

NOTICE OF INTENT

**Department of Health
Bureau of Health Services Financing**

**Ambulatory Surgical Center
Licensing Standards
(LAC 48:I.Chapter 45)**

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 48:I.Chapter 45 as authorized by R.S. 36:254 and R.S. 40:2131-2141. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Act 35 of the 2023 Regular Session of the Louisiana Legislature directed the Department of Health to require licensed healthcare facilities that provide any surgical procedure using heat-producing equipment to adopt and implement policies for a surgical smoke plume evacuation plan to mitigate and remove the surgical smoke plume. In compliance with Act 35, the Department of Health, Bureau of Health Services Financing proposes to amend the provisions governing the licensing of ambulatory surgical centers (ASCs) in order to require ASCs to adopt and implement policies for a surgical smoke plume evacuation plan for surgical procedures using heat-producing equipment.

**Title 48
PUBLIC HEALTH-GENERAL
Part I. General Administration
Subpart 3. Licensing and Certification**

Chapter 45. Ambulatory Surgical Center

Subchapter A. General Provisions

§4503. Definitions

Surgical Smoke Plume-the byproduct of using heat-producing equipment on tissue during surgery.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:1732 (September 2017), amended LR 49:

§4507. Initial Licensure Application Process

A. ...

B. The initial licensing application packet shall include:

1. - 4. ...
5. proof of each insurance coverage as follows:
 - a. - b. ...
 - c. professional liability insurance of at least \$100,000 per occurrence/\$300,000 per annual aggregate, or proof of self-insurance of at least \$100,000, along with proof of

enrollment as a qualified health care provider with the Louisiana Patient's Compensation Fund (PCF):

i. if the ASC is not enrolled in the PCF, professional liability limits shall be \$1 million per occurrence/\$3 million per annual aggregate; and

B.5.d. - E. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:1734 (September 2017), amended LR 49:

§4515. Renewal of License

A. The ASC shall submit a completed license renewal application packet to the department at least 30 days prior to the expiration of the current license. The license renewal application packet shall include:

1. - 5. ...

6. proof of each insurance coverage as follows:

a. - b. ...

c. professional liability insurance of at least \$100,000 per occurrence/\$300,000 per annual aggregate, or proof of self-insurance of at least \$100,000, along with proof of enrollment as a qualified health care provider with the Louisiana Patient's Compensation Fund (PCF):

A.6.c.i. - E. . . .

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:1736 (September 2017), amended LR 49:

Subchapter F. Safety, Sanitization and Emergency Preparedness

§4575. General Provisions

A. The ASC shall have policies and procedures, approved and implemented by the medical staff and governing body, that address provisions for:

1. sanitizing, disinfecting and sterilizing supplies, equipment and utensils;
2. the safe use of cleaning supplies and solutions that are to be used and the directions for use, including:
 - a. . . .
 - b. cleaning of the OR/procedure rooms between surgical and nonsurgical procedures; and
3. surgical smoke plume evacuation to mitigate and remove surgical smoke plume during a surgical procedure that uses heat-producing equipment, including but not limited to electrosurgery and lasers.

B.- D. . . .

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:1752 (September 2017), amended LR 49:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability and autonomy as described in R.S. 49:972.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

Small Business Analysis

In compliance with the Small Business Protection Act, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule will have no impact on small businesses.

Provider Impact Statement

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, no direct or indirect cost to the provider to provide the same level of service, and will have no impact on the provider's ability to provide the same level of service as described in HCR 170.

Public Comments

Interested persons may submit written comments to Tasheka Dukes, RN, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821. Ms. Dukes is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on September 29, 2023.

Public Hearing

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on September 11, 2023. If the criteria set forth in R.S. 49:961(B)(1) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on September 28, 2023 in Room 118 of the Bienville Building, which is located at 628 North Fourth

Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after September 11, 2023. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing.

Stephen R. Russo, JD

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Veronica Dent Dept.: Health
Phone: 342-3238 Office: Bureau of Health Services Financing
Return Address: P.O. Box 91030 Rule Title: Ambulatory Surgical Center
Baton Rouge, LA Licensing Standards

Date Rule
Takes Effect: November 20, 2023

SUMMARY
(Use complete sentences)

In accordance with Section 961 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 23-24. It is anticipated that \$756 will be expended in FY 23-24 for the state's administrative expense for promulgation of this proposed rule and the final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will not affect revenue collections as this measure has no impact on licensing fees.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS (Summary)

This proposed rule amends the provisions governing the licensing of ambulatory surgical centers (ASCs) in order to require ASCs to adopt and implement policies for a surgical smoke plume evacuation plan for surgical procedures using heat-producing equipment, in compliance with Act 35 of the 2023 Regular Session of the Louisiana Legislature. It is anticipated that implementation of this proposed rule may result in an indeterminable impact to ambulatory surgical centers for FY 23-24, FY 24-25, and FY 25-26, as a result of policies the providers may adopt and implement to address evacuation of the surgical smoke plume.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Tasheka Dukes
Signature of Agency Head or Designee

Tasheka Dukes, RN
Deputy Assistant Secretary
LDH Health Standards Section
Typed Name & Title of Agency Head or Designee

8/8/23
Date of Signature


Debbie Thomas, Deputy Fiscal Officer
Legislative Fiscal Officer or Designee

8/09/2023
Date of Signature

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

This proposed rule amends the provisions governing the licensing of ambulatory surgical centers (ASCs) in order to require ASCs to adopt and implement policies for a surgical smoke plume evacuation plan for surgical procedures using heat-producing equipment, in compliance with Act 35 of the 2023 Regular Session of the Louisiana Legislature.

B. Summarize the circumstances, which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

Act 35 of the 2023 Regular Session of the Louisiana Legislature directed the Department of Health to require licensed healthcare facilities that provide any surgical procedure using heat-producing equipment to adopt and implement policies for a surgical smoke plume evacuation plan to mitigate and remove the surgical smoke plume. In compliance with Act 35, the Department of Health, Bureau of Health Services Financing proposes to amend the provisions governing the licensing of ambulatory surgical centers (ASCs) in order to require ASCs to adopt and implement policies for a surgical smoke plume evacuation plan for surgical procedures using heat-producing equipment.

C. Compliance with Act 11 of the 1986 First Extraordinary Session

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

No. It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 23-24. In FY 23-24, \$756 is included for the state's administrative expense for promulgation of this proposed rule and the final rule.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) _____ Yes. If yes, attach documentation.

(b) _____ NO. If no, provide justification as to why this rule change should be published at this time

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 24	FY 25	FY 26
Personal Services			
Operating Expenses	\$756	\$0	\$0
Professional Services			
Other Charges			
Equipment			
Major Repairs & Constr.			
TOTAL	\$756	\$0	\$0
POSITIONS (#)			

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

In FY 23-24, \$756 will be spent for the state's administrative expense for promulgation of this proposed rule and the final rule.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 24	FY 25	FY 26
State General Fund	\$756	\$0	\$0
Agency Self-Generated			
Dedicated			
Federal Funds			
Other (Specify)			
TOTAL	\$756	\$0	\$0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

Yes, sufficient funds are available to implement this rule.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

This proposed rule has no known impact on local governmental units.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

There is no known impact on the sources of local governmental unit funding.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

REVENUE INCREASE/DECREASE	FY 24	FY 25	FY 26
State General Fund			
Agency Self-Generated			
Dedicated Funds*			
Federal Funds			
Local Funds			
TOTAL	\$0	\$0	\$0

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS

A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

This proposed rule amends the provisions governing the licensing of ambulatory surgical centers (ASCs) in order to require ASCs to adopt and implement policies for a surgical smoke plume evacuation plan for surgical procedures using heat-producing equipment, in compliance with Act 35 of the 2023 Regular Session of the Louisiana Legislature.

B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

It is anticipated that implementation of this proposed rule may result in an indeterminable impact to ambulatory surgical centers for FY 23-24, FY 24-25, and FY 25-26, as a result of policies the providers may adopt and implement to address evacuation of the surgical smoke plume.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

This rule has no known effect on competition and employment.