SOS APA Form 001

Mississippi Secretary of State
125 South Congress St., P. O. Box 136, Jackson, MS 39205-0136

ADMINISTRATIVE PROCEDURES NOTICE FILING

AGENCY NAME		CONTACT PERSON	TELEPHONE NUMBER	
Mississippi State Board Of Medical Licensure		Mike Lucius	(601)987-0248	
ADDRESS		CITY	STATE	ZIP
1867 Crane Ridge Drive, Suite 200-B		Jackson	MS	39216
EMAIL	SUBMIT DATE	Name or number of rule(s):		
mboard@msbml.ms.gov	12/7/18	Part 2635 Chapter 13 Complementary and Alternative Therapies, Rule 13.9		

Short explanation of rule/amendment/repeal and reason(s) for proposing rule/amendment/repeal: Creation of regulations regarding complementary and alternative therapies. Rule 13.9 sorts forth requirements regarding advertising practices.

Specific legal authority authorizing the promulgation of rule: 73-43-11

List all rules repealed, amended, or suspended by the proposed rule: None

ORAL PROCEEDING:

☐ An oral proceeding is scheduled for this rule on Date: _____ Time: _____ Place: _____

☒ Presently, an oral proceeding is not scheduled on this rule.

If an oral proceeding is not scheduled, an oral proceeding must be held if a written request for an oral proceeding is submitted by a political subdivision, an agency or ten (10) or more persons. The written request should be submitted to the agency contact person at the above address within twenty (20) days after the filing of this notice of proposed rule adoption and should include the name, address, email address, and telephone number of the person(s) making the request; and, if you are an agent or attorney, the name, address, email address, and telephone number of the party or parties you represent. At any time within the twenty-five (25) day public comment period, written submissions including arguments, data, and views on the proposed rule/amendment/repeal may be submitted to the filing agency.

ECONOMIC IMPACT STATEMENT:

☒ Economic impact statement not required for this rule. ☐ Concise summary of economic impact statement attached.

TEMPORARY RULES	PROPOSED ACTION ON RULES	FINAL ACTION ON RULES
_____ Original filing	**Action proposed:**	**Date Proposed Rule Filed:** _____
_____ Renewal of effectiveness	X____ New rule(s)	**Action taken:**
To be in effect in _____ days	_____ Amendment to existing rule(s)	_____ Adopted with no changes in text
Effective date:	_____ Repeal of existing rule(s)	_____ Adopted with changes
____ Immediately upon filing	_____ Adoption by reference	_____ Adopted by reference
_____ Other (specify): _____	**Proposed final effective date:**	_____ Withdrawn
	X____ 30 days after filing	_____ Repeal adopted as proposed
	_____ Other (specify): _____	**Effective date:**
		_____ 30 days after filing
		_____ Other (specify): _____

Printed name and Title of person authorized to file rules: Mike Lucius, Deputy Director

Signature of person authorized to file rules: Mike Lucius

OFFICIAL FILING STAMP	DO NOT WRITE BELOW THIS LINE OFFICIAL FILING STAMP	OFFICIAL FILING STAMP
	FILED DEC 0 7 2018 MISSISSIPPI SECRETARY OF STATE	
Accepted for filing by	**Accepted for filing by** #23826	**Accepted for filing by**

The entire text of the Proposed Rule including the text of any rule being amended or changed is attached.

Title 30, Part 2635 Practice of Medicine

Part 2635: Chapter 13: Complementary and Alternative Therapies

Rule 13.9 | Advertising

As to the advertising of alternative therapies, data purportedly supporting unproven interventions commonly undermine information about risks and overemphasize information about benefits. Information presented in advertising, including but not limited to clinic websites and social media, should be represented accurately and come from reputable peer-reviewed publications or respected external organizations.

Even where an appropriate informed consent process seems to be in place, deceptive or fraudulent information contained within practice advertising, websites, and other marketing materials could mislead patients into consenting to treatment, thereby invalidating the informed consent process.

Treatment options described and accompanied by supporting information in the form of journal articles, patient testimonials, claims of partnerships with academic institutions, mentions of affiliations with professional societies or networks, statements regarding receipt of FDA approval or explicit mention of exemption from FDA oversight, listings of patents granted, statements that clinical trials of investigational interventions are being conducted, and accolades related either to the practice itself or its affiliated physicians and researchers, which serve to exaggerate, inflate, or misrepresent information derived from legitimate or questionable sources, shall be deemed a violation of the Board's advertising regulations[1] and unprofessional conduct likely to deceive, defraud, or harm the public.[2]

Although not all-encompassing, the following represents instances of improper or misleading advertising practices which the Board would consider unprofessional and deceptive in nature:

1. Asserting certification of products or practices by international standards organizations or claiming training certification, in order to legitimize alternative therapies;
2. Convening scientific or medical advisory boards featuring prominent business leaders and academic faculty members in order to legitimize alternative therapies;
3. Registering trials whose apparent purpose is solely to attract patients willing to pay to participate in them;
4. Using the statement or impression of "ethics review" to convey a sense of legitimacy to products or procedures;
5. Renting of laboratory or business space within a legitimate scientific or government institution in order to legitimize alternative therapies;
6. Joining established academic or professional societies to suggest legitimacy by association;
7. Publication of open-ended voluntary monitoring data sets rather than undertaking controlled clinical trials;

[1] Title 30, Part 2635 Chapter 12: Physician Advertising

[2] Miss. Code Ann., §73-25-29(8)(d)

8. Suggesting that patent applications or grants indicate clinical utility rather than initiation of an application process or recognition of novelty and inventiveness;
9. Publishing research and commentary in journals with limited anonymous peer review;
10. Citing preclinical and other research findings to justify clinical application without sufficient efficacy testing in humans;
11. Forming organizations to self-regulate in ways that support premature commercialization; and
12. Providing expert opinions or celebrity comments on unsupported clinical uses or standing of the provider.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

Title 30, Part 2635 Practice of Medicine

Part 2635: Chapter 13: Complementary and Alternative Therapies

Rule 13.9 | Advertising

As to the advertising of alternative therapies, data purportedly supporting unproven interventions commonly undermine information about risks and overemphasize information about benefits. Information presented in advertising, including but not limited to clinic websites and social media, should be represented accurately and come from reputable peer-reviewed publications or respected external organizations.

Even where an appropriate informed consent process seems to be in place, deceptive or fraudulent information contained within practice advertising, websites, and other marketing materials could mislead patients into consenting to treatment, thereby invalidating the informed consent process.

Treatment options described and accompanied by supporting information in the form of journal articles, patient testimonials, claims of partnerships with academic institutions, mentions of affiliations with professional societies or networks, statements regarding receipt of FDA approval or explicit mention of exemption from FDA oversight, listings of patents granted, statements that clinical trials of investigational interventions are being conducted, and accolades related either to the practice itself or its affiliated physicians and researchers, which serve to exaggerate, inflate, or misrepresent information derived from legitimate or questionable sources, shall be deemed a violation of the Board's advertising regulations[1] and unprofessional conduct likely to deceive, defraud, or harm the public.[2]

Although not all-encompassing, the following represents instances of improper or misleading advertising practices which the Board would consider unprofessional and deceptive in nature:

1. Asserting certification of products or practices by international standards organizations or claiming training certification, in order to legitimize alternative therapies;
2. Convening scientific or medical advisory boards featuring prominent business leaders and academic faculty members in order to legitimize alternative therapies;
3. Registering trials whose apparent purpose is solely to attract patients willing to pay to participate in them;
4. Using the statement or impression of "ethics review" to convey a sense of legitimacy to products or procedures;
5. Renting of laboratory or business space within a legitimate scientific or government institution in order to legitimize alternative therapies;
6. Joining established academic or professional societies to suggest legitimacy by association;
7. Publication of open-ended voluntary monitoring data sets rather than undertaking controlled clinical trials;

[1] Title 30, Part 2635 Chapter 12: Physician Advertising

[2] Miss. Code Ann., §73-25-29(8)(d)

8. Suggesting that patent applications or grants indicate clinical utility rather than initiation of an application process or recognition of novelty and inventiveness;
9. Publishing research and commentary in journals with limited anonymous peer review;
10. Citing preclinical and other research findings to justify clinical application without sufficient efficacy testing in humans;
11. Forming organizations to self-regulate in ways that support premature commercialization; and
12. Providing expert opinions or celebrity comments on unsupported clinical uses or standing of the provider.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).