legal case of the month

Medical Director Liability

AN ACCIDENT WAITING TO HAPPEN?

By Paddy Deighan, MBA, J.D.

T he proliferation of medical spas and the vertical integration of medical services into salons and spas have given new meaning to the existing role of medical directors. In the past, medical directors really had a limited, albeit it important, role in the medical environment. Their role was clearly defined. Accordingly, the risks which were presented to them and their organization were narrowly focused and simple to address.

This traditional role has evolved; and a discussion of this evolution is appropriate since many medical

directors, spa owners, and even general counsel are unaware of the pitfalls of this developing role.

Historically, a medical director was responsible for the

supervision of medical services performed within an organization. The director was responsible for compliance, regulatory review, and to ensure that the internal protocols were being successfully implemented and followed. Whenever a new procedure or device was utilized, the director prepared a written policy, protocol, and prepared a plan to implement the new product or service.

The role was clearly defined, and the risks were known and relatively easy to assess.

CHOOSING AN APPROPRIATE MEDICAL DIRECTOR

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"medical" procedures.

Today, this traditional role has changed tremendously. Medical directors are being called upon to supervise non-medical personnel and to supervise

> new procedures and devices. Many medical spas are employing physicians solely for the purpose of enabling the facility to perform "medical" procedures. Many of these

physicians are being asked to supervise technology and personnel without proper familiarization. Another consideration is that for the first time, the medical director is supervising a facility other than the one in which he or she works exclusively. aesthetic

This situation creates a number of concerns. Naturally, the medical director should be concerned with the additional responsibility and the liability which is connected to it. However, the facility should be very concerned as well.

The medical spa director (or medical director of a spa or facility) is frequently a physician who has decided to try something new. They are entering into a new area of medicine. The danger is that they are now responsible for personnel and procedures with which they are unfamiliar. The facility needs a medical director to enable them to perform "medical" treatments, and the physician has decided, for whatever

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reason, that the medical director role is desirable.

It is very difficult for this physician to develop, implement,

and control policies, procedures, and protocols for these new concepts. However, this function is critical. It is the basis of the purpose behind being a medical director. Accordingly, care should be utilized in the selection process of a director. For example, if the facility desires to add health and wellness medical services, the services should be performed by an appropriate medically trained individual; and the director should be from a background which includes experience in these areas. Health and wellness programs may call for a medical director who is from family, internal, osteopathic, holistic, or similar medical specialty. The director may have chiropractic and or acupuncture training as well. If the facility is embarking on a beauty or cosmetic service menu, a dermatologist and/or plastic surgeon would be appropriate. A facility which is established in diet and nutrition should consider medical directors who are from cardiology (Dr. Robert Atkins was a cardiologist), internal medicine, endocrinology or other similar medical specialty. There should also be registered dieticians and nutritionists on staff.

There are many physicians practicing medicine outside of their training and experience. The expanded roles of medical directors have significantly contributed to this trend. Many physicians have been flattered by being asked to be a "medical director." However, they frequently underestimate the responsibility and liability which comes along with the title.

WRITTEN POLICIES AND PROTOCOLS

The physician acting as medical director should analyze every procedure and treatment which a facility offers to determine which of these MAY be considered medical. For each such treatment or procedure, the medical director should establish written policies and These should include a protocol that protocols. determines which category of personnel may provide In many instances, personnel are the service. performing services at the delegation of the physician. The general rule is that if the physician deems a person to be trained and otherwise adequate, it is acceptable for them to provide the treatment. The physician is "sponsoring" the work of his employee, agent or servant.

However, in many current scenarios, the medical director is not present on a daily basis in the facility. In other situations, the physician does not own or control the facility. These situations present certain dangers. It can be argued that the physician is not adequately supervising the personnel if he or she is not on site. Accordingly, the personnel may be practicing medicine without a license. Historically, states rarely took action on individuals practicing medicine without a license,

but some unscrupulous conduct in many states has given rise to a flurry of activity in this area of law.

There have been many actions taken against individuals in Florida, Texas, and California for example. Many of these actions stemmed from injection of various filling substances for cosmetic indication. For whatever reason, some people believe that these procedures are not medical. However, the device utilized (the filler) is medical, and the implementation device (syringe) is medical, so the administration of the product is clearly medical and not appropriate for anyone other than medical personnel. An esthetician is not appropriate for this function.

Therefore, the protocols should include consideration of the relative role which the medical director has in the daily operation of the facility. If the director is truly on site, there is





more latitude in the treatment options. Caution should be employed if the medical director is not on site every day and the protocols should clearly indicate which procedures can be performed and by which category of personnel. Underlying this concept is the expertise and training of the medical director. If one has been selected who may not have all of the background to direct certain services, another appropriate physician could be utilized to prepare protocols for the medical director to follow.

CLEARLY DEFINE WHICH PROCEDURES ARE MEDICAL

It is clearly difficult to determine which procedures are medical. There are common sense guidelines. If a treatment or product is offered to cure or treat a medical condition, it is clearly a medical procedure. If the device utilized in the treatment is a medical device (laser, for example), the treatment is a medical treatment. This may sound overly simplistic, but there are many nonmedical facilities which offer acne treatments; and this is arguably the practice of medicine, and caution should be utilized. There are estheticians who purport to be "medical estheticians," but this has little legal significance without specific training and certification. It certainly does not provide for greater medical treatment capability.

The facility should also protect itself from the liability arising out of the medical director. It, too, should have a written set of protocols for the medical director to follow. This will protect the facility from activities of the director who may have been outside the intended business relationship. The facility should be concerned with the appropriateness of the procedures as well and not rely on the medical director to insulate them from liability.

Just as the medical director role has certain implications for the physician, it has similar implications for the facility. Did you know that merely having a medical director may classify the facility as a "medical facility?" There are many ramifications to this including insurance, real estate issues, plumbing, electrical, sterilization, certifications and licenses, etc.

INSURANCE & LIABILITY ISSUES

Perhaps the biggest area of concern regarding medical director liability is insurance. Many physicians and facilities believe that they have insurance coverage for all losses attributed to the operation of the business. There are many physicians who receive a monthly sum of money to be a medical director, but the amount of money is not even enough to pay the insurance premiums, so I can only conclude that the proper insurance is not in effect. The malpractice carrier of the physician will deny coverage for a loss as a result of the physician being employed as a medical director. The facility's business liability insurance will also deny coverage because a loss may be outside the scope of coverage.

There are policies for such coverage, but they are

separate from the above. There is, for example, Directors and Officers (D&O) coverage available to insure against such

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losses. A safe rule of thumb is to contact your insurance company or agent, provide them a copy of your brochures, advertisements, and protocols, and ask if you are adequately covered. The medical director needs coverage separately to prevent liability from flowing back to the facility. A facility could be legally responsible for actions and inactions of the medical director. The proper insurance provides a measure of protection and validation. If an insurance company or agent indicates that there is no coverage for a particular loss, you should rethink whether you wish to perform the service. If an insurance company indicates that there is no coverage available, you should realize that they are not comfortable with the risk; and you should not be comfortable either. An example of this scenario is that many non-medical facilities have acquired lasers to perform hair removal. They have had tremendous difficulty in getting insurance. It may be time to rethink the strategy. It could be argued that hair removal is not the practice of medicine, but the device utilized is medical, hence, the difficulty in insuring the risk.

The good news is that the adequate protection of medical directors and facilities is readily available. The further good news is that it is not a difficult or burdensome task. With proper preparation by following the above guidance, everyone will be able to sleep at night.

Paddy Deighan is featured on our editorial advisory panel page (see pg. 5). For further information regarding this topic and other legal issues, please address correspondence to: Paddy Deighan, President & CEO, DermAmerica Inc.,1000 Main Street, Suite 103, Vorhees, NJ 08043, p 856.751.5647, email:dermusa@aol.com.