiene proceedings. In order to overcome any objections, it is prudent for facilities to provide the records that will be offered into evidence to the patient's attorney in advance.

Advantages of Remote Hearings to Patient and Facility

There are several benefits of conducting mental hygiene hearings remotely to both the facility and the patient. At the forefront is an increase in patient safety. Remote hearings avoid the need to transfer a patient from a secure unit to a public courtroom, decreasing the risk of patient elopement and acts of physical aggression by agitated patients. In addition, travel during inclement weather is avoided and costs associated with transportation are eliminated. Moreover, there is an obvious public health advantage. A remote hearing

process mitigates exposure to infectious diseases such as the influenza virus or COVID-19 for all parties including court staff and attorneys.

There is also a conservation of facility staffing resources. With remote hearings, attending physicians, nursing staff, patient escorts and hospital police no longer need to appear in court for what may be a full day and are available to provide services at the facility. Specifically, attending physicians have the ability to treat other patients admitted to the unit while waiting for their case to be called.

There are also several advantages to the patient including clinical benefits. Remote hearings afford minimal disruption to patient treatment and routines. By remaining in the facility as opposed to court, patients benefit from uninterrupted inpatient care and treatment which otherwise could not be provided if they were waiting for their cases to be heard outside of a courtroom. This is especially advantageous in the event a patient has an episode necessitating emergent care which otherwise could not be managed in a non-hospital environment. Patients with high risk behavior such as aggression or self-harm benefit from such consistency. Remote hearings also eliminate the risk of patient agitation precipitated by a long wait in an unfamiliar environment. In addition, if patients withdraw their petitions once the calendar begins, they can continue to receive services on the unit as opposed to unnecessarily waiting in court. There is also a removal of patient perceived barriers to access to the court system. The remote hearing process is likely less intimidating to patients than presenting in court before all parties, including the judge and court officers. Therefore, patients may be more engaged during their hearings and more willing to exercise their right to a hearing than they otherwise would with in-person hearings.

Disadvantages of Remote Hearings to Patient and Facility

The disadvantages of conducting hearings remotely to the facility are limited and are primarily associated with information technology issues. Also, in contrast to in-person proceedings, there is a lack of court security personnel, which may leave facility staff to feel somewhat vulnerable or apprehensive during a remote hearing. Finally, the severity of a patient's illness may not convey through a video conference as it would be in person and may result in diminished viability of a facility's retention or treatment over objection application. This point may also serve as the basis for any opposition to remote hearings in general, as an argument could be made that a patient's due process rights are not satisfied by remote, rather than in-person, hearings.

The use of remote hearings also has some limited disadvantages to patients. Remote hearings are difficult for patients who are not comfortable with technology. Patients who are paranoid or delusional may be wary of the legitimacy of hearings conducted remotely and may become agitated during the proceeding. In addition, patient family members may not have access to technology preventing them from appearing remotely. In these instances, the facility could then arrange for the family member to present to the facility in person. Finally, while patients do not currently have in-person access to their counsel during their hearings due to the pandemic, there is no reason why counsel cannot be present in the facility as pandemic-related visitor restrictions ease.

Lessons Learned from Mental Hygiene Hearings Over the Past 10 Months

The aforementioned advantages to conducting mental hygiene hearings remotely strongly support their continued use post-pandemic. Remote hearings are safer for both patients and facility staff. Moreover, there is a significant clinical benefit to both patients scheduled for hearings and those remaining on the unit. Patients with calendared proceedings can benefit from uninterrupted care and treatment throughout the day but for the time they are before the court. In addition, the other admitted patients have the benefit of receiving services from an attending physician who would otherwise be required to remain in court.

Conclusion

The COVID-19 pandemic has presented enormous and unprecedented challenges for treatment facilities. Notwithstanding these challenges, mental hygiene proceedings must take place in order to afford patients of their rights to a hearing and facilities an opportunity to obtain court orders for treatment. As a result of these difficult times, the New York City courts have successfully transitioned to a new system including the electronic filing of mental hygiene matters and conducting mental hygiene hearings remotely. After only ten months, it is abundantly clear that there are significant advantages to both patients and facilities. These gains warrant an organized effort among facilities offering inpatient behavioral health services across the state to advocate for the continued use of electronic filing and remote video hearings post-pandemic. Such an effort will require collaboration among all interested parties involved including the New York State Unified Court System and counsel representing patients. Advocacy efforts must also include engaging in a careful analysis of whether a patient's due

process rights are adequately protected and satisfied by remote hearings. This analysis will likely lead to proposed procedural safeguards designed to protect a patient's due process rights during remote hearings. In addition, legislative action may be necessary given that mental hygiene hearings are conducted in accordance with the requirements prescribed by the New York State Mental Hygiene Law. As the pandemic continues, advocacy efforts should move forward to ensure that gains seen from using an electronic filing system and remote hearing process are not lost post-pandemic.

References on page 31

About the Authors



Preethi Swamy is a Senior Counsel in the Office of General Counsel at NYC Health + Hospitals. Ms. Swamy provides guidance to senior management and clinicians across the system's facilities on a broad range of medical legal issues concerning both patients and providers. These issues include behavioral health operations and matters arising under the NYS Mental Hygiene Law; confidentiality and privacy; consent to treatment; advance directives; matters arising under the Family Health Care Decisions Act; guardianship proceedings; and medical staff matters. Ms. Swamy embarked on her legal career as a litigator defending major health care systems and individually named providers against medical malpractice claims as an associate at a prominent New York City medical defense firm and subsequently in-house at NYC Health + Hospitals. Prior to practicing law, Ms. Swamy was a Senior Financial Analyst for a large metropolitan health care system in the area of managed care. Ms. Swamy received her BSc in Physiology from McGill University in 2000, her MPA from New York University in 2002, and her JD magna cum laude from New York Law School in 2010. Ms. Swamy is admitted to practice in New York. She is also admitted to practice in the United States District Court for the Eastern and Southern District of New York.



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New York Leads the Way in Providing Liability Protections to Health Care Workers

By Peter Kolbert and Caryn Lilling



The country is in the midst of a crisis in size and scope not seen since 1918, and the medical community is on the front lines protecting and helping the public. To successfully navigate this dangerous and unprecedented environment, incredible measures must be taken. There is no vaccine to stop the spread of this deadly virus and no medicine to provide a simple cure. There are not enough tests. There is not enough personal protective equipment for medical personnel. There are not enough ventilators, hospital beds, and staff to handle the mounting crisis. In fact, Gov. Andrew Cuomo sent out a call to ask retirees and health care workers from around the country to come to New York to treat its patients, and thousands have answered that call. Field hospitals have been set up in Central Park and at the US Open Tennis Center. The naval hospital ship, the USNS Comfort arrived in New York on March 30, 2020 to help with the lack of available beds. Moreover, all elective surgeries and procedures have been cancelled to increase the number of beds available for COVID-19 victims. With all these challenges, the medical community is nonetheless doing an extraordinary job, putting them- selves at risk, to protect, serve and care for their fellow citizens. In turn they certainly deserve our gratitude and protection.

Recognizing this, on March 23, 2020, Governor Cuomo used his authority under New York's Disaster Act to immunize health care workers from liability from lawsuits alleging ordinary negligence, while assisting New York's response to the COVID-19 pandemic (see Executive Order 202.10). This effort was hailed as an appropriate response to the COVID-19 crisis. See, e.g., Thomas A. Moore and Matthew Gaier, "COVID-19: Gov. Cuomo's Executive Order and Other Legal Measures," NYLJ (March 30, 2020). Shortly thereafter, the Legislature adopted the spirit of Executive Order 202.10 and codified it by amending the Public Health Law to immunize physicians, nurses, hospitals, nursing homes, administrators, board members and other health care workers from claims of ordinary negligence. See Public Health Law §3082. The statute took effect immediately upon its enactment and applies retroactively with regard to any acts or omissions that took place on March 7, 2020 and will continue in effect until the COVID-19 crisis abates.

The swift actions of the Governor and Legislature should serve as a model for legislation to be implemented across the country. See Robert Klitzman, M.D., "Wrenching Decisions They Face," New York Times (April 4, 2020). Health care workers are facing an unprecedented pandemic with equipment and supply shortages, and overcrowded hospitals. To promote the public health, safety and welfare of everyone, Hospitals and medical providers need to be able to make treatment, staffing or resource allocation decisions during this crisis without concerns about the specter of future litigation. The medical community as a whole deserves our gratitude, understanding and support for their efforts, and now in New York, they will be afforded broad legal protection from civil claims alleging negligence.

The New Additions to the Public Health Law

Newly enacted Public Health Law §3082(a) states that health care providers and health care facilities shall be immune from civil or criminal liability "for any harm or damages alleged to have been sustained as a result of an act or omission in the course of arranging for or providing care" when three elements are satisfied.

The first requirement for immunity is that the care is being arranged or provided "pursuant to a COVID-19 emergency rule or otherwise in accordance with applicable law." Public Health Law §3082[1][a]. A COVID-19 emergency rule is an executive order, declaration, rule or regulation by either the state or federal governments that waives standards of care. See Public Health Law §3081[7]. For example, Executive Order 202.10 or the actions taken under the federal PREP Act would be but some examples of a "COVID-19 emergency rule."

The second requirement for immunity is that: the act or omission occurs in the course of arranging for or providing health care services and the treatment of the individual is impact- ed by the health care facilities or health care professional's decisions or activities in response to or as a result of the COVID-19 outbreak and in support of the state's directives Public Health Law §3082[1][b]. This provision makes clear that immunity will apply to the care of patients with or without COVID-19. This is appropriate as the current crisis impacts all aspects of health care. Elective surgeries and procedures have been cancelled. Work hour limitations have been suspended to facilitate staffing during the crisis. Physician resources have been reallocated leading some health care providers to treat patients outside of their core specialties. Supervision rules have been relaxed enabling a variety of professionals to provide primary treatment. Each of these challenges, impacts not only the care rendered to COVID-19 patients, but also other patients who would be treated by the physicians now being called into service to treat COVID-19. The issue of staff shortages will no doubt be compounded further if the shortage of personal protective equipment is not resolved and health care providers themselves become ill. America is engaged in a battle from coast to coast that is impacting every citizen, and the legislature's recognition of this reality is a critical aspect of this statute enabling health care providers to make these difficult decisions to hopefully save lives.

The third element for immunity is straightforward. The care being provided must be done "in good faith." Public Health Law

§3082[2][c]. The good faith requirement has been included because the statute does provide an exception to immunity. Immunity does not apply when the conduct constitutes "willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm by the heath care facility or health care professional." Public Health Law §3082[2]. It specifically provides that any actions taken as a result of staffing shortages or supply short- ages "shall not be considered willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm" Id. On August 3, 2020, the Legislature amended the Public Health Law to limit the immunity given to healthcare workers only to cases relating to "the diagnosis or treatment of COVID-19;" or "the assessment or care of an individual as it relates to COVID-19, when such individual has a confirmed or suspected case of COVID-19." This version of the statute applies to cases arising out of care rendered on or after August 3, 2020. Cases involving care rendered before August 3, 2020, will be subject to the terms of the original statute outlined above.

The Gross Negligence Standard

The only way, therefore, to pierce the statutory immunity provided by the Legislature is to establish that the acts or omissions with regard to treatment amount to gross negligence or its equivalent. In Sommer v. Federal Signal, 79 N.Y.2d 540 (1992), the Court of Appeals reviewed the distinction between ordinary negligence and gross negligence. The defendant in Sommer was an alarm system company who entered into a contract with its customer that limited the alarm company's liability in tort to gross negligence. A few days prior to the incident, the alarm company's customer asked that its system be deactivated because of construction work. The system continued to transmit information to the alarm company, but the alarm company did not report the information to authorities. A few days later, the customer called back and wanted the alarm reactivated. However, the alarm company employee was confused by the call. Instead of reactivating the system, the employee deactivated it. Thus, fire alarm signals were received by the company, but the employee did not call the fire department because he believed the customer had deactivated service. As a result, a four-alarm fire engulfed the property unchecked, causing significant damage.

The ***Sommer*** defendant moved for summary judgment and that motion was denied. In affirming that denial, the Court first defined the standard of gross negligence. The court held that gross negligence "is conduct that evinces reckless indifference to the rights of others." Id. at 554. The court then applied this standard to the evidence in ***Sommer*** and found there was a possibility that the defendant acted with gross negligence. "Another reasonable view of the evidence, however, is propounded [by the building owner]: that instead of pausing to dispel any confusion surrounding the subscriber's instruction to activate the system—without verification or investigation—rushed to his own conclusion, recklessly indifferent to the consequences that might flow from a misrepresentation." Id. at 555.

Gross Negligence in Response to COVID-19

As the Governor has pointed out, New York is likely going to be faced with a shortage of medical equipment, staff and hospital beds. Difficult decisions and actions will need to be made by health care providers. Indeed, Executive Order 202.10 modifies other provisions of the Education Law and New York Code related to work hours, staffing, and credentials in order to enable physicians to better respond to this mounting crisis. See, e.g., Education Law §§6530[32]; 6542[1]; 6549[1]; 8 NYCRR 29.2 (a)(3); 10 NYCRR §§58-1.11, 405.4[g][2][11], 405,4[b][6], 405.10, 405.13, 405.22. Recognizing this, the Legislature has made the policy determination that decisions with regard to staffing or supplies can never be considered gross negligence. Public Health Law §3082[2]. Put differently, health care providers and facilities are appropriately immune from suit when the claim arises out of staffing or supply issues. Furthermore, to the extent the statute allows for a gross negligence analysis with regard to treatment itself, it is important to note that gross negligence, like the standard of care, must reflect the realities of the situation when care was rendered. Any attempted future liability claim, therefore, cannot be judged within the context of the ordinary standard of medical care. These are extraordinary times and the ordinary standard of care is no longer applicable. Thus, in turn, gross negligence must also be viewed in the proper context of these extraordinary times and the difficult choices medical professionals have had to make under these circumstances.

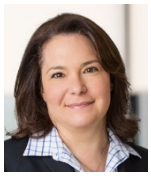
The Governor, through the powers granted to him by the Legislature, has taken the necessary steps to make sure that health care providers are insulated from claims of ordinary malpractice. The Legislature then took the next step in codifying these immunities in the Public Health Law. As a result, the fact patterns that could potentially meet the gross negligence standard, if any, should be very few and far between. Our medical professionals have risked and are continuing to risk their lives to protect and help us during this crisis. They deserve our continued support, understanding and protection as well. New York has taken the lead through executive and legislative action to protect its health care workers. These actions should serve as a model for other states to follow.

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Information Blocking: What Do I Do Next?

By Mario C. Giannettino

In March 2020 the U.S. Department of Health and Human Services (HHS) issued two rules designed to grant patients unprecedented access to their medical data. The rules, issued by the HHS Office of the National Coordinator for Health Information Technology (ONC) and The Centers for Medicare & Medicaid Services, implement interoperability and patient access provisions of the 21st Century Cures Act. The rules require healthcare "Actors" – i.e., providers, developers of health information technology, or health information exchanges – to provide patients with immediate, digital access to virtually all of their health records via a third-party application of the patient's choosing, such as smartphones, tablets or other mobile devices. The idea is that if patients have all their healthcare information in one place this flow of data will increase patient engagement and allow patients to view treatment options, compare costs and make informed health care decisions. While certain phases of the final rules were scheduled to launch in November 2020, they have been delayed to April 2021 to allow healthcare providers and their partners to concentrate on the Coronavirus pandemic. Even with additional time to prepare for implementation of the final rules many questions remain about the Cures Act and how it will be applied.

One such question revolves around "information blocking." Generally, information blocking is any practice that is likely to interfere with, prevent, or materially discourage the access, change or use of electronic health information. Information blocking encompasses any action that limits access to electronic health information, such as disabling or restricting the use of a particular app to receive EHI; refusing access to a patient's preferred software application (assuming there is not a legitimate security risk); imposing technical barriers between healthcare exchanges that would limit the flow of EHI; charging excessive fees; delaying the exchange of EHI if the provider has the capability to provide same day EHI; or requiring a patient's written consent before sharing electronic heath information with an unaffiliated provider.

The final rules interpret the information blocking prohibition broadly and require disclosure unless an appropriate exception can be identified and used. There are two categories of information blocking exceptions:

1. Not fulfilling requests to access, exchange, or use electronic health information

    a. Preventing harm exception
    b. Privacy exception
    c. Security exception
    d. Infeasibility exception
    e. Health Information Technology performance exception

2. Procedures for fulfilling requests to access, exchange, or use electronic health information

    a. Content and manner exception
    b. Fees exception
    c. Licensing exception

The nuances of each exception are highly technical and the ONC has tried to promote clarity by issuing guidance on each of the safe harbor provisions[1]. However, it remains to be seen how the guidance will actually be interpreted. Regardless, it is clear that the final rules are at their core fundamentally different than HIPAA, where a hugely complex body of federal regulation defines when protected health information is permitted, but is not required, to be exchanged. By contrast, information blocking regulations require Actors, unless a safe harbor exception applies, to provide access, exchange, and use of electronic health information.

In addition to the safe harbor exceptions, other situations exist that do not implicate information blocking such as when disclosure of health information is restricted by law (e.g., federal regulations that prevent the disclosure of substance abuse records; disclosure of HIV status; psychotherapy notes; and notes that the provider has a reasonable assumption could be used in a civil or criminal court case or administrative proceeding.) Information blocking also does not apply when there is expressed patient preference not to disclose the records; or specific and identifiable risk of physical harm to the patient.

Failure to meet one of the exceptions also does not automatically mean a practice actually constitutes information blocking. ONC has stated that "any conclusions

regarding (information blocking) would be based on fact-finding specific to each case and would need to consider the applicability of the exceptions[2]." This ambiguity brings to mind Justice Potter Stewart's famous threshold test for identifying obscenity: "I know it when I see it." This vagueness places risk managers and providers in a dilemma. For example, Patient X asks his doctor to send test results to an app which the patient has downloaded on to his phone. The doctor is concerned that the app is not secure and that the patient does not comprehend the security risks. Under information blocking the doctor is not permitted to withhold the records unless one of the safe harbors described above exists. The doctor is not sure what to do as s/he has no idea what potential penalties may be issued if denial of the patient's request constitutes information blocking.

There is another important point to underscore in our hypothetical physician example above: information blocking will be judged differently depending on the Actor. Both the Cures Act and the final rules contain an intent standard for the violation of the information blocking prohibition. For Developers[3], Health Information Networks and Health Information Exchanges[4], the intent standard is "knows, or should know" that a practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. For providers, the intent standard is "knows that such practice is unreasonable" and is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI[5]. You may ask why does this matter? The answer is that the HHS Office of the Inspector General may issue civil money penalties ($1,000,000 per incident) for information blocking. However, the foregoing penalty only applies to certified health IT developers and health networks/ exchanges. Providers are not subject to financial penalties by the Office of the Inspector General. Rather, healthcare providers will be subject to "appropriate disincentives" but to date, there is no clarification as to what form appropriate disincentives may take. However, healthcare providers can meet the definition of a developer of certified health IT under certain circumstances, meaning the provider *would* be exposed to the financial penalties.

Ultimately, how the final rules will be interpreted and enforced will only be clarified with future rule-making. What this means for the here and now is that until the final rule develops and is applied in concrete terms to real life situations, the entire healthcare spectrum will need to document their compliance with information blocking prohibitions and use of the safe harbor provisions.

Documentation will require articulating the specific facts and circumstances associated with the response to deny or restrict a patient's request for electronic health information. All Actors in the healthcare ecosystem must develop transparent and non-discriminatory organizational policies and data governance frameworks that address the criteria set forth in the Cures Act and final rules. Not only does this require training and education on the specific requirements and exceptions to the provisions but all existing contracts and agreements between physicians and other businesses, associates or entities need to be updated and revised as necessary to comply with the final rules.

As with any new set of regulations there will be a period of uncertainty concerning the Cures Act. From a risk mitigation standpoint, the lack of qualified legal advice, and case law adds layers of complexity to an already complex regulation. Clearly, the full impact of the final rules will require near and long-term actions at the regulatory, legislative and judicial levels to address the questions that currently exist and to provide peace of mind and clarity for healthcare organizations and their partners as they continue to navigate the Cures Act.

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Mario C. Giannettino is a partner at Kaufman, Borgeest & Ryan and his practice is in the firm's Medical Malpractice, General Litigation and Nursing Home and Long Care practice groups. He represents a range of health care professionals and providers including residential health care and assisted living facilities, physicians, physician's assistants, hospitals and home health agencies. In addition to defending suit from inception and through discovery, Mario also serves as a trial attorney. He has extensive experience in alternate dispute resolution methods, such as mediation and arbitration.

In addition to litigation, Mario provides a broad spectrum of services to clients, including staff training, in-servicing and risk assessment. Mario also provides a variety of services to assist in compliance with privacy and security under the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) with respect to the use, disclosure, exchange, retention and destruction of health information.

Mario regularly publishes and speaks nationally on matters relating to all aspects of health care defense. In addition to practicing throughout New York State, Mario serves as supervisory/monitoring counsel for residential health care facilities nationwide and is also admitted to practice law in the State of Connecticut.

Mental Health Concerns and the Importance of Self-Care During COVID-19

By Carolyn Reinach Wolf and Jamie A. Rosen

The COVID-19 pandemic is taking a major toll on our collective mental health. Even with vaccines being distributed across the world, we still face uncertainty in our daily lives. Couple that with civil unrest and political tension and we have the perfect storm for a mental health crisis. One year later we are still dealing with anxiety, confusion, and judgment from others as we continue to manage our "new normal". We must all take steps to monitor our mental health and engage in personal and professional self-care. It is important to know the signs of stress in yourself, your loved ones, and your colleagues, identify those red flags, and implement coping mechanisms to minimize the impact of fear and anxiety.

Everyone reacts differently to stressful situations. Some individuals have strong coping skills and solid support systems. Others face one or more serious risk factors. Look out for signs of serious distress and anxiety such as excessive worrying, increased irritability, changes in appetite and energy, difficulty concentrating, difficulty sleeping or nightmares, and increased use of alcohol or drugs. Given the encouragement, and in some cases, mandates, to isolate ourselves or self-quarantine, be especially cognizant of signs of depression such as feelings of hopelessness or sadness, inability to carry out activities of daily living, or sleeping too much.

There are several things that everyone can do to reduce stress and cope with anxiety. While it is important to stay informed, it is equally important to take breaks from watching, reading or listening to the news, including social media. Second, take care of your physical health. Stretch, meditate, journal, get enough sleep, and continue to eat as healthy as possible. Despite the recommendations for "social distancing", it is important to keep in touch with your friends, family and colleagues. Regular phone calls, text messages or video chats are encouraged. If you are working remotely, hold virtual team meetings to help coworkers stay connected.

In addition to personal self-care, everyone must also engage in professional self-care to avoid work burnout. Many of us have returned to work in healthcare facilities or offices, operating our businesses in completely new ways with new protocols and procedures to keep everyone as safe as possible. We must stay current on the Governor's Executive Orders as well as Federal, State and local regulations to maintain and constantly update the new safety precautions. Many of us have been exposed to illness and maybe even experienced the death of a loved one or a patient. Part of self-care and avoiding burnout is taking time to grieve, creating appropriate professional boundaries, and learning effective coping strategies. Take an actual lunch break, go for a walk outside, and take your vacation days, even if not travelling. Understand that it is acceptable, and even encouraged, to seek out a mental health professional and talk about anxiety, triggers, and fears. For example, Lawyer Assistance Programs provide free, confidential mental health services to the legal community including peer support, crisis intervention and referrals.

Once we have taken proper care of ourselves, putting on our own oxygen masks first, then we must look outward to our colleagues and clients. For example, legal professionals must maintain contact with clients and continually educate them on their legal options and rights, which frequently change pursuant to different Executive Orders and court rules. Being flexible is key, as plans and business strategies change. We must also manage client expectations and anxieties about how the pandemic is affecting their business or causing other complications. Assure clients that you are always available to assist them, in good times and in bad times.

As mental health attorneys who work closely with families coping with loved ones' emotional distress, as well as serious mental health and substance abuse issues, the volume of calls has increased during this pandemic. There is no shame in relying on our friends and family in a time of crisis as well as turning to experts for information and advice.

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Keeping the Patient's Perspective

By Samantha E. Quinn, Pamela Monastero, and Dr. Julie Monroe

For over ten years, I have made contributions to the AHRMNY Risk Management Journal in my role as a medical malpractice defense litigator. Today, I am writing from a different perspective – that of a patient. Having recently had a lot of experience as a patient has changed the way I approach my job. And despite the fact that the "lawyer" part of me understood the reasoning behind certain events as I was experiencing them, they were nonetheless difficult for me as the "patient." Therefore, having gained the benefit of this new perspective, I want to be sure to keep it in mind in my work going forward. I can only imagine how relevant this perspective is for those actually on the front lines with patients, rather than those who, like me, deal with issues forensically. I am therefore grateful to have the privilege of being joined in this column by both a Risk Manager and a Physician, to give the benefit of their perspectives as well. In each AHRMNY Risk Management Journal, we will discuss a new topic, addressed from these various points of view, and in doing so, we hope to highlight the importance of always keeping the patient's perspective.



Discussing Difficult Diagnosis: How Much is Too Much?

From the Patient's Perspective

As a lawyer, I've done countless depositions where I asked a plaintiff to describe conversations with his/her doctor and details of a visit. I was often struck by how much the patient's recollection differed from the chart. As a patient, however, I have recently taken note of how difficult it actually is to recall details of visits and conversations, particularly when the information imparted during the visit is unexpected or traumatic. I have tried to recall the discussions the day of my own difficult diagnosis and my recollection is spotty at best.

What I do recall is that, despite the importance of the conversation and my role in being adequately informed to make treatment decisions, there was only so much I was able to process at that time. From the patient's perspective, I wanted to know that there was a plan, but also wanted to be told the details on a "need to know" basis. Additionally, and this may seem contradictory, I wanted to know the whole story. In other words, I wanted to know everything, but only in so much detail as I needed and could handle.

Thankfully, my doctor knew what was enough but not too much information to share. Despite my questions about all the details of the expected treatment and my prognosis, she did not overwhelm me with information at that first visit. In retrospect, I absolutely would have been overwhelmed to know then what I know now. She was, however, very frank with me about prognosis in our subsequent conversations. I recall a conversation early on where I had just gotten reassuring test results and we were discussing the next step for treatment. I asked what would have differed had the test gone the other way. I was shocked when she told me that the treatment would have been less aggressive since the goal wouldn't have been a cure. But I knew from that conversation that I could trust when she did tell me something was going to be OK, which is really important for a patient to know.

The most important takeaway that I have from my own experience is that I probably only absorbed a small percentage of the conversation that first day. Therefore, a physician delivering a difficult diagnosis has to be very cognizant of the fact that not everything they are saying is going to be heard and understood. A few possible strategies for countering this are to provide written materials when possible, to provide a detailed visit summary in your own notes which can be shared with the patient, to assume the patient has little or no medical background when making your explanations, and to encourage questions and / or note taking. Having another person present at the visit, which may not always be feasible, can be helpful, but may not be depending upon that person's medical savvy and his or her own emotional constraints.

I really benefitted from the printed materials which I was given and went back and reviewed those at home when I was unclear in my recollection of events, and when emotions had subsided. I also learned for future visits to go with a list of questions and write things down. Ultimately, though, it is a part of the art of practicing medicine to know when enough, but not too much information, has been conveyed to the patient. The issue of prognosis, treatment options, second opinions, realistic outlook, and emphasizing the importance of hope without making unrealistic promises are all part of this delicate balance. One should also avoid "defensive doctoring" (more on this in a future

column) – i.e. – discussing every conceivable risk, regardless of how remote, with the mindset that everything should be included in case of a future lawsuit. Because of my profession, I see "defensive doctoring" all too often, and it creates needless anxiety. So, it is great to be thorough and consider everything, but there has to be a balance, and good communication is paramount. And of course, careful documentation of your conversation is essential, both so that the patient can refer back to it, and also in case there is a future litigation.

In sum, if you haven't actually sat on the other side of the desk, it is important to try to put yourself there before having the difficult diagnosis discussion. The patient's anxiety and perhaps limited capability for processing information in the wake of a difficult diagnosis is not to be underestimated. It is essential to be truthful, but difficult news must be delivered at the appropriate time and with compassion. I say this as a patient, and not a lawyer, but in the end, treating patients with humanity and concern is likely the best defense against a future lawsuit there is.

From the Patient Safety/Risk Manager Perspective:

Sam's story and experience is very powerful. Despite being educated, intelligent and well-versed in medicine, she struggled when presented with a serious and unexpected diagnosis and admits to having absorbed this information fractionally. Sam highlights the importance of having the support of a friend or family member for key office visits. The conflicting position of simultaneously wanting to know everything about a diagnosis versus wanting information on a "need-to-know" basis, overlayed by one's inability to absorb what is being imparted, is a challenge for all physicians. What can physicians do to ensure that patients have a full understanding of their diagnosis and treatment options?

1. If the patient is unaccompanied, encourage the patient to call a significant other/family member/friend to be present (even virtually) for this discussion if possible. Alternatively, offer to schedule time to speak to the patient and their support person in the immediate near future.
2. Speak in simple, laymen's terms, even when addressing the well-educated, medically savvy patient. Regardless of a patient's health literacy and English language skills (e.g., patients with limited English-proficiency, those who speak other languages, those who may be uneducated or unsophisticated), the physician's job is to communicate clearly and succinctly and to ensure that the message is heard and understood. Consider the patient's emotional and mental status when conveying a life altering diagnosis—be empathetic, this is critical for the patient's psyche. Be realistic and honest regarding the patient's prognosis but, again, consider a patient's psyche in cases that appear hopeless—remember that while a patient needs to understand the reality and gravity of a diagnosis, they also need to hold onto some shred of hope as mental well-being is definitely related to physical health. Nothing is more powerful than hope!
3. As Sam mentioned, it is helpful to provide written material (after visit summary, next steps e.g., consults, literature related to the diagnosis and prognosis, etc.)
4. Sam also touched briefly on defensive medicine and the importance of documentation in the medical record. She highlighted balancing information shared with the patient, and that this should be tailored to the individual patient and their circumstances. Again, when possible, the provider should consider social detriments of health, health literacy, etc. when speaking with patients about their diagnosis and treatment options. Documenting in this way also imparts that the provider is knowledgeable about his or her patient, is engaged and empathetic to the patient.

From the Physician's Perspective:

In considering how much is too much when it comes to information, my goal is to do my best to avoid any surprises for my patients and their families without overwhelming them.

Sam's experience of remembering only a fraction of the information presented to her during consultations with her physicians is not an unusual one. In fact, studies have shown that most patients only properly recall one-third of the information relayed to them during doctors' appointments. For this reason, I always encourage patients to bring family members or friends with them to their consultations and if they cannot be present in person, have them on the telephone or, more often now, on the telehealth platform. It's usually best if one person other than the patient takes notes during the visit. At the end of each visit, I try to summarize our plan and next steps so it is clear to all.

If a patient's condition requires multiple treatment modalities such as surgery, chemotherapy and radiation therapy, I lay out a broad bird's-eye view of the treatment plan but avoid going into too much detail of each step in the treatment process. Rather, I focus on the important information for the first modality of treatment knowing there is time in the future to discuss the other steps along the way.

When discussing possible risks or side effects of treatments, it's important not to overwhelm with a laundry list of possibilities, as is often done on pharmaceutical advertisements. I make a point of describing the most common side effects with information on how likely it is to happen, when to expect it, how it will feel and what can be done if it does occur avoiding overly medical terminology. I also try to mention any potentially serious side effects or complications but again, put it in perspective in terms of how likely or unlikely it is to occur. Once again, my objective is to do my best to make sure patients

are prepared and do not experience any surprises as they proceed with their treatment.

During follow up visits, I try to repeat the important information discussed previously, erring on the side of repetition rather than having things forgotten or missed. Even when the patient is only coming in for a short follow up visit during chemotherapy, as busy as I may be, I try to make a point of sitting down and asking the patient if they have any questions. When physicians are standing, or even worse, standing with one foot towards the door, patients are less likely to feel comfortable asking questions assuming the doctor is too busy to answer them. This can create a lot of anxiety around simple questions that go unanswered because they were not given the opportunity to ask.

In terms of prognosis, I find the question of how much is too much really depends on each individual patient and where they are in their disease course. As an oncologist, I often meet with patients for the first time knowing they have a terminal condition – one for which there is no cure and are likely to have a limited life expectancy. Yet, that is not typically a discussion I have with them at that first visit. It's important to present them with hope while avoiding false promises or expectations. I focus on how we can treat the disease and the goals of treatment but make it clear that cure is not one of them.

I view my responsibility in treating such patients and families, to gradually ease them into the reality of their condition, to allow them the time to come to terms with and eventually accept their fate. The discussions become more and more frank as their disease progresses. The timeline for such gradual transition can be different for each patient and family. Part of the art of medicine is knowing when each patient is ready to hear the news and have the discussions. It's important to take cues from the patient themselves.

They often do not ask but when patients do inquire about prognosis, it's important for physicians to answer truthfully and honestly. I recall a case in which a young woman with terminal cancer was being treated by a colleague. She had a very aggressive malignancy with limited life expectancy and was clearly not doing well. At each visit she appeared weaker and weaker. When she and her husband asked the treating physician on several occasions how much time she had left, the physician replied with a pat on the shoulder, "Oh don't worry you'll be fine." The physician himself was clearly uncomfortable having the discussion and perhaps felt like a failure for not being able to cure the patient. However, this left the young couple confused. Her deteriorating condition suggested she was dying but the doctor said she would be "fine". When she passed a few weeks later it was no surprise to the medical team caring for her but it was a big shock to the family. She had two young children who were completely unprepared to lose their mother and family overseas who would have flown in to be with her had they known the end was near. The case itself was a tragedy but perhaps the even greater tragedy was how it left the mourning family. The husband was so distressed he asked to come in to the office after his wife's passing to question the physician on why he wasn't honest with them. Again, if communication is done properly there should never be any surprises for patients and families.

Of course, there are times when surprises do happen and we're not always allotted the benefit of time to have these discussions and allow patients and families to come to terms with adverse outcomes. There are medical emergencies where frank discussions must take place immediately and it's important for physicians to show compassion as they convey such information in a truthful yet empathetic way.

About the Authors



Samantha E. Quinn is a partner with the firm of Schiavetti, Corgan, DiEdwards, Weinberg & Nicholson, LLP, which specializes in the defense of hospitals, doctors and other health care providers. She heads the office's appellate practice, and has briefed and argued appeals in New York's highest Court, the Court of Appeals, as well as New York's First and Second Appellate Departments. She has also had significant success overturning unsuccessful verdicts in post-trial applications, including obtaining JNOVs on several multi million-dollar Bronx verdicts which were later upheld on appeal. Ms. Quinn has handled Office of Professional Medical Conduct investigations for individual physicians, treatment over objection applications for hospital clients and has counseled hospital clients during the course of Department of Health investigations and other quality assurance matters. Ms. Quinn has a Bachelor of Arts in History from Brown University and a Juris Doctor from Boston College Law School. She has been a contributing author to the AHRMNY Journal since 2007.



Pamela Monastero has over twenty-five years of experience in patient safety and risk/quality management. She holds the position of Assistant Director, Patient Safety/Risk Management at NYU Langone Hospital-Brooklyn. In 2011 and 2012, she assisted in coordinating the evacuation of patients for Hurricane Irene and Super Storm Sandy. In 2015, Ms. Monastero received the Patient Safety Champion award from New York City Health + Hospitals for development and implementation of the close call reporting program. She is a former President and Treasurer of the AHRMNY. She is an active member of the Publications Committee and authors the "Risky Business" column for The Risk Management Journal on topics of relevance to risk, quality and patient safety managers. She is bronze-level trained in LEAN methodology. She also holds BBA and MBA degrees from Pace University.



Julie Monroe is a board-certified hematologist and medical oncologist with over twenty years' experience practicing oncology in Westchester County, NY. Formerly Chair of the Department of Hematology and Oncology at White Plains Hospital, she is currently a Concierge Oncology Consultant at Cancer Consulting Services. She is also a bioethics consultant and Chairs the Bioethics Committee at White Plains Hospital. She serves as the Physician Liaison to the Commission on Cancer for the White Plains Hospital Cancer Center where she oversees quality improvement projects. After graduating from Cornell University Medical College, Dr. Monroe trained at New York Presbyterian Hospital-Cornell Medical Center and Memorial Sloan Kettering Cancer Center. Developing a reputation as a leader in her field, Dr. Monroe was voted by her peers over multiple years as one of Westchester Magazines Best Doctors in Oncology.

AHRMNY Webinar Summary

Telehealth and the Covid-19 Pandemic Regulations and Risk

by Samantha E. Quinn



On September 23, 2020, AHMRNY sponsored its first educational webinar of the 2020 – 2021 year on telehealth and its evolution during the COVID-19 pandemic. The webinar was presented by Joanna Bergmann, Esq., MPH, Mbe, Senior Associate General Counsel for the Office of Legal Affairs at Northwell Health, Melody Mahla, Esq., Director of Insurance & Risk Management at Northwell Health, and Lisa Gibbons, Esq., MA, Claims Counsel in the Risk Management Department at Northwell Health. The following will summarize the highlights of the program.

Ms. Bergman began the program with an overview of telehealth, a discussion of how it has evolved during the COVID-19 pandemic, and what this means from a risk management perspective. The definition of telehealth is "the delivery of health care services remotely through the use of electronic information and communication technologies." Telehealth may include assessment, diagnosis, consultation, treatment, education, care management and/or self-management of a patient performed remotely. As one might expect, telehealth services have increased significantly (approximately 64%) during the pandemic. It is likely that telehealth will remain a key component in the practice of medicine even after COVID restrictions are no longer in place. However, the current regulatory landscape is dynamic and unstable due to the emergent nature of certain accommodations.

Essentially, telehealth is meant to be a virtual version of what was previously an in-person encounter, and a key aspect of telehealth is whether it will be reimbursable. Although the scope of services which are reimbursable has not changed due to the pandemic, the key question being whether the service is clinically appropriate, both the eligible provider types and the eligible modalities have been expanded. There are also issues regarding the location of the patient and provider which have evolved.

The list of qualified providers under Medicare was expanded under COVID to include physical therapists, occupational therapists, and speech language pathologists. Under Medicaid, all restrictions on provider type were waived for COVID; in other words, as long as the services are appropriate for telehealth and within the provider's scope of practice, they are allowed. Similarly, the list of eligible modalities has been expanded under both Medicare and Medicaid during COVID. Previously, Medicare required, at a minimum, audio and video equipment permitting two-way, real-time interactive communications between the patient and the distant site provider; specifically excluded telephones, fax machines and email, and required HIPAA compliance. As a result of COVID, the Office of Civil Rights gave notice of "enforcement discretion" and has allowed providers during the emergency to use any non-public facing remote communication product which is available to communicate with patients. Similarly, Medicaid limited telehealth to HIPAA compliant two-way audiovisual communications before the pandemic but has expanded modalities to include audio-only (i.e. telephone) communication going forward.

Another critical aspect of telehealth from a regulatory perspective is the location of the patient and the provider. Because telehealth opens up the possibility that the patient may be located in a different state, the issue of state licensure must be addressed. The basic rule is that the provider must be licensed in the state in which the patient is located. However, during COVID, CMS has waived the requirement that an out of state provider be licensed in the state where the patient is located if the provider is licensed in another state and the following conditions are met:

1. the provider is enrolled in Medicare;
2. the provider possesses a valid license to practice in the state, which relates to his or her Medicare enrollment.
3. the provider is furnishing services in a state in which the emergency is occurring in order to contribute to relief efforts in his/her professional capacity; and
4. the provider is not excluded from practice in the state or any other state.

Additionally, prior to the pandemic, both Medicare and Medicaid had specific requirements about where the patient was to be located (a/k/a "originating site"), most notably, that under Medicare, a patient couldn't receive services from home. These restrictions have been waived for COVID. With respect to the provider location (a/k/a "distant site"), any secure site was acceptable prior to COVID, and that remains the rule. Finally, several other limitations regarding new patients, credentialing and informed consent have been waived or modified due to the pandemic in order to facilitate making telehealth more accessible. It should be noted that although many of these changes are for the duration of the emergency, the extent to which regulations will revert to being more restrictive after COVID cannot be determined.

Ms. Mahla continued the program with a discussion of insurance and risk considerations regarding telehealth and COVID. The applicable policies include professional liability/errors & omissions (medical malpractice)

and cyber/privacy breach liability. Interestingly, the expansion of telehealth services raises the issue of international insurance coverage, since it is now possible that a provider could be rendering medical treatment via telehealth outside of the United States. More likely, however, providers will have to deal with insurance coverage issues across state lines.

The first consideration regarding malpractice insurance coverage is the specific language of a provider's policy. Anyone rendering telehealth services should review his/her coverage to see whether telehealth is specifically included, specifically excluded, or whether the policy is silent as to telehealth coverage. Best practice is to consult your insurance broker to clarify anything which is unclear. Additionally, language regarding the policy territory should be reviewed to determine whether there are any limitations or jurisdictional restrictions of coverage. Certain states require minimum insurance coverage limits to be maintained by medical professionals, and also, there are states which require that the insurer be licensed in that state in order for the insured practitioner to be covered under the state guarantee fund.

Another critical question regarding insurance is what will be considered the location of the medical incident if the provider and the patient are in two different jurisdictions. This could affect insurance coverage if the policy is jurisdictionally limited. As an insurer, particularly in an international context, it is important to consider a jurisdiction's malpractice coverage requirements and whether it allows non-admitted carriers to provide insurance coverage, or whether a local policy would be required. If an insurer is considering coverage which may span different states, the state specific requirements regarding coverage limits and insurer licensure must be reviewed. The nature of the jurisdiction in terms of litigiousness and damage awards should also be considered. Internationally, this can be even more of a concern since in addition to coverage limits, insurer licensure requirements and litigation climate, egregious malpractice can be considered criminal in some foreign countries.

In addition to malpractice insurance considerations, there are cyber/privacy liability concerns with respect to telehealth. It is prudent to either purchase a cyber liability policy or to add cyber coverage as a rider to an existing malpractice policy. It is also important to ensure the security and HIPAA compliance of your treatment platforms, such as Zoom, WebEx, etc. Executing Business Associate Agreements (BAAs) with the platform providers is a good opportunity to transfer risk and limit liability.

The final segment of the webinar was given by Ms. Gibbons, and dealt with managing telehealth malpractice claims. Some of the malpractice considerations overlap with the regulatory and insurance issues discussed above. There are also some issues which are unique to managing malpractice claims from telehealth, and some advantages to telemedicine which include the ability to engage a second opinion from a distant location, patient data collection and analytics, and possible minimization of medical errors.

The overlapping areas include possible liability exposure for unlicensed practice if the patient is in a different state than the provider, and one where the provider is not licensed. Although this is a burgeoning area of both medicine and law, it seems that the assumption is being made that the locus of the "treatment" will be considered the location of the patient. This can result in physicians inadvertently exceeding the scope of their medical licenses as telemedicine crosses state lines. It can also result in practitioners being held to different standards of care, subject to different statutes of limitations, and perhaps being brought to court in unfavorable (from a litigation point of view) jurisdictions. One suggestion discussed during the webinar was to clarify and document the location of the patient as a standard part of the telehealth visit. Another potentially problematic area which overlaps with the insurance and regulatory perspectives is liability from failed communications (technological failure) or a security breach.

There are also "negligence" concerns which may be either unique to telehealth or exacerbated by rendering medical care via a remote platform. For example, the limitations of doing a "physical examination" of a "virtual patient" are obvious. It is incumbent upon the remote practitioner to realize the limitations of a telemedicine visit and if he or she is not able to assess the patient sufficiently using that modality, an in-person visit must be recommended. In fact, most of the existing telemedicine liability cases deal with negligent prescription of medication over state lines without a sufficient examination of the patient.

Telehealth practice may also be more susceptible to incorrect reading of testing / imaging due to distortion, miscommunication among providers as to the urgency of an assessment, misdiagnosis, and inadequate monitoring. As with in-person treatment, thorough contemporaneous documentation is essential. Additionally, hospitals and providers should consider drafting specific telemedicine guidelines and informed consent forms which include privacy concerns specific to telemedicine. Of course, when there is a bad outcome, the argument will always be made that there should have been in-person rather than virtual treatment. But the benefits of the accessibility of telehealth will need to be weighed against that risk.

About the Author



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Million Dollar Claims……from page 4

[1] The Medical Professional Liability Association (MPL Association) is the insurance industry trade association that represents a full range of entities doing business in the medical professional liability (malpractice) arena. The MPL Association's Data Sharing Project (DSP) was created to provide critical information needed to pinpoint areas of medical practice that have proven most vulnerable to MPL claims, as well as support efforts seeking effective medical liability reform.
[2] ECRI is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings worldwide.

COVID-19 Immunity Laws (PREP Act)……from page 8

[1] 42 U.S.C. § 247d-6d.
[2] 42 U.S.C. § 247d-6d(c)(3).
[3] 42 U.S.C. § 247d-6d(i)(7) and other sections.
[4] 42 USC § 247d-6d(i)(7)(A).
[5] 42 U.S.C. § 262.
[6] Id. § 247d-6d(i)(7)(B) and 21 U.S.C. § 360bbb-3(b)(1)(C).
[7] See, 85 Fed. Reg. 15,198, 15,202 (March 17, 2020) and 42 U.S.C. § 247d-6d(i)(1)(D).
[8] See, https://www.fda.gov/media/136702/download; Appendix B and https://www.fda.gov/media/136832/ download
[9] 42 U.S.C. § 247d-6d(i)(2).
[10] 42 U.S.C. § 247d-6d(i)(8). The Act also extends to volunteers.
[11] See, e.g., 42 U.S.C. § 247d-6d(a)(4)(B). Similarly, if the product is not a covered countermeasure if the person or entity reasonably could have believed that the product was a covered countermeasure, they will be provided immunity.
[12] (42 USC § 247d-6d(d)(1).
[13] 42 U.S.C. § 247d-6d(e)(1), (5). 42 U.S.C. and § 247d-6d(c)(3).
[14] Public Health Law § 3082(2).
[15] Id.
[16] Public Health Law § 3082(3).

Remote Mental Hygiene Hearings……..……from page 18

[1] Order of Chief Administrative Judge Lawrence K. Marks

Information Blocking……..……from page 23

[1] https://www.healthit.gov/curesrule/resources/information-blocking-faqs
[2] 85 Fed. Reg. at 25,812
[3] See, 45 C.F.R. § 171.102, for definition of health IT developer,
[4] Health information network or health information exchange means an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information: 1. Among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and 2. That is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164.
[5] 42 U.S.C.A. §300JJ-52.

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