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WILLIAM H. TRICE III (1946-2014)

September 9, 2019

Via email and U.S. Mail
jessica@arkleg.state.ar.us

Ms. Jessica Sutton, Committee Staff
Bureau of Legislative Research
State Capitol Building, Room 315
Little Rock, AR 72201

**RE: My Client: Arkansas State Medical Board
Rule 43 Genetic Counselor Licensure**

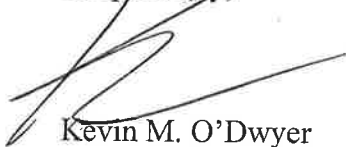
Dear Jessica:

Enclosed please find the following:

1. Two copies of the completed Questionnaire and Financial Impact Statement.
2. Two copies of the Proposed Rule (clean copy).
3. Two copies of a Summary.
4. Two copies of the Notice of Hearing that is being published, setting forth the public hearing for October 3, 2019.

Please let me know if you need anything further at this time.

Respectfully,



Kevin M. O'Dwyer
Attorney for the Arkansas State Medical Board

KMO:ena
Enclosures

cc w/encl.: Arkansas Secretary of State, register@sos.arkansas.gov
Amy Embry, Executive Director, amy.embry@armedicalboard.org

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

DEPARTMENT/AGENCY Arkansas State Medical Board
DIVISION _____
DIVISION DIRECTOR Amy Embry, Interim Executive Director
CONTACT PERSON Kevin M. O'Dwyer, Attorney
ADDRESS 211 S. Spring Street, Little Rock, AR 72201
PHONE NO. 501-372-4144 FAX NO. 501-372-7480 E-MAIL kodwyer@htolaw.com
NAME OF PRESENTER AT COMMITTEE MEETING Kevin M. O'Dwyer
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, 5th Floor
Little Rock, AR 72201**

1. What is the short title of this rule? Rule 44 – Genetic Counselor Licensure

2. What is the subject of the proposed rule? To add new regulation for Genetic Counselors

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 licensure of genetic counselors.

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 §17-1-11101; Act 686 of 2019

7. What is the purpose of this proposed rule? Why is it necessary? To add new regulation regarding licensure of genetic counselors.

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: _____

Time: 8:00 a.m.

Place: 1401 W. Capitol Ave. Suite 340,
Little Rock AR 72201

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

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

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. Please see attached. 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; Arkansas Osteopathic Association.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas State Medical Board

DIVISION _____

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 Regulation 44 – Genetic Counselor Licensure Act

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

| | |
|------------------|------------|
| General Revenue | <u>N/A</u> |
| Federal Funds | _____ |
| Cash Funds | _____ |
| Special Revenue | _____ |
| Other (Identify) | _____ |
| Total | _____ |

Next Fiscal Year

| | |
|------------------|------------|
| General Revenue | <u>N/A</u> |
| 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

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

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 44

GENETIC COUNSELOR LICENSURE

A. Pursuant to Arkansas Code Annotated § 17-95-1101, this subchapter shall be known and cited as the “Arkansas Genetic Counselor Licensure Act.”

B. Pursuant to Arkansas Code Annotated § 17-95-1102, definitions as used in this subchapter: “Genetic counseling” means the process of assisting individuals with understanding and adapting to the medical, psychological, and familial implications of genetic contributions to disease, which includes without limitation:

1. Interpreting family and medical histories to assess the chance of disease occurrence or recurrence.
2. Educating an individual or an individual’s family about inheritance, testing, management, prevention, resources, and research.
3. Counseling an individual or an individual’s family to promote informed choices and adaption to the risk or condition.
4. Estimating the likelihood of occurrence or recurrence of any potentially inherited or genetically influenced condition which may involve:
 - a. Obtaining and analyzing a complete health history of the individual and the individual’s family;
 - b. Reviewing the pertinent medical records;
 - c. Evaluating the risks from exposure to possible mutagens or teratogens; and
 - d. Discussing genetic testing to assist in the diagnosis of a condition to determine the carrier status of one (1) or more family members.
5. Assisting the individual, the individual’s family, the individual’s healthcare provider, or the public to:
 - a. Appreciate the medical, psychological, and social implications of a disorder, including the features, variability, usual course, and management options of the disorder;
 - b. Learn how genetic factors contribute to the disorder and affect the chance for recurrence of the condition in other family members;
 - c. Understand available options for coping with, preventing, or reducing the chance of occurrence or recurrence of a condition; and

- d. Understand genetic tests, including without limitation diagnostic genetic tests, screening tests, or predisposition AL genetic tests, coordinate testing for inherited disorders, and interpret complex genetic test results.
6. Facilitating an individual's or an individual's family's:
 - a. Exploration of the perception of risk and burden associated with a genetic disorder;
 - b. Decision-making regarding testing or medical interventions consistent with their beliefs, goals, needs, resources, culture, and ethical or moral views; and
 - c. Adjustment and adaption to the condition or their genetic risk by addressing needs for psychological, social, and medical support.
 7. "Licensed genetic counselor" means a person who is licensed under this subchapter to engage in the practice of genetic counseling; and
 8. "Supervision" means the ongoing, direct clinical review for the purposes of training or teaching, by an approved supervisor who monitors the performance of a person's supervises interaction with a client and provide regular documented face-to-face consultation, guidance, and instructions with respect to the clinical skills and competencies of the person supervised.
 9. "Supervision" may include without limitation the review of case presentation, audio tapes, video tapes, and direct observation.
- C. Pursuant to Arkansas Code Annotated § 17-95-1103 exemptions from genetic licensure. This subchapter does not require licensure as a genetic counselor of:
1. An individual who is *licensed* or *lawfully* permitted to *practice by this* state as a healthcare professional and who is practicing within his or her scope of practice, including without limitation a physician or an advanced practice registered nurse.
 2. An *individual* who has successfully completed an accredited genetic counseling training program and who is:
 - a. Reapplying for the American Board of Genetic Counseling certification examination and gathering logbook case numbers under supervision in an approved genetic counseling training site; or
 - b. Practicing under direct supervision of a licensed physician.

3. A student enrolled in an approved academic program in genetic counseling if the practice constitutes a part of a supervised course of study and the student is designated by a title that clearly indicates the student's status as a student or trainee.

4. An individual who is employed by a state genetics center to provide education regarding single gene conditions, including without limitation sickle cell, cystic fibrosis, and hemoglobinopathies.

5. An individual described in subdivision E(4) of this section shall not use the title "genetic counselor" or any other title tending to indicate that he or she is a genetic counselor unless he or she is licensed in this state.

a. A visiting genetic counselor who is certified by the American Board of Genetic Counseling or American Board of Medical Genetics from outside the state performing activities and services for a period of thirty (30) days each year.

b. A visiting genetic counselor shall be licensed if the license is available in his or her home state.

D. Pursuant to Arkansas Code Annotated § 17-95-1104, Authority of the Arkansas State Medical Board. The Arkansas State Medical Board shall:

1. Develop appropriate rules necessary to regulate genetic counselors.

2. Receive, review, and approve applications for genetic counselor licensure.

3. Issue, renew, suspend, revoke, or deny licensure as a genetic counselor.

4. Conduct hearings on investigative and disciplinary proceedings.

5. Maintain a database of all licensees and all persons whose license have suspended, revoked, or denied.

a. Access to a database under subdivision D of this section shall be available upon written request and payment of an appropriate fee as determined by the Board.

6. Perform other functions and duties required to carry out this subchapter.

E. Pursuant to Arkansas Code Annotated § 17-95-1105 Title Protection. A person shall not use or assume the titled "licensed genetic counselor" or "genetic counselor" or use any words, letters, abbreviations, or insignia indicating or implying that the person holds a genetic counselor license unless the person is licensed by the Arkansas State Medical Board.

F. Pursuant to Arkansas Code Annotated § 17-95-1106 Genetic counselor licensure. The Arkansas State Medical Board shall license as a *licensed genetic* counselor an applicant who:

1. Submits an application approved by the Arkansas State Medical Board.
 2. Pays an application fee approved by the Arkansas State Medical Board that is comparable to other fees for licensure of other midlevel healthcare professionals licensed by the Arkansas State Medical Board and provides evidence of:
 - a. Having earned a master's degree from a genetic counseling training program that is accredited by the American Board of Genetic Counseling or an equivalent as determined by the American Board of Genetic Counseling or the American Board of Medical Genetics; and
 - b. Meets the examination requirements for certification and has current certification as a genetic counselor by the American Board of Genetic Counseling or the American Board of Medical Genetics.
 3. The Arkansas State Medical Board may issue a license to an applicant who provides evidence that he or she is licensed to practice as a genetic counselor in another state or territory if the requirements for licensure in the other state or territory are equal to the requirements in this subchapter.
 4. The issuance of a license by reciprocity shall be at the sole discretion of the Arkansas State Medical Board.
- G. Pursuant to Arkansas Code Annotated § 17-95-1107, Removal of genetic counselor license.
1. Except in the case of a temporary license under § 17-95-1108, a license shall be valid for a two-year period from the date of issuance.
 2. Upon receipt of a renewal application and renewal fees as determined by the Arkansas State Medical Board, the Board shall renew a license to practice as a *licensed genetic* counselor.
 3. As a condition of licensure renewal, a *licensed genetic* counselor shall submit documentation that he or she has completed fifty (50) hours of continuing education units approved by the Board.
 4. A *licensed genetic* counselor is responsible for maintaining:
 - a. Competent records of having completed qualified professional education for a period of four (4) years after close of the two-year period to which the records pertain; and
 - b. Information with respect to having completed a qualified professional education to demonstrate that the education meets the requirements of this subchapter.

5. The Arkansas State Medical Board may waive the continuing education requirement or grant an extension of time to complete the continuing education requirement in cases of retirement, illness, disability, or other undue hardship.

H. Pursuant to Arkansas Code Annotated § 17-95-1108 Temporary License. The Arkansas State Medical Board may issue a temporary license to an applicant who does not meet the certification requirement in § 17-95-1106.

1. If the applicant has been granted an active-candidate status by the American Board of Genetic Counseling.

2. Applies for and takes the certification examination within twelve (12) months of the issuance of a temporary license and submits an application and appropriate application fees with the Arkansas State Medical Board.

3. A temporary license is valid for one (1) year from the date of issuance.

4. A temporary license may be renewed for one (1) year if the applicant fails his or her first attempt to pass the certification examination of the American Board of Genetic Counseling or the American Board of Medical Genetics and Genomics.

5. An application for renewal shall be signed by a supervisor of the applicant.

6. A temporary license shall expire automatically upon the earliest of:

a. The date of issuance a license under § 17-95-1106;

b. Ninety (90) days after the date that the applicant fails on his or her second attempt to pass the certification examination; or

c. The date printed on the temporary license.

7. As a condition of a temporary licensure, an applicant shall work under the supervision of a licensed genetic counselor or a licensed physician with current American Board of Genetic Counseling certification in clinical genetics when the applicant provides genetic counseling services.

8. A temporary license shall not be issued if the applicant has failed the American Board of Genetic Counseling certification examination more than two (2) times.

I. Pursuant to Arkansas Code Annotated § 17-95-1109 Denial, Suspension, Revocation, or Refusal to Renew – Consure.

1. The Arkansas State Medical Board may deny, suspend, revoke, or refuse to renew a license, or may reprimand, censure, place on probation, or otherwise discipline a licensee, upon proof that the licensee has:

- a. Obtained or attempted to obtain a license by fraud or deception;
 - b. Been convicted of a felony under state or federal law;
 - c. Been adjudicated mentally ill or incompetent by a court;
 - d. Used illicit drugs or intoxicating *liquors, narcotics, controlled substances, or other drugs or stimulants* to an extent that adversely affects the practice of genetic counseling;
 - e. Engaged in unethical or unprofessional conduct, including without limitation willful acts, negligence, or incompetence in the course of professional practice;
 - f. Violated any provision of this subchapter or any rule of the Board; or
 - g. Been denied licensure or disciplined in another state or territory in connection with a license in another state or territory.
2. A licensee under subsection I(1) of this section shall promptly deliver his or her license to the Board if the licensee:
- a. Has his or her license suspended or revoked; or
 - b. Surrenders his or her license with or without prejudice if the surrender is approved by the Board.
3. The Board may restore a license or remove a probation on a license based upon the decision of the Board.
- J. Pursuant to Arkansas Code Annotated § 17-95-1110 Surrendering license due to retirement.
1. In order to retire his or her license, a genetic counselor shall file an affidavit with the Arkansas State Medical Board stating the date on which the individual will retire or has retired, and other information determined necessary by the Board.
 2. If a licensed genetic counselor retires his or her license as described in subsection J(1) of this section, the license shall apply for licensure as provided in § 17-95-1106 and is not liable for renewal fees that may accrue during the retirement period.

REGULATION 44

SUMMARY

Act 686 of 2019 Arkansas State Legislature creates the Arkansas Genetic Counselor Licensure Act