

# ARKANSAS REGISTER

## Proposed Rule Cover Sheet



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Name of Department Department of Health

Agency or Division Name Division of Health Related Boards and Commissions/Arkansas State Medical Board

Other Subdivision or Department, If Applicable \_\_\_\_\_

Previous Agency Name, If Applicable \_\_\_\_\_

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Name of Rule Proposed New Rule 46 - Minor Aesthetic/Cosmetic Surgical Procedures Guideline

Newspaper Name Daily Record

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Final Date for Public Comment 7/7/2020

Location and Time of Public Meeting 1401 West Capitol Avenue, Suite 340, Little Rock, AR 72201

## **RULE 46**

### **Summary**

Proposed Rule 46 sets out guidelines for minor aesthetic/cosmetic surgical procedures.

## PROPOSED

### RULE 46 - MINOR AESTHETIC/COSMETIC SURGICAL PROCEDURES GUIDELINE

Pursuant to Ark. Code Ann. §17-95-202 the practice of medicine involves the use of surgery for the diagnosing and treatment of human disease, ailment, injury, deformity, or other physical conditions. Surgery is further defined by this board as any procedure in which human tissue is cut, altered, or otherwise infiltrated by mechanical means.

Minor aesthetic/cosmetic surgical procedures are defined by this board as those surgical procedures, which cut, alter or infiltrate into and or below the dermis to include soft tissue fillers, which are permanent or temporary in nature, chemical peels, as well as the infiltration of deeper subcutaneous tissues with neuromodulators for aesthetic or cosmetic purposes. The use of Lasers, light based systems, and devices which affect the deep subcutaneous tissues and subcutaneous fat layers are addressed in Rule number 22.

The delegation of minor aesthetic/cosmetic surgical procedures must comply with the following protocol:

1. The physician must show sufficient training and experience in the procedures being delegated. This may include but is not limited to Board certification in core specialties of Cosmetic, Plastic, Facial Plastic, Dermatology and Oculoplastics. Further, documentation of training and experience shall include but is not limited to:
  - a. Anatomy, physiology, and pathophysiology regarding the integumentary system as well as systems specific to the procedures being performed.
  - b. Proper technique for each procedure delegated.
  - c. Proper knowledge of client selection, history taking, physical assessment, indications and contraindications for treatment.
  - d. Pharmacology including drug actions and interactions, side effects, contraindications, and untoward effects.
  - e. Proper selection, maintenance and utilization of equipment.
  - f. Realistic and expected outcomes of the procedure(s).
  - g. Potential complications and side effects of the procedure(s).
  - h. Management of complications or adverse reactions.
  - i. Infection control and safety precautions.
  - j. Documentation of supervised clinical experience
  - k. Validation of competency
2. The physician must personally diagnose and document the condition of the patient, prescribe the treatment and procedure to be performed and is responsible for the acts of the employee performing the delegated minor aesthetic/cosmetic surgical procedure.
3. The physician may delegate the minor aesthetic/cosmetic surgical procedures to properly trained non-physician personnel who hold an Arkansas State license or privilege to practice as a Registered Nurse (RN).



Advanced Practice Nurse (APRN) Physician Assistant (PA) and/or other personnel whose practice act allows the performance of these procedures and can document experience and training in aesthetic/cosmetic surgery practice. Physicians may delegate to unlicensed personnel only those procedures that comply with the provisions of rule 31 act 472 of 2009. Delegation of these procedures to a Licensed practical nurse (LPN) or licensed aesthetician is prohibited.

4. The physician must be available at the time the minor surgical procedure is performed and must be available to respond to the patient should there be any complications from the minor aesthetic/cosmetic surgical procedure.
5. All non-Physician personnel to whom minor aesthetic/cosmetic surgical procedures are delegated must have a legal written agreement or be contracted with a physician; or be an employee of the physician and /or a physician owned business as described in regulation 4-29-301 "Medical Corporation Act."
6. Collaboration with Advanced Practice Registered Nurse (APRN)
  - a. All Physicians collaborating with an (APRN) to provide minor aesthetic/cosmetic procedures must be board certified in one of the core specialties to include Cosmetic, Plastic, Facial Plastics, Dermatology and Oculoplastics or must show sufficient training and clinical experience in performing the procedures to be performed by the APRN.
  - b. Physicians may only collaborate to provide minor aesthetic/cosmetic surgical procedures with an (APRN) who has Completed Board Certification by the International Society of Aesthetic Nurses or meets the equivalent requirements for board certification or has completed core specialty training in aesthetic medicine as defined by the Arkansas State Board of Nursing, unless specifically authorized by their respective practice acts or rules.

The physician who does not comply with the above-stated protocol when performing minor surgical procedures will be considered as exhibiting gross negligence, subjecting the physician to a disciplinary hearing before the Board pursuant to the Medical Practices act and the Rules of the Board.

Ark. Code. Ann. §17-95-409(a)(2)(G) states that the Board may revoke an existing license, or suspend the same, if a physician has committed unprofessional conduct, further defined as committing gross negligence or ignorant malpractice. The board finds that a physician has; in fact, committed gross negligence if the physician or physicians delegated personnel performs minor surgical procedures on patients without the benefit of appropriate clinical training and experience.

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**SUMMARY OF OPPOSITION TO RULE 46 MINOR AESTHETIC  
COSMETIC SURGICAL PROCEDURES GUIDELINES**

We received a total of 725 letters that includes letters from the Cosmetic Health Coalition (CHC), letters from Newman, MD, Plastic Surgery, Advanced Dermatology & Skin Cancer Center, PLLC, Women's Health Associates, Salman Hashmi, Abeer Hashmi, and Taylor Plastic Surgery in opposition to Rule 46.

At the public hearing, four (4) people spoke. Three (3) were against the Rule and one (1) was for the Rule.

We received 719 letters from CHC and six additional letters from other sources as stated above opposing Rule 46. We received three additional letters approving of Rule 46 as stated above.

The objections are as follows (there is overlap of objections because each letter stated several objections).

Of the total 725 received, the main objections are as follows:

637 - Requires a physician to enter into a collaborative agreement to allow an APRN to provide minor cosmetic procedures, the APRN must have too much training.

373 - Do not like the documentation requirements.

373 - This rule is an unreasonable restriction on practice for APRNs in Arkansas.

637 - The proposed rule requires the physician to personally diagnose wrinkles, yet the diagnosis stage is not the stage which exposes patient to significant risk, which is the delivery stage. The rule permits doctors to delegate duties to a Medical Assistants.

371 - Unfair to collaborating doctors.

646 - Believe this is just a rerouting of the industry to doctors for profit. This is a scheme to create a monopoly and take money, business and ultimately the livelihood of the individuals currently performing these treatments. This causes a financial burden. This is costly to patients and unnecessary.

2 - I should be able to choose who I go to. My person has fixed a few mess ups from a dermatologist. Cosmetic decisions should be left to the patient and whom they choose to perform the work.

2 - This is not considered a medical procedure and should not require a medical approval. Clear case of overreach.

629 - Advance Practice Nurses are performing much more invasive procedures in the state of Arkansas without this much oversight.

286 - Limits access to healthcare.

633 - The rule prohibits aesthetician from delivering any chemical peels even though chemical peels are part of their education and training.

636 - This rule is intended to make the cosmetic industry more complex and competitive and not about patient safety.

1 – This is a scope of practice and should be controlled by the Legislature.



## **SUMMARY OF APPROVAL OF RULE 46 MINOR AESTHETIC COSMETIC SURGICAL PROCEDURES GUIDELINES**

We received the following letters from AmSpa, American Society of Plastic Surgeons and Michael Spann, M.D. approving of Rule 46.

### **AmSpa**

Alex R. Thiersch, CEO of AmSpa states that they are glad that the Arkansas State Medical Board has recognized that practitioners in medical spas need to be properly trained. AmSpa is dedicated to ensuring the non-invasive aesthetic industry is safe and that practitioners are train, qualified and compliant. They applaud and support the decision to address the issue of unsupervised and unqualified practitioners in med spas. The definition of procedures covered by the rule should be clarified. The section addressing neuromodulators should be expanded. The training requirements for physicians should make clear that while board certification is one way to meet the requirements, competency and skill can be gained from a number of sources. Aesthetic medical practices should be able to employ telemedicine to enhance their services. A physician who has sufficient knowledge and experience should be able to delegate a procedure to an APRN with similar training and experience. Licensed practical nurses could perform cosmetic medical procedures under the supervision of a physician or advanced practice registered nurse trained in procedures. In most states, physician assistants and nurse practitioners are permitted to perform patient examinations and prescribe treatments when working in a supervised or collaborative relationship with a physician. AmSpa believes these standards together with the enforcement of existing prohibitions on the unauthorized practice of medicine will eliminate the bad actors and provide the public with confidence that medical spas are safe.

### **AMERICAN SOCIETY OF PLASTIC SURGEONS**

Lynn Jeffers, M.D., President of American Society of Plastic Surgeons, states that plastic surgeons in the state are concerned with patient safety. Some med spas are operated independently by nurses and nonmedical aestheticians which leads to non-physician providers performing procedures within the practice of medicine without the supervision of a physicians. Medical directors are involved in ownership of med spas and are not trained to perform and handle potential complications. It is appreciated that Rule 46 will provide guidance to physicians about the required experience and training.

### **MICHAEL SPANN, M.D.**

Dr. Spann is a plastic surgeon and has board certifications in both general surgery and plastic and reconstructive surgery. The FDA clearly answers that having fillers injected should be considered a medical procedure and not a cosmetic treatment. Most injectors have surprisingly minimal exposure to dealing with complications and essentially learn by trial and error at the expense of the patient. Arkansas law clearly defines the practice of medicine as one who diagnoses, prescribes drugs and performs procedures. The statute makes it clear that the practice of medicine is for those possessing medial degrees. Nurse owned, physician supervised cosmetic clinics falls within the definition of unlicensed practice of medicine. Cosmetic injectors limited learning methods are

being employed by or apprentice for a physician who trains them, enrolling in a course or learning by self-study. All of these are inconsistent and inadequate for independent practice. A patient undergoing a medical procedure deserves a competent injector. He asks that Rule 46 be approved.