MIEC

The Exchange

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INSIDE

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From The Chairman of the Board

James O. Gemmer, MD, Chairman MIEC Board of Governors

Dear California MIEC Policyholders:

It is now official. Proponents of an initiative to make it easier and more profitable for lawyers to sue doctors, hospitals, and health care providers have qualified a measure for the November 2014 ballot.

MIEC has joined Patients and Providers to Protect Access and Contain Health Costs, a broad and bipartisan coalition of doctors, community health centers, hospitals, local governments, public safety groups, professional liability carriers, and business and labor groups, to fight this trial lawyer-funded ballot measure.

The lawyers want to make it easier to sue health care providers by weakening California's Medical Injury Compensation Reform Act (or MICRA) law by quadrupling MICRA's non-economic damages cap from $250,000 to $1.1 million. It should not be surprising that 100% of the funding for the signature gathering campaign came from trial lawyers and their allies. It should also not be any surprise that the lawyers' change will triple the amount of money that plaintiffs' lawyers will make on the non-economic portion of awards unless we defeat this misguided measure.

Background on California's MICRA

California's MICRA applies in legal proceedings when someone is injured while receiving medical treatment. The law ensures that injured patients receive fair compensation, and also preserves patients' access to health care by including disincentives for lawyers to file meritless lawsuits against health care providers which do nothing but increase health care costs. In turn, this keeps medical liability rates low for doctors, nurses, and health care providers so they can remain in practice, treating patients.

MICRA preserves patients' access to fair compensation when they have justifiable claims, including:

- UNLIMITED compensation for all economic or out-of-pocket costs for past and future medical care;
- UNLIMITED compensation for any past and future lost wages or lost earning potential;
- UNLIMITED compensation for punitive damages; and
- Up to $250,000 for non-economic damages.
  - ➤ The $250,000 cap reduces incentives to file meritless lawsuits, while at the same time ensures that legitimate claims can move forward.

Prior to the passage of MICRA, California was in a medical liability crisis. Lawsuits against health care providers filed by enterprising attorneys were driving medical liability premiums sky high. With MICRA, medical liability rates have stabilized and health care consumers have saved billions of dollars. Since its inception, lawyers have been trying to change MICRA's non-economic damages cap, but have failed. Now they have turned to the ballot.

Ballot measure provisions

In addition to the MICRA provisions, the lawyers have deceptively included other provisions in a crass attempt to lure voter support. Key provisions of the measure:

Quadruples MICRA's non-economic damages cap

The ballot proposition's main provision will quadruple MICRA's non-economic damages cap—from the current $250,000 to nearly $1.1 million. This single change will triple lawyers' legal fees in these types of health care lawsuits. Lawyers will make more money, but providers, consumers, and taxpayers will see higher health care costs.

Additional voter "sweeteners" added

The measure contains two other provisions dealing with drug testing and prescription drug databases which have been included to act as a voter sweetener, an attempt to disguise the MICRA change and the financial benefit to lawyers. One of supporters of the proposition admitted it. According to the Los Angeles Times: "The drug rules are in the initiative because they poll well, and the backers figure that's the way to get the public to support the measure. 'It's the ultimate sweetener,' says Jamie Court, the head of Consumer Watchdog."

As California Medical Association (CMA) President Dr. Richard Thorp recently stated, "[The drug testing and CURES monitoring] are only 'window dressing'…"; the real purpose of the law is to increase the cap for non-economic damages from $250,000 to $1.1 million.

I have a few thoughts I'd like to offer for your consideration as practicing physicians in the state of California and as owners of MIEC.

Consequences of the lawyers' measure are costly and disruptive to patients

This ballot measure will be costly for providers, consumers, and taxpayers

If medical lawsuits are increased,

somebody has to pay, and that will be physicians through higher liability rates. Today, California has among the lowest medical liability rates in the nation.

Consumers and taxpayers also will feel the hit. According to a study by California's former Legislative Analyst, this proposition will increase health care costs across all sectors by $9.9 billion annually, or about $1,000 for a family of four. Furthermore, California's current independent Legislative Analyst's Office (LAO) warns that the proposition could increase state and local government medical liability and health care costs by "hundreds of millions of dollars annually."

This ballot measure will also jeopardize patient access to quality health care

As you know, cost pressures on health care providers could cause doctors to leave the state and practice in places where malpractice insurance rates are lower. Many people could lose their personal physician if this measure were to become law.

Community health centers, such as Planned Parenthood Affiliates of California, say this measure will raise insurance costs that will cause specialists, including OBGYNs, to reduce or eliminate services to their patients. Finding doctors to deliver babies in rural areas and work in community clinics is already difficult, and reducing services will make a bad situation worse.

Additional problems for physicians

CURES Database Problems Could Jeopardize Patient Access to Needed Medications: The Controlled Substance Utilization Review and Evaluation System (CURES) database today lacks important functionality, preventing doctors and other prescribing health care providers from complying with the provisions in the trial lawyers' health care lawsuit ballot measure—thus jeopardizing patient access to needed medications.

The proposition mandates that licensed health care practitioners and pharmacists consult the CURES database prior to prescribing or dispensing Schedule II or Schedule III controlled substances. This new mandate takes effect the day after the November 2014 election—an impossible implementation timeline given the current state of CURES.

Without an upgraded CURES database and improved functionality, prescribing health care providers and pharmacists would be legally required to use a database that has, in practice, not been available. According to a recent review of the CURES database and the provisions in the ballot measure, *"providers would face the choice of denying treatment to their patients or violating the stated terms of the initiative."*

Drug Testing Provisions Impose A Presumption Of Professional Negligence: This ballot measure also flips on its head "innocent until proven guilty," and instead institutes a presumption of professional negligence in any action against a health care provider arising from:

- an act or omission by a physician or surgeon who tested positive for drugs or alcohol
- an act or omission by a physician or surgeon who refused or failed to take a test for drugs or alcohol
- the failure of a health care practitioner to comply with the mandatory CURES rules

Here's how you can get involved.

As the first doctor-owned professional liability insurance company formed during the malpractice crisis, MIEC stands resolute in joining with Patients and Providers to Protect Access and Contain Health Costs to oppose the trial-lawyer-sponsored ballot measure that will increase health care costs and reduce patient access to care.

I urge you to join medical associations, community clinics, public safety groups, local government groups, professional liability carriers, hospitals, dentists, business and taxpayer groups and many others to help defeat the ballot measure in November. The Board of Governors of MIEC asks for your support in the following ways:

Visit the No campaign website. From the website you can:

- Sign up to **become an official opponent:** http://stophigherhealthcarecosts.com. When you sign up to be an official opponent, you will receive frequent campaign updates and important campaign news.
- **Get important facts,** downloads and information that will help you spread the word about this costly measure: http://stophigherhealthcarecosts.com/.
- **Send an email** to your organization's members, to your friends and/or to your colleagues encouraging them to sign up with the campaign to oppose the measure: http://stophigherhealthcarecosts.com/take-action/tell-a-friend.
- **Be part of our outreach team.** Get campaign talking points and materials so you can talk to your patients about this ballot measure. Send an email to info@stophigherhealthcarecosts.com. The campaign will enroll you in a special provider outreach program. You'll receive pamphlets and other materials to help you explain to your patients why they should oppose this flawed ballot measure.
- **Participate in message/media training.** The campaign also is looking for physicians interested in taking on a more public role speaking to community groups about why this ballot measure should be defeated. Send an email to info@stophigherhealthcarecosts.com if you want to participate in the media training being offered by the campaign.
- If you haven't already, **join your county medical society and the CMA.** They advocate for all physicians and play a key role in defending MICRA.
- **Contribute to MIEC's Political Action Committee (PAC).** This support helps MICRA-friendly candidates win elections and serve in the State Legislature. To learn how to contribute, contact MIEC at 510/428-9411 or toll free at 800/227-4527.

You can also contact your local medical society, CMA, or MIEC. The defeat of this measure is very important for the future of healthcare in California and we need all hands on deck.

It is early, but the campaign has been underway for months to plan our best strategy. We have hired the best consultants to manage the campaign. We have conducted polls, had focus groups, and tested messages. We are ready for a contentious campaign, but need your help to ensure victory in November.

Sincerely,

James O. Gemmer, MD, Chairman
MIEC Board of Governors

Telemedicine and its evolution

Telemedicine is no longer an adjunct to the practice of medicine; rather, it is becoming integrally woven into the modern day delivery of healthcare, health education, and more, under the overarching concept of "telehealth."

According to the National Telehealth Policy Resource Center (http://telehealthpolicy.us), telehealth is defined as ". . . the use of electronic information and telecommunications technologies to support distance clinical health care, patient and professional health-related education, public health and health administration . . . The term telehealth is often used interchangeably with telemedicine. However, telehealth is becoming increasingly more common as it recognizes the use and importance of telecommunications technology in related fields outside of clinical medicine. These include public health, mental/behavioral health, oral health, eye care and allied health disciplines such as occupational therapy and speech pathology."[1] *The American Telemedicine Association (ATA) (http://www.americantelemed.org) adds: "Telemedicine is not a separate medical specialty. Products and services related to telemedicine are often part of a larger investment by health care institutions in either information technology or the delivery of clinical care. Even in the reimbursement fee structure, there is usually no distinction made between services provided on site and those provided through telemedicine and often no separate coding required for billing of remote services. ATA has historically considered telemedicine and telehealth to be interchangeable terms, encompassing a wide definition of remote health care. Patient consultations via video conferencing, transmission of still images, e-health including patient portals, remote monitoring of vital signs, continuing medical education, consumer-focused wireless applications and nursing call centers, among other applications, are all considered part of telemedicine and telehealth."*[2]

Three primary types of technology encompass telehealth medical services today. **Video conferencing** is used for real-time physician-patient consultations, discussions between health care providers, and language translation services.

Federation of State Medical Boards release updated Telemedicine model

On April 26, 2014, representatives from state medical licensing boards approved the Federation of State Medical Boards' (FSMB) updated *Model for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*.

A key provision of the revised model states that the "standards of care that have historically protected patients during in-person medical encounters must apply to medical care delivered electronically. Care providers using telemedicine must establish a credible patient-physician relationship, ensuring that patients are properly evaluated and treated and that providers adhere to well-established principles guiding privacy and security of personal health information, informed consent, safe prescribing," appropriate record-keeping, physician licensure within the state where the patient is located, continuity of care, and more.

Unfortunately, the model has created some confusion as to the definition of telemedicine when it states, "Generally, telemedicine is not an audio-only, telephone conversation, email/instant messaging conversation, or fax." In a letter to the FSMB in advance of the model's approval, The American Telemedicine Association warned that telephone communication is an important tool within patient interactions and will account for approximately 250,000 telephone-based consultations made by two web-based providers alone within any given year. The letter stated:

"Use of the word 'generally' in the existing language does not clarify the problem of a rigid policy disallowing any use of telephones or emails as telemedicine. State policies that prohibit any such use could set back the practice of medicine and significantly limit the delivery of care."

Sources:

- Federation of State Medical Boards news release, dated 4/26/2014.
- Federation of State Medical Boards Model for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.
- http://medicaleconomics.modernmedicine.com/medical-economics/news/news/new-telemedicine-guidelines-emphasize-video-rather-audio, 5/15/2014.

1 http://telehealthpolicy.us/what-telehealth
2 http://www.americantelemed.org/learn/what-is-telemedicine

Primary care physicians and medical specialists use **"store-and-forward" (asynchronous) technologies** to electronically transmit pre-recorded videos and digital images such as X-rays, video clips, and photographs to each other. Electronic devices communicate patient health information to clinicians for the purpose of **remote patient monitoring**.[3] **Mobile health (mHealth) technologies** are rapidly expanding. Mobile internet-based communication devices, such as smart phones and tablets, are being used to provide services and transmit protected health information. (For more information about the use of smart phones and mobile internet-based communication devices, see ***The Exchange***, July 2012, starting at page 11.)

Why is telehealth vital to health care?

Health care access, improved quality of medical care, better outcomes, and reduced health care costs are all attainable goals through access to telehealth resources. The National Telehealth Policy Resource Center states, "By removing barriers of time, distance, and provider scarcities, telehealth can deliver important medical and other health and education services where they are needed most; in remote, rural areas and medically underserved urban communities. As states across the country and employers, private payers and consumers prepare for the implementation of the Affordable Care Act, telehealth becomes an increasingly important tool for increasing access to care, improving the quality of care that leads to better patient outcomes, and ultimately reducing the per capita cost of care."[4]

All modes of telehealth medical services can enhance health education by making classes, patient portals, online discussion forums and training programs available to patients, and health care professionals alike. "Public health services include disaster management systems, which can expand the capacity of local emergency medical providers, and pandemic/epidemic public communications activities."[5]

Barriers to telemedicine

In spite of the certainty that telehealth can expand health care capabilities and accessibility, notable road blocks remain for its use as a means to providing patient care. Licensure requirements vary from state to state; credentialing challenges exist; reimbursement for services provided is inconsistent; litigation venues are uncertain; PHI requires confidentiality; and prescribing medications via telehealth is dangerous,—to name a few of the barriers.

Licensure: The Robert J. Waters Center for Telehealth and e-Health Law (CTeL) (http://ctel.org) reminds health care providers that they **must obtain a medical license in the state(s) where they would like to provide patient care or, stated in another way, they must possess a full license in the state in which the patient resides or is physically present.** Because states have the right to regulate the practice of medicine within their geographical borders to ensure that healthcare providers administering care are competent, states can require a medical license.[6] "For decades, the issue of licensure was simple, meaning that if a physician wished to practice medicine within a specific state, (they) would first need to seek medical licensure.

3 http://cchpca.org/what-is-telehealth
4 http://telehealthpolicy.us/what-telehealth
5 http://cchpca.org/what-is-telehealth
6 http://ctel.org/expertise/physican-licensure/

However, with the onset of telehealth in the administration of care, these once clearly defined legal and regulatory lines have now become blurred because physicians can physically be in one state and simultaneously administer care to a patient in another state. As a result, once basic practices pertaining to physician licensure have become more complex."[7] The Federation of State Medical Boards confirms that all state medical boards plus the District of Columbia Board of Medicine require that physicians engaging in telemedicine be licensed in the state in which the patient is located.[8] Some states offer reciprocal licenses under specific limited circumstances. (**See Figure 1** for the Federation of State Medical Boards' Telemedicine Overview as it applies to physicians in the states of Alaska, California, Hawaii and Idaho.)[9]

Credentialing: Prior to 2011, telehealth technologies created challenges for healthcare organizations to credential and privilege specialists who provide telemedicine services. However, on May 5, 2011, the Centers for Medicare and Medicaid Services (CMS) released its final rule that makes changes to CMS's Conditions of Participation (CoPs) as they pertain to the credentialing and privileging of telehealth providers. "This final rule will permit hospitals and critical access hospitals (CAHs) to implement a new credentialing and privileging process for physicians and practitioners providing telemedicine services. The removal of unnecessary barriers to the use of telemedicine may enable patients to receive medically necessary interventions in a timely manner. It may enhance patient follow-up in the management of chronic disease conditions. These revisions will provide more flexibility to small hospitals and CAHs in rural areas and regions with a limited supply of primary care and specialized providers. In certain instances, telemedicine may be a cost-effective alternative to traditional service delivery approaches and, most importantly, may improve patient outcomes and satisfaction."

This rule may conflict with established state policies; therefore, it is important to check with your state Medicare/Medicaid office on its telehealth credentialing policies. Check your state's law as well. For example, California's Business & Professions Code mirrors the federal regulation:

(1) Notwithstanding any other provision of law and for purposes of this section, the governing body of the hospital whose patients are receiving the telehealth services may grant privileges to, and verify and approve credentials for, providers of telehealth services based on its medical staff recommendations that rely on information provided by the distant-site hospital or telehealth entity, as described in Sections 482.12, 482.22, and 485.616 of Title 42 of the *Code of Federal Regulations.*

(2) By enacting this subdivision, it is the intent of the Legislature to authorize a hospital to grant privileges to, and verify and approve credentials for, providers of telehealth services as described in paragraph (1)." *Business & Professions Code* §2290.5(g)(1)-(2)

Medicare/Medicaid and private insurer reimbursement: The US Department of Health and Human Services' Health Resources and Services Administration (HRSA) advises that not all telehealth costs are reimbursed. According to

7 *ibid*
8 http://www.fsmb.org/pdf/grpol_telemedicine_licensure.pdf
9 Federal Register Vol. 76, No. 87, May 5, 2011, beginning at page 25550

California Medical Association's On-Call Document #3300, starting at page 5, Medicare reimburses for telehealth services when each of the following requirements are met:

(1) The Medicare beneficiary received the telemedicine service at an acceptable "originating site" located in a Health Professional Shortage Area (HPSA) or in a county that is outside of any Metropolitan Statistical Area (MSA). "Originating sites" must be one of the following: a physician or practitioner's office, inpatient or outpatient hospital, critical access hospital, rural health clinic, federally qualified health center, renal dialysis center, skilled nursing facility or community mental health center; it cannot be in a patient's home. Medicare requires that a "telepresenter" be physically present with the Medicare beneficiary at the "originating site" if the distant-site physician determines that this is medically necessary for the telemedicine service.

(2) An "approved telemedicine modality" was used, meaning telemedicine services delivered in live, real-time situations in which the physician and Medicare beneficiary are interacting face-to-face via an interactive telecommunications system (Hawaii and Alaska's telemedicine demonstration projects are the exception to this rule). Medicare does not reimburse telemedicine services provided via fax, email or telephone.

(3) An approved service and billing code was used. Approved services (which are re-evaluated annually) include:

- Initial and follow-up inpatient telehealth consultations;
- Office or other outpatient visits;
- Individual psychotherapy;
- Pharmacologic management;
- Psychiatric diagnostic interview examination;
- End stage renal disease related services;
- Individual medical nutrition therapy;
- Neurobehavioral status examination; and
- Individual health and behavior assessment and intervention.

(4) An approved health care provider delivered the telemedicine service at a "distant site." Physicians, nurse practitioners, physician assistants, nurse midwives, clinical nurse specialists, clinical psychologists, clinical social workers and registered dietitians or nutrition professionals are considered "approved healthcare providers."[10]

According to the HRSA, Medicare covers store-and-forward applications, such as teleradiology and remote EKG applications, as they do not typically involve direct interactions with patients. In Alaska and Hawaii only, Medicare reimburses store-and-forward applications, such as teledermatology.[11]

The HRSA warns, "There is no single widely-accepted standard for private payers. Some insurance companies value the benefits of telehealth and will reimburse a wide variety of services. Others have yet to develop comprehensive reimbursement policies, and so payment for telehealth may require

10 MA On-Call Document #3300, Telemedicine, January 2013, pp.5-7
11 http://www.hrsa.gov/healthit/toolbox/RuralHealthITtoolbox/Telehealth/whatarethereimbursement.html

prior approval. Likewise, different states have various standards by which their Medicaid programs will reimburse for telehealth expenses. Check with the major insurance companies and the Medicaid program in the state to get a clearer policy perspective on coverage."[12]

Resources: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Telehealth-Srvcsfctsht.pdf

Center for Telehealth and e-Health Law 50 State survey on Medicaid Telehealth and Telehome Policies
http://ctel.org/expertise/reimbursement/medicaid-reimbursement/

Litigation venue: Uncertainty still remains in the legal community as to where a lawsuit would be filed in which the delivery of negligent health care is alleged using telehealth services. Generally accepted legal practices require a suit to be venued where the injury occurred and/or where the patient resides; however, the facts of some cases might warrant otherwise. Clearly, a case would be filed in the patient's home state in which, for example, a California consultant examines a patient in Arizona via video conferencing or a radiologist in New Mexico interprets films for a patient in New York. But consider the scenario of two consulting physicians in which the "controlling provider" (i.e., the physician who is managing a patient's care) lives and is licensed in the patient's home state, while the consultant is located out-of-state. The out-of-state physician may not be required to obtain a full, unrestricted license in the patient's home state because his interaction is with the managing provider and not directly with the patient. The "controlling provider" relies upon the consultant's recommendation, carries out a treatment, and the patient is injured. Where would the lawsuit against the consulting physician be filed? Would the consulting physician be protected by the laws of his/her licensing state (e.g., tort reform laws), or would the laws of the patient's home state be invoked? The answers remain unclear.

Confidentiality: State and federal laws and regulations (e.g., HIPAA/HITECH) continue to mandate that protected health information (PHI) is ensured confidentiality and privacy. Telehealth capabilities enable timely physician/patient encounters via video conferencing, and access to data by store-and-forward methods, email and texts between providers and/or doctors and their patients, etc. However, physicians must ensure that telemedicine encounters are protected as readily as maintaining PHI in the electronic medical records. Consider a few examples:

(1) Using Skype to videoconference might not be HIPAA-compliant because unauthorized individuals can view the data generated during such an encounter. Ultimately, health care providers who use Skype to videoconference should have a signed Business Associate Agreement with Microsoft or Skype Communications to address confidentiality issues. Physicians might consider other resources, such as VSee, another videoconferencing application that is not accessible by a third-party. For more information about Skype, VSee and HIPAA, visit www.personcenteredtech.com, a website particularly helpful for

12 *ibid*

behavioral health care providers.

Visit MIEC's website at www.miec.com and visit our HIPAA resources page, as well as the publication page for newsletters on smartphones, social media, HIPAA, and confidentiality.

(2) Providers should refrain from accessing or reviewing store-and-forward data on their laptops or smartphones while in a public locations unless they do so via a virtual private network and in such a manner that unauthorized individuals cannot see PHI directly on the device (e.g., Starbucks, on public transportation, anywhere where unauthorized individuals might be able to view the PHI).

(3) All providers are strongly encouraged to ensure that their computer software systems, particularly for data storage and transmission of PHI, meet all HIPAA/HITECH standards. Attorney Keith Brown advises, "Physicians should be mindful that not all software and telecommunication packages are HIPAA/HITECH compliant. For example some of the Microsoft Office 365 commercial Enterprise-level packages can, when properly configured, provide for file encryption so as to provide for secure email transmission and data storage. The home version of Office 365 does not, nor does the home version of Microsoft's SkyDrive. Neither iCloud nor Dropbox are HIPAA compliant although the latter is moving in that direction. I think there is a real danger that group practice managers and smaller practice settings may be simply unaware of these distinctions. At a minimum, healthcare providers should obtain written assurance from the manufacturer or its representative that these packages are HIPAA/HITECH compliant."

Prescribing medication via telehealth: How to establish the physician-patient relationship in order to prescribe medications via telemedicine is a liability question that has been researched by numerous telehealth resources. In 2011, with the help of the Federation of State Medical Boards and each of the 50 state boards of medicine, CTeL compiled research from all fifty states on the prescribing laws, regulations, and policies as they relate to telemedicine prescribing practices. CTeL determined that many states require some form of "face-to-face" or "in-person" examination to establish the physician-patient relationship in order to prescribe. However, how that examination can be accomplished (i.e., physically vs. video conferencing "face-to-face") remains unclear. (See Figure 2 for the prescribing laws as they apply in Alaska, California, Hawaii, and Idaho.)

In Alaska it is considered "unprofessional conduct" to prescribe medications based solely upon a patient-supplied history which the physician has received via telephone, fax, or email. California requires a good faith examination. Hawaii and Idaho require the establishment of a physician-patient relationship and also consider it inappropriate (less than the standard of care) to rely solely upon an online questionnaire to determine a legitimate medical purpose for the requested prescription.

Recommendations

As physicians continue to expand patient access to health care via telehealth modalities, MIEC recommends that you:

(1) Contact the medical licensing boards in the states where patients are

located for licensing requirements and applications.

(2) Be familiar with your state's laws as they apply to telemedicine and telehealth (i.e., its definition, accepted modalities, sites, on-line prescribing, etc.). See Figures 1 and 2.

(3) Be knowledgeable about Medicare/Medicaid and private payer reimbursement policies to ensure payment for telehealth services rendered.

(4) Be familiar with MIEC's policy and its limitations as they apply to telemedicine. See Sidebar.

(5) Notify MIEC in writing of telemedicine activities.

(6) Promote patient safety and reduce your liability when providing patient care via telehealth:

(a) Obtain a detailed medical history, conduct a good faith examination, develop an impression and plan before prescribing medications, ordering diagnostic tests, or referring patients to specialists;

(b) Specialists who use "store and forward" technology: Obtain and review meaningful clinical information to assist you in your evaluation and ultimate interpretation;

(c) Maintain quality records to document patient encounters;

(d) Ensure confidentiality of protected health information (PHI);

(e) Obtain informed consent when required by law, and document the discussion; and

(f) Develop follow-up systems to manage prescribed medications, to review ordered diagnostic tests and consultation reports, and to ensure proper patient care.

MIEC's policy, General Conditions, Paragraph 21, PLACE OF PRACTICE AND TELEMEDICINE reads:

21. PLACE OF PRACTICE

A. You agree that insurance coverage under this policy is available only if you maintain your principal place of practice in the location identified by you in written notification to MIEC within 30 days after establishing your principal place of practice, and that relocation by you to another principal place of practice without notification to and agreement by MIEC as evidenced by MIEC's issuance of a policy declaration or endorsement shall constitute an automatic termination of insurance coverage under this policy.

B. You agree that insurance coverage under this policy is available only for acts, or the alleged failure to act, occurring or undertaken within the state wherein your place of practice identified in a policy declaration or endorsement is located, except for (1) services rendered in an emergency, without compensation or other consideration, and on an irregular or infrequent basis, (2) services rendered as part of the training you receive in the course of a formal program of continuing medical education or (3) services rendered by you when acting as an independent forensic psychiatric medical examiner or in the provision of professional forensic psychiatric advice or consultation at the request of parties to civil or criminal legal proceedings regarding the health or condition of a person who is not a patient, only if you have previously notified MIEC in writing of your intention to provide such services.

C. You agree that insurance coverage under this policy is available for acts, or the alleged failure to act, when providing health care services to patients remotely by information and/or communication technologies only when such telemedicine or telehealth services are provided in accordance with the laws of any jurisdiction wherein such act or failure to act (or any part thereof) is alleged to have occurred, only you are duly licensed or permitted under such laws to engage in such practice in such jurisdiction, and only if you have previously notified MIEC in writing of your intention to engage in such services in such jurisdiction and MIEC has agreed in writing to provide coverage for such activities.

Our thanks to the following attorneys for their legal consultation:

Phillip Goldberg, Esq., Hassard Bonnington in San Francisco, CA

Thomas Cook, Esq., Lyons, Brandt, Cook & Hiramatsu in Honolulu, HI

Keely E. Duke, Esq., Hall, Farley, Oberrecht & Blanton in Boise, ID

Keith Brown, Esq., Brown, Waller, & Gibbs, in Anchorage, AK

Federation of State Medical Boards Telemedicine Overview (in part)

Figure 1

Last updated August 2012

STATE	LICENSURE REQUIRED	LEGISLATION/REGULATIONS/POLICY GUIDELINES
Alaska	Must obtain an Alaska license.	" 'Telemedicine' means the practice of health care delivery, evaluation, diagnosis, consultation, or treatment, using the transfer of medical data, audio, visual or data communications that are performed over two or more locations between providers who are physically separated from the recipient or from each other." 7 *Alaska Administrative Code §110.639(4).*
California	Must obtain a California license. Requires reimbursement for telemedicine services.	" 'Telehealth' means the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while the patient is at the originating site and the health care provider is at a distant site. Telehealth facilitates patient self-management and caregiver support for patients and includes synchronous interactions and asynchronous store and forward transfers." *California Business and Professions (B&P) Code §2290.5(a)(6)* "(a) For purposes of this division, the following definitions shall apply: (1) 'Asynchronous store and forward' means the transmission of a patient's medical information from an originating site to the health care provider at a distant site without the presence of the patient. (2) 'Distant site' means a site where a health care provider who provides health care services is located while providing these services via a telecommunications system. (3) 'Healthcare provider' means a person who is licensed under this division. (4) 'Originating site' means a site where a patient is located at the time healthcare services are provided via a telecommunications system or where the asynchronous store and forward service originates. (5) 'Synchronous interaction' means a real-time interaction between a patient and a health care provider located at a distant site. (b) Prior to the delivery of health care via telehealth, the health care provider at the originating site shall verbally inform the patient that telehealth may be used and obtain verbal consent from the patient for this use. The verbal consent shall be documented in the patient's medical record. (c) The failure of a health care provider to comply with this section shall constitute unprofessional conduct. Section 2314 shall not apply to this section. (d) This section shall not be construed to alter the scope of practice of any health care provider or authorize the delivery of health care services in a setting, or in a manner, not otherwise authorized by law. (e) All laws regarding the confidentiality of health care information and a patient's rights to his or her medical information shall apply to telehealth interactions. (f) This section shall not apply to a patient under the jurisdiction of the Department of Corrections and Rehabilitation or any other correctional facility. " *California B&P Code §2290.5(a)-(f)* "For the purposes of this subdivision, 'telehealth' shall include 'telemedicine' as the term is referenced in Sections 482.12, 482.22, and 485.616 of Title 42 of the Code of Federal Regulations." *California B&P Code §2290.5(g)(3*) "(b) It is the intent of the Legislature to recognize the practice of telehealth as a legitimate means by which an individual may receive health care services from a health care provider without in-person contact with the health care provider.

STATE	LICENSURE REQUIRED	LEGISLATION/REGULATIONS/POLICY GUIDELINES
California cont.	Must obtain a California license. Requires reimbursement for telemedicine services.	(c) No health care service plan shall require that in-person contact occur between a health care provider and a patient before payment is made for covered services appropriately provided through telehealth." *California Health & Safety Code §1374.13(b)(c)*
Hawaii	Must obtain a Hawaii license. Requires reimbursement for telemedicine services.	"Practice of telemedicine. "(a) Nothing in this section shall preclude any physician acting within the scope of the physician's license to practice from practicing telemedicine as defined in this section. (b) For the purposes of this section, 'telemedicine' means the use of telecommunications services, including real-time video or web conferencing communication or secure web-based communication, to establish a physician-patient relationship, to evaluate a patient, or to treat a patient.'Telehealth' as used in chapters 431, 432, and 432D, includes 'telemedicine' as defined in this section. (c) Telemedicine services shall include a documented patient evaluation, including history and a discussion of physical symptoms adequate to establish a diagnosis and to identify underlying conditions or contra-indications to the treatment recommended or provided. (d) Treatment recommendations made via telemedicine, including issuing a prescription via electronic means, shall be held to the same standards of appropriate practice as those in traditional physician-patient settings that do not include a face-to-face visit but in which prescribing is appropriate, including on-call telephone encounters and encounters for which a follow-up visit is arranged. Issuing a prescription based solely on an online questionnaire is not treatment for the purposes of this section and does not constitute an acceptable standard of care. For the purposes of prescribing a controlled substance, a physician-patient relationship shall be established pursuant to chapter 329 (329-1 defines the physician-patient relationship). (e) All medical reports resulting from telemedicine services are part of a patient's health record and shall be made available to the patient. Patient medical records shall be maintained in compliance with all applicable state and federal requirements including privacy requirements. (f) A physician shall not use telemedicine to establish a physician-patient relationship with a patient in this State without a license to practice medicine in Hawaii. Once a provider-patient relationship is established, a patient or physician licensed in this State may use telemedicine for any purpose, including consultation with a medical provider licensed in another state, authorized by this section, or as otherwise provided by law." *Hawaii Revised Statutes (HRS) §453-1.3* "Exceptions to the licensure requirement apply to a practitioner of medicine and surgery from another state when in actual consultation, including in-person, mail, electronic, telephonic, fiber-optic or other telemedicine consultation with a licensed physician or osteopathic physician of Hawaii., if the physician from out-of-state is licensed to practice in the state in which the physician resides at the time of consultation and he/ she does not open an office, appoint a place to meet patients in Hawaii, or receive calls within the state; the physician licensed in Hawaii retains control and responsibility for the provision of care for the in-state patient; etc." *HRS §453-2(b)(3)*. " 'Telemedicine' means the use of telecommunications services, including real-time

STATE	LICENSURE REQUIRED	LEGISLATION/REGULATIONS/POLICY GUIDELINES
Hawaii (cont.)	Must obtain a Hawaii license. Requires reimbursement for telemedicine services.	video conferencing-based communication, secure interactive and non-interactive web-based communication, and secure asynchronous information exchange, to transmit patient medical information, such as diagnostic-quality digital images and laboratory results for medical interpretation and diagnosis, and deliver health care services and information to parties separated by distance." *HRS §453-2(b)(6)*. "No mutual benefit society plan that is issued, amended or renewed shall require face-to-face contact between a health care provider and a patient as a prerequisite for payment for services appropriately provided through telehealth in accordance with generally accepted health care practices." *HRS §432:1-601.5(b)*. "A radiologist licensed in another state may use telemedicine in Hawaii to provide radiology services to a patient located in the state in which the radiologist is licensed." *HRS §453-2(b)(6)*.
Idaho	Must obtain an Idaho license.	The "practice of medicine" means: "To investigate, diagnose, treat, correct or prescribe for any human disease, ailment, injury, infirmity, deformity or other condition, physical or mental, by any means or instrumentality." *Idaho Code §54-1803(1)(a)* While Idaho has not statutorily defined "telemedicine," the Idaho Department of Health & Welfare has enacted regulations defining Psychiatric Telehealth and reimbursement by Medicaid. Psychiatric telehealth is defined as "an electronic real time synchronous audio-visual contact between a physician and participant." The State Medicaid program in Idaho does reimburse for psychiatric telehealth services including diagnostic assessments, pharmacological management, and psychotherapy. See *IDAPA 16.03.09 subsection 500 and 502*. Telehealth is identified in the Idaho Rural Health Care Access Program which was created by the state treasury as a fund to be used exclusively for the purpose of grants for improving access to primary care medical services in areas with primary care health professional shortages and areas that are medically underserved. The fund allocates three categories of rural health care access grant assistance which includes telehealth projects – "Grant funds may be used for projects that involve the use of telecommunications technologies for distance learning and for projects to improve access to care for rural communities." *Idaho Code §§39-5902, 39-5906(1)(a)*. "Idaho will leverage its statewide purchasing power for the IEN [Idaho education network] to promote private sector investment in telecommunications infrastructure that will benefit other technology applications such as telemedicine, telecommuting, telegovernment and economic development." *Idaho Code §67-5754E(2)(c)*.

Federation of State Medical Boards Internet Prescribing Language

Figure 2

STATE	STATUTES
Alaska	***"Unprofessional conduct"*** For purposes of AS 08.64.240 (b) and AS 08.64.326, "unprofessional conduct" means an act or omission by an applicant or licensee that does not conform to the generally accepted standards of practice for the profession for which the applicant seeks licensure or a permit under AS 08.64 or which the licensee is authorized to practice under AS 08.64. "Unprofessional conduct" includes the following: (27) providing treatment, rendering a diagnosis, or prescribing medications based solely on a patient-supplied history that a physician licensed in this state received by telephone, facsimile, or electronic format. *Alaska Administrative Code, Title 12, §40.967*

STATE	STATUTES
Alaska (cont.)	***"Prescribing controlled substances"*** When prescribing a drug that is a controlled substance, as defined in AS 11.71.900, an individual licensed under this chapter shall create and maintain a complete, clear, and legible written record of care that includes, at a minimum, (1) a patient history and evaluation sufficient to support a diagnosis; (2) a diagnosis and treatment plan for the diagnosis; (3) monitoring the patient for the primary condition that necessitates the drug, side effects of the drug, and results of the drug, as appropriate; (4) a record of drugs prescribed, administered, or dispensed, including the type of drug, dose, and any authorized refills. *Alaska Administrative Code, Title 12, §40.975* ***"Sanctions"*** The board may impose a sanction if the board finds after a hearing that a licensee: (5) has procured, sold, prescribed, or dispensed drugs in violation of a law regardless of whether there has been a criminal action. *Alaska Statutes §08.64.326(a)(5)*
California	***Internet Prescribing: Ordering prescriptions through the Internet? Buyer beware!*** Ordering drugs without a relationship with a physician is potentially dangerous. By law, prescription drugs must be prescribed by a physician. There is good reason for this, as drugs should only be prescribed after an examination is performed and the cause of the problem or condition is diagnosed. Online "consultations" cannot, with any certainty, provide enough information to make a verifiable diagnosis. Many of the sites offering prescriptions for drugs are operating illegally. In California, the law requires that physicians and pharmacists be licensed, and that physicians perform a physical exam prior to prescribing drugs. It is generally impossible for consumers to determine the licensing status of the physician or pharmacist by the information on Internet pharmacy Web sites. In addition, many sites only require a questionnaire and do not verify the most basic facts needed for physicians to prescribe pharmaceuticals safely. www.mbc.gov/consumers/internet_prescribing.aspx ***"Unprofessional Conduct"*** (a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without a good faith prior examination and medical indication therefor, constitutes unprofessional conduct. (b) No licensee shall be found to have committed unprofessional conduct within the meaning of this section if, at the time the drugs were prescribed, dispensed, or furnished, any of the following applies: (1) The licensee was a designated physician and surgeon or podiatrist serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and if the drugs were prescribed, dispensed, or furnished only as necessary to maintain the patient until the return of his or her practitioner, but in any case no longer than 72 hours. (2) The licensee transmitted the order for the drugs to a registered nurse or to a licensed vocational nurse in an inpatient facility, and if both of the following conditions exist: (A) The practitioner had consulted with the registered nurse or licensed vocational nurse who had reviewed the patient's records. (B) The practitioner was designated as the practitioner to serve in the absence of the patient's physician and surgeon or podiatrist, as the case may be. (3) The licensee was a designated practitioner serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and was in possession of or had utilized the patient's records and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription in strength or amount or for more than one refilling. (4) The licensee was acting in accordance with Section 120582 of the Health and Safety Code. *California B&P Code §2242(a)(b)* ***"Internet prescribing"*** (a) No person or entity may prescribe, dispense, or furnish, or cause to be prescribed, dispensed or furnished,

STATE	STATUTES
California (cont.)	dangerous drugs or dangerous devices as defined in Section 4022, on the Internet for delivery to any person in this state, without an appropriate prior examination and medical indication, except as authorized by Section 2242. *California B&P Code §2242.1(a)* (a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations. (b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars ($25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars ($25,000) per occurrence. (c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b). (d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund. (e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter. (f) For the purposes of this section, “good faith prior examination” includes the requirements for a physician and surgeon in Section 2242 and the requirements for a veterinarian in Section 2032.1 of Title 16 of the California Code of Regulations. *California B&P Code §4607(a)-(f)*
Hawaii	**See Figure 1, Hawaii, HRS §453-1.3, paragraph (d)**
Idaho	(1) A prescription or drug order for a legend drug is not valid unless it is issued for a legitimate medical purpose arising from a prescriber-patient relationship which includes a documented patient evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment. Treatment, including issuing a prescription or drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship does not constitute a legitimate medical purpose. A prescription drug order may be issued either: (a) By a practitioner acting in the usual course of his profession; or (b) By a physician, dentist, veterinarian, scientific investigator or other person, other than a pharmacist, who is licensed in a jurisdiction other than the state of Idaho and is permitted by such license to dispense, conduct research with respect to or administer the prescribed legend drugs in the course of his professional practice or research in such jurisdiction, so long as the individual is acting within the jurisdiction, scope and authority of his license when issuing the prescription drug order. *Idaho Code§54-1733*

CRICO Corner

The MIEC/CRICO Strategies partnership carries on with an analysis of thematic drivers of loss impacting claims made against MIEC radiologists (radiology includes diagnostic radiology, nuclear medicine, and interventional radiology) between 2006-2011. Eighty-three (83) of MIEC's radiology cases were coded in great detail and benchmarked against 577 comparable CRICO peer claims. The peer group consisted of CRICO-insured radiologists in academic medical centers, hospital systems, free-standing radiology centers, and community hospitals.

In the most recent claims analysis, CRICO Strategies' analysts found that radiology was named as the primary responsible service in 41 medical events and was responsible for 4% of cases overall and 7% of total incurred losses of the approximately 1000 MIEC cases deep coded by CRICO Strategies to date. The data revealed that out of 41 cases, 78% involved diagnosis-related allegations as compared to 56% in the peer group, and accounted for $9 million (60%) of the total $15 million incurred loss.

Severity of Injury: MIEC's cases in which radiology is named as the primary service most often resulted in high severity injuries (32% of which ended in death) and accounted for approximately $6.4 million in incurred loss. The high severity cases included: 13 cancer of the breast, kidney or lung medical events; seven complications of care including bleeding, nerve injuries, and contrast reaction; four gastrointestinal-related conditions such as appendicitis and hernia; four orthopedic conditions such as strains, sprains, and fractures; two cardiac-related, aortic aneurysms claims; and two neurologic events (i.e., subarachnoid hemorrhage and concussion).

Outpatient setting: Comparable to peers, the majority of MIEC's radiology cases occurred in the outpatient setting (84%

In a Nutshell:

Majority of radiology cases are **diagnosis-related**, resulting in **high-severity injuries**

- 78% of radiology claims, $9M in losses
- Larger proportion of MIEC radiology cases result in death (32%) compared to peers

Cases driven by **Clinical Judgment and Communication** challenges

- Failures to perceive (narrow diagnostic focus) and misinterpretation
- Communication with ordering providers

Loss prevention and patient safety opportunities center around:

- Development of **standard processes for communication** between ordering provider and radiologists
- Clear expectations for information needed prior to imaging
- Clarity on process for communication of findings

and 74%, respectively) and account for 59% of the total incurred losses versus 70% of the peers' radiology cases. The remaining inpatient cases (8 cases total) resulted in indemnity payments of $6,188,591. While this number represents only 20% of the total number of cases, it represents 41% of total monies paid.

Primary contributing factors: Issues with clinical judgment and poor communication proved to be the primary contributing factors for MIEC radiologists, a finding similar to those experienced by CRICO peers. Deeper analysis of the clinical judgment challenge revealed that, in a majority of the medical events (78%), the interpreting radiologists failed to properly assess the patients' condition due to an ordering physician's failure to provide sufficient, meaningful historical data. The result: failure to perceive or a narrow focus when evaluating the study's results and misinterpretation of the findings. Multiple interruptions and excessive numbers of images to review on any given day also were found to impact the radiologists' perception.

A CLOSER LOOK AT THE NUMBERS – Major Allegations

Allegation	Number of Cases	Total Incurred
Diagnosis-related	32	$9,033,992
Medical Treatment	5	$1,901,155
improper performance of treatment/procedure	3	
premature end of treatment/abandonment	1	
retained foreign body, medical treatment	1	
Medication-related (gadolinium contrast)** See Figure 3	2	$4,047,436
Safety and Security	2	$ 46,316

Lack of information to direct a radiologist's focus prior to an ordered study and absence of clear communication protocols to report significant findings post-study were the contributing communication factors found in 24% of MIEC radiology claims versus 17% of peer claims. Selection and management of the therapy (specifically, the use of gadolinium when contraindicated) were contributing factors in 22% of the cases versus 14% of peer medical events. Failure to communicate test results to patients and/or their families was found to impact the outcome in 22% of the cases versus 13% of peer claims.

CRICO Strategies' analysis also looked at cases in which radiology was named as the secondary responsible service. In these cases, when radiologists are involved, but are not central to the care, surgery and medicine are most often the responsible services. Clinical judgment issues and poor communication remain the primary contributing factors. The analysis found that the responsible services fail to note the clinical information offered by the consulting radiologists, and communication issues among treating providers regarding patient condition prove to be problematic.

Recommendations

Targeted interventions that protect both patients and providers create a safer environment for delivering clinical care, reducing both injuries and financial loss. Based upon its analysis, CRICO Strategies offers the following recommendations for reducing risks in radiology:

1. **Educate insured providers on clinical judgment and communication vulnerabilities.**
   a. Given the prevalence of clinical judgment challenges in radiology, what presentations and/or radiologic studies pose the greatest challenge?

b. What external and internal distractions may hinder radiologists' concentration and focus?

c. What are the gaps in information exchange? What processes do providers have in place to keep themselves and their patients safe? What findings would respond to a communication algorithm?

2. Develop standards (at the personal and/or practice-level) to communicate with ordering providers.

a. Pre-imaging communication:

(1) Articulate key clinical information required from ordering physician, especially indications for the scan, pertinent medical history, and co-morbidities.

(2) Post requirements on the practice website, and/or create an information sheet for working with the chosen radiology practice.

b. Post-imaging communication:

(1) Establish a procedure for communicating significant, high-risk, and critical test results, including turnaround time for results; specific method of communication for benign, urgent, and critical results; and whether radiologist (or ordering MD) communicates directly with patient, especially for abnormal, high-risk, and critical findings.

3. Develop consistent practice for post-imaging documentation.

a. Clearly state critical findings (and all important points) up front—i.e., Don't "bury the lede."

b. In addition to the obvious elements to be documented in a radiology report (history, imaging technique used, findings and impression), radiologists should include comparison with other studies whenever applicable.

c. Articulate clinical rationale, especially when ordering (or not) additional images/views.

d. Clearly document communication (how, when, what) with ordering physician and patient especially regarding incidental or critical findings.

e. Establish clarity regarding responsibility for uploading images into EMR.

4. Practice with awareness of and attention to clinical judgment vulnerabilities.

a. Carefully consider potential distractions and their impact on clinical judgment.

(1) External distractions, e.g., reading room environment (noise, lighting, etc.)

(2) Internal distractions, e.g., emotional, administrative (pagers, scheduling issues)

MIEC is dedicated to ensuring our policyholders are implementing improvement strategies and best practices by seeking opportunities to improve their accuracy, better communicate results, help close the loop on follow-up care, and reduce the risk of a missed diagnosis. While malpractice cases only provide part of any specialty's risk profile, the data are a valuable tool to pinpoint those vulnerabilities most likely to harm patients and leave providers susceptible to an allegation of malpractice.

Radiologists Across Entire CRICO Database

(18,238 cases (claims and suits), with losses in excess of $3.6 billion, asserted against all specialties from 2007–2011)

- Radiology is the seventh most frequently named service
- Four percent of all cases involved Radiology as the responsible service
- Radiology represents 6% of all losses across all specialties
- 46% of the radiology cases involved a death or permanent significant injury
- 68% of cases occurred in ambulatory setting
- Of all defendants named in all cases, 56% were MDs, 40% were the health care organization

Types of Allegations

- 56% of cases alleged a diagnosis-related error
- 24% of cases alleged mismanaged medical treatment
- 78% of diagnosis-related cases were assessed as having a test interpretation issue

Types of Diagnosis Related Cases

- 50% of the diagnosis-related cases involved cancer
  - ✓ 45% involved breast cancer
  - ✓ 13% alleged missed or delayed diagnosis of breast cancer
  - ✓ 19% involved lung cancer
  - ✓ 8% alleged a missed fracture

Visit the Patient Safety Toolbox (under the Manage Your Risk tab) on MIEC's website at www.miec.com. Find helpful resources to promote patient safety in your office. These include:

- CRICO Strategies monthly newsletter Strategies for Patient Safety
- CRICO Strategies Annual Comparative Benchmark Reports, dated 2009-2013, Topics: Routine Medical Procedures, Emergency Medicine, Obstetrics, Surgery
- Register with PDR.net to stay current on FDA drug alerts and black box warnings.

Gadolinium case:

Figure 3

A 53-year-old male presented to the ED following an episode where he fainted and temporarily lost his vision. The patient believed he had suffered a stroke. He had a history of chronic renal disease. The patient's primary care physician (PCP) admitted him to the hospital on the first day (March 2007). The admitting diagnosis was headache, hypertension, and renal failure (ESRD with peritoneal dialysis). The patient's past medical history was significant for hypertension, renal disease and cardioversion.

The PCP planned to evaluate the patient's renal vascular disease. He spoke with the radiologist to help determine which study to order. They considered ultrasound, angiogram or CT with contrast and an arteriogram with CO2. The PCP decided to cancel the renal ultrasound and instead ordered an MRI/MRA of the abdomen (with and without contrast). The order was silent as to whether or not to use gadolinium contrast for the diagnostic study.

On Day 2, pursuant to the PCP's order, the radiologist first performed the abdominal MRI without contrast. The study demonstrated moderate ascites and bilateral renal cysts containing proteinaceous or hemorrhagic fluid. The finding of multiple cysts was suggestive of polycystic kidney disease. There was NO PRESCREENING to determine kidney function. The radiologist then proceeded with a 3-D contrast-enhanced MRA of the aorta and renal arteries. She administered a standard dose (30 cc's) of the gadolinium contrast to the patient for the study. The radiologist found no evidence of significant renal artery stenosis in either of the main renal arteries. The patient did not receive hemodialysis within two hours of the MRA.

Sometime following the MRA, the patient began to develop muscle weakness, pain, and swelling in his extremities. After consulting with several nephrologists, he was diagnosed with nephrogenic systemic fibrosis (NSF). His condition is permanent and progressive; there is no effective treatment for NSF. In May 2010, the patient underwent a kidney transplant. He is wheelchair-bound and requires full assist with ADLs.

Defendants included the radiologist, his group (vicarious liability) and the PCP. Ultimately, the lawsuit was settled between $2 million and $4 million plus defense costs on behalf of the radiologist, not the group.

Significant facts:

- First FDA Advisory was published in June 2006 warning patients and physicians of the possible connection between gadolinium and NSF.
- The radiologist acknowledged that there was a secondary FDA Public Health Advisory issued in December 2006 warning that patients can develop NSF following the administration of gadolinium.
- In late 2006 to early 2007, the radiologist sent emails to her colleagues in the community asking what they were doing about the use of gadolinium. She also received the ACR's Alerts.
- Early March 2007 (shortly before she administered gadolinium to the patient), the radiologist had attended a conference specifically focusing on the connection between the contrast agent and NSF.
- The FDA issued the Black Box Warning in May 2007.
- Glomerular filtration rate (GFR) was not documented in the chart.
- The radiologist did not advise the patient of the risk of NSF with the use of the contrast (NO INFORMED CONSENT). At the time of the patient's MRA, it was not the group's practice to consent patients for MRAs with contrast. The radiologist also believed that the contrast agent used was safer than the contrast connected to the gadolinium cases leading to NSF.
- The group was not found vicariously liable for the acts and omissions of its member given the superior knowledge that the treating radiologist had in this case.

For a copy of the ACR's new manual on contrast, visit http://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources/Contrast%20Manual/2013_Contrast_Media.pdf. Starting at page 77, see information about adverse reactions to gadolinium; page 81 begins the discussion on NSF.

Coping with the Stress of Litigation

“ I’m being sued? By whom? It must be a mistake!”

“ I experienced emotions similar to the five stages of grief.”

“ I felt tremendous, tremendous anxiety.”

“ Depression crept into the picture.”

“ My whole world was being threatened by something I thought could take it all away.”

“ I had to face reality; it wasn’t going away.”

These statements, made by MIEC physicians, are just a few examples of the extreme emotions physicians may experience upon learning they have been sued and throughout the subsequent litigation process.

How likely is a physician to be sued?

Most physicians are sued or face the threat of being sued at least once in their career. According to a study by Anupam B. Jena, MD, PhD, and Seth Seabury, PhD, et al., published in *The New England Journal of Medicine*, August 18, 2011, 7.4% of all physicians included in the study have had a malpractice claim, 1.6% have a claim leading to a payment with 78% of all claims **not resulting** in payments (i.e., indemnity) to claimants.[13] The group analyzed malpractice data from 1991 through 2005 for all physicians covered by a large professional liability insurer with a nationwide client base and reported on 25 specialties. Their findings showed those physicians facing a claim **each year** ranged from 19.1% in neurosurgery, 18.9% in thoracic-cardiovascular surgery, and 15.3% in general surgery to 5.2% in family medicine, 3.1% in pediatrics, and 2.6% in psychiatry. The mean indemnity payment was $274,887 and median was $111,749. Mean payments ranged from $117,832 for dermatology to $520,923 for pediatrics. The study estimated that 75% of physicians in low-risk specialties will have faced a malpractice claim by age 65, as compared to 99% of high-risk specialty physicians. **See Figure 4**.

Physicians have described the experience of being sued and the litigation process as one of the most stressful periods of their lives. Often, the stress manifests itself in variety of symptoms known collectively as malpractice litigation stress syndrome. This article will discuss what physicians can expect during the stages of litigation, the signs and symptoms of malpractice litigation stress syndrome, and some practical Loss Prevention tips to avoid litigation. Most importantly, the article will discuss coping strategies to help physicians through this difficult time.

Anatomy of a lawsuit–what to expect during the litigation process

The litigation process often takes years before the lawsuit is resolved. Experts agree that understanding the legal process and knowing what to expect can help alleviate some of the stress of

13 Jena, Anupam B., Seabury, Seth, Lakdawalla, Darius, Chandra, Amitabh. “Malpractice Risk According to Physician Specialty.” *The New England Journal of Medicine*. August 18, 2011. 365;7;629-636.

Specialty Allegation	Physicians facing any Claim (%)		Physicians facing an indemnity Claim (%)	
	Age 45	Age 65	Age 45	Age 65
Internal medicine and its subspecialties	54.9	88.5	12.1	34.4
General surgery and surgical specialties	79.7	98.4	26.3	63.3
Obstetrics and gynecology	74.1	97.2	30.0	71.2
Anesthesiology	56.7	90.3	16.6	53.2
Family medicine	42.3	76.7	10.8	31.2
Pathology	37.5	80.8	5.6	28.7

Figure 4

Of note: The study clearly demonstrated that although there is a high likelihood physicians will experience at least one claim in their lifetime, most claims do not result in payments to patients. Although the researchers found that the annual rates of paid claims are low, the annual and career risks of a malpractice claim are high, "suggesting that the risk of being sued alone may create a tangible fear among physicians." Further, "Physicians can insure against indemnity payments through malpractice insurance, but they cannot insure against the indirect costs of ligation, such as time, stress, added work, and reputational damage."[14]

14 ibid

(litigation and help restore a sense of empowerment.

1) Pre-filing requirements

Depending on the state, there are different procedural requirements which have to be met before a medical malpractice lawsuit may be filed. In California, physicians will often receive a Notice of Intent (90-Day Notice) in letter form stating the patient's intention to sue. Idaho and Hawaii both require a pre-litigation hearing where both sides present their case (Medical Inquiry and Conciliation Panel in Hawaii, Pre-Litigation Screening Panel in Idaho). The findings of the panels are non-binding and are inadmissible in any subsequent lawsuit. The goals of the pre-litigation panel are for early resolution of cases and to prevent frivolous cases from proceeding to litigation; however, neither party is bound by the opinions of the panel or barred from proceeding to litigation. In Alaska, some cases are reviewed by an Expert Advisory Panel. After a hearing, the Panel issues an opinion which is admissible in any subsequent litigation. The Panel is not being utilized in some parts of the state, and in other cases the court may determine that a panel is not necessary.

2) Summons and Complaint

The Summons and Complaint is formal notice that you are being sued. It generally lists who is being sued and the plaintiff's allegations. Always notify the MIEC Claims Department immediately upon receipt of a Summons and Complaint. Do not ignore a Summons and Complaint. There are specific time frames in which a defendant must respond to the Complaint. Ignoring those timeframes puts you at risk for a default judgment (a ruling issued in the plaintiff's favor when the defendant fails to timely respond).

You will be assigned a claims representative who will guide you through the process. The claims representative will discuss the facts of the case with you, obtain your preliminary opinion of the merits of the case, discuss attorney assignment, and request a copy of the legal pleadings and the patient's medical record.

The claims representative will assign legal counsel to represent you. Develop a good working relationship with the defense attorney; be inquisitive, express your thoughts and opinions. Being an active participant in your defense can help you regain a feeling of control and relieve stress. You are encouraged to contact your claims representative or defense attorney at any time during the litigation

process should you have questions or concerns.

3) Discovery

The discovery phase of litigation occurs after filing the Summons/Complaint/Answer but before trial. It is the fact gathering phase of litigation. Both sides use various methods to "discover" the evidence the other parties will present. Methods of discovery include requests for production of documents (medical records, billing records, employment records); interrogatories (written questions submitted to a party which require answers under oath); and depositions (oral questions asked by counsel of the plaintiffs, defendants, and witnesses; answers are given under oath and can be submitted at the time of trial). Physicians should be prepared to devote a large amount of time (at least several hours and in some cases, days) preparing for their deposition. Many attorneys feel that the deposition of the defendant physician is one of the most important points in the case. The physician's cooperation while preparing for the deposition is crucial.

4) Mediation

Mediation is a confidential and informal way to resolve a dispute with the help of a neutral third person (mediator). The mediator works with both parties to help them reach a mutually agreeable solution to their differences. The mediator can't force the parties to resolve their differences, but the mediator can help the parties reach a solution agreeable to both of them. If the parties work out all or some of their differences, the resolution-or agreement-is put in writing and signed by both the parties. Courts often order mediation, but sometimes parties choose to proceed with mediation voluntarily with hopes of avoiding the time and expense of a courtroom trial.

5) Settlement

In some cases, due to the facts and merits of the case, MIEC will recommend to the physician that the case be settled before trial. The physician will be advised as to the reasons for the settlement recommendation and has the opportunity to express any concerns or ask questions about the settlement. MIEC physicians must give their consent before any settlement is made.

6) Trial

If a case is not resolved via mediation or settlement, the case may proceed to trial. In some cases, the trial might occur years after the filing of the Complaint. Witnesses for both sides will be called to present the facts of the case. Witnesses may include the patient, family members, other treating physicians, expert witnesses, and the defendant physician. As with a deposition, a physician should be prepared to devote a substantial amount of time to preparing for his/her testimony at trial. In addition, defense attorneys stress the importance of the defendant physician's presence in court for some if not all of the trial. The physician being present allows the jury to see him/her as a human being, not just a name. It also demonstrates to the jury that legality and defending his or her name are the utmost priorities for the physician.

Malpractice Litigation Stress Syndrome

Malpractice litigation stress syndrome is a term used to describe the complex physical and emotional responses that physicians may have to a malpractice suit.

Anxiety Symptoms (S. Sandy Sanbar, MD, PhD, JD, et al.)

- Excessive worry that occupies over 50% of waking hours
- Restlessness
- Tiredness
- Difficulty concentrating
- Irritability
- Tense muscles
- Insomnia
- Anger
- Bitterness
- Shock
- Dismay
- Guilt
- Shame
- Frustration
- Distrust
- Loneliness
- Diminished self-esteem
- Hyperactivity
- Emotional distancing from family members, friends, professional colleagues
- Diminished interest in work, food, recreation, sex
- Insecurity
- Develop concerns about ability and competency to make decisions
- Compulsively order unnecessary tests on patients
- Thoughts of changing careers
- Resort to alcohol or self-medication
- Exacerbation of preexisting medical illnesses such as coronary artery disease, diabetes, hypertension, or gastrointestinal disease

Figure 5

One study on physicians' reactions to malpractice cases revealed that 95% of physicians experience periods of emotional distress during all or portions of the litigation process.[15] A 2008 study by the Physicians' Foundation, an organization that helps physicians with practice improvements, ranked medical liability pressures as the third leading cause of stress in medical practice, behind long hours and insurance issues.[16] The central psychological event of litigation is the accusation of having failed to meet the standard of care.[17] According to S. Sandy Sanbar, MD, PhD, JD, and Marvin H. Firestone, MD, JD, the primary manifestations of medical malpractice stress syndrome are psychological symptoms (e.g., acute or chronic anxiety and depression), and the secondary manifestations are physical symptoms **(see Figure 5)**.[18]

The intensity of the reaction differs depending on the personality of the physician. Personality traits of physicians in general make them particularly vulnerable to suffering from litigation stress. Some common personality traits seen in physicians are perfectionism, possessing a strong sense of personal responsibility, being highly self-critical, and the need to be in control. These traits do not conform well to the atmosphere of a lawsuit. The physician's skill and competence are called into question and many aspects of the lawsuit are completely outside the physician's control.

In litigation, there are periods of activity followed by months of inactivity which can take physicians on an emotional rollercoaster. Physicians' emotions can go up one week and down another with alternating feelings of confidence and low self-esteem, of assurance and doubt.[19]

Physicians should be aware of their emotional and physical reactions to being sued. They should utilize coping strategies such as those listed below to try to alleviate the severity of their reactions. If symptoms such as physical illness, depression, or substance misuse persist, physicians should not ignore the symptoms but seek help from their personal physician.

Coping strategies

Experts recommend several stategies for coping with the stress of medical malpractice lawsuit:

1. Educate yourself about the legal process. Know what to expect during the various stages of litigation. Ask your lawyer to describe your role in each step of the process. Take an active role with your attorney in the defense of your case. G. Patrick Galloway, Esq. of the law firm Galloway, Lucchese, Everson and Picchi in Walnut Creek, California, offers fours ways to reduce stress and maximize your defense: (a) Contact your malpractice carrier immediately upon receipt of the Summons and Complaint; (b) actively participate in your case and work closely with your defense attorney; (c) learn to manage self-blame and self-doubt; and (d) adjust to the lengthy legal process. Accept that the timeframe of the legal process is out of your control.
2. Schedule time in advance for attorney interviews, depositions, trial, and other appearances.
3. Reach out for social support. Discuss

15 Charles, SC, Psykoty CE, Nelson A. "Physicians on trial: self-reported reactions to malpractice trials." West J. Med. 1988;148:358-360.
16 Sorrel, Amy Lynn. "Litigation stress: Being sued is personal as well as professional." Amednews. Posted November 2, 2009.
17 Ibid.
18 Sanbar, SS, Firestone, M. "Medical Malpractice Stress Syndrome." Medical Malpractice Survival Handbook, 2007. Chapter 2. 9-15.
19 Charles, SC. "Coping with a medical malpractice suit." West J.Med 2001;174:55-58.

your feelings with trusted family, friends, or colleagues. Contact your local medical society or specialty society for a referral to a support group. Remember not to discuss specific details of your case.

4. Take care of yourself. Exercise regularly and eat well. Maintain healthy balance of career and other interests.
5. Work to restore mastery and self-esteem. Review your career objectively. Reflect on the input of legal and insurance counsel about the case. Work hard to acknowledge the "truth" about the events in question.
6. Engage in activities that will increase your competence: courses, accreditation activities, teaching, simulation programs, continuing medical education, or hospital or clinic committee work.
7. Learn from the experience. Modify practices that make you vulnerable.
8. Spend quality leisure time with family and friends.
9. Recognize that litigation is often about compensation, not your competence as a physician.
10. Look reflectively at your life on all levels: personal, professional, financial, and recreational. Take stock of the good in your life. Seen in perspective, litigation may be less overwhelming than it appears.

When to seek expert help

According to the Sara Charles, PhD, MD, and her very helpful website Physician Litigation Stress Resource Center (www.physicianlitigationstress.org), the following experiences are indicators that a physician should consider a professional consultation:

1. When feelings of anxiety and distress interfere with daily work and relationships.
2. When self-medication and excessive reliance on alcohol or other drugs are used to dampen anxiety or get a good night's sleep.
3. When friends and family share observations about changes in your behavior.
4. When the quality of your life and work seem significantly compromised.
5. When symptoms emerge that are related to newly developed or previously experienced physical or emotional condition.[20]

Important "Do Nots" for physicians

Upon receipt of Summons and Complaint –

DO NOT:

1) Call the patient.
2) Call the patient's attorney.
3) Change or modify the medical record.
4) Ignore the Summons and Complaint.
5) Discuss the merits of the case with colleagues.
6) Conduct internet research regarding underlying issues in case. (If asked, you may have to disclose any research you have done, including articles or opinions that may be detrimental to your case.)

20 Physician Support Resources. www.physicianlitigationstress.org/physician_support_when.html

How to avoid liability: some Loss Prevention Recommendations and Resources

Acknowledging that a claim may be filed against you, using coping strategies, and seeking expert help should you require it are all definitive ways to manage the stress of litigation. However, avoiding liability altogether is a far better solution. Unfortunately, it is true that patients can sue whenever they like, but there are effective steps you can take to help decrease that possibility. Develop well-defined office policies and procedures, as well as follow-up systems for diagnostic tests, referrals, and failed appointments. Avoid breakdowns in communication and develop protective record-keeping practices. The Loss Prevention section of MIEC's website at www.miec.com has numerous articles and resources to help you address these areas of risk. Call the Loss Prevention team at 800/227-4527 with your general liability questions.

Outpatient Practice Excellence Certification

MIEC to pay half SCOPE fees for OB/Gyn policyholders who successfully complete SCOPE certification!

To support patient safety initiatives and quality improvement measures in the offices of MIEC's OB/GYN policyholders, the company is committed to helping physicians participate in the SCOPE certification process. OB/GYNs who successfully complete the certification process can submit the invoice to MIEC, who will reimburse half of the documented fees.

To learn more about SCOPE, contact scope@ac og.org or call 800/266-8043. For more information about fee reimbursement, call Loss Prevention at 510/428-9411 or toll free at 800/227-4527.

Safety Certification in Outpatient Practice Excellence for Women's Health Program (SCOPE for Women's Health Program)

SCOPE for Women's Health is an opportunity for the American Congress of Obstetricians and Gynecologists (ACOG) and its fellows to take a leadership role in defining quality and safety indicators for women's health care in the office setting.

Key goals of the SCOPE Program include:

- Promote the highest-quality of health care for women.
- Provide a trusted solution to meet the external demand for quality and safety activities.
- Reduce redundant review programs for physicians and offices.

What is SCOPE?

- The SCOPE review is a multi-step process toward a three-year SCOPE Certification.
- SCOPE focuses solely on processes associated with enhancing the safety environment and reducing risk for patients in the office setting.
- Any medical practice in which obstetrics and/or gynecology services are provided can submit an Application for SCOPE review.
- Each SCOPE review focuses on a single office location. In a practice or system with multiple offices, each office must complete an application (the questionnaire with supporting documentation), sign a SCOPE participation agreement and pay the program fee. Each office will then be eligible for review and certification individually.
- Clinical and non-clinical staff, both full-time and part-time, are included in a SCOPE review.

SCOPE History: ACOG is committed to helping improve patient safety in all settings in which women's health care is provided. Knowledge and implementation of patient safety measures can reduce medical errors and lead to positive patient outcomes.

In 2010, Quality and Safety in Women's Health Care, Second Edition, was published, joining a long line of publications and programs developed by ACOG to inform and assist obstetricians and gynecologists in managing quality improvement programs for inpatient and outpatient settings. This primer also includes the report of the 2008 - 2009 Presidential Task Force on Patient Safety in the Office Setting appointed by then President Dr. Douglas H. Kirkpatrick, which provides proposals for creating a culture of patient safety within the office practice.

ACOG has taken the next step in addressing patient safety by creating the SCOPE for Women's Health Program, a voluntary, comprehensive patient safety review program available to medical practices in which obstetrics and/or gynecology services are provided. SCOPE assesses the implementation and use of patient safety concepts and techniques in an individual office setting.

To my OB/GYN colleagues:

Our practice recently underwent the SCOPE review. This program is easy and painless for doctors to participate in. It consists of a form/questionnaire completed by your office staff that requires minimal physician input. Then there is a site visit by a member of ACOG's SCOPE team that lasts one day, and again, only a small amount of time, typically 10-30 minutes is needed with the physicians in the practice. At the end of the survey, you will receive a comprehensive list of suggestions designed to improve safety and quality in the OB/GYN office setting.

The Surveying team found several areas that we are now actively working on to improve for the sake of our patients. For instance, we have instituted quarterly drills (for allergic reactions, syncope, etc.) and have already implemented a privileging administrative process for all clinical staff to ensure that our clinical providers are limited to the procedures for which they have ongoing competence. We also have eliminated medication sampling as this was an area of potential danger for our staff and patients. We had wanted to make some of these changes in the past, but we were not motivated to do so until we had the suggestions in hand from the SCOPE team.

Our group achieved SCOPE certification and we are recognized for our excellent quality and safety processes that protect and benefit our patients. You can do the same!

SCOPE is easy, requires little physician effort, and it is a benefit to your patients. The SCOPE program is so valuable for improving safety and decreasing liability risks, and MIEC will cover half of your costs! For more information visit: www.scopeforwomenshealth.org, email scope@acog.org, or call 800/266-8043.

Lee Parsons, MD
OB/Gyn Associates
Caldwell, Meridian, Nampa and Eagle, Idaho

How to reach MIEC

PHONE:

Oakland Office: 510/428-9411

Honolulu Office: 808/545-7231

Boise Office: 208/344-6378

Alaska Office: 907/868-2500

Outside: 800/227-4527

FAX:

Main Oakland Fax: 510/654-4634

Honolulu Fax: 808/531-5224

Boise Fax: 208/344-7903

Alaska Fax: 907/868-2805

E-MAIL:

Lossprevention@miec.com

Underwriting@miec.com

Claims@miec.com