

ARKANSAS REGISTER



Proposed Rule Cover Sheet

Secretary of State
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Little Rock, Arkansas 72201-1094
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Name of Department Arkansas Department of Health
Agency or Division Name Div. of Health Related Boards & Commissions
Other Subdivision or Department, If Applicable Arkansas State Board of Dental Examiners
Previous Agency Name, If Applicable _____
Contact Person Meredith Rogers
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Name of Rule XXIV: Adverse Events Reporting
Newspaper Name Arkansas Democrat-Gazette
Date of Publishing June 26-28, 2022
Final Date for Public Comment July 26, 2022
Location and Time of Public Meeting There were no comments.



Arkansas Department of Health

Arkansas State Board of Dental Examiners
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Governor Asa Hutchinson

José Romero, MD, Secretary of Health

Meredith Rogers, Executive Director

PROPOSED AMENDMENT TO THE ARKANSAS STATE BOARD OF DENTAL EXAMINERS

PURPOSE

The Arkansas Department of Health is seeking Governor Hutchinson's review of proposed amendments to the Board of Dental Examiners Rule promulgated by the Board.

BACKGROUND

Because a function of the Board is to protect the citizens of Arkansas, it deems it important to be made known if a morbidity or mortality incident occurred as a result of a dental procedure. The Board approved this proposed Article at its May 14, 2021 meeting.

KEY POINTS

The proposed Article:

- Requires a dentist to file a morbidity report within 30 days of the incident or event.
- Requires a dentist to file a mortality report within 5 days after the occurrence of the death, or such time as the dentist becomes aware of the death.

DISCUSSION

The rule is to protect the citizens of Arkansas.

RECOMMENDATION

We recommend that the proposed Article to the Board's rules be approved as proposed by the Board.

QUESTIONNAIRE
FOR FILING PROPOSED RULES WITH THE
ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Arkansas Department of Health
DIVISION Division of Health Related Boards & Commissions/Arkansas State Board of Dental Examiners
DIVISION DIRECTOR Matt Gilmore/Meredith Rogers
CONTACT PERSON Meredith Rogers
ADDRESS 101 E. Capitol Avenue, Suite 111, Little Rock AR 72201
PHONE NO. (501) 682-2085 **FAX NO.** (501) 682-3543 **E-MAIL** meredith.rogers@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Meredith Rogers
PRESENTER E-MAIL meredith.rogers@arkansas.gov

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
- D. Rule" below.
- E. Submit two (2) copies of the 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 C. 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? Adverse Events Reporting

2. What is the subject of the proposed rule? Reporting mortality and morbidity reports to the Board

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? _____

When does the emergency rule expire? _____

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 rule.

This Article requires dentist to report a morbidity event within 30 days of the incident and a mortality event within 5 days of the incident.

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.

Ark Code Annotated Section 17-90-204

7. What is the purpose of this proposed rule? Why is it necessary?

The purpose of this proposed rule is to protect the citizens of the state of Arkansas.

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).

<https://www.healthy.arkansas.gov/programs-services/topics/arkansas-state-board-of-dental-examiners>

9. Will a public hearing be held on this proposed rule? Yes No If yes, please complete the following:

Date: 01/14/2022

Time: 9:00 am

Place: 101 E. Capitol Avenue (Cox Conference Room - basement), Little Rock AR 72201

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

01/14/2022

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

02/01/2022

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. See attached

13. Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e). See attached

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 State Dental Association (Billy Tarpley, Executive Director)

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health

DIVISION Division of Health Related Boards & Commissions/Arkansas State Board of Dental Examiners

PERSON COMPLETING THIS STATEMENT Meredith Rogers

TELEPHONE NO. (501) 682-2085 **FAX NO.** (501) 682-3543 **EMAIL:** meredith.rogers@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two (2) copies with the Questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Adverse Events Reporting

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 \$ 0.00
Federal Funds \$ 0.00
Cash Funds \$ 0.00
Special Revenue \$ 0.00
Other (Identify) \$ 0.00

Total \$ 0.00

General Revenue \$ 0.00
Federal Funds \$ 0.00
Cash Funds \$ 0.00
Special Revenue \$ 0.00
Other (Identify) \$ 0.00

Total \$ 0.00

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

Current Fiscal Year

Next Fiscal Year

General Revenue \$ 0.00
Federal Funds \$ 0.00
Cash Funds \$ 0.00
Special Revenue \$ 0.00
Other (Identify) \$ 0.00

Total \$ 0.00

General Revenue \$ 0.00
Federal Funds \$ 0.00
Cash Funds \$ 0.00
Special Revenue \$ 0.00
Other (Identify) \$ 0.00

Total \$ 0.00

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

Next Fiscal Year

\$ 0

\$ 0

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

Next Fiscal Year

\$ 0

\$ 0

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.

Article XXIV: Adverse Events Reporting**“Morbidity” and “Mortality” defined; Reporting Requirements.**

- (1) As used in this rule:
 - (a) “Morbidity” means an incident that results in mental or physical impairment which is related to or results from a dental procedure, administration of local anesthesia, oral conscious sedation, intravenous sedation, or general anesthesia.
 - (b) “Mortality: means an incident that results in a death related to a dental procedure, administration of local anesthesia, oral conscious sedation, intravenous sedation, or general anesthesia.

- (2) A dentist shall file a morbidity report with the board within 30 days after the occurrence or such a time as the dentist becomes aware of or reasonably should have become aware of the incident. This includes the hospitalization of a dental patient, as a possible consequence of receiving dental services from the reporting dentist. Hospitalization shall be defined as an examination at a hospital or emergency medical facility that results in an in-patient admission for the purpose of treatment or monitoring.

- (3) A dentist shall file a mortality report with the board within 5 days after the occurrence of a death, or such time as the dentist becomes aware or reasonably should have become aware of the death.

- (4) A dentist who fails to file a report as required by this rule and the board is in violation of Article XXIV of the Rules and Regulations and is subject to all penalties and fines associated with this violation.

Article XXIV: Adverse Events Reporting

“Morbidity” and “Mortality” defined; Reporting Requirements.

(5) As used in this rule:

(c) “Morbidity” means an incident that results in mental or physical impairment which is related to or results from a dental procedure, administration of local anesthesia, oral conscious sedation, intravenous sedation, or general anesthesia.

(d) “Mortality: means an incident that results in a death related to a dental procedure, administration of local anesthesia, oral conscious sedation, intravenous sedation, or general anesthesia.

(6) A dentist shall file a morbidity report with the board within 30 days after the occurrence or such a time as the dentist becomes aware of or reasonably should have become aware of the incident. This includes the hospitalization of a dental patient, as a possible consequence of receiving dental services from the reporting dentist. Hospitalization shall be defined as an examination at a hospital or emergency medical facility that results in an in-patient admission for the purpose of treatment or monitoring.

(7) A dentist shall file a mortality report with the board within 5 days after the occurrence of a death, or such time as the dentist becomes aware or reasonably should have become aware of the death.

(8) A dentist who fails to file a report as required by this rule and the board is in violation of Article XXIV of the Rules and Regulations and is subject to all penalties and fines associated with this violation.