NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Hospital Licensing Standards
Obstetrical and Newborn Services
(LAC 48:I.Chapter 93)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 48:I.Chapter 93 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.

The Department of Health, Bureau of Health Services Financing promulgated a Notice of Intent that proposed to amend the provisions governing the licensing of hospitals in order to update the standards for obstetrical and newborn services to reflect current requirements for staffing and levels of care units and to relocate the existing provisions of LAC 48:I.9511-9515 to LAC 48:I.9519-9523 (*Louisiana Register*, Volume 47, Number 12). As a result of comments received, the department determined that it was necessary to abandon the Notice of Intent published in the December 20, 2021 edition of the *Louisiana Register*.

The department now proposes to promulgate a revised Notice of Intent in order to amend the provisions governing the licensing of hospitals to update the requirements for

obstetrical and newborn services and relocate the existing provisions of LAC 48:I.9511-9515 to LAC 48:I.9519-9523.

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

Subchapter S. Obstetrical and Newborn Services (Optional)

§9505. General Provisions for Hospitals Licensed as of January 1, 2022

A. Sections 9509-9409 shall be effective immediately upon publication of these provisions for existing hospitals licensed as of July 1, 2022, and shall remain in effect through November 30, 2023. Such hospitals must be in compliance with Sections 9511-9517 beginning December 1, 2023.

NOTE Repealed.

1. The level of care of the neonatal intensive care unit (NICU) is not required to match or exceed the level of obstetrical care for each level of obstetrical service.

2. For facilities that change the level of care and services of the facility’s NICU unit, either decreasing or increasing the level provided, the facility shall submit an attestation of this change to the department’s Health Standards Section (HSS) in writing and on the appropriate state neonatal services Medicaid attestation form. Such notice shall be submitted to the HSS within 90 days of the facility’s change in

NICU level provided. For facilities that change the level of care and services of a facility's obstetrical unit, by either decreasing or increasing the level provided, the facility shall submit written notice of this change to HSS within 90 days of such change.

B. – G. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2427 (November 2003), amended LR 33:284 (February 2007), amended by the Department of Health, Bureau of Health Services Financing, LR 43:75 (January 2017), LR 46:1087 (August 2020), LR 48:

§9511. General Provisions for Hospitals Licensed After January 1, 2022, and for Existing Hospitals Beginning July 1, 2023

A. Sections 9511-9517 shall be effective immediately upon publication of these provisions for hospitals licensed after January 1, 2022.

1. Sections 9511-9517 shall be effective for existing hospitals (those licensed by or before January 1, 2022) beginning July 1, 2023.

B. The level of care of the neonatal ICU is not required to match or exceed the level of obstetrical care for each level of obstetrical service.

1. – 5. Repealed.

C. For facilities that change the level of care and services of the facility’s NICU unit, either decreasing or increasing the level provided, the facility shall submit an attestation of this change to the department’s HSS in writing and on the appropriate state neonatal services Medicaid attestation form. Such notice shall be submitted to the HSS within 90 days of the facility’s change in NICU level provided. For facilities that change the level of care and services of a facility’s obstetrical unit, by either decreasing or increasing the level provided, the facility shall submit written notice of this change to HSS within 90 days of such change.

D. For purposes of this Subchapter, the requirements for hospital staff and/or equipment as being physically present at all times specifies the person and/or equipment shall be on-site in the location 24 hours a day, 7 days a week.

E. For purposes of this Subchapter, the requirements for hospital staff and/ or equipment as being readily available at all times specifies the person shall be available, as approved by hospital policy, 24 hours a day, 7 days a week.

F. Any transfer agreements shall be in writing and approved by the hospital medical staff and by each hospital's governing body. Transfer agreements shall be reviewed at least annually and revised as needed.

G. For those hospitals providing transports, the qualifications of the transport team shall be in writing, defined by hospital policy and approved by each hospital's governing body. Such qualifications shall be reviewed at least annually and revised as needed.

H. The hospital shall have data collection and retrieval capabilities in use, and shall cooperate and report the requested data to the appropriate supervisory agencies to review.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2428 (November 2003), amended LR 33:286 (February 2007), amended by the Department of Health, Bureau of Health Services Financing, LR 43:78 (January 2017), LR 48:

§9513. Organization and Staffing

A. For purposes of this Subchapter, hospital privileges are such privileges that are unrestricted and approved by the

medical staff committee and the governing body that allows the practitioner to perform all duties within their scope of practice and certification(s) at the hospital in which the privileges are granted and such duties are performed.

1. The requirements for privileges, such as active privileges, inpatient privileges or full privileges, shall be defined in hospital policy and approved by each hospital's governing body.

1.a. – 2.c. Repealed.

B. In accordance with R.S. 40:2109, a hospital located in a parish with a population of 250,000 people or less shall not be required to maintain personnel in-house with credentials to administer obstetric anesthesia on a 24-hour basis in order to qualify for Medicaid reimbursement for level III, neonatal or obstetric medical services, or as a prerequisite for licensure to provide such services. Personnel with such credentials may be required to be on staff and readily available on a 24-hour on-call basis and demonstrate ability to provide anesthesia services within 20 minutes.

1. – 3.a.ii Repealed.

NOTE: The provisions of §9513.B shall not apply to any hospital with level IIIS, IIIR or IV obstetrical and neonatal services.

C. For purposes of this Subchapter, the requirements for hospital staff and/or equipment as being physically present at all times means that the person and/or equipment shall be on-site in the location 24 hours a day, 7 days a week.

1. – 5.b. Repealed.

D. For purposes of this Subchapter, the requirements for hospital means that the person shall be available 24 hours a day, 7 days a week.

1. – 3.a.i. Repealed.

E. Any transfer agreements shall be in writing and approved by the hospital medical staff and by each hospital's governing body. Transfer agreements shall be reviewed at least annually and revised as needed.

1. – 2.b.Table. Repealed.

F. For those hospitals providing transports, the qualifications of the transport team shall be in writing, defined by hospital policy and approved by each hospital's governing body. Such qualifications shall be reviewed at least annually and revised as needed.

G. The hospital shall have data collection and retrieval capabilities in use, and shall cooperate and report the requested data to the appropriate supervisory agencies to review.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2429 (November 2003), amended LR 33:286 (February 2007), amended by the Department of Health, Bureau of Health Services Financing, LR 43:78 (January 2017), LR 43:1979 (October 2017),LR 48:

§9515. Obstetrical Units

A. These requirements are applicable to those hospitals which provide obstetrical and neonatal services.

B. Levels of Care Units. These are five established obstetrical levels of care units:

1. obstetrical level I unit;

2. obstetrical level II unit;

3. obstetrical level III unit;

4. obstetrical level III regional unit; and

5. obstetrical level IV.

C. The guidance for these standards is based on *Obstetric Care Consensus: Levels of Maternal Care* published in August 2019. Each advanced level of care unit shall provide all services and meet the personnel requirements of the lower designated units, as applicable, i.e., a level IV unit shall

meet the requirements of a level I, II, III and III regional unit.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2429 (November 2003), amended LR 33:288 (February 2007), amended by the Department of Health, Bureau of Health Services Financing, LR 43:82 (January 2017), LR 48:

§9517. Obstetrical Unit Functions

A. Obstetrical Level I Unit (Basic Care)

1. General Provisions

a. Care and supervision for low risk pregnancies greater or equal to 35 weeks gestation and postpartum patients who are generally healthy and do not have medical, surgical, or obstetrical conditions that present a significant risk of maternal morbidity or mortality, shall be provided.

b. Participation in the state perinatal quality collaborative, which is under the authority of the Louisiana Commission on Perinatal Care and Prevention of Infant Mortality, is required and defined as reporting national perinatal measures

determined by the Louisiana Commission on Perinatal Care and Prevention of Infant Mortality.

c. There shall be a triage system present in policies and procedures for identification, stabilization and referral of high risk maternal and fetal conditions beyond the scope of care of a level I unit, including situations where an infant will require a higher level of care than what may be provided by the neonatal level of care of the facility.

d. Postpartum care facilities shall be available on-site.

e. There shall be capability to provide for resuscitation and stabilization of inborn neonates.

f. The hospital shall have a policy for infant security and an organized program to prevent infant abductions.

g. The hospital shall have a program in place to address the needs of the family, including parent-sibling-neonate visitation.

h. The hospital shall have a written transfer agreement with another hospital that has an approved appropriate higher level of care.

i. The hospital shall have the capability to screen, provide brief intervention and refer to treatment through consultation with appropriate personnel for behavioral

health disorders, including depression, and substance use disorder.

j. Social services, pastoral care and bereavement services shall be provided as appropriate to meet the needs of the patient population served.

2. Personnel Requirements

a. Obstetrical services shall be under the medical direction of a qualified physician who is a member of the medical staff with obstetric privileges. The physician shall be board certified or board eligible in obstetrics/gynecology or family practice medicine. The physician has the responsibility of coordinating perinatal services with the pediatric chief of service.

b. The nursing staff shall be adequately trained and staffed to provide patient care at the appropriate level of service. Registered nurse to patient ratios may vary in accordance with patient needs.

c. The unit shall provide credentialed medical staff to ensure the capability to perform emergency cesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits.

d. The maternal care providers, including midwives, family physicians or obstetricians, shall be readily available at all times.

e. Anesthesia, radiology, ultrasound, electronic fetal monitoring (along with personnel skilled in the use of these) and laboratory services shall be readily available at all times.

f. At least one credentialed physician or certified registered nurse midwife shall attend all deliveries, and at least one individual who is American Academy of Pediatrics (AAP) certified in neonatal resuscitation and capable of neonatal resuscitation shall attend all deliveries.

g. The nurse manager shall be a registered nurse (RN) with specific training and experience in obstetric care. The RN manager shall participate in the development of written policies, procedures for the obstetrical care areas, and coordinate staff education and budget preparation with the chief of service. The RN manager shall name qualified substitutes to fulfill duties during absences.

h. A facility shall have at least one individual with additional education in breastfeeding who is available for support, counseling and assessment of breastfeeding mothers.

i. A facility shall have ability to initiate education and quality improvement programs to maximize patient safety, and/or collaborate with higher-level facilities to do so.

3. Physical Plant

a. Laboring and postpartum patients shall not be placed in rooms with non-obstetrical patients.

b. Each room shall have at least one toilet and lavatory basin for the use of obstetrical patients.

c. The arrangement of the rooms and areas used for obstetrical patients shall be such as to minimize traffic of patients, visitors, and personnel from other departments and prevent traffic through the delivery room(s).

d. There shall be an isolation room provided with hand washing facilities for immediate segregation and isolation of a mother and/or baby with a known or suspected communicable disease.

e. For any new construction or major alteration of the obstetrical unit/suite, the hospital shall ensure that the OB unit has a cesarean delivery room (surgical operative room) to perform cesarean deliveries at all times.

4. Program Functions and Services

a. Laboratory and Blood Bank Services

i. There shall be protocols and capabilities for massive transfusion with process to obtain more blood and component therapy as needed, emergency release of blood products and management of multiple component therapy available on-site.

b. Medical Imaging Services

i. Ultrasound equipment shall be physically present at all times in the hospital and available during labor and delivery.

ii. Basic ultrasound imaging for maternal or fetal assessment including interpretation, shall be readily available at all times.

c. Obstetrical Services

i. Ensure the availability and interpretation of non-stress testing and electronic fetal monitoring.

ii. A trial of labor for patients with prior cesarean delivery may be attempted only if the necessary personnel to perform a cesarean delivery and perform maternal resuscitation are physically present. This personnel includes, all credentialed medical staff needed to perform an emergency cesarean delivery.

iii. The facility shall have written guidelines or protocols for various conditions that place the pregnant or postpartum patient at risk for morbidity and/or mortality, including promoting prevention, early identification, early diagnosis, therapy, stabilization, and transfer. The guidelines or protocols shall address at a minimum:

(a). massive hemorrhage and transfusion of the pregnant or postpartum patient in coordination with the blood bank, including management of unanticipated hemorrhage and/or coagulopathy;

(b). hypertensive disorders in pregnancy;

(c). sepsis and/or systemic infection in the pregnant or postpartum patient; and

(d). venous thromboembolism in the pregnant and postpartum patient, including assessment of risk factors, prevention, and early diagnosis and treatment.

B. Obstetrical Level II Unit (Specialty Care)

1. General Provisions

a. the role of an obstetrical level II unit is to provide care for pregnant and postpartum patients with medical, surgical and/or obstetrical conditions that present a moderate risk of maternal morbidity or mortality; and

b. women with high risk of morbidity or mortality or conditions that would result in the delivery of an infant weighing less than 1,500 grams or less than 32 weeks gestation that will require a higher level of care than what may be provided by the neonatal level of care of the facility, shall be referred to an approved level III or above unit unless the attending physician has documented that the patient is unstable

to transport safely. Written transfer agreements with approved obstetrical level III and above units for transfer of these patients shall exist for all obstetrical level II units.

2. Personnel Requirements

a. Obstetric Service Leadership

i. The physician obstetric leader shall be a board-certified obstetrician or a board eligible candidate for certification in obstetrics. This obstetrician has the responsibility of coordinating perinatal services with the neonatal healthcare provider in charge of the neonatal intensive care unit (NICU).

b. Personnel

i. A board-certified or board eligible OB-GYN physician shall be readily available at all times.

EXCEPTION: For those hospitals whose staff OB-GYN physician(s) do not meet the provisions of §9517.B.2.b.i, such physician(s) may be grandfathered as satisfying the requirement of §9517.B.2.b.i when the hospital has documented evidence that the OB-GYN physician(s) was granted clinical staff privileges by the hospital prior to the effective date of this Rule. This exception applies only to the physician at the licensed hospital location and shall not be transferrable.

ii. A licensed physician board-certified or board eligible in maternal fetal medicine (MFM) shall be readily

available at all times for consultation on-site, by telephone or by telemedicine, as needed. Timing and need to be on-site or available by telemedicine shall be directed by the urgency of the clinical situation.

iii. Anesthesia services shall be readily available at all times to provide labor analgesia and surgical anesthesia. A board-certified anesthesiologist with specialized training or experience in obstetric anesthesia shall be readily available at all times for consultation.

iv. A board-certified radiologist and a board-certified clinical pathologist shall be readily available at all times. Internal or family medicine physician(s) and general surgeon(s) shall be readily available at all times for consultation to stabilize obstetric patients who have been admitted to the facility or transferred from other facilities.

v. There shall be a continuous availability of qualified RNs with the ability to stabilize and transfer high-risk women.

vi. A lactation consultant or counselor shall be on staff to assist breastfeeding mothers as needed.

vii. The lactation consultant or counselor shall be certified by a nationally recognized board on breastfeeding. If individuals with such certification are not on staff, services may be obtained from certified providers

through the use of telehealth, subject to requirements of any licensing board(s).

3. Program Functions and Services

a. Medical Imaging Services

i. Computed tomography (CT) scan, magnetic resonance imaging (MRI), non-obstetric ultrasound imagining and maternal echocardiography with interpretation shall be readily available at all times.

ii. Specialized obstetric ultrasound and fetal assessment with interpretation shall be readily available at all times.

C. Obstetrical Level III Unit (Subspecialty Care)

1. General Provisions

a. This unit shall provide care for moderate to high-risk perinatal conditions. Women with such conditions requiring a medical team approach not available to the perinatologist in an obstetrical level III unit shall be transported to a higher-level unit.

b. The unit shall have written cooperative transfer agreements with approved higher level units for the transport of mothers and fetuses requiring care unavailable in an obstetrical level III unit or that are better coordinated at a higher level unit.

c. The hospital shall have advanced imaging services readily available at all times which shall include MRI and CT.

d. The hospital shall have medical and surgical ICUs to accept pregnant women and women in the postpartum period and, shall have qualified critical care providers readily available at all times to actively collaborate with MFM physicians.

e. Equipment and qualified personnel, adequate in number, shall be available on-site to ventilate and monitor women in labor and delivery until they can be safely transferred to the ICU.

f. This unit shall accept maternal transfers as deemed appropriate by the medical staff and governing body.

2. Personnel Requirements

a. Obstetric Leadership

i. The physician obstetric leader shall be a board-certified OB-GYN with active staff privileges in obstetrical care.

ii. A board-certified anesthesiologist with specialized training or experience in obstetric anesthesia shall be in charge of obstetric anesthesia services.

iii. The director of MFM services shall be a board-certified or board eligible MFM physician.

b. Personnel

i. This unit shall have a board-certified or board-eligible OB-GYN readily available at all times and available to be physically present within 20 minutes of request to be on-site.

ii. This unit shall have a board-certified or a board-eligible anesthesiologist qualified in the delivery of obstetric anesthesia services readily available at all times. Personnel with such credentials shall be required to be on staff and readily available on a 24-hour on-call basis, and demonstrate the ability to provide anesthesia services within 20 minutes.

iii. A board-certified or board-eligible MFM physician with inpatient privileges shall be readily available at all times, either on-site, by telephone or by telemedicine.

iv. A full complement of subspecialists, including subspecialists in critical care, general surgery, infectious disease, urology, hematology, cardiology, nephrology, neurology, gastroenterology, internal medicine, behavioral health, neonatology and pulmonology shall be readily available at all times for inpatient consultations.

v. Anesthesia services shall be physically present at all times, unless otherwise provided by R.S. 40:2109(B)(6).

vi. The delivery of safe and effective perinatal nursing care requires appropriately qualified registered nurses in adequate numbers to meet the nursing needs of each patient. The hospital shall develop, maintain and adhere to an acuity-based classification system based on nationally recognized staffing guidelines and shall have documentation of such.

vii. A nutritionist and a social worker shall be on staff and available for the care of these patients as needed.

D. Obstetrical Level III Regional Unit (Regional Transfer Unit).

1. General Provisions

a. This unit shall provide care for the most challenging of perinatal conditions. Women with such conditions requiring a medical team approach not available to the MFM physician in an obstetrical level III regional unit shall be transported to a level IV unit.

b. This unit shall have written cooperative transfer agreements with a level IV unit for the transport of mothers and fetuses requiring care that is unavailable in the level III regional unit or that is better coordinated at a level IV.

c. This unit shall accept maternal transfers as deemed appropriate by the medical staff and hospital governing body.

2. Personnel Requirements

a. This unit shall have a board-certified or board-eligible OB-GYN physically present at all times.

b. The director of MFM services for this unit shall be a board-certified MFM physician.

c. This unit shall have an anesthesiologist qualified in the delivery of obstetric anesthesia services physically present at all times.

E. Obstetrical Level IV Unit (Regional Subspecialty Perinatal Health Care Centers)

1. General Provisions

a. This unit shall provide on-site medical and surgical care of the most complex maternal conditions and critically ill pregnant women and fetuses throughout antepartum, intrapartum, and postpartum care.

2. Unit Requirements

a. This unit shall have perinatal system leadership, including facilitation of maternal referral and transport, outreach education for facilities and health care providers in the region and analysis and evaluation of regional

data, including perinatal complications and outcomes and quality improvement.

3. Personnel

a. Obstetric Leadership

i. The physician obstetric leader for this unit shall be a board-certified MFM physician.

b. Personnel

i. This unit shall have a MFM care team with the expertise to assume responsibility for pregnant women and women in the postpartum period who are in critical condition or have complex medical conditions. This includes co-management of ICU-admitted obstetric patients. The MFM team members shall have full privileges and shall be available 24 hours per day for on-site consultation and management. This team shall be led by a board-certified MFM physician.

ii. This unit shall have qualified subspecialists on staff, readily available at all times, to provide consultation and treatment as needed on-site in the care of critically ill pregnant women in the following areas:

(a). cardiothoracic surgery and

(b). neurosurgery.

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:

§9519. Neonatal Intensive Care

[Formerly LAC 48:I.9511]

A. This §9519 is applicable to those hospitals which provide obstetrical and neonatal services.

B. Levels of Care. There are five established neonatal levels of care units:

1. neonatal level I unit;

2. neonatal level II unit;

3. level III NICU unit;

4. level III surgical NICU; and

5. level IV NICU unit.

C. Each advanced level of care unit shall provide all services and meet the personnel requirements of the lower designated units, as applicable, i.e., a level III surgical unit must meet the requirements of the level I, II, and III units.

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:

§9521. Neonatal Unit Functions

[Formerly LAC 48:I.9513]

A. Level I Neonatal Unit (Well Newborn Nursery)

1. General Provisions

a. This unit shall have the capability for resuscitation and stabilization of all inborn neonates in accordance with Neonatal Resuscitation Program (NRP) guidelines. The unit shall stabilize unexpectedly small or sick neonates before transfer to the appropriate advanced level of care.

b. The unit shall stabilize and provide care for infants born at 35 weeks or greater gestation and who remain physiologically stable. The requirements for maternal transport at lesser gestations for transfer to a higher level of care shall be determined by the medical staff and approved by the hospital governing body.

c. This unit shall have the capability to stabilize newborns born at less than 35 weeks gestational age for transfer to higher level of care.

d. This unit shall maintain consultation and written transfer agreements with an approved level II or III as appropriate.

e. This unit shall have a defined, secured nursery area with limited public access and/or secured rooming-in facilities with supervision of access.

f. Parent and/or sibling visitation/interaction with the neonate shall be provided.

2. Personnel Requirements

a. The unit's chief of service shall be a physician who is board-certified or board-eligible in pediatric or family practice medicine.

b. The nurse manager shall be a registered nurse with specific training and experience in neonatal care. The RN manager shall participate in the development of written policies and procedures for the neonatal care areas, and coordinate staff education and budget preparation with the chief of service. The RN manager shall name qualified substitutes to fulfill duties during absences.

c. Registered nurse to patient ratios may vary in accordance with patient needs. If couplet care or rooming-in is used, a registered nurse who is responsible for the mother shall coordinate and administer neonatal care. If direct assignment of the nurse is also made to the nursery to cover the newborn's care, there shall be double assignment (one nurse for the mother-neonate couplet and one for just the neonate if returned to the nursery). A registered nurse shall be available 24 hours a day, but only one may be necessary as most neonates will not be physically present in the nursery. Direct care of neonates in the nursery may be provided by ancillary personnel under the registered nurse's direct supervision. Adequate staff is needed to respond to acute and emergency situations.

B. Neonatal Level II Unit (Special Care Nursery)

1. General Provisions

a. This unit shall provide care for infants born at more than 32 weeks gestation and weighing more than 1,500 grams.

i. infants who have medical problems that are expected to resolve rapidly and are not anticipated to need emergent subspecialty services from a higher level NICU as determined by the attending medical staff.

b. This unit shall have the capability to provide mechanical ventilation and/or CPAP for a brief duration (less than 24 hours) for infants born at more than 32 weeks and weighing more than 1,500 grams.

c. Neonates requiring greater than 24 hours of continuous ventilator support shall be transferred to a higher-level neonatal intensive care facility.

d. This unit shall have the ability to stabilize infants born before 32 weeks gestation and/or weighing less than 1,500 grams until transfer to a higher level neonatal intensive care facility.

e. Neonates requiring transfer to a higher-level neonatal intensive care facility may be returned to a level II unit for convalescence.

2. Personnel Requirements

a. A board-certified neonatologist shall be the chief of service.

NOTE: This unit shall have continuously available medical staff defined as available 24 hours per day/7 days per week/365 days per year on call for consultation as defined by medical staff bylaws.

b. Registered nurse to patient ratios may vary in accordance with patient needs.

c. This unit shall have at least one full-time social worker to be available as needed to assist with the socioeconomic and psychosocial problems of high-risk mothers, sick neonates, and their families.

d. This unit shall have at least one occupational or physical therapist to be available as needed to assist with the care of the newborn.

e. This unit shall have at least one registered dietitian/nutritionist to be available as needed who can plan diets as required to meet the special needs of mothers and high-risk neonates.

f. This unit shall have staff available 24 hours per day who have the demonstrated knowledge, skills, abilities and training to provide the care and services to infants in this unit, such as but not limited to:

i. nurses;

ii. respiratory therapists;

iii. radiology technicians; and

iv. laboratory technicians.

3. Equipment Requirements

a. This unit shall have hospital based equipment to provide care to infants available 24 hours per day, such as but not limited to:

i. portable x-ray machine;

ii. blood gas analyzer.

C. Level III NICU

1. General Provisions

a. There shall be a written neonatal transport agreement with an approved level III surgical unit or level IV unit.

b. This unit shall have either a neonatologist or a neonatal nurse practitioner or a neonatology fellow in-house 24 hours per day.

c. The staffing of this unit shall be based on patient acuity and consistent with the recommended staffing guidelines of the 2012 Seventh Edition of the *AAP Guidelines for Perinatal Care*. For medical sub-specialty requirements, refer to Table 1, Neonatal Medical Subspecialties and Transport Requirements.

NOTE: All provisions of level III NICUs are required of level IIIS and IV NICUs.

2. Personnel Requirements

a. The chief of service of a level III NICU shall be a board-certified neonatologist.

EXCEPTION: In 1995, those physicians in existing units who were designated as the chief of service of the unit and who were not neonatal or perinatal board-certified, were granted a waiver by written application to the Office of the Secretary, Department of Health. This waiver shall be maintained as it applies only to the hospital where that chief of service's position is held. The physician cannot relocate to another hospital nor can the hospital replace the chief of service for whom the exception was granted and retain the exception.

b. This unit shall have at least one full-time social worker available as needed who has experience with the socioeconomic and psychosocial problems of high-risk mothers and fetuses, sick neonates, and their families. For units with greater than 30 patients, the social worker staffing ratios shall be at least one social worker to 30 patients (additional social workers may be required in accordance with hospital staffing guidelines.

c. This unit shall have at least one occupational or physical therapist available as needed with

neonatal expertise and at least one individual skilled in evaluation and management of neonatal feeding and swallowing disorders (e.g., speech-language pathologist).

d. This unit shall have at least one registered dietitian/nutritionist available as needed who has training or experience in perinatal nutrition and can plan diets that meet the special needs of high-risk mothers and neonates.

e. Delivery of safe and effective perinatal nursing care requires this unit to have qualified registered nurses in adequate numbers to meet the nursing needs of each patient. To meet the nursing needs of this unit, hospitals shall develop and adhere to an acuity based classification system based on nationally recognized staffing guidelines and have documentation available on such guidelines.

f. This unit shall have the following support personnel immediately available as needed to be on-site in the hospital, including but not limited to:

i. licensed respiratory therapists or registered nurses with specialized training who can supervise the assisted ventilation of neonates with cardiopulmonary disease.

3. Equipment Requirements

a. This unit shall have the following support equipment, in sufficient number, immediately available as needed in the hospital that includes, but is not limited to:

i. advanced imaging with interpretation on an urgent basis (computed tomography, ultrasound (including cranial ultrasound), MRI, echocardiography and electroencephalography); and

ii. respiratory support that allows provision of continuous mechanical ventilation for infants less than 32 weeks gestation and weighing less than 1,500 grams.

4. Transport

a. It is optional for level III NICUs to provide transports. If the unit performs transports, the unit shall have a qualified transport team and provide for and coordinate neonatal transport with level I and level II units throughout the state.

b. Transport shall be in accordance with national standards as published by the American Academy of Pediatrics' section on neonatal and pediatric transport and in accordance with applicable Louisiana statutes.

5. Quality Improvement Collaborative

a. Facilities with level III NICUs and above shall participate in a quality improvement collaborative and a

database selected by the Medicaid quality committee, neonatology sub-committee.

b. Proof of current participation by the facility will be available from the LDH website.

D. Level III Surgical NICU

1. General Provisions

a. This unit shall have a transport team and provide for and coordinate neonatal transport with level I, level II units and level III NICUs throughout the state as requested. Transport shall be in accordance with national standards as published by the American Academy of Pediatrics' section on neonatal and pediatric transport and in accordance with applicable Louisiana statutes.

NOTE: All provisions of level III NICUs are required of level IIIS and IV NICUs.

2. Personnel Requirements

a. For medical sub-specialty requirements refer to Table 1–Neonatal Medical Subspecialties and Transport Requirements.

EXCEPTION: Those hospitals which do not have a member of the medical staff who is a board certified/eligible pediatric anesthesiologist but whose anesthesiologist has been granted staff privileges to perform pediatric anesthesiology, such physician(s) may be grandfathered as

satisfying the requirement of §9521.2.a when the hospital has documented evidence that the anesthesiologist was granted clinical staff privileges by the hospital prior to the effective date of this Rule. This exception applies only to such physician at the licensed hospital location and is not transferrable.

3. Equipment Requirements

a. This unit shall have the following support equipment, in sufficient number, immediately available as needed in the hospital that includes, but is not limited to:

i. a full range of respiratory support that incudes high frequency ventilation and inhaled nitric oxide.

E. Level IV NICU

1. General Provisions

a. This unit shall be located within an institution with the capability to provide surgical repair of complex conditions (e.g., congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation).

2. Personnel Requirements

a. for medical sub-specialty requirements, refer to Table 1–Neonatal Medical Subspecialties and Transport Requirements;

NOTE: All provisions of level IIIS NICUs are required of level IV NICUs.

b. Neonatal Medical Subspecialties and Transport Requirements;

Table 1—Neonatal Medical Subspecialties and Transport Requirements				
Text denoted with asterisks (*) indicates physician shall be available in person on-site as needed by the facility. Each higher level NICU unit shall meet the requirements of each lower level NICU unit.				
Level I (Well Nursery)	**Level II**	**Level III**	**Level IIIS**	**Level IV**
Board Certified/Eligible Pediatric or Family Practice Physician	Board Certified/Eligible Pediatric or Family Practice Physician	Pediatric Cardiology[1]	Pediatric Surgery[4]	Pediatric Surgery[4]
	Board Certified Neonatologist	Ophthalmology[2]	Pediatric Anesthesiology[5] §9513(2)a—See Exception	Pediatric Anesthesiology[5]
	Social Worker		Neonatal Transport	Neonatal Transport
	Occupational Therapist	Social Worker Ratio 1:30	Ophthalmology[2*]	Ophthalmology[2*]
	Physical Therapist	OT or PT/neonatal expertise	Pediatric Cardiology*	Pediatric Cardiology*
	Respiratory Therapists	RD/training in perinatal nutrition	Pediatric Gastroenterology*	Pediatric Cardiothoracic Surgery*
	Registered dietician/nutritionist	RT/training in neonate ventilation	Pediatric Infectious Disease*	Pediatric Endocrinology*
	Laboratory Technicians	Neonatal feeding/swallowing-SLP/ST	Pediatric Nephrology*	Pediatric Gastroenterology*
	Radiology Technicians		Pediatric Neurology[3*]	Pediatric Genetics*
			Pediatric Neurosurgery*	Pediatric Hematology-Oncology*
			Pediatric Orthopedic Surgery*	Pediatric Infectious Disease*
			Pediatric Otolaryngology[6*]	Pediatric Nephrology*
			Pediatric Pulmonology*	Pediatric Neurology[3*]
				Pediatric Neurosurgery
				Pediatric Orthopedic Surgery
				Pediatric Otolaryngology[7*]
				Pediatric Pulmonology*
				Pediatric Radiology*
				Pediatric Urologic Surgery*
			Transport note:	
[1]There shall be at least one board certified or board eligible pediatric cardiologist as a member of medical staff. For Level III facilities,			Transport shall be in accordance with national standards as published by the American Academy of Pediatrics' Section on neonatal and pediatric transport	

Table 1—Neonatal Medical Subspecialties and Transport Requirements Text denoted with asterisks (*) indicates physician shall be available in person on-site as needed by the facility. Each higher level NICU unit shall meet the requirements of each lower level NICU unit.				
Level I (Well Nursery)	**Level II**	**Level III**	**Level IIIS**	**Level IV**
staff using telemedicine shall be continuously available.			and in accordance with applicable Louisiana statutes.	
[2]There shall be at least one board certified or board eligible ophthalmologist with sufficient knowledge and experience in retinopathy or prematurity as a member of the medical staff. An organized program for monitoring retinotherapy of prematurity shall be readily available in Level III and for treatment and follow-up of these patients in Level IIIS and IV facilities.				
[3]There shall be at least one board certified or board eligible pediatric neurologist as a member of medical staff.				
[4]For pediatric surgery, the expectation is that there is a board certified or eligible pediatric surgeon who is continuously available to operate at that facility.				
[5]There shall be at least one board certified or board eligible pediatric anesthesiologist as a member of the medical staff.				
[6]Board eligible or certified in Otolaryngology; special interest in Pediatric Otolaryngology or completion of Pediatric Otolaryngology Fellowship.				

Table 1—Neonatal Medical Subspecialties and Transport Requirements				
Text denoted with asterisks (*) indicates physician shall be available in person on-site as needed by the facility. Each higher level NICU unit shall meet the requirements of each lower level NICU unit.				
Level I (Well Nursery)	**Level II**	**Level III**	**Level IIIS**	**Level IV**
[7]Board eligible or certified in Otolaryngology; completion of Pediatric Otolaryngology Fellowship.				
For specialties listed above staff shall be board eligible or board certified in their respective fields with the exception of otolaryngology as this field has not yet pursued certification.				

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:

§9523. Additional Support Requirements

[Formerly LAC 48:I.9515]

A. A bioethics committee shall be available for consultation with care providers at all times.

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 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, 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 August 29, 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 August 9, 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 August 25, 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 August 9, 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
Baton Rouge, LA
Rule Title: Hospital Licensing Standards
Obstetrical and Newborn Services

Date Rule Takes Effect: October 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 22-23. It is anticipated that $4,320 will be expended in FY 22-23 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)

This proposed rule amends the provisions governing the licensing of hospitals in order to update the standards for obstetrical and newborn services to ensure that the administrative rule reflects current requirements for staffing and levels of care units. Additionally, the existing provisions of LAC 48:I.9511-9515 are being relocated to LAC 48:I.9519-9523. Facilities choosing to offer certain obstetric and newborn services may experience an increase in operational costs in FY 22-23, FY 23-24, and FY 24-25; however, there is no way to determine the number of hospitals that may be impacted nor estimate the potential costs to these providers.

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

Alan M. Boxton
Legislative Fiscal Officer or Designee

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

6/30/2022
Date of Signature

7/1/22
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 hospitals in order to update the standards for obstetrical and newborn services to ensure that the administrative rule reflects current requirements for staffing and levels of care units. Additionally, the existing provisions of LAC 48:I.9511-9515 are being relocated to LAC 48:I.9519-9523.

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

The Department of Health, Bureau of Health Services Financing promulgated a Notice of Intent that proposed to amend the provisions governing the licensing of hospitals in order to update the standards for obstetrical and newborn services to reflect current requirements for staffing and levels of care units and to relocate the existing provisions of LAC 48:I.9511-9515 to LAC 48:I.9519-9523 (*Louisiana Register*, Volume 47, Number 12). As a result of comments received, the department determined that it was necessary to abandon the Notice of Intent published in the December 20, 2021 edition of the *Louisiana Register*.

The department now proposes to promulgate a revised Notice of Intent in order to amend the provisions governing the licensing of hospitals to update the requirements for obstetrical and newborn services and relocate the existing provisions of LAC 48:I.9511-9515 to LAC 48:I.9519-9523.

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 22-23. In FY 22-23, $4,320 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 23	FY 24	FY 25
Personal Services			
Operating Expenses	$4,320	$0	$0
Professional Services			
Other Charges			
Equipment			
Major Repairs & Constr.			
TOTAL	$4,320	$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 22-23, $4,320 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 23	FY 24	FY 25
State General Fund	$4,320	$0	$0
Agency Self-Generated			
Dedicated			
Federal Funds			
Other (Specify)			
TOTAL	$4,320	$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 23	FY 24	FY 25
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.

This proposed rule amends the provisions governing the licensing of hospitals in order to update the standards for obstetrical and newborn services to ensure that the administrative rule reflects current requirements for staffing and levels of care units. Additionally, the existing provisions of LAC 48:I.9511-9515 are being relocated to LAC 48:I.9519-9523.

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.

Facilities choosing to offer certain obstetric and newborn services may experience an increase in operational costs in FY 22-23, FY 23-24, and FY 24-25; however, there is no way to determine the number of hospitals that may be impacted nor estimate the total costs to these providers.

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.