

**QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS  
WITH THE ARKANSAS LEGISLATIVE COUNCIL**

**DEPARTMENT/AGENCY** Department of Health  
**DIVISION** Division of Health Related Boards and Commissions/Arkansas State Medical Board  
**DIVISION DIRECTOR** Matt Gilmore, ADH Boards and Commissions  
**CONTACT PERSON** Amy Embry, Director, Arkansas State Medical Board  
**ADDRESS** 1401 West Capitol Avenue, Suite 340, Little Rock, AR 72201  
**PHONE NO.** 501-296-1802 **FAX NO.** 501-296-1805 **E-MAIL** Amy.embry@armedicalboard.or  
**NAME OF PRESENTER AT COMMITTEE MEETING** Kevin M. O'Dwyer, Attorney  
**PRESENTER E-MAIL** kodwyer@htolaw.com

**INSTRUCTIONS**

- A. Please make copies of this form for future use.
- B. Please answer each question **completely** using layman terms. You may use additional sheets, if necessary.
- C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
- D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Jessica Sutton  
Administrative Rules Review Section  
Arkansas Legislative Council  
Bureau of Legislative Research  
One Capitol Mall, 5<sup>th</sup> Floor  
Little Rock, AR 72201

**RECEIVED**  
APR 16 2020  
BUREAU OF  
LEGISLATIVE RESEARCH

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1. What is the short title of this rule? Rule 46 – Minor Aesthetic/Cosmetic Surgical Procedures

2. What is the subject of the proposed rule? Minor Aesthetic/Cosmetic Surgical Procedures

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes  No   
If yes, please provide the federal rule, regulation, and/or statute citation. \_\_\_\_\_

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes  No

If yes, what is the effective date of the emergency rule? N/A

When does the emergency rule expire? N/A

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes  No

5. Is this a new rule? Yes  No

If yes, please provide a brief summary explaining the regulation. To add new regulation regarding physician assistants.

Does this repeal an existing rule? Yes  No

If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. \_\_\_\_\_

Is this an amendment to an existing rule? Yes  No

If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. ACA §17-95-202

7. What is the purpose of this proposed rule? Why is it necessary? To add new regulation regarding physician assistants.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). www.armedicalboard.org

9. Will a public hearing be held on this proposed rule? Yes  No

If yes, please complete the following:

Date: June 4, 2020

Time: 8:50 a.m.

1401 W. Capitol Ave. Suite 340,

Place: Little Rock AR 72201

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)

June 4, 2020

11. What is the proposed effective date of this proposed rule? (Must provide a date.)

Unknown

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. Proof of publication will be provided as soon as it is received.

13. Please provide proof of filing the rule with the Secretary of State and the Arkansas State Library as required pursuant to Ark. Code Ann. § 25-15-204(e). Will provide after approval by Governor.

14. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known. Arkansas Medical Society.

**FINANCIAL IMPACT STATEMENT**

**PLEASE ANSWER ALL QUESTIONS COMPLETELY**

**DEPARTMENT** Department of Health

**DIVISION** Division of Health Related Boards and Commissions/Arkansas State Medical Board

**PERSON COMPLETING THIS STATEMENT** Kevin M. O'Dwyer, Attorney

**TELEPHONE** 501-372-4144 **FAX** 501-372-7480 **EMAIL:** kodwyer@htolaw.com

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

**SHORT TITLE OF THIS RULE** Rue 46 – Minor Aesthetic/Cosmetic Surgical Procedures Guideline

- 1. Does this proposed, amended, or repealed rule have a financial impact?      Yes       No
- 2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?      Yes       No
- 3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered?      Yes       No

If an agency is proposing a more costly rule, please state the following:

(a) How the additional benefits of the more costly rule justify its additional cost;  
N/A

(b) The reason for adoption of the more costly rule;  
N/A

(c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;  
N/A

(d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.  
N/A

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

(a) What is the cost to implement the federal rule or regulation?

**Current Fiscal Year**

**Next Fiscal Year**

General Revenue    N/A

Federal Funds      \_\_\_\_\_

Cash Funds          \_\_\_\_\_

Special Revenue    \_\_\_\_\_

Other (Identify)    \_\_\_\_\_

Total                    \_\_\_\_\_

General Revenue    N/A

Federal Funds      \_\_\_\_\_

Cash Funds          \_\_\_\_\_

Special Revenue    \_\_\_\_\_

Other (Identify)    \_\_\_\_\_

Total                    \_\_\_\_\_

(b) What is the additional cost of the state rule?

**Current Fiscal Year**

General Revenue   N/A    
Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_  
Other (Identify) \_\_\_\_\_  
  
Total \_\_\_\_\_

**Next Fiscal Year**

General Revenue   N/A    
Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_  
Other (Identify) \_\_\_\_\_  
  
Total \_\_\_\_\_

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

**Current Fiscal Year**

\$   N/A  

**Next Fiscal Year**

\$   N/A  

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6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

**Current Fiscal Year**

\$   N/A  

**Next Fiscal Year**

\$   N/A  

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7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes  No

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
  - (a) justifies the agency's need for the proposed rule; and
  - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
  - (a) the rule is achieving the statutory objectives;
  - (b) the benefits of the rule continue to justify its costs; and
  - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

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~~ medications and procedures are defined by this board as those ~~surgical~~ procedures, ~~as the use of Botox and fillers and any other aesthetic/cosmetic medication and~~ 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 ~~to a physician assistant (PA), Advanced Practice Registered Nurse (APRN), a Registered Nurse (RN) or collaboration with an APRN or supervising a PA under a protocol~~ of minor aesthetic/cosmetic ~~surgical~~ procedures must comply with the following protocol:

1. The physician must ~~be able~~ show ~~sufficient~~ training and experience with the use of these medications and 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 with the use of the medications and the procedure involved in the administration of these medications 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.~~

2. The physician when delegating to a PA, APRN or RN must personally diagnose, 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 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. When delegating these procedures, the physician must be available at the time the minor aesthetic/cosmetic procedure is performed and must be available to respond to the patient should there be any complications from the minor aesthetic/cosmetic procedure.
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 Plasties, Dermatology and Oculoplasties 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~~ Any physician who does not comply with the above-stated protocol when ~~performing~~ delegating the minor surgical aesthetic/cosmetic procedures ~~will~~ may be considered as ~~exhibiting gross negligence, subjecting the physician to a disciplinary hearing before the~~ by the Arkansas State Medical Board pursuant to the to be in violation of the Arkansas 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.~~



**RULE 46 - MINOR AESTHETIC/COSMETIC PROCEDURES**

Pursuant to Ark. Code Ann. §17-95-202 the practice of medicine involves the diagnosing and treatment of human disease, ailment, injury, deformity, or other physical conditions.

Minor aesthetic/cosmetic medications and procedures are defined by this board as those medications and procedures, such as the use of Botox and fillers and any other aesthetic/cosmetic medication, that 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 to a physician assistant (PA), Advanced Practice Registered Nurse (APRN), a Registered Nurse (RN) or collaboration with an APRN or supervising a PA under a protocol of minor aesthetic/cosmetic - procedures must comply with the following protocol:

1. The physician must be able to show training and experience with the use of these medications and the procedures.
2. The physician, when delegating to a PA, APRN or RN 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 procedure.
3. The physician may delegate the minor aesthetic/cosmetic 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 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. When delegating these procedures, the physician must be available at the time the minor aesthetic/cosmetic procedure is performed and must be available to respond to the patient should there be any complications from the minor aesthetic/cosmetic procedure.
5. All non-Physician personnel to whom minor aesthetic/cosmetic 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."

Any physician who does not comply with the above-stated protocol when delegating the minor surgical aesthetic/cosmetic procedures may be considered by the Arkansas State Medical Board to be in violation of the Arkansas Medical Practices Act.

**DEPARTMENT OF HEALTH, DIVISION OF HEALTH RELATED BOARDS AND COMMISSIONS, STATE MEDICAL BOARD**

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**SUBJECT:** Rule 46 – Minor Aesthetic/Cosmetic Surgical Procedures

**DESCRIPTION:** The Arkansas State Medical Board’s proposed Rule 46 sets out guidelines for minor aesthetic/cosmetic surgical procedures.

Beginning about five years ago, following numerous complaints received by the Arkansas State Medical Board, the Arkansas State Board of Nursing (ASBN), and the Arkansas State Board of Cosmetology (ASBC), representatives of these Boards began meeting to discuss safety issues regarding the use and complications associated with Botox and “fillers.” It was subsequently agreed that the injection of these is the practice of medicine and should be regulated as such. A prescription is required to obtain Botox and fillers and significant complications can occur with their injections. Therefore, appropriate training is important for patient safety.

There has never been such a high level of agreement, cooperation and coordination between ASMB’s Board and the ASBN Board. Both Boards are very concerned about the patient safety implications of injecting Botox and fillers, and are in complete agreement that regulation is necessary. So, the Boards decided to work closely in preparing complementary rules, and to support the other Board’s Rule. The ASBN rule has already had a public hearing and the ASMB Rule public hearing was held on July 23, 2020.

The detractors point to this rule limiting or prohibiting certain providers from performing procedures or injecting Botox and/or fillers. It does not. The Rule only deals with physicians and physician assistants and either may perform the functions related to Rule 46, so long as they have training. The rule sets up guidelines for the administration of Botox and fillers and the need for training in the application of those products and how to deal with complications. This rule is simply about patient safety. This rule does not limit nurse practitioners at all as the Medical Board does not regulate nurses. The Nursing Board rule, which is supported by the Medical Board, relates to the nursing practitioners.

**NOTE: On September 16, 2020, the Administrative Rules subcommittee of the Arkansas Legislative Council considered Rule 46. After hearing individuals who spoke in favor of the rule and individuals who opposed the rule, the Administrative Rules subcommittee referred the rule to the House and Senate Committees on Public Health, Welfare, and Labor Committee for further consideration. Subsequent to the referral, the agency submitted a revised markup and clean copy of the rule for consideration on October 8, 2020. Revisions to the rule include: (1) removal of the definition of surgery and references to surgery throughout the rule; (2) replacement of the term “minor aesthetic/cosmetic surgical procedures” with “minor aesthetic/cosmetic medications and procedures” throughout the rule; (3) explicit inclusion of “the use of Botox and fillers and any other aesthetic/cosmetic medication” in defining minor aesthetic/cosmetic medication and procedures; (4)**

**removal of board certification requirements or specific educational requirements for supervising physicians; and (5) removal of paragraph 6 concerning collaboration with APRNs.**

**PUBLIC COMMENT:** A public hearing was held on July 23, 2020. The public comment period expired on July 23, 2020. The State Medical Board provided the following summary of the comments received and its responses thereto:

**SUMMARY OF OPPOSITION TO RULE 46 MINOR AESTHETIC COSMETIC SURGICAL PROCEDURES GUIDELINES AND ARKANSAS STATE MEDICAL BOARD RESPONSES**

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.

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

373 -Do not like the documentation requirements.

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

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

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

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. The proposed effective date is pending legislative review and approval.

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

371 - Unfair to collaborating doctors.

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

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.

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

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.

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

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

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

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

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

286 - Limits access to healthcare.

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

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

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

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

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

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

BOARD'S RESPONSE: The Board doesn't believe that the Rule states this position. The Rule adequately protects patients and allows physicians who are adequately trained to perform the procedures.

#### 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 trained, 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 physician. 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 medical 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.

Suba Desikan, an attorney with the Bureau of Legislative Research, asked the following questions and received the following answers prior to consideration of the rule by the Administrative Rules subcommittee on September 16, 2020:

1. The terms ‘surgery’ and ‘minor aesthetic/cosmetic surgical procedures’ are defined in the proposed rule. Are these terms defined only in this rule 46 or are these definitions located in other rules of the board? If they are located in other rules, could you please cite those rules? **RESPONSE:** The terms are defined in this rule specific to this rule.
2. What is the board’s rationale for requiring physicians to show sufficient training and experience in the procedures being delegated? **RESPONSE:** To protect patients of Arkansas. The Board has discovered situations in which physicians and those persons to whom the procedure is delegated are not sufficiently trained to ensure safety or even basic knowledge of the procedures and the negative outcomes of the procedures. Complications from these procedures are significant.
3. The rule requires that the “physician must personally diagnose and document the condition of the patient, [and] prescribe the treatment and procedure to be performed.” What is the board’s reasoning behind this requirement? **RESPONSE:** This is really a restatement of an already existing rule. Rule 2.8 requires physicians to establish a proper patient/physician relationship prior to diagnosis and treatment. The reason is to ensure

that properly trained professionals are treating patients prior to injecting a prescribed foreign substance into the human body.

4. Does this rule preclude practitioners other than physicians from performing minor aesthetic/cosmetic surgical procedures? **RESPONSE:** No

5. Could you please explain the board's reasoning concerning the prohibition of delegation of these procedures to a licensed practical nurse or licensed aesthetician? **RESPONSE:** The practice acts governing those two professionals currently prohibits those practitioners from performing these procedures.

6. The rule provides that the physician "must be available at the time the minor surgical procedure is performed." What does the board interpret this to mean (physically present, on site, be able to come on-site if there is a complication, etc.)? **RESPONSE:** It means that the physician must be available by phone and have physician "back-up" should anything go wrong. It does not mean the physician must be "on site".

7. Why does the section concerning collaboration with an APRN use mandatory language concerning board certification of the collaborating physician ("must be board certified..."), whereas the general delegation provision only uses permissive language ("may include but is not limited to board certification...")? **RESPONSE:** It does not require board certification. The last part of the sentence states "or must show sufficient training and clinical experience in performing the procedures to be performed by the APRN."

8. Concerning the language "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," (a) Wouldn't this determination be made on a case-by-case basis depending on the facts alleged in a particular complaint? **RESPONSE:** Yes. The Board would be required to give notice to the physician of a hearing and serve a "charging document" on the physician. A hearing would have to be conducted and evidence presented in order to determine if the physician violated the rule.

(b) Would this determination be subject to the procedural provisions contained in Ark. Code Ann. § 17-95-410? **RESPONSE:** Yes.

**NOTE: On September 16, 2020, the Administrative Rules subcommittee of the Arkansas Legislative Council considered Rule 46. After hearing individuals who spoke in favor of the rule and individuals who opposed the rule, the Administrative Rules subcommittee referred the rule to the House and Senate Committees on Public Health, Welfare, and Labor Committee for further consideration. Subsequent to the referral, the agency submitted a revised markup and clean copy of the rule for consideration on October 8, 2020. Revisions to the rule include: (1) removal of the definition of surgery and references to surgery throughout the rule; (2) replacement of the term "minor aesthetic/cosmetic surgical procedures" with "minor aesthetic/cosmetic medications and procedures" throughout the rule; (3)**



**explicit inclusion of “the use of Botox and fillers and any other aesthetic/cosmetic medication” in defining minor aesthetic/cosmetic medication and procedures; (4) removal of board certification requirements or specific educational requirements for supervising physicians; and (5) removal of paragraph 6 concerning collaboration with APRNs.**

**FINANCIAL IMPACT:** The State Medical Board indicated that the proposed rules do not have a financial impact.

**LEGAL AUTHORIZATION:** The Arkansas State Medical Board has authority to:

- (1) make and adopt all rules and bylaws not inconsistent with the laws of this state or of the United States and necessary or convenient to perform the duties and to transact the business required by law. *See Ark. Code Ann. § 17-95-303(1);*
- (2) promulgate and put into effect such rules as are necessary to carry out the purposes of the Arkansas Medical Practices Act, § 17-95-201 *et seq.*, § 17-95-301 *et seq.*, and § 17-95-401 *et seq.*, and the intentions expressed therein. *See Ark. Code Ann. § 17-95-303(2);*
- (3) promulgate rules limiting the amount of Schedule II narcotics that may be prescribed and dispensed by licensees of the board. *See Ark. Code Ann. § 17-95-303(8);* and
- (4) adopt rules that establish standards to be met and procedures to be followed by a physician with respect to the physician’s delegation of the performance of medical practices to a qualified and properly trained employee who is not licensed or otherwise specifically authorized by the Arkansas Code to perform the practice. *See Ark. Code Ann. § 17-95-208(a).* Rules adopted pursuant to this section shall provide that the delegating physician remains responsible for the acts of the employee performing the delegated practice, that the employee performing the delegated practice is not represented to the public as a licensed healthcare provider, and that medical practices delegated under this section shall be performed under the physician’s supervision. *See Ark. Code Ann. § 17-95-208(c).*