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CME - RISKS ASSOCIATED WITH MEDICAL SPAS

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Q1
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CME - RISKS ASSOCIATED WITH MEDICAL SPAS

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with material from Gracie Awalt, Laura Hale Brockway, Robin Desrocher, and Susie Edwards

OBJECTIVES

Upon completion of this course, the physician will be able to:

1. describe the doctrine of corporate practice of medicine as applicable to medical spas;
2. discuss the risks involved with accepting the role of medical director at a medical spa; and
3. list the top five reasons medical spas are investigated by regulatory entities.

COURSE AUTHOR

Wayne Wenske is the senior marketing coordinator at TMLT.

DISCLOSURE

Wayne Wenske has no commercial affiliations/interests to disclose related to this activity. TMLT staff, planners, and reviewers have no commercial affiliations/interests to disclose related to this activity.

TARGET AUDIENCE

This 1-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for medical liability.

CME CREDIT STATEMENT

The Texas Medical Liability Trust is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The Texas Medical Liability Trust designates this enduring material for a maximum of 1 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

PRICING

A fee of $75 will be charged when accessing this CME course online at https://lonestara.inreachce.com.

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This course has been designated by TMLT for 1 credit in medical ethics and/or professional responsibility.

TEST

To receive CME credit, physicians should complete the test questions that follow the activity. A passing score of 70% or better earns the physician 1 CME credit.

INSTRUCTIONS

the Reporter CME test and evaluation forms must be completed online. After reading the article, go to https://lonestara.inreachce.com. Follow the online instructions to complete the forms and download your certificate.

Questions about the CME course? Please call TMLT Risk Management at 800-580-8658.

ESTIMATED TIME TO COMPLETE ACTIVITY

It should take approximately 1 hour to read this article and complete the questions and evaluation form.

RELEASE/REVIEW DATE

This activity is released on March 24, 2020 and will expire on March 24, 2023.

INTRODUCTION

In recent years, more and more physicians have expanded their practices to offer services typically found in a medical spa. Medical spas provide a variety of aesthetic or cosmetic medical procedures, often in addition to traditional spa offerings (such as massages and facials), under the supervision of a physician.

While the procedures themselves may be performed by estheticians, nurses, therapists, or other providers, a physician must supervise treatments before a facility can be called a "medical spa."

Services offered by medical spas generally range from treatments for acne, aging skin, and hair removal to treatments often found in dermatology or plastic surgery clinics, such as light or laser treatments, injectables like botulinum toxin or hyaluronic acid, and chemical face peels.

There are a variety of reasons for the proliferation of medical spas, but those reasons often involve increased profitability. These services often help physicians increase the size of their practice; build retention rates; and significantly boost revenue. Also, because these procedures are elective, they are not covered by insurance and represent a cash transaction for the medical spa and physician.

By 2025, it is estimated that the worldwide medical aesthetics market could reach more than $22 billion. Drivers for this growth include an increased awareness among patients; the rise of medical spa treatments being sought by geriatric patients — the largest growing patient population; and the growing adoption by health care providers to perform minimally invasive and noninvasive aesthetic procedures within their medical practices.[1]

Hospitals, clinics, and medical spas are expected to hold the largest share of this market, as opposed to traditional health spas, beauty salons, or home care settings. (Patients have also been known to hold "Botox Parties" in their homes.) Patients prefer medical spas, because they offer the promise of clinical care performed by skilled professionals with advanced instruments, devices, and treatments.[1]

However, there are key legal and risk management factors with medical spas that physicians must consider before adopting these services in their practices or working as a "medical director" for a medical spa.

LEGAL CONSIDERATIONS OF MEDICAL SPAS – CORPORATE OWNERSHIP, SCOPE OF PRACTICE, AND MEDICAL DIRECTORSHIP

Medical spa management, ownership, and oversight require careful attention to the intersection of the corporate practice of medicine, licensing, and other legal and regulatory issues. Determining the best business structure for a medical spa is a complicated task and should be approached with the advice and guidance of your state medical board and attorney. Your medical malpractice underwriter should also be notified about any changes to your practice.

While most states do not specifically regulate medical spas, all facilities that provide "medical care" are subject to the same laws and regulations as health care facilities, including those laws pertaining to scope of practice and corporate ownership.[2]

State licensing laws dictate how a medical spa is structured. Most states define the "practice of medicine" in such terms as "diagnosing and treating disease," and make the unlicensed practice of medicine a felony.

Legal concerns can arise because courts often define terms such as "diagnose" and "treatment" broadly. Non-physicians with a state license as a professional health care provider (to perform laser treatments, injections, chemical peels, etc.) have limited licensure, which means the state's licensing statute and regulations clearly define the role of these providers, precluding the ability to "diagnose" and "treat."[3]

Scope of practice

The range of professional activities legally available to these providers is known as the "scope of practice." The scope of practice is explicitly defined to ensure that these non-physician providers do not diverge from performing activities that fall within their legally authorized scope of practice into the unlicensed practice of medicine.[3]

Scope of practice laws can be confusing, in part because the definition of "scope of practice" varies widely from state to state. To protect patients and provide guidance to practitioners, some state regulatory boards have established policies that clearly define their positions on scope of practice. Yet other state boards make determinations on a patient-by-patient basis or provide advice specific to an individual provider based on that provider's training, skills, and experience.

Others indicate that scope of practice determinations will not be made until or unless a complaint against the provider has been filed, and those determinations are made based upon the specific facts of the case.[4]

Managing scope of practice issues is further complicated by changing regulations. New regulations that expand or restrict scope of practice can be passed at any time.[4]

Therefore, it is recommended that a physician or caregiver working in or with a medical spa personally research the applicable state and federal requirements of their work to ensure full legal and safety compliance.

It is also recommended to consult with your state medical board, attorney, or professional boards, where appropriate, to help you create and adopt policies and procedures that adhere with federal and state law. As part of your policies and procedures, establish a regular review of federal and state laws and regulations on an annual or biannual basis to ensure compliance is up to date.

Corporate ownership

According to the American Med Spa Association, there is currently "no national standard regulating the ownership of med spas in the United States, so what may be commonplace in one state is strictly prohibited in another. While in Illinois, New York, Pennsylvania and Wisconsin, the laws regarding med spa ownership are clear that med spas must be physician-owned, some states do not make such a distinction."[5]

Most states observe a doctrine known as the corporate practice of medicine, which dictates that only a physician or physician-owned corporation can receive payment for medical services. Since many of the treatments offered at medical spas are medical in nature, this doctrine typically extends to medical spas.

However, non-physicians who want to open a medical spa do so by setting up a management services organization (MSO). An MSO provides business management services, including marketing, accounting, and human resources. They can then partner with a physician, medical practice, hospital, or managed care facility in an arrangement called a management service agreement (MSA). This arrangement allows non-physicians to operate a medical spa with one stipulation — they cannot provide the medical services themselves. All medical procedures must be performed or supervised by a physician.

Before entering into this type of arrangement, a physician must be aware of the risks. First and most importantly, the physician must always be responsible for making all medical and clinical decisions in the medical spa. If the physician fails to do this and medical decisions are made and procedures conducted by non-physicians (estheticians, registered nurses (RNs), cosmetologists), the physician

may be subject to severe consequences, including possible license forfeiture and fines.

Also, the MSO may be found practicing medicine without a license. In such an instance, a physician could be found guilty of aiding and abetting the unauthorized practice of medicine; lose his or her medical license; and incur steep fines and penalties for operating a medical practice illegally.

State laws on working as a medical director vary by state, as well. For example, in Illinois, it is illegal for a physician to be employed by a non-physician for work in a medical spa. If caught, the physician's license can be suspended or revoked, and the medical spa made to pay high fines.[5]

For any physician considering entering into an MSA as a medical director with a medical spa, it is recommended that you speak with your attorney, medical liability underwriter, and state medical board.

Medical directorship

Dr. Michelle Harden, an obstetrician-gynecologist in San Antonio, Texas and a governing board member for TMLT, offered the following advice to those physicians considering a medical director position at a medical spa.

"Physicians need to consider what it could do to their medical license and reputation. They often don't realize the implications on their license when they supervise non-medical personnel providing cosmetic or 'spa' procedures," says Dr. Harden.

"Many of these procedures have not been studied adequately. These physicians need to ask themselves, 'May I possibly be causing harm to my patient?' If not now, what about further down the road? Will there be long-term effects? Do you know for certain that you are not doing harm?" [6]

These sentiments echo advice given by the American Med Spa Association, which warns, "many physicians don't understand that becoming a medical director means that they are assuming ultimate responsibility for all of the patients that are seen and treated at the med spa."

"The medical director is responsible for ensuring proper protocols are in place, overseeing treatment plans, ensuring confidentiality – all of the things that the medical spa itself handles. While many of these tasks can be delegated, it is the physician, not the med spa owner or administrator, who is going to be held responsible if something goes wrong." [7]

Medical spa staff members

Medical spa staff members often include advanced practice registered nurses (APRNs), RNs, physician assistants (PAs), and medical assistants. But often staff members also include cosmetologists, massage therapists, and nutritionists. Most of the medical spas researched for this article employed estheticians and medical aestheticians on their staffs.

An esthetician is a skincare specialist who performs skin exfoliation, aromatherapy, facials, and skin analysis to help identify any potential health problems. Estheticians usually work in beauty salons, fitness clubs, and resorts.

A medical aesthetician (also known as a clinical or paramedical aesthetician) is a skincare specialist with a clinical focus. They treat facial skin damaged from fire, surgery, chemotherapy treatments, and other incidents. Medical aestheticians work with cancer patients, burn victims, and others with health-related issues. They often work in hospitals, burn units, trauma centers, and reconstructive surgery centers.

Both estheticians and medical aestheticians are trained in cosmetology; all states require medical aestheticians to have a professional license.

STATE LAWS AND REGULATIONS

Only a few states have comprehensive medical spa laws, including Colorado, Iowa, and Maryland. But many states regulate medical spas through other types of laws, including:

- business laws, including how businesses can be formed and operated;
- safety laws that govern the use of equipment and protect consumers/patients from any type of physical or emotional harm;
- licensing laws;
- consumer protection laws that protect against deceptive and misleading practices;
- building code laws for safety, emergency readiness, ADA compliance, and cleanliness; and
- ethics laws including requirements from states and state medical associations.[8]

If you are considering opening a medical spa or working with one as a medical director, become familiar with the laws in your state and the rules of your state medical board applicable to medical spas. You should contact your medical liability underwriter to discuss coverage as a medical director.

TEXAS MEDICAL BOARD (TMB) RULES

Texas leads the nation with the highest number of medical spas. Many malpractice lawsuits involving medical spas in Texas are linked to improper supervision.

In Texas, physicians who delegate duties are vicariously liable for the activities performed by staff members. (For a case study on this issue, please see the next page.)

The TMB has established guidelines for non-surgical medical cosmetic procedures to be performed by a qualified non-physician. These guidelines are in addition to rules on standing delegation orders and supervision of non-physician practitioners.

These procedures include injections and the use of prescription medical devices for cosmetic purposes. Some treatments, such as laser hair removal and the use of nonprescription devices, are excluded from these rules. Physicians who delegate performance of non-surgical cosmetic procedures should review TMB rule 193.17 in full.[9]

According to the TMB, a physician must be "appropriately trained, including hands-on training, in a Procedure prior to performing the Procedure or delegating the performance of a Procedure. The physician must keep a record of his or her training in the office and have it available upon request by a patient or a representative of the board."[9]

Procedures must be performed while a physician or other mid-level practitioner is on site, or a physician must be available for an emergency consult or appointment if a complication occurs. Mid-level practitioners and non-physicians can only perform procedures under proper, required physician supervision.[9]

Before a procedure, the physician or supervised mid-level practitioner must do the following:

1. obtain a patient history and perform an appropriate physical examination;
2. appropriately diagnose and recommend treatment;
3. develop a detailed, written treatment plan;
4. obtain the patient's informed consent;
5. provide instructions for emergency and follow-up care;
6. prepare and maintain an appropriate medical record;
7. have signed and dated written protocols;
8. have signed and dated written standing orders; and
9. document the performance of the items listed above in the patient's medical record.

The supervising physician must also ensure that the individuals performing procedures have received appropriate training in the following areas:

- techniques for each procedure;
- cosmetic or cutaneous medicine;
- procedural indications and contraindications;

- pre-procedural and post-procedural care;
- recognition and acute management of potential complications; and
- infectious disease control involved in each treatment.

Regardless of who performs the procedure, the supervising physician is responsible for the safety of the patient and for all aspects of the procedure. The physician should also ensure the procedure is documented. If the procedure is performed by unlicensed personnel, the physician should co-sign the documentation.

More information can be found here:

- Texas Medical Board Standing Delegation Orders — Chapter 193
- Texas Medical Board Rule 193.17 (Nonsurgical medical cosmetic procedures)

FEDERAL LAWS

Federal laws that apply to medical spas include the following.[8, 10]

- The Physician Self-Referral Law is commonly referred to as the Stark Law. With a few exceptions, this law prohibits physicians from referring Medicare or Medicaid patients to entities with which the physician or an immediate family member has a financial relationship.

- The Anti-Kickback Statute makes it a crime to knowingly and willingly offer, pay, solicit, or receive any remuneration directly or indirectly to induce or reward patient referrals or the generation of business involving any item or service reimbursable by a federal health care program.

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) law affects maintaining the privacy of patients' electronic medical records.

Many federal agencies enforce rules and regulations that apply to medical spas. These include:

- The Food and Drug Administration (FDA). The FDA regulates a variety of different medical procedures. They also regulate the sale and use of different products that can affect a person's health in any way, including cosmetics, skin care products, and aesthetic products.

- The Occupational Safety and Health Administration (OSHA) regulates the safety of medical spas.

(Continued on page 9.)

CLOSED CLAIM STUDY: FAILURE TO SUPERVISE MEDICAL AESTHETICIAN

The following closed claim study illustrates how a failure to supervise a medical aesthetician can result in allegations of medical liability and gross negligence.

Presentation

A 33-year-old woman sought laser hair removal for her sideburns and underarms at a plastic surgeon's medical spa, which was located next to his medical office.

Physician action

The patient was seen by a medical aesthetician, an employee of the plastic surgeon. The aesthetician evaluated the patient and documented the patient had Skin Type IV on the Fitzpatrick scale, a numerical classification system for skin. The scale estimates how different skin types will respond to ultraviolet light. Type IV skin is defined as, "Burns minimally, tans moderately and easily."[14]

The aesthetician documented that the informed consent discussion took place, including the possible short- and long-term effects of the treatment. The practice's consent form for light-based hair removal listed risks of discomfort, redness, swelling, bruising, pigment changes (hyperpigmentation and hypopigmentation), wounds, infection, scarring, and eye exposure.

The patient's signature appeared on the consent form; however, the signature looked different from the signature on the patient's registration form. The laser treatment was documented for "Skin Type V, Fitzpatrick scale."

Treatment was performed on the patient's sideburns and underarms. The progress note indicated the patient tolerated the procedure well. However, redness and swelling were noted on the right side of the patient's cheek. The left side of the face had no redness. The patient was given Phyto Corrective Gel to treat the affected area.

Later that day, the patient went to a local emergency department (ED) reporting patchy burns and multiple blisters on her right cheek. The ED physician diagnosed the patient with second degree burns.

The patient was given a tetanus shot. She was prescribed a triple antibiotic ointment for the right cheek and tramadol for pain. The patient was also given a handout on second-degree burns. She was instructed to return to the plastic surgeon for follow up.

The ED physician called the plastic surgeon to inform him of the patient's condition and to schedule a follow-up appointment for the patient. The plastic surgeon agreed to see the patient within a week. No documentation of the phone call was recorded by the plastic surgeon.

Instead of returning to the plastic surgeon, the patient visited her dermatologist for an unrelated condition. The dermatologist diagnosed the patient with superficial burns with possible early impetigo. Before the visit, the patient received a prescription for silver sulfadiazine from a family member, also a physician.

The dermatologist instructed the patient to continue applying the silver sulfadiazine for two days; prescribed an antibiotic ointment and an over-the-counter antihistamine for four days; and recommended an over-the-counter skin protectant.

Hyperpigmentation and some post inflammatory erythema were noted during two additional follow-up visits with the dermatologist. Visit notes at one week and three weeks indicated the patient's condition was improving.

Allegations
A lawsuit was filed against the plastic surgeon and the medical spa. The allegations included gross negligence in performing the procedure and failure to:

- adequately hire, train, and supervise the medical aesthetician performing the laser procedures;
- competently perform the procedure;
- perform test spots on the plaintiff's face before attempting laser hair removal;
- use adequate equipment or adequate settings on the laser while performing the procedure on the patient's face; and
- properly obtain informed consent for the procedure.

The lawsuit included an additional allegation of fraud by forging the patient's name to the consent document.

Legal implications
There were several areas of weakness in this case, as outlined by defense consultants.

The primary weakness was the apparent forgery of the patient's signature on the consent form. When comparing the patient's signature on the new patient paperwork to the consent document, it was obvious that the patient did not sign the consent form.

All the consultants agreed that the documentation was minimal and inadequate. The progress note was created three days after the actual office visit. The progress note also failed to provide details of the discussion with the patient about the risks and possible complications of the procedure. The patient's oral consent to proceed was also not included.

Laser settings were not recorded, and the dates of the procedure were incorrect in the chart. The patient's date of birth was also improperly entered into the record. The poor documentation raised concerns that the aesthetician was not properly trained and supervised by the physician.

Disposition
This case was settled on behalf of the plastic surgeon and the practice.

Risk management considerations
Physicians who delegate duties in their practices and medical spas are vicariously liable for the activities performed by staff members. Therefore, physicians should maintain employee records for each staff member that include a written job description, signed confidentiality agreements, current licenses and verification, signed acknowledgment of policies and procedures, and transcripts for all training obtained.

Poor documentation was a weakness in this case. It can be helpful to have a standard template for providers and staff when creating progress notes. The progress note template will remind the author to consistently include adequate and detailed information about the visit.

In this instance, it would have helped the defendant's case if he had been regularly monitoring and reviewing medical record documentation created by staff members to ensure the documentation was comprehensive and well maintained.

In addition to documentation issues, the plastic surgeon in this case had not obtained entity or premises coverage for the medical spa. The entity was included in the claim and exposed without medical liability coverage.

For those managing a medical spa in Texas specifically, the Texas Department of Licensing and Regulation, Health and Safety Code, Chapter 401, Subchapter M, Section 501-502, states that individuals performing laser hair removal must properly apply and meet listed requirements for a certificate or license.[15]

- Medicare and Medicaid enforce the proper billing, record keeping, and other requirements before reimbursement. While most procedures performed in medical spas are cash pay, there may be occasional exceptions.[8]

REASONS MEDICAL SPAS ARE INVESTIGATED

Due to the rapid growth of medical spas, regulatory investigations into these services have increased. According to the American Med Spa Association, here are the top five reasons medical spas are investigated.[11, 12]

1. **Improper intake procedures**
   The primary reason medical spas are investigated is due to improper patient intake procedures. Because most procedures performed at medical spas are considered medical, many states require that a physician, APRN, or PA perform a face-to-face exam before treating each patient.

   Some nurses have performed medical procedures without an intake exam because they believe their background and experience eliminates the requirement for an exam.

   Although certain licensed practitioners can perform intake exams, such as an APRN or PA, physicians are ultimately in charge of managing and/or supervising all medical procedures.

2. **Improper or lack of physician oversight of employees**
   Sometimes physicians serve as the medical director for several medical spas simultaneously, which could indicate the physician is being stretched too thin and may not be able to pay close attention to what is happening at each of the medical spas. This may create a risk for improper oversight of employees.

   Some medical spa procedures that have not traditionally been considered medical, such as microneedling and dermaplaning, have recently been recognized as medical procedures. Check your state regulations and with your attorney for information about the rules relevant to your practice.

3. **Improper marketing**
   Medical spa owners should not exaggerate the scope of their services. Since medical advertising regulations are strict, practices must be honest about the skills and accomplishments of their medical spa practitioners.

   Make sure you are not violating HIPAA patient privacy laws or state medical board regulations. Unless you obtain a patient's consent in advance, any social media post that identifies a patient violates federal law. (For a case study on this issue, please see the next page.)

4. **Non-approved drugs and equipment**
   Any drugs or equipment purchased from other countries runs the risk of not being approved by the FDA. Only legal purchases made in the United States can be positively cleared by the FDA.

   "Parallel importation" is a practice in which products sold for a lower price in other countries are re-sold in the U.S. at a much lower price. This practice is illegal, and the FDA will prosecute.

5. **Failure to file with the state board of cosmetology**
   Practices offering aesthetic services should make sure they are compliant with their state board of cosmetology. Most state boards require practices to apply for a cosmetology "establishment license," which will confirm that aesthetic services are being performed.

ADDITIONAL RISK MANAGEMENT CONSIDERATIONS

These risk management considerations provide a baseline of safety measures for use when supervising a medical spa or medical spa procedures in a clinical setting. This list is not comprehensive, and regulations can vary from state to state.[4, 13]

- In a medical spa scenario, it is recommended that physicians or advanced practice providers be onsite when a procedure is performed by unlicensed personnel, in case of an emergency.

- Use FDA-approved equipment and employ qualified, certified providers and staff members.

- A medical director or supervising physician has the duty to assess the qualifications of each staff member who will carry out medical or clinical procedures. The physician must ensure the person performing a procedure is trained appropriately.

- Maintain records of each individual's licensure, training, certification status, knowledge, and experience in every procedure the staff member will perform.

- Verify that each procedure falls within the provider's legal scope of practice (licensed staff) or services (unlicensed assistive personnel). No procedure should be delegated to a provider who has not satisfactorily demonstrated current skill and training in the necessary competencies for the procedure.

CLOSED CLAIM STUDY: PATIENTS IDENTIFIED ON SURGEON'S WEBSITE

Below is a closed claim study based on alleged violations of HIPAA privacy rules by a plastic surgeon's medical practice. The privacy issue in this case is relevant to medical spas.

A plastic surgeon's website featured "before and after" photos of patients. The patients' names were not used and the photos were posted in a way that preserved patient anonymity.

However, unknown to the plastic surgeon and his staff, the patients' names had not been properly removed from the meta tags associated with the photos. Meta tags are content descriptors that describe webpage content to search engines. Meta tags do not appear on the page but are found in the HTML code for the page.

The issue was discovered when a patient performed a Google search on herself and her images from the plastic surgeon's site appeared in the search results. Although he was told about the meta tag issue, the plastic surgeon did not immediately remove the photos. Fifteen patients filed lawsuits against the plastic surgeon. The Office of Civil Rights also investigated the plastic surgeon for possible HIPAA violations.

Risk management considerations

When patient photographs are completely de-identified, HIPAA requirements are satisfied. If patient photos are not de-identified, written authorization from the patient is required to post or share the photos. In all cases, even if fully de-identified photos are used, patient consent is strongly recommended.

To de-identify a photo based on the HIPAA Safe Harbor de-identification standard, the following identifiers of the individual or of relatives, employers, or household members of the individual, must be removed:

(A) "Names
(B) All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
    1. The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
    2. The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
(C) All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
(D) Telephone numbers
(L) Vehicle identifiers and serial numbers, including license plate numbers
(E) Fax numbers
(M) Device identifiers and serial numbers
(F) Email addresses
(N) Web universal resource locators (URLs)
(G) Social security numbers
(O) Internet protocol (IP) addresses
(H) Medical record numbers
(P) Biometric identifiers, including finger and voice prints
(I) Health plan beneficiary numbers
(Q) Full-face photographs and any comparable images
(J) Account numbers
(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section;[16] and
(K) Certificate/license numbers."[17]

Additional risk management considerations

- Obtain patient consent to take photographs. Specify how you plan to use the photos (i.e. medical records only, marketing, website, journal article) on the consent form.
- Do not name or save photo files with any of the above identifiable information in any publicly accessible area. (Clearly, if you are just adding photos to medical records, they can contain identification.)
- Audit photos that have been added to your website. Check the site page for tags, meta tags, keywords, or anything that could be used to identify patients.
- Do not store photos of patients in an unencrypted device, such as a camera, cell phone, tablet, or personal laptop.

(Continued from page 9.)

- Create and maintain policies and procedures for staff members, including responsibilities, scope of practice, and standing delegation orders.

- Create and maintain written protocols for each procedure provided by the medical spa for the person performing the procedure to follow.

- Have providers and staff members sign the protocols to acknowledge their understanding of the policies and the procedures of all services they may be delegated to perform, including emergency protocols.

- Many states, including Texas, have regulations requiring the supervising physician or medical director to possess the same knowledge, skill, and ability to personally perform each procedure that he or she may delegate. In Texas, a record of training must be kept in the office and available upon request by a patient or TMB representative.

- Other states require the physician *only* to perform the procedures in his or her practice. Check your state regulations, state medical board, or legal counsel for clarification in your state.

- Each provider must be readily identified by a name tag or similar means that clearly delineates the identity and credentials of the person. In medical spas, patients are often met by staff members wearing lab coats who do not have any medical or clinical training or experience. This could be interpreted as misrepresentation and be an issue in a board complaint or liability claim.

- Ensure that any time a procedure is performed, at least one person trained in basic life support is onsite.

- In the case of an emergency, consider establishing a written transfer agreement with the nearest acute care hospital to ensure patients obtain prompt emergency care. Train staff on how to respond to an emergency.

- Treat all procedures as medical procedures, whether or not they are performed by physicians or other providers, in a medical spa or clinical setting. This means:

    - follow HIPAA regulations;
    - obtain and document patient history, including medications;
    - perform a physical exam before ordering treatment;
    - conduct an informed consent discussion before treatment and obtain a patient signature on consent forms that reflects the discussion took place and the patient understands the treatment goals and risks; and
    - maintain patient records, including initial assessment, course of treatment, informed consent, and any postoperative or follow-up care provided.

CONCLUSION

For physicians who are interested in serving as a medical director or opening a medical spa, Dr. Harden offers the following advice.

> "1) do your research; 2) move slowly; and 3) if it seems too good to be true — it probably is. If these treatments turn out to be harmful to the patient, you may have regrets. The immediate economic advantages may not be worth what you could harm long-term — a patient, your license, or your reputation. Stay true to the principles of why you became a doctor and do no harm." [6]

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16. "(c) Implementation specifications: re-identification. A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:
(1) Derivation. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
(2) Security. The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification."
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FAILURE TO FOLLOW UP AND TIMELY DIAGNOSE ECTOPIC PREGNANCY

by Gracie Awalt, Marketing Associate, and Wayne Wenske, Senior Marketing Coordinator

PRESENTATION

On July 11, a 26-year-old woman came to her obstetrician-gynecologist (ob-gyn A) with reports that on July 9 she went to the emergency department (ED) of a medical center with pain in her right lower abdomen. Her last menstrual period was on June 29.

This closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of the physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician's defensibility. This study has been modified to protect the privacy of the physicians and the patient.

PHYSICIAN ACTION

During this ED visit on July 9, the on-call emergency medicine physician ordered blood work; a pregnancy test; and an abdominal CT scan. The results of both the patient's CT scan and pregnancy test were negative.

During the July 11 office visit, ob-gyn A noted the patient's right adnexa was tender. After ordering a pelvic ultrasound, the patient was diagnosed with vaginitis and scheduled for a follow-up appointment on July 29.

On July 18, the patient called ob-gyn A's office and left a message that she was experiencing excruciating pain on her right side. The office called the patient instructing the patient to come to the office for an ultrasound and evaluation. The patient never came in.

On July 21, the patient went to see another physician, ob-gyn B, on referral from a friend. The patient told ob-gyn B about pain on her right side and her menstrual cycle history. The physician ordered an ultrasound and urine pregnancy test. The ultrasound was negative, but the pregnancy test was positive with the hCG level at 1264 mIU/mL. (Anything above 25 is considered positive for pregnancy.) These results were not communicated to the patient.

On August 4, the patient went to an urgent care center with reports of severe abdominal pain. The patient was transferred by ambulance to a medical center where she was diagnosed with a ruptured ectopic pregnancy. The on-call obstetrician, ob-gyn C, performed a laparoscopic right salpingectomy to remove the patient's right fallopian tube and ectopic pregnancy.

The patient was discharged the next day. She went to a follow-up appointment with ob-gyn B on August 19. The patient was noted to be healing nicely.

ALLEGATIONS

A lawsuit was filed against ob-gyn B. Allegations included failure to:

- review lab results indicating the patient was pregnant;
- order appropriate follow-up testing; and
- timely diagnose and treat the ectopic pregnancy so the patient could avoid surgical treatment.

LEGAL IMPLICATIONS

Consultant ob-gyns for TMLT noted that the fragmented nature of the patient's care contributed to the difficulty in diagnosing the source of her pain. They also agreed that the patient needed follow-up hCG testing; however, they acknowledged that the location of the pregnancy could not be determined by an ultrasound until the patient's hCG levels exceeded 5,000 mIU/mL.

One consultant stated that had the ectopic pregnancy been diagnosed earlier it could have been medically treated with methotrexate. However, there was no guarantee the patient would not require surgical treatment. Although the patient did not follow-up with ob-gyn A, she did follow up with ob-gyn B within the recommended timeframe.

A consultant for the plaintiff noted that ob-gyn B should have documented the positive pregnancy results and scheduled follow-up hCG and ultrasound testing. This consultant also voiced the opinion that an early diagnosis could have been medically treated with methotrexate. The patient could have also received a linear salpingostomy to remove the pregnancy instead of the entire right fallopian tube.

The majority of consultants reviewing the case for the defense stated that the surgical removal of the patient's fallopian tube was unavoidable. These consultants believed that even if ob-gyn B had noted the hCG results in a timely manner, treatment with methotrexate was not an option for this patient.

DISPOSITION

The case was settled on behalf of ob-gyn B.

RISK MANAGEMENT CONSIDERATIONS

Establishing and maintaining strong follow up and communication policies and procedures can help enhance patient care. In this case, the patient's condition and test results were not reviewed, acted upon, or communicated to the patient in a timely manner. Had clear follow-up procedures been established, this case may have had a different outcome and been easier to defend.

A physician who orders tests is responsible for reviewing results when received; documenting his or her review in the medical record; and initiating appropriate follow up. Ob-gyn B did not communicate the positive pregnancy result to the patient or schedule appropriate follow up testing.

A problem for many practices is the lack of a clearly defined tracking system for managing test results used across facilities, offices, laboratories, and other institutions. While tracking systems will vary from practice to practice, there are four basic steps physicians can follow to help ensure test results are managed properly:

1. track tests until results are received;
2. notify patients of the results;
3. document that the notification occurred; and
4. ensure that patients with abnormal results receive recommended follow-up care.[1]

Instituting a clear system for effective patient follow up is also recommended. In establishing policies and procedures, consider the following.

- Prioritize test results with "urgent," "critical," "action needed," or "pending results." A coding system may heighten awareness and trigger appropriate follow up.
- Standardize and simplify processes by using checklists, flow sheets, or tracking systems.
- Adopt technologies that employ built-in systems such as reminders, alerts, and the flagging of documentation issues. Recognize that these types of systems are only effective if there is a commitment to use them.[1]

Avoid using the "no news is good news" approach for dealing with test results. Abnormal test results can be sent to the wrong office, misplaced, or accidently filed without physician review.

Consider enlisting your patients in helping you track test results. Encourage your patients to call if they have not received their test results within a previously agreed upon timeline. Another way to enlist patients in their own care is to hold them accountable to their follow-up appointments. Emphasize the importance of follow up and encourage them to keep their appointments.

While involving patients in their own care can help overall outcomes, their involvement does not relieve the physician of his or her responsibility to follow up.[1]

SOURCE

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DELAY IN OBTAINING MRI

By Wayne Wenske, Senior Marketing Coordinator

PRESENTATION

On June 22, a 58-year-old man came to the emergency department (ED) of hospital A. He reported fatigue, nausea, vomiting, difficulty with balance and walking, chest pain, weakness, and flu-like symptoms for one week. The patient had a history of poorly controlled type 2 diabetes mellitus, hypertension, morbid obesity, alcoholism, and smoking.

The patient was examined by an emergency physician and diagnosed with diabetic ketoacidosis (DKA) and left leg weakness. The patient was admitted to the hospital under the care of an internal medicine physician.

This closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of the physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician's defensibility. This study has been modified to protect the privacy of the physicians and the patient.

PHYSICIAN ACTION

Just after being admitted, the patient reported numbness and weakness in both legs. The internal medicine physician ordered a neurology consult. In turn, the neurologist ordered an MRI, but the patient complained of chest discomfort and could not breathe when lying flat. The MRI study was rescheduled for the next morning. An additional CT scan was also ordered.

The next morning, June 23, the patient refused to have the MRI. The neurologist documented that the MRI was again not performed, and that the patient would need sedation before an MRI could be attempted. The neurologist also documented that the results of the CT scan did not explain the patient's symptoms.

On June 24, a pulmonologist saw the patient and suggested an MRI, but the patient refused. The pulmonologist documented that the MRI could not be performed because the patient's weight prohibited him from fitting into the hospital's MRI machine.

Calls were made to numerous hospitals to transfer the patient to a facility with an MRI machine that could accommodate the patient and that had the staff and resources to sedate the patient.

On June 26, the patient was transferred to hospital B, a facility that could accommodate him and perform the MRI. The results of the MRI revealed an epidural fluid collection with associated spinal cord injury from T1 to T5.

The patient's condition was classified as an "A" on the American Spinal Injury Association (ASIA) Impairment Scale. The A rating represents "complete" impairment, with no sensory or motor function preserved in sacral segments S4-S5.

A neurosurgeon at hospital B discussed the findings with the patient and the need for spinal decompression. He advised the patient that the procedure would not reverse the condition and paraplegia was unavoidable.

Eight days after surgery, the patient was discharged to a rehabilitation facility with persistent paraplegia.

ALLEGATIONS

The patient filed a lawsuit against the internal medicine physician, the neurologist, the pulmonologist, and hospital A. Allegations included delay in obtaining MRI to diagnose spinal epidural abscess. It was further alleged that the delay allowed the spinal epidural abscess to grow and cause the patient's permanent paralysis.

LEGAL IMPLICATIONS

Consultants who reviewed this case for the defense were mostly supportive of the care provided by the physicians. Most of the consultants felt the logistics involved with transferring a patient whose condition was rapidly deteriorating and who could not physically be tested in the facility were the major factors in the outcome of this case.

During his admissions at hospitals A and B, the patient experienced multiple complications, including hip abscess, colostomy, renal failure, and decubitus ulcers. Several of these complications prevented transfer and/or surgery.

The patient's size and need for general anesthesia before the MRI prevented the test from being performed at many facilities. Six hospitals refused to admit him. It was noted that once the patient was stabilized, every effort was made to obtain the scan. Yet, by the time he was stable for transport and the scan, it was probable that surgical intervention would not reverse the paraplegia.

Consultants for the plaintiff were more critical. One consultant criticized the emergency medicine physician and the internal medicine physician for not recognizing the possibility of a spinal epidural abscess when the patient first came to hospital A. She felt this oversight contributed to the delay in diagnosis. She also noted that the internal medicine physician did not see the patient for 36 hours after ordering the neurology consult.

Another consultant felt the neurologist could have been more proactive and aggressive about obtaining the MRI, and that he should have consulted with a neurosurgeon earlier. The neurologist was responsible for following up with his order for an MRI and ensuring the test was conducted in a timely manner. However, the patient's poor condition and size, combined with the lack of an appropriate MRI machine delayed the process. These consultants also noted a lack of communication between the various providers seeing the patient.

An accusation of bias due to the patient's obesity was also noted as a possible contributor to the delay and lack of urgency by the providers.

DISPOSITION

Due to the severity of the patient's condition, the case was settled on behalf of the physicians.

RISK MANAGEMENT CONSIDERATIONS

When multiple providers are involved in the care of a patient, continuity of care can become a greater challenge. That challenge can be overcome with increased direct communication between providers and with more detailed documentation in the patient record.

In this case, the different physicians were communicating primarily through the patient record, and the neurologist was not fully documenting his examinations, findings, or communications with the patient.

For example, the pulmonologist stated that he was not aware that the patient could not fit into the MRI machine until he first met the patient on June 24. This was two days after the patient had been admitted and one day after the patient's first scheduled MRI had been cancelled. When reviewing the record before seeing the patient, the pulmonologist had assumed the patient refused due to anxiety.

While the patient could be seen as non-compliant in this case, his reasons for non-compliance were reasonable. His refusal was due to an inability to breathe while lying down and not being able to fit in the machine. The physicians should have more urgently removed the barriers so that the patient could have received more timely care.

While the Americans with Disabilities Act (ADA) does not currently recognize obesity as a disability, the definition of the term "disability" has been expanded to make it easier for obese individuals to make disability claims.

Obese patients often do not seek health care services due to feelings of embarrassment, stigma, and disrespect in health care settings. Negative bias exists in our society — including the health care sector.

It is important to approach obese patients with empathy and respect, and to maintain a clinical setting with suitable equipment and supplies. For obese patients, this could include providing sturdy, wide exam tables; extra-large patient gowns; restrooms with high, easy-rise toilets and extra space around the toilets; large adult blood pressure cuffs; and a discreetly located scale with the capacity to weigh patients who weigh more than 400 pounds.

The lack of urgency in this case was troubling. Every practice should have patient care protocols for prioritizing cases, tests, follow up, and appointments to assure continuity of care. Written patient care protocols can assist in defining appropriate actions for staff to follow to prevent important issues or serious conditions from being overlooked. When written protocols, policies, and procedures do not exist, the defense of a claim can be more difficult.

The staff members at hospital A also lost time because they did not know which facilities in their area could accommodate the patient. In addition to written protocols, maintaining a record of medical resources available in the area, including specialists, equipment, and locations, would have helped staff members at hospital A find appropriate services for the patient in a timely manner.

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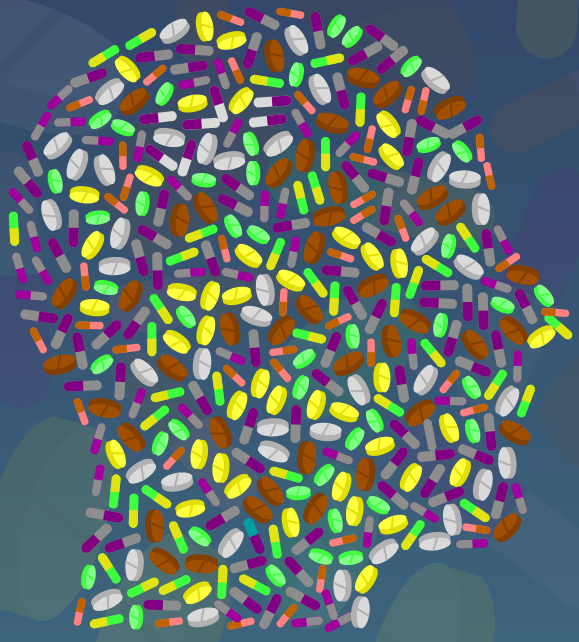

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