

NOTICE OF INTENT

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

**Hospital Licensing Standards
Newborn Safety Devices
(LAC 48:I.9573)**

The Department of Health, Bureau of Health Services Financing proposes to adopt LAC 48:I.9573 as authorized by R.S. 36:254 and 40:2100 et seq. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Act 421 of the 2021 Regular Session of the Louisiana Legislature authorized the Department of Health to regulate the installation of newborn safety devices (NSDs) located inside of hospital facilities which have 24-hour emergency departments. In compliance with Act 421, the Department of Health, Bureau of Health Services Financing proposes to adopt provisions governing the installation and use of NSDs in hospitals.

Title 48

PUBLIC HEALTH-GENERAL

Part I. General Administration

Subpart 3. Licensing and Administration

Chapter 93. Hospitals

Subchapter V. Newborn Safety Devices

§9573. General Provisions

A. In accordance with the Louisiana Children's Code (La. Ch. Code 1149 et seq.), a parent may leave an infant in a newborn safety device (NSD) that is physically located inside a facility which is licensed as a hospital in accordance with R.S. 40:2100 et seq., and has an emergency department that is staffed 24 hours per day.

B. Each NSD shall meet all of the following specifications:

1. voluntarily installed in the designated hospital;
2. installed in a location that ensures the anonymity of the relinquishing parent;
3. installed in a climate-controlled environment consistent with the internal temperature of the hospital;
4. installed by a licensed contractor in accordance with manufacturer's recommendations;
5. have an access door that locks automatically upon closure when an infant is in the device;
6. have a supporting frame that is anchored so as to align the bed portion of the NSD directly beneath the access door and prevent movement of the unit as a whole; and
7. feature a safe sleep environment which includes a firm, flat bassinet mattress and a sheet that fits snugly on and overlaps the mattress, and is free of pillows, bumpers, blankets and other bedding.

C. The hospital shall post appropriate signage approved by the Department of Children and Family Services at the site of the NSD that clearly identifies the NSD, and provides both written and pictorial instruction to the relinquishing parent to open the access door, place the infant inside the NSD and close the access door to engage the lock. The signage shall also clearly indicate all of the following:

1. the maximum age of the infant who may be relinquished in accordance with the Louisiana Children's Code;
2. that the infant must not have been previously subjected to abuse or neglect; and
3. that by placing an infant in the NSD, a parent is foregoing all parental responsibilities with response to the infant, and is giving consent for the state to take custody of the infant.

D. The hospital shall be responsible for:

1. the cost of the installation of the NSD;
2. installation of an adequate dual alarm system that shall be connected to the physical location of the NSD. The hospital shall ensure all of the following with respect to the alarm system:

- a. the alarm system generates an audible alarm at a central location within the facility 60 seconds after the opening of the access door to the NSD;

b. the alarm system generates an automatic call to 911 if the alarm is activated and not turned off from within the hospital less than 60 seconds after the commencement of the initial alarm;

c. the alarm system is tested at least one time per week to ensure that it is in working order; and

d. the alarm system is visually checked at least two times per day to ensure that it is in working order.

3. obtaining Department of Health (LDH), Health Standards Section (HSS) approval prior to the use of the NSD; and

4. submission of written notification to the LDH, HSS of the hospital's intent to implement the use of the device.

E. Prior to use of the NSD, an onsite survey shall be conducted by the LDH, HSS.

F. The hospital shall ensure that the device is checked at least daily for debris and is cleaned and sanitized with a hospital-quality disinfectant at least weekly and after any infant relinquishment into the NSD.

G. The hospital shall maintain documentation of the testing of the alarm system and the cleaning and sanitation of the NSD.

H. The hospital shall install a cardholder adjacent to the NSD and shall keep the cardholder stocked with safe haven

informational cards and other safe haven informational materials produced in accordance with La. Ch. Code 1160 and required by the Department of Children and Family Services.

I. The hospital shall develop and implement written policies and procedures that include, but are not limited to, receiving an infant who has been relinquished into the NSD, the use of an adequate NSD alarm system, testing of the NSD alarm system, cleaning of the NSD, documentation, and training of staff responsible for implementing the policies and procedures of the NSD, in accordance with La. Ch. Code 1149 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:

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 Act 820 of the 2008 Regular Session of the Louisiana Legislature, 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, as described in R.S. 49:978.1 et seq.

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, but will have an impact on hospital facilities that choose to have a newborn safety device installed as the hospital will be responsible for paying for the device as well as its installation and maintenance.

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 January 31, 2022.

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 January 10, 2022. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on January 27, 2022 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 January 10, 2022. 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. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing

attendees when the parking ticket is presented to LDH staff at the hearing.

Dr. Courtney N. Phillips

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: Hospital Licensing Standards

Baton Rouge, LA Newborn Safety Devices

Date Rule
Takes Effect: March 20, 2022

SUMMARY
(Use complete sentences)

In accordance with Section 953 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 21-22. It is anticipated that \$756 will be expended in FY 21-22 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 have no effect on revenue collections since the licensing fees, in the same amounts, will continue to be collected.

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

In compliance with Act 421 of the 2021 Regular Session of the Louisiana Legislature, this proposed rule adopts provisions governing the installation and use of newborn safety devices (NSDs) in hospitals. Implementation of this proposed rule will impact hospitals that elect to purchase and install NSDs, since any costs will be incurred by the hospital. Since hospitals may choose whether or not to purchase and install an NSD, it is not possible to estimate the potential impact to these providers in FY 21-22, FY 22-23 and FY 23-24, as there are currently no hospitals that have indicated their intent to pursue this option. This proposed rule will be beneficial to hospitals that pursue this option by providing guidance for the installation and use of an NSD.

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

12/7/2021
Date of Signature

Alan M. Bator
Legislative Fiscal Officer or Designee

12/8/21
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).

In compliance with Act 421 of the 2021 Regular Session of the Louisiana Legislature, this proposed rule adopts provisions governing the installation and use of newborn safety devices (NSDs) in hospitals.

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

Act 421 of the 2021 Regular Session of the Louisiana Legislature authorized the Department of Health to regulate the installation of newborn safety devices (NSDs) located inside of hospital facilities which have 24-hour emergency departments. In compliance with Act 421, the Department of Health, Bureau of Health Services Financing proposes to adopt provisions governing the installation and use of NSDs in hospitals.

- 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 20-21. In FY 20-21, \$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 22	FY 23	FY 24
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 21-22, \$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 22	FY 23	FY 24
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.

The 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 22	FY 23	FY 24
State General Fund			
Agency Self-Generated			
Dedicated Funds*			
Federal Funds			
Local Funds			
TOTAL			

*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.

In compliance with Act 421 of the 2021 Regular Session of the Louisiana Legislature, this proposed rule adopts provisions governing the installation and use of newborn safety devices (NSDs) in hospitals.

- 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.

Implementation of this proposed rule will impact hospitals that elect to purchase and install NSDs, since any costs will be incurred by the hospital. Since hospitals may choose whether or not to purchase and install an NSD, it is not possible to estimate the potential impact to these providers in FY 21-22, FY 22-23 and FY 23-24, as there are currently no hospitals that have indicated their intent to pursue this option. This proposed rule will be beneficial to hospitals that pursue this option by providing guidance for the installation and use of an NSD.

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.