

Cosmetic Procedures

What's the Risk?

Many practitioners who offer to help patients achieve a new look are licensed. Some are not. Many work within the scope of their medical specialty. Some do not. Most will be able to meet their patients' expectations. Some will not. A few practitioners who perform cosmetic procedures are likely to become involved in medical malpractice litigation.

Failing to meet expectations is one of the leading reasons why patients undergoing cosmetic procedures file medical malpractice suits.

When Is This Risk an Issue?

The following are some aspects of cosmetic procedures that are important from a risk management perspective.

Malpractice Insurance

Policies may cover a practitioner's clinical activities with respect to cosmetic procedures. Many policies will not cover the practitioner's administrative activities, for example, as medical director of a spa or other facility.

State Regulations

In some states, the performance of cosmetic procedures is considered the practice of medicine and may only be done by a physician or an advanced practice clinician. In other states, some procedures may be carried out by an appropriately trained registered nurse.

Education and Experience

Physicians in many specialties are now offering cosmetic procedures, particularly non-surgical cosmetic procedures, to their patients. Many have learned to perform the procedure(s) in a one-day or weekend workshop. Such training may not be sufficient for the provider to practice at the standard of care to which he/she may be held in the event of a claim or suit.

In many practices, individuals other than a physician are performing non-surgical cosmetic procedures. Some are licensed. Some are not.

From a risk management perspective, on-site supervision is always the ideal, giving staff members the advantage of having someone immediately available to answer questions and to help in the event of an emergency.

Cosmetic Procedures

Patient Protocol

Not every patient who wants or requests a cosmetic procedure, whether surgical or non-surgical, is a candidate for one.

Pre-procedure and post-procedure photographs may prove helpful, particularly if the patient is unhappy with the results or there is an unintended outcome.

Informed Consent

Practitioners should not offer more to the patient than they are able to deliver.

Consent forms signed en masse at a BOTOX® cosmetic party or other group encounter may not be considered “informed consent” if a medical malpractice case arises. Patients in such settings might argue that they did not ask questions they considered important because they did not want to appear “stupid” or “silly.”

Location of Services

Clinical procedures should be provided in a clinical environment with available infection control and prevention practices, the appropriate support staff, and appropriate emergency supplies. Coverys does not support the practice of providing cosmetic services in locations other than a clinical setting, such as hotel rooms and personal residences.

Pharmaceuticals

A few significant adverse reactions have been traced to pharmaceuticals purchased online from questionable sources.

Equipment

From a risk management perspective, it is important that malfunctioning equipment be left in the condition it was at the time it malfunctioned; it should not be touched until after it has been properly inspected by biomedical personnel and/or a representative of the manufacturer.

Independent Contractors/Nurses

The physician, office or marketing material that allows or leads patients to believe that the work of an independent contractor is guided or approved by the physician or practice has significant risk exposure.

Signs posted in the office are an effective way of letting patients know whether the independent contractor's work is in any way guided or controlled by the physician, for example, as an employee.

Sponsoring an independent nurse, particularly when the physician is not on-site and actively involved in the nurse's practice, may represent a significant risk exposure.

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How Can I Reduce Risk?

The following risk management suggestions will minimize the risk of medical malpractice litigation.

Implement Administration Protocol

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| Restrict procedures | <ul style="list-style-type: none">• Restrict office-based procedures performed by any one practitioner or practice to those with minimal risk, those for which the practitioner and staff members have adequate training, and those for which the office is technologically equipped. |
| Implement policies and procedures | <ul style="list-style-type: none">• Ensure that written policies and procedures address all aspects of performing the cosmetic procedures that will be carried out in the office. |
| Maintain written transfer agreement | <ul style="list-style-type: none">• Maintain a written transfer agreement with a nearby acute care facility, in case of an emergency. |
| Confirm medical malpractice insurance coverage | <ul style="list-style-type: none">• Do NOT assume adequate medical malpractice coverage is in place. Confirm that coverage is in place, know exactly what is covered, and determine whether any additional coverage may be needed. |

Implement Protocol for Physicians and Staff Members

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| Know and follow state regulations | <ul style="list-style-type: none">• Be familiar with and strictly adhere to the laws of the state and the regulations of the boards which license nurses, estheticians, and cosmetologists, with respect to who is authorized to perform which non-surgical cosmetic procedures. |
| Obtain sufficient education and experience | <ul style="list-style-type: none">• Ensure that physicians are adequately trained to effectively deal with unanticipated side effects, complications and emergencies. |
| Ensure sufficient training for staff | <ul style="list-style-type: none">• Ensure that all staff members have sufficient education and training to enable them to perform competently and to enable them to recognize and treat complications and emergencies. |
| Encourage certification | <ul style="list-style-type: none">• Ensure that staff members performing non-surgical cosmetic procedures are certified in each procedure they perform. Require written evidence of training in a nationally or regionally accepted program if no certification exists and keep it in the employee's personnel file. |

Implement Protocol for Physicians and Staff Members

Provide on-site supervision

- Know when on-site supervision of staff members performing cosmetic procedures may be required.

Obtain Informed Consent

Implement thorough consent process

- Obtain the informed consent of the patient for each cosmetic procedure. Document the informed consent discussion in the medical records and execute a properly completed consent form.

Be realistic

- Do NOT offer or promise more than can be delivered to the patient.

Discuss with patient

- Discuss the following with every patient who is scheduled for a cosmetic procedure:
 - The proposed procedure.
 - The most commonly reported and the most serious side effects and potential complications.
 - The need for repeat procedures, if applicable - for example, BOTOX® Cosmetic usually requires repeated administration.
 - Statement concerning off-label use of a pharmaceutical or other product as applicable - if the planned use of the biological or pharmaceutical is not included in the "indications for use" contained in the package insert, the intended use would be considered off-label.

Restrict discussion to office

- Ensure that informed consent discussions take place in a professional environment, ideally, the practitioner's office or a surgical center.

Encourage questions

- Encourage patients to ask all of their questions. Be sure to provide complete answers.

Evaluate patient understanding

- Ensure that patients comprehend what is said during the informed consent discussion by using teach-back. For example, "It is very important that you understand the procedure to which you are agreeing. I want to make sure I have done a good job explaining it. Please explain the procedure to me as you understand it."

Obtain Informed Consent

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| Update consents | <ul style="list-style-type: none">• Ensure that consent forms signed for procedures that will be repeated on an intermittent or regular basis are updated at least annually. |
| Require separate consent for anesthesia | <ul style="list-style-type: none">• Require a separate signed consent form for anesthesia or moderate sedation. Be sure to specify risks of the anesthetic agent in the anesthesia consent form. |
| Document consent | <ul style="list-style-type: none">• Document in the medical record that the informed consent process took place. Document the use of teach-back and the provision of any written materials to the patient. Alternatively, the physician might note, "Standard teaching packet given," ensuring that a copy of that packet remains available in the office. Document any relevant films or videos watched by the patient in the medical record. |

Implement Protocol for Procedures

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| Perform all procedures in professional setting | <ul style="list-style-type: none">• Ensure that all cosmetic procedures, including non-surgical procedures such as the administration of BOTOX® Cosmetic are performed in a professional environment with a physician on-site. |
| Use FDA-approved pharmaceuticals | <ul style="list-style-type: none">• Use only FDA-approved pharmaceuticals that have been purchased from licensed distributors representing reputable pharmaceutical companies. |
| Follow drug manufacturer guidelines | <ul style="list-style-type: none">• Use and store drugs used during cosmetic procedures according to the manufacturer's directions. For example, BOTOX® Cosmetic is supplied in vials that are designed for one patient, one use. After the product is opened and reconstituted, it should be refrigerated and used within four hours. |
| Create and implement protocols for lasers | <ul style="list-style-type: none">• See the chapter titled <u>Laser Therapy</u> for more specific recommendations on lasers. |
| Create and implement protocols for moderate sedation | <ul style="list-style-type: none">• See the chapter titled <u>Surgery: Office-Based</u> for more specific recommendations on moderate sedation. |

Implement Protocol for Procedures

Be present until discharge

- Ensure that a physician, advanced-practice nurse, or physician assistant remains on-site until every patient who has undergone a cosmetic procedure is discharged.

Provide preprinted discharge instructions

- Ensure that each patient has the information they need for the post-discharge period by giving him/her preprinted discharge instructions.

Follow Safe Injection Practices

Use single-dose vials appropriately

- Do NOT use single-dose vials for more than one patient. According to the CDC, "There have been multiple outbreaks resulting from healthcare personnel using single-dose or single-use vials for multiple patients."¹
- Discard single-dose vials after use. To decrease the risk of inadvertent reuse, purchase the smallest single-dose vial available.
- Do NOT pool single-dose "leftovers" to create additional doses.
- Inspect vial contents for particulates, discoloration and unusual cloudiness before use. Do not use the vial if these are noted, and notify the manufacturer.
- Cleanse the vial rubber stopper with 70 percent isopropyl alcohol, using a circular motion; permit the alcohol to dry before accessing the vial.
- Use a new sterile needle and syringe each time the vial is entered.

Use multiple-dose vials appropriately

- If a multi-dose has been opened or accessed (e.g., needle-punctured), date and discard within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.²
- If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), discard according to the manufacturer's expiration date.³

Follow Safe Injection Practices

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- Cleanse the vial rubber stopper with 70 percent isopropyl alcohol using a circular motion; permit the alcohol to dry before accessing the vial.
- Use a new sterile needle and syringe each time the vial is entered.

Prepare for Emergencies

Ensure availability of medications

- Ensure that unexpired medications that may be needed in case of an emergency are readily accessible.

Consider mock codes

- Conduct mock codes regularly, to familiarize staff members with their roles in an emergency.

Document Medical Record

Create record for each patient

- Ensure that every patient undergoing a cosmetic procedure has a medical record. Include the following in the record:
 - Reason or justification of procedure.
 - Note concerning informed consent discussion and consent form signed by the patient.
 - Description of the proposed or actual treatment and the patient's response.
 - Photographs of the area to be treated, before and after the procedure.
 - Patient's status at discharge.
 - Discharge instructions, including follow-up plans.

Ensure that Equipment Works Properly

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| Schedule preventive maintenance | <ul style="list-style-type: none">• Ensure that all equipment used for patient care is inspected, maintained and serviced on a regular basis. |
| Maintain emergency equipment | <ul style="list-style-type: none">• Maintain emergency equipment at the same level as equipment that is in use on a regular basis. |
| Develop protocol for malfunctions | <ul style="list-style-type: none">• Develop a protocol that addresses managing equipment malfunctions. |
| Seek more information | <ul style="list-style-type: none">• See the chapter titled <u>Practice Management: Equipment Maintenance</u> for more specific recommendations on maintaining equipment. |

Develop and Implement Protocol for Medical Spas

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| Be an active medical director | <ul style="list-style-type: none">• Be on-site and actively involved in the cosmetic procedures being performed at the spa. |
| Staff appropriately | <ul style="list-style-type: none">• Ensure that the staff members providing cosmetic services have documented training and competency. When possible, hire certified/licensed staff members, such as aestheticians. |
| Take an active role in supervision | <ul style="list-style-type: none">• Play a major role in the hiring and firing of staff members.• Assume the role of approving the policies and procedures that serve as guidelines for staff members.• Be on-site to answer questions and help in emergencies. |
| Know malpractice limitations | <ul style="list-style-type: none">• Be aware of malpractice coverage before agreeing to assume the role of medical director.⁴ |
| Monitor the website | <ul style="list-style-type: none">• A website may be the first point of contact for individuals who are seeking information about the practice. It is essential to make sure that the contents are appropriate, current and provide correct information. Review website content at least annually and ensure the following: |

Develop and Implement Protocol for Medical Spas

- The content is accurate and does not contain promises or statements that cannot be objectively met/proven.
 - Provider lists are current and providers are identified appropriately. For example, advanced practice providers (nurse practitioners and physician assistants) are differentiated from physicians.
 - Contact information is current and includes physical address, phone numbers and/or email addresses.
 - The Notice of Privacy Practices is current and linked to the site.
 - Patient educational materials are approved by the providers. The organization either developed the information or has written permission to post the information developed by others.
 - Signed authorizations have been obtained for all identifiable patient photographs on the site.
- The “Contact Us” section contains a disclaimer that the form is not intended for emergency communications.
 - Facilitate patient privacy by asking patients their preferred method of communication prior to initiating treatment, since many patients receiving cosmetic services do not want anyone else to know. Determine if it is acceptable to leave a voice message. Confirm the billing address with the patient and use plain envelopes.

Ensure patient confidentiality

Inform Patients of Independent Contractor Status

Disclose the use of independent contractors

- Reduce the liability risk of using independent contractors as follows:

Inform Patients of Independent Contractor Status

- Disclose the use of independent contractors by placing signs in the reception and treatment areas.
- Do not provide or permit independent contractors to wear nametags or lab coats displaying practice logos.
- Bill separately or clearly differentiate the independent contractor's services on itemized bills.
- Do not advertise for independent contractors or include them in the practice's advertising.
- Consult with an attorney to determine the proper language for contracts, lease agreements and practice signage.

Seek more information

- See the chapter titled [**Vicarious Liability & Ostensible Agency**](#) for more specific recommendations on reducing the risk of using independent contractors.

References:

1. Centers for Disease Control and Prevention (CDC), "FAQs about Single-Dose/Single-Use Vials in Clinical Settings," Page last updated August 30, 2012, <http://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html>, 04/14/2014.
2. Centers for Disease Control and Prevention (CDC), "Questions about Multi-Dose Vials," Page last updated February 9, 2011, http://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html, 04/14/2014, citing United States Pharmacopeia (USP), *Guidebook to Pharmaceutical Compounding – Sterile Preparations*, Second Edition, June 1, 2008, General Chapter 797.
3. Ibid.
4. American Academy of Dermatology, *Position Statement on Medical Spa Standards of Practice*, Approved by the Board of Directors May 7, 2011, Amended by Board of Directors August 18, 2012.