NOTICE OF INTENT

Department of Health and Hospitals
Bureau of Health Services Financing

Hospital Licensing Standards
Obstetrical and Newborn Services
(LAC 48:I.9505-9515)

The Department of Health and Hospitals, Bureau of Health Services Financing proposes to amend LAC 48:I.9505–9515 as authorized by R.S. 40:2100-2115. This proposed Rule is promulgated in accordance with the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amended the provisions governing the licensing of hospitals in order to clarify those provisions and to align the requirements for obstetrical and newborn services with recommendations from the *National Guidelines for Perinatal Care* (*Louisiana Register*, Volume 33, Number 2).

The department has determined it is necessary to amend the provisions governing the hospital licensing standards in order to align these provisions with current standards of practice and staffing guidelines.

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

Chapter 95. Hospitals

Subchapter S. Obstetrical and Newborn Services (Optional)

§9505. General Provisions

A. This Subchapter S requires that the level of care on the ~~O~~obstetrical ~~U~~unit and the ~~N~~neonatal ~~I~~intensive ~~C~~care ~~U~~unit shall be at the identical level except for free standing children's hospitals. All hospitals with existing obstetrical and neonatal services ~~must~~shall be in compliance with this Subchapter S within one year of the promulgation date of this Rule. All new providers of obstetrical and neonatal services ~~will~~shall be required to be in compliance with this Subchapter S immediately upon promulgation.

Note: 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 HSS within 90 days of the facility's change in NICU level provided. For facilities that change the level of care and services of the facility's obstetric 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. 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.

C. 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.

Note: The provisions of §9505.C shall not apply to any hospital with level IIIS, IIIR or IV obstetrical and neonatal services.

D. For purposes of this Subchapter, the requirements for hospital staff and/or equipment as being immediately or readily available shall be defined by hospital policy and approved by each hospital's governing body.

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.

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.

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 and Hospitals, Bureau of Health Services Financing, LR 42:

§9507. Obstetrical Units

A. …

B. Levels of Care Units. There are ~~four~~five established obstetrical levels of care units:

1. ~~O~~obstetrical ~~L~~level I ~~U~~unit;

2. ~~O~~obstetrical ~~L~~level II ~~U~~unit;

3. ~~O~~obstetrical ~~L~~level III ~~U~~unit; ~~and~~

4. ~~O~~obstetrical ~~L~~level III ~~R~~regional ~~U~~unit~~.~~; and

5. obstetrical level IV.

C. Obstetrical services shall be provided in accordance with ~~current~~ acceptable standards of practice as delineated in the ~~current~~ 2014 *AAP/ACOG Guidelines for Perinatal Care*. 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 ~~L~~level ~~III~~IV ~~regional~~ unit must meet the requirements of a ~~L~~level I, II, ~~and~~ 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 29:2427 (November 2003), amended LR 33:284 (February 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 42:

§9509. Obstetrical Unit Functions

A. – A.1.a. …

b. 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 ~~L~~level I ~~U~~unit.

c. There shall be ~~a written transfer agreement with a hospital which has an approved appropriate higher level of~~

~~care~~protocols and capabilities for massive transfusion, emergency release of blood products, and management of multiple component therapy available on-site.

d. ~~The unit~~ Postpartum care facilities shall ~~provide detection and care for unanticipated maternal-fetal problems encountered in labor~~be available on-site.

e. ~~Blood and fresh frozen plasma for transfusion~~ There shall be ~~immediately available~~ capability to provide for resuscitation and stabilization of inborn neonates.

f. ~~Postpartum care facilities~~The hospital shall ~~be available~~have a policy for infant security and an organized program to prevent infant abductions.

g. ~~There~~The hospital shall ~~be capability to provide for resuscitation~~ have a data collection and retrieval system and ~~stabilization of inborn neonates~~shall report the required data to the appropriate departmental agency or section.

h. The ~~facility~~hospital shall have a ~~policy for infant security and an organized~~ program in place to ~~prevent infant abductions~~address the needs of the family, including parent-sibling-neonate visitation.

i. The ~~facility~~ hospital shall ~~support breast feeding~~have a written transfer agreement with another hospital that has an approved appropriate higher level of care.

~~j. The facility shall have data collection and retrieval capabilities including current birth certificate in use, and shall cooperate and report the requested data to the appropriate supervisory agencies for review.~~

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

~~l. The facility shall have written transport agreements. The transport service must be designed to be adequately equipped and have transport personnel with appropriate expertise for obstetrical and neonatal care during transport. Transport services shall meet appropriate local, state, and federal guidelines~~j. - l. Repealed.

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 ~~B~~board ~~C~~certified or b~~B~~oard e~~E~~ligible in obstetrics/gynecology or ~~F~~family ~~P~~practice ~~M~~medicine. The physician has the responsibility of coordinating perinatal services with the pediatric chief of service.

b. The nursing staff ~~must~~shall be adequately trained and staffed to provide patient care at the appropriate level of service. ~~The facility shall utilize the guidelines for staffing as~~

~~provided by the AAP and the ACOG in the current Guidelines for Perinatal Care (See Table 2-1 in §9515, Additional Support Requirements)~~Registered nurse to patient ratios may vary in accordance with patient needs.

c. …

d. Anesthesia, radiology, ultrasound, electronic fetal monitoring (along with personnel skilled in ~~its~~the use of these) and laboratory services shall be available on a 24-hour basis. Anesthesia services shall be available to ensure performance of a Cesarean delivery within 30 minutes as specified in Subparagraph c above.

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

f. …

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

h. 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. – 3.d. …

e. For ~~A~~any new construction or major alteration of the obstetrical unit~~s~~/suite, the hospital shall ~~have~~ ensure that the OB unit has a ~~facility~~ Cesarean delivery room (surgical operative room) to ~~enable~~ perform Cesarean ~~section~~ deliveries ~~in the obstetrical unit~~ at all times.

B. – B.1.a. …

b. Women with ~~C~~conditions ~~which~~that would result in the delivery of an infant weighing less than 1,500 grams or less than 32 weeks gestation shall be referred to an approved ~~L~~level III or ~~Level III regional obstetrical~~ above unit unless the attending physician has documented that the patient is ~~too~~ unstable to transport safely. Written transfer agreements with approved obstetrical ~~L~~level III and above~~/or obstetrical Level III regional~~ units for transfer of these patients shall exist for all obstetrical ~~L~~level II units.

c. ~~The unit~~Ultrasound equipment shall be ~~able to manage maternal complications of a mild to moderate nature that do not surpass the capabilities of a board certified obstetrician/gynecologist~~on site, in the hospital, and available to labor and delivery 24 hours a day.

~~d. The needed subspecialty expertise is predominantly neonatal although perinatal cases might be appropriate~~

~~to co-manage with a perinatologist.~~

~~c. Ultrasound equipment shall be on site, in the hospital, and available to labor and delivery 24 hours a day.~~d. - e. Repealed.

2. Personnel Requirements

a. The chief of obstetric services shall be a board-certified obstetrician or ~~an~~ a board eligible ~~active~~ candidate for certification in obstetrics. This obstetrician has the responsibility of coordinating perinatal services with the neonatologist or pediatrician in charge of the neonatal intensive care unit (NICU).

b. …

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

d. A board-certified or board eligible OB-GYN physician shall be available 24 hours a day.

e. A licensed physician board-certified in maternal fetal medicine (MFM) shall be available 24 hours a day for consultation onsite, by telephone, or by telemedicine, as needed.

f. Anesthesia services shall be available 24 hours a day to provide labor analgesia and surgical anesthesia.

g. A board-certified anesthesiologist with specialized training or experience in obstetric anesthesia shall be

available 24 hours a day for consultation.

h. Medical and surgical consultants shall be available 24 hours a day to stabilize obstetric patients who have been admitted to the facility or transferred from other facilities.

C. – C.1. …

a. ~~There~~ Women with conditions requiring a medical team approach not available to the perinatologist in an obstetrical level III unit shall be ~~provision of comprehensive perinatal care for high risk mothers~~ transported to a higher-level unit.

b. The unit shall ~~provide care~~ have written cooperative transfer agreements with approved higher level units for the ~~most challenging of perinatal conditions. Only those conditions~~transport of mothers and fetuses requiring ~~a medical team approach not available to the perinatologist~~ care unavailable in an obstetrical ~~L~~level III unit ~~shall be transported to an obstetrical Level III regional~~ or that are better coordinated at a higher level unit.

c. ~~Cooperative transfer agreements with approved obstetrical Level III regional units~~ The hospital shall ~~exist for the transport of mothers~~ have advanced imaging services available 24 hours a day which will include magnetic resonance imaging (MRI) and computed topography (CT)~~fetuses requiring care unavailable in an obstetrical Level III unit or that are better coordinated at an~~

~~obstetrical Level III regional unit~~.

d. ~~Obstetric imaging capabilities to perform targeted ultrasound examination in cases of suspected abnormalities~~ The hospital shall ~~be~~have medical and surgical ICUs to accept pregnant women and have qualified critical care providers available as needed to actively collaborate with MFM physicians 24 hours a day.

e. ~~Genetic counseling and diagnostics shall be provided~~Participation is required in a statewide quality collaborative and database selected by the Medicaid Quality Committee, Maternity subcommittee, with a focus on quality of maternity care. Proof of such participation will be available from the Louisiana DHH website.

f. ~~Ongoing educational opportunities~~ Equipment and qualified personnel, adequate in number, shall be ~~provided through organized educational programs~~ available onsite to ventilate and monitor women in labor and delivery until they can be safely transferred to the ICU.

g. This unit shall ~~provide for and coordinate~~ accept maternal ~~transport with obstetrical Level I and II units~~transfers as deemed appropriate by the medical staff and governing body.

2. Personnel Requirements

a. The ~~chief~~delivery of ~~the obstetrical unit providing maternal-fetal medicine at a Level III unit shall assure~~

~~that appropriate care is provided by~~ safe and effective perinatal nursing care requires appropriately qualified registered nurses in adequate numbers to meet the ~~primary attending physician for high risk maternal patients~~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 ~~be:~~have documentation of such.

~~i. board-certified in maternal-fetal medicine; or~~

~~ii. an active candidate for subspecialty certification in maternal-fetal medicine; or~~

~~iii. a board-certified obstetrician with experience in maternal-fetal medicine and credentialing to care for high risk mothers.~~i. – iii. Repealed.

b. ~~If there is no hospital-based perinatologist, a written consultative agreement shall exist with an approved obstetrical Level III or Level III regional obstetrical unit with a hospital-based perinatologist. The agreement~~ A board-certified or board-eligible MFM physician with inpatient privileges shall ~~also provide for a review of outcomes and case management for all high risk obstetrical patients for educational purposes~~be available 24 hours a day, either onsite, by telephone, or by telemedicine.

c. ~~A~~ The director of MFM services shall be a board-

certified ~~anesthesiologist with special training or experience in maternal-fetal anesthesia services at a Level III unit shall direct obstetrical anesthesia services. Personnel, including certified registered nurse anesthetists (CRNAs), with credentials to administer obstetric anesthesia shall be in-house 24 hours a day~~or board eligible MFM physician.

d. The director of obstetric service shall be a board-certified OB-GYN with active staff privileges in obstetrical care.

e. Anesthesia services shall be available 24 hours a day onsite.

f. A board-certified anesthesiologist with specialized training or experience in obstetric anesthesia shall be in charge of obstetric anesthesia services and shall be available onsite as needed.

g. A full complement of subspecialists, including subspecialists in critical care, general surgery, infectious disease, urology, hematology, cardiology, nephrology, neurology, neonatology and pulmonology shall be available for inpatient consultations.

h. A lactation consultant shall be on staff to assist breastfeeding mothers as needed.

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

D. – D.1. …

a. ~~The~~This unit shall~~ have the ability to~~ provide care for ~~both mother and fetus in~~the most challenging of perinatal conditions. Women with such conditions requiring a~~ comprehensive manner in an area dedicated~~ medical team approach not available to the ~~care of the critically ill parturient~~MFM physician in an obstetrical level III Regional unit shall be transported to a level IV unit.

b. ~~These~~ This unit shall~~ provide~~ have written cooperative transfer agreements with a level IV unit for ~~and coordinate maternal and neonatal~~ the transport ~~with Level I, II and~~ of mothers and fetuses requiring care that is unavailable in the level III ~~NICU~~ regional unit~~s throughout the state~~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. …

a. ~~The chief of service at the Level III regional obstetrical~~This unit ~~must be~~ shall have a board-certified ~~perinatologist~~or board-eligible OB/GYN available onsite 24 hours a day.

b. ~~The obstetrical Level III Regional~~The director of MFM services for this unit shall~~ have the following obstetrical~~

~~specialties or subspecialties on staff and clinical services available to provide consultation and care to the parturient~~ be board-certified in ~~a timely manner:~~ MFM.

~~i. maternal-fetal medicine;~~

~~ii. cardiology;~~

~~iii. neurology; and~~

~~iv. hematology.~~i. – iv. Repealed.

c. ~~Subspecialists to provide consultation~~ This unit shall have an anesthesiologist qualified in the ~~care~~ delivery of ~~the critically ill parturient shall~~ obstetric anesthesia services available to be ~~on staff in the following areas:~~ onsite 24 hours a day.

~~i. adult critical care;~~

~~ii. cardiothoracic surgery;~~

~~iii. nephrology;~~

~~iv. pulmonary medicine;~~

~~v. neurosurgery;~~

~~vi. endocrinology;~~

~~vii. urology;~~

~~viii. infectious disease; and~~

~~ix. gastroenterology.~~

~~d. Personnel qualified to manage obstetrical emergencies shall be in-house 24 hours per day, including CRNAs, with~~

~~credentials to administer obstetrical anesthesia.~~

~~c. A lactation consultant shall be on staff to assist breast feeding mothers.~~

~~f. Registered nurses with experience in the care of high risk maternity patients shall be in house on a 24-hour basis.~~

~~g. A nutritionist and a social worker shall also be available for the care of these patients.~~c.i. - g. Repealed.

E. Obstetrical Level IV Unit

1. General Provisions

a. This unit shall provide onsite 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.

b. The hospital shall have a data collection and retrieval system and shall report the required data to the appropriate departmental agency or section.

c. Participation is required in the department's

designated statewide quality collaborative program.

Note: The hospital shall acquire and maintain documented proof of participation.

3. Personnel

a. 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 onsite consultation and management. This team shall be led by a board-certified MFM physician.

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

c. This unit shall have qualified subspecialists on staff to provide consultation in the care of critically ill pregnant women in the following areas:

i. cardiothoracic surgery;

ii. neurosurgery;

iii. endocrinology; and

iv. gastroenterology.

d. Obstetrical Medical Subspecialties

Table 1 - Obstetrical Medical Subspecialties

Each higher level Obstetrical unit shall meet the requirements of each lower level Obstetrical unit.				
Level I	Level II	Level III	Level III Regional	Level IV
Board Certified or Eligible OB/GYN or Family Practice Physician	Board Certified/Eligible OB/GYN	Board Certified Anesthesiologist	Board Certified Anesthesiologist	Board Certified Anesthesiologist
_	Anesthesiologist*	Board Certified OB/GYN	Board Certified OB/GYN	Board Certified OB/GYN
_	Clinical Pathologist[1]	Board Certified/Board Eligible MFM[1]**	Board Certified/Board Eligible MFM**	Board Certified MFM**
_	Clinical Radiologist	Clinical Pathologist[1]	Clinical Pathologist[1]	Clinical Pathologist[1]
_	MFM[1]**	Clinical Radiologist[1]	Clinical Radiologist[1]	Clinical Radiologist[1]
_	Lactation Consultant[1]	Critical Care[1]	Critical Care[1]	Critical Care[1]
_	_	General Surgery[1]	General Surgery[1]	General Surgery[1]
_	_	Infectious Disease[1]	Infectious Disease[1]	Infectious Disease[1]
_	_	Urology[1]	Urology[1]	Urology[1]
_	_	Hematology[1]	Hematology[1]	Hematology[1]
_	_	Cardiology[1]	Cardiology[1]	Cardiology[1]
_	_	Nephrology[1]	Nephrology[1]	Nephrology[1]
_	_	Neurology[1]	Neurology[1]	Neurology[1]
		Neonatology[1]	Neonatology[1]	Neonatology[1]
		Pulmonology[1]	Pulmonology[1]	Pulmonology[1]
		Lactation Consultant[1]	Lactation Consultant[1]	Lactation Consultant[1]
		Nutritionist[1]	Nutritionist[1]	Nutritionist[1]
		Social Worker[1]	Social Worker[1]	Social Worker[1]
				Cardiothoracic Surgery[1]
				Gastroenterology[1]
				Endocrinology[1]
[1] physician shall be available in person on site as needed by the facility.				Neurosurgery[1]
*Anesthesia services shall be available 24 hours a day to provide labor analgesia and surgical anesthesia.				
**Licensed MFM shall be available for consultation onsite, by telephone, or by telemedicine, as needed.				

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 and Hospitals, Bureau of Health Services Financing, LR 42:

§9511. Neonatal Intensive Care

A. …

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

1. ~~N~~neonatal ~~l~~level I ~~u~~unit;

2. ~~N~~neonatal ~~l~~level II ~~u~~unit;

3. ~~l~~level III NICU ~~u~~unit; ~~and~~

4. ~~l~~level III ~~regional~~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 ~~l~~level III ~~regional~~surgical unit must meet the requirements of the ~~l~~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 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 and Hospitals, Bureau of

Health Services Financing, LR 42:

§9513. Neonatal Unit Functions

A. Level I Neonatal Unit (Well Newborn Nursery)

1. …

a. ~~The~~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 ~~maintain consultation~~ stabilize and ~~transfer agreements with an approved Level II or III as appropriate,~~provide care for infants born at 35 weeks or greater gestation and who remain physiologically stable. The requirements for ~~an approved Level III regional NICU, emphasizing~~ maternal transport ~~when possible~~ 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. ~~There~~ This unit shall ~~be a defined nursery area with limited access and security or rooming-in facilities with security~~ have the capability to stabilize newborns born at less than 35 weeks gestational age for transfer to higher level of care.

d. ~~Parent and/or sibling visitation/interaction with the neonate~~ This unit shall ~~be provided~~ maintain consultation and

written transfer agreements with an approved Level II or III as appropriate.

e. ~~The~~ This unit shall have ~~the capability for data collection and retrieval~~ 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.

g. The hospital shall have a data collection and retrieval system and shall report the required data to the appropriate departmental agency or section.

A.2. - A.2.b. …

c. Registered nurse to patient ratios may vary in accordance with patient needs. ~~However, the ratio for a Level I neonatal unit shall be 1:6-8. This ratio reflects traditional newborn nursery care.~~ If couplet care or rooming-in is used, a registered nurse who is responsible for the mother ~~should~~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~~at all times~~, 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. …

a. ~~There~~ This unit shall ~~be management of small, sick neonates with a moderate degree of illness that are admitted or transferred~~ 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. ~~There shall be neonatal ventilatory support, vital signs monitoring, and fluid infusion in the defined area of the nursery. Neonates requiring greater than 24-hour continuous ventilatory support~~ This unit shall ~~be transferred~~ have the capability to ~~an approved Level III or Level III regional unit~~ 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 ~~born at a Level II facility with a birth~~

~~weight~~ requiring greater than 24 hours of ~~less than 1,500 grams~~ continuous ventilator support shall be transferred to ~~an approved Level III or Level III regional NICU unit unless~~ a higher-level neonatal intensive care facility~~neonatologist is providing on-site care in the hospital~~.

d. ~~Neonates requiring~~ 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 ~~Level III or Level III regional NICU may be returned to an approved Level II unit for convalescence~~ 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 ~~pediatrician with special interest and experience in neonatal care or a~~ 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. ~~However, the ratio for a Level II~~

~~neonatal unit shall be 1:3-4 (See Table 2-1 of §9515, Additional Support Requirements).~~

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. – C.1. …

a. There shall be a written neonatal transport agreement with an approved ~~l~~level III ~~regional~~surgical unit or level IV unit. ~~There shall be an organized outreach educational program.~~

b. ~~If the neonatologist is not in-house, there~~ This unit shall ~~be~~ have either a ~~pediatrician who has successfully completed the Neonatal Resuscitation Program (NRP)~~ neonatologist or ~~one~~ a neonatal nurse practitioner or a neonatology fellow in-house ~~for Level III NICU patients~~ 24 hours per day.

c. ~~Direct consultation with a neonatologist~~ The staffing of this unit shall be ~~available 24 hours per day~~ based on patient acuity and consistent with the recommended staffing guidelines of the 2014 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. …

a. The chief of service of a ~~l~~level III NICU shall

be a board-certified neonatologist. ~~The following exceptions are recognized.~~

~~i. A board-certified pediatrician who is an active candidate for a subspecialty certification in neonatal medicine.~~

~~ii. 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 and Hospitals. 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.~~i. - ii. Repealed.

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 and Hospitals. 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. ~~Medical and surgical consultation~~ This unit shall ~~be readily available and pediatric subspecialists may be used in consultation~~ have at least one full-time social worker available as needed who has experience with ~~a transfer agreement~~ the socioeconomic and psychosocial problems of high-risk mothers and fetuses, sick neonates, and their families. For units with ~~a Level III regional NICU~~ greater than thirty patients, the social worker staffing ratios shall be at least one social worker to thirty patients (additional social workers may be required in accordance with hospital staffing guidelines.

c. ~~Registered nurse to patient ratios may vary in accordance with patient needs. However, the ratio for a Level III NICU unit shall be 1:2-3 (See Table 2-1 of §9515, Additional Support Requirements).~~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, MRI and echocardiography); and

ii. a full range of respiratory support that includes conventional and/or high frequency ventilation and inhaled nitric oxide.

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 Louisiana DHH Website.

D. Level III ~~Regional~~Surgical NICU

1. General Provisions

a. ~~Twenty-four hours per day in-house coverage~~ This unit shall ~~be provided by~~ have a ~~neonatologist, a second year or higher pediatric house officer, or a neonatal nurse practitioner. If~~ transport team and provide for and coordinate neonatal transport with level I, level II units and level III NICUs throughout the ~~neonatologist is not in-house, there~~ state as requested. Transport

shall be ~~immediate consultative ability with~~ in accordance with national standards as published by the ~~neonatologist~~ American Academy of Pediatrics' Section on neonatal and pediatric transport ~~-~~and ~~he/she shall be available to be on-site~~ in ~~the hospital within 30 minutes~~accordance with applicable Louisiana statutes.

~~b. The 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. Transport shall be in accordance with national standards as published by the American Academy of Pediatrics' Section on neonatal and pediatric transport.~~

~~c. The unit shall be recognized as a center of research, educational and consultative support to the medical community.~~b. - c. Repealed.

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

2. …

a. ~~The chief of service shall be a board-certified neonatologist~~For medical sub-specialty requirements refer to Table 1 - Neonatal Medical Subspecialties and Transport Requirements.

~~b. Nurse to patient ratios may vary in accordance with patient needs. However, the ratio for a Level III regional NICU shall be 1:1-2 (See Table 2-1 in §9515, Additional Support Requirements).~~

~~c. The unit shall have the following pediatric specialties/subspecialties on staff and clinical services available to provide consultation and care to neonates in a timely manner:~~

~~i. anesthesia;~~

~~ii. pediatric surgery;~~

~~iii. pediatric cardiology; and~~

~~iv. pediatric ophthalmology.~~

~~d. Subspecialists to provide consultation in the care of the critically ill neonate shall be on staff in the following areas:~~

~~i. pediatric neurology;~~

~~ii. pediatric hematology;~~

~~iii. genetics;~~

~~iv. pediatric nephrology;~~

~~v. pediatric endocrinology;~~

~~vi. pediatric gastroenterology;~~

~~vii. pediatric infectious disease;~~

~~viii. pediatric pulmonary medicine;~~

~~ix. orthopedic surgery;~~

~~x. pediatric urologic surgery;~~

~~xi. ENT surgery; and~~

~~xii. cardiothoracic surgery.~~2.b. - 2.d.xii. Repealed.

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]	Pediatric Anesthesiology[5]
_	Social Worker	Pediatric Neurology[3]	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, staff using telemedicine shall be continuously available.			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.	
[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]Level III facilities shall be able to perform electroencephalogram and cranial ultrasounds and have the ability to have them interpreted by someone with experience in neonatal electroencephalograms and neonatal cranial ultrasounds. 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.				
[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 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 and Hospitals, Bureau of Health Services Financing, LR 42:

§9515. Additional Support Requirements

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

~~B. The following support personnel shall be available to~~

~~provide consultation and care and services to Level II, Level III and Level III regional obstetrical, neonatal, and NICU units in a timely manner:~~

~~1. at least one full-time medical social worker who has experience with the socioeconomic and psychosocial problems of high-risk mothers and fetuses, sick neonates, and their families (additional medical social workers may be required if the patient load is heavy);~~

~~2. at least one occupational or physical therapist with neonatal expertise; and~~

~~3. at least one registered dietitian/nutritionist who has special training or experience in perinatal nutrition and can plan diets that meet the special needs of high-risk mothers and neonates.~~

~~C. The following support personnel shall be immediately available to be on-site in the hospital for Level II, Level III and Level III regional obstetrical, neonatal, and NICU units:~~

~~1. qualified personnel for support services such as laboratory studies, radiological studies, and ultrasound examinations (these personnel shall be readily available 24 hours a day); and~~

~~2. registered respiratory therapists or registered nurses with special training who can supervise the assisted ventilation of neonates with cardiopulmonary disease (optimally, one therapist is needed for each four neonates who are receiving assisted~~

ventilation).

D. The staffing guidelines shall be those recommended by the current AAP/ACOG Guidelines for Perinatal Care. (See Table 2-1 below).

TABLE 2-1. RECOMMENDED REGISTERED NURSE/PATIENT RATIOS FOR PERINATAL CARE SERVICES

Nurse/Patient Ratio	Care Provided
Intrapartum	
1:2	Patients in labor
1:1	Patients in second stage of labor
1:1	Patients with medical or obstetric complications
1:2	Oxytocin induction or augmentation of labor
1:1	Coverage for initiating epidural anesthesia
1:1	Circulation for Cesarean delivery
Antepartum/ Postpartum	
1:6	Antepartum/postpartum patients without complications
1:2	Patients in postoperative recovery
1:3	Antepartum/postpartum patients with complications but in stable condition
1:4	Recently born infants and those requiring close observation

~~Nurse/Patient Ratio~~	~~Care Provided~~
~~Newborns~~	
~~1:6-8~~	~~Newborns requiring only routine care~~
~~1:3-4~~	~~Normal mother-newborn couplet care~~
~~1:3-4~~	~~Newborns requiring continuing care~~
~~1:2-3~~	~~Newborns requiring intermediate care~~
~~1:1-2~~	~~Newborns requiring intensive care~~
~~1:1~~	~~Newborns requiring multi-system support~~
~~1:1 or Greater~~	~~Unstable newborns requiring complex critical care~~

B. – Table 2.1. Repealed.

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 and Hospitals, Bureau of Health Services Financing, LR 42:

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 a positive impact on family functioning, stability or autonomy as described

in R.S. 49:972 by ensuring the safe operation of hospitals that provide obstetrical and newborn services as a means of reducing infant mortalities.

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.

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 may have an adverse impact on the staffing level requirements or qualifications required to provide the same level of service and may increase direct or indirect cost to the provider to provide the same level of service. This proposed Rule may negatively impact the provider's ability to provide the same level of service as described in HCR 170.

Interested persons may submit written comments to Cecile Castello, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821 or by email to MedicaidPolicy@la.gov. Ms. Castello is responsible for responding to inquiries regarding this proposed Rule. A public hearing on this proposed Rule is scheduled for Thursday, April 28, 2016 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit

data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E. Gee MD, MPH

Secretary