Topics:

Neonatal and Maternal Standards of Care

1. DHSR should update 10A NCAC 14C. 1401 Criteria and Standards for Neonatal Services to include the guidelines set forth by the AAP
    - Include frequency in which they will be reviewed
    - Include language from previous recommendation that will allow for updates without having to go through legislation
    - The Division of Health Services Regulation should update the level of care neonatal service definitions ("Level I neonatal service", Level II neonatal service", "Level III neonatal service", and "Level IV neonatal service") in the **North Carolina Administrative Code 10A NCAC 14C. 1401 Criteria and Standards for Neonatal Services** to reflect the most recent Levels of Neonatal Care guidelines set forth by the American Academy of Pediatrics ("AAP"). DHSR should review the AAP Guidelines every five years and update the state standards….

North Carolina Administrative Code 10A NCAC 14C. 1401	**AAP Guidelines Text**
"**Level I neonatal services**" means services provided by an acute care hospital to full term and pre-term neonates that are stable, without complications, and may include neonates that are small for gestational age or large for gestational age.	**Level I:** a hospital nursery organized with the personnel and equipment to perform neonatal resuscitation, evaluate and provide postnatal care of healthy newborn infants, provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable, and stabilize ill newborn infants or infants born at less than 35 weeks' gestational age until transfer to a facility that can provide the appropriate level of neonatal care.

Definitions – AAP Levels of Care Chart

Level of Care	Capabilities	Provider Types[a]
Level I	• Provide neonatal resuscitation at every delivery	Pediatricians, family physicians, nurse practitioners, and other advanced practice registered nurses
Well newborn nursery	• Evaluate and provide postnatal care to stable term newborn infants	
	• Stabilize and provide care for infants born 35–37 wk gestation who remain physiologically stable	
	• Stabilize newborn infants who are ill and those born at <35 wk gestation until transfer to a higher level of care	

North Carolina Administrative Code 10A NCAC 14C. 1401	AAP Guidelines Text
"**Level II neonatal service**" means services provided by an acute care hospital in a licensed acute care bed to neonates and infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level III or Level IV neonatal services, but still require more nursing hours than normal infants; and infants who require close observation in a licensed acute care bed.	**Level II:** a hospital special care nursery organized with the personnel and equipment to provide care to infants born at 32 weeks' gestation or more and weighing 1500 g or more at birth who have physiologic immaturity, such as apnea of prematurity, inability to maintain body temperature, or inability to take oral feedings; who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis; or who are convalescing from a higher level of intensive care. A level II center has the capability to provide continuous positive airway pressure and may provide mechanical ventilation for brief durations (less than 24 hours).

Definitions – AAP Levels of Care Chart

Level of Care	Capabilities	Provider Types[a]
Level II	Level I capabilities plus:	Level I health care providers plus:
Special care nursery	• Provide care for infants born ≥32 wk gestation and weighing ≥1500 g who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis	Pediatric hospitalists, neonatologist, and neonatal nurse practitioners.
	• Provide care for infants convalescing after intensive care	
	• Provide mechanical ventilation for brief duration (<24 h) or continuous positive airway pressure or both	
	• Stabilize infants born before 32 wk gestation and weighing less than 1500 g until transfer to a neonatal intensive care facility	

North Carolina Administrative Code 10A NCAC 14C. 1401	AAP Guidelines Text
"**Level III neonatal service**" means services provided by an acute care hospital in a licensed acute care bed to neonates or infants that are high-risk, small (approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not intensive care. Level III neonates or infants require less constant nursing care than Level IV services, but care does not exclude respiratory support.	**Level III:** a hospital NICU organized with personnel and equipment to provide continuous life support and comprehensive care for extremely high-risk newborn infants and those with critical illness. This includes infants born weighing <1500 g or at <32 weeks' gestation. Level III units have the capability to provide critical medical and surgical care. Level III units routinely provide ongoing assisted ventilation; have ready access to a full range of pediatric medical subspecialists; have advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography; have access to pediatric ophthalmologic services with an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity; and have pediatric surgical specialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery. Level III units can facilitate transfer to higher-level facilities or children's hospitals, as well as back-transport recovering infants to lower-level facilities, as clinically indicated.

Definitions – AAP Levels of Care Chart

Level of Care	Capabilities	Provider Types[a]
Level III	Level II capabilities plus:	Level II health care providers plus:
NICU	• Provide sustained life support	Pediatric medical subspecialists[b], *pediatric anesthesiologists*[b], pediatric surgeons, and pediatric opthalmologists[b].
	• Provide comprehensive care for infants born <32 wks gestation and weighing <1500 g and infants born at all gestational ages and birth weights with critical illness	
	• Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric opthalmologists	
	• Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide	
	• Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography	

North Carolina Administrative Code 10A NCAC 14C. 1401	AAP Guidelines Text
"**Level IV neonatal service**" means neonatal intensive care services provided by an acute care hospital in a licensed acute care bed to high-risk medically unstable or critically ill neonates (approximately under 32 weeks of gestational age) or infants requiring constant nursing care or supervision not limited to continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.	**Level IV** units have the capabilities of a level III NICU and are located within institutions that can provide on-site surgical repair of serious congenital or acquired malformations. Level IV units can facilitate transport systems and provide outreach education within their catchment area.

Definitions – AAP Levels of Care Chart

Level of Care	Capabilities	Provider Types[a]
Level IV	Level III capabilities plus:	Level III health care providers plus:
Regional NICU	• Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions	Pediatric surgical subspecialists
	• Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site	
	• Facilitate transport and provide outreach education	

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2. A) DHSR should update 10A NCAC 14C. 1401 Criteria and Standards for High Risk Maternal Care to include the guidelines set forth by ACOG & SMFM
    - Include frequency in which they will be reviewed
    - Include language from previous recommendation that will allow for updates without having to go through legislation
    - The Division of Health Services Regulation should ~~update the high-risk maternal care definition~~revise ("high-risk obstetric patients") ~~in~~ the **North Carolina Administrative Code 10A NCAC 14C. 1401 Criteria and Standards for Neonatal Services** to ~~reflect the most recent~~include Levels of Maternal Care guidelines set forth by the American College of Obstetricians and Gynecologists ("ACOG") and the Society for Maternal-Fetal Medicine ("SMFM"). Add text about reviewing and updating every five years.

   B) DHSR should update the Hospital License Renewal Application to include a question under section C (Designations and Accreditations) if the facility complies with the Maternal Level of Care guidelines set forth in the NCAC.
    - The Division of Health Services Regulation should update the Hospital License Renewal Application under the **Facility Data** headline, **section C – Designations and Accreditations**, to include the following question:

      Does this facility comply with coded Level of Maternal Care guidelines set forth in the NCAC*? Highest Level of Designation met: _____

      **Maternal Service levels are designated in 10A NCAC 14C. 1401*

Maternal Service levels designated in 10A NCAC 14C. 1401
"Obstetric services" means any normal or high-risk services provided by an acute care hospital to the mother and fetus during pregnancy, labor, delivery and to the mother after delivery *"High-risk obstetric patients" means those patients requiring specialized services provided by an acute care hospital to the mother and fetus during pregnancy, labor, and delivery and to the mother after delivery. The services are characterized by specialized facilities and staff for the intensive care and management of high-risk maternal and fetal patients before, during, and after delivery*

Birth Center	
Definition	*Peripartum care of low-risk women with uncomplicated singleton term pregnancies with a vertex presentation who are expected to have an uncomplicated birth*
Capabilities	• *Capability and equipment to provide low-risk maternal care and a readiness at all times to initiate emergency procedures to meet unexpected needs of the woman and newborn within the center, and to facilitate transport to an acute care setting when necessary.* • *An established agreement with a receiving hospital with policies and procedures for timely transport.* • *Data collection, storage, and retrieval.* • *Ability to initiate quality improvement programs that include efforts to maximize patient safety.* • *Medical consultation available at all times.*
Types of health care providers	*Every birth attended by at least two professionals:* • *Primary maternal care providers. This includes CNMs, CMs, CPMs, and licensed midwives who are legally recognized to practice within the jurisdiction of the birth center; family physicians; and ob-gyns.* • *Availability of adequate numbers of qualified professionals with competence in level I care criteria and ability to stabilize and transfer high-risk women and newborns.*
Examples of appropriate patients (not requirements)	• *Term, singleton, vertex presentation*

Level I (Basic Care)	
Definition	*Care of uncomplicated pregnancies with the ability to detect, stabilize, and initiate management of unanticipated maternal–fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until patient can be transferred to a facility at which specialty maternal care is available*
Capabilities	*Birth center capabilities plus* • *Ability to begin emergency cesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care.* • *Available support services, including access to obstetric ultrasonography, laboratory testing, and blood bank supplies at all times.* • *Protocols and capabilities for massive transfusion, emergency release of blood products, and management of multiple component therapy.* • *Ability to establish formal transfer plans in partnership with a higher-level receiving facility.* • *Ability to initiate education and quality improvement programs to maximize patient safety, and/or collaborate with higher-level facilities to do so.*
Types of health care providers	*Birthing center providers plus* • *Continuous availability of adequate number of RNs with competence in level I care criteria and ability to stabilize and transfer high-risk women and newborns.* • *Nursing leadership has expertise in perinatal nursing care.* • *Obstetric provider with privileges to perform emergency cesarean available to attend all deliveries.* • *Anesthesia services available to provide labor analgesia and surgical anesthesia.*
Examples of appropriate patients (not requirements)	*Any patient appropriate for a birth center, plus capable of managing higher-risk conditions such as* • *term twin gestation* • *trial of labor after cesarean delivery* • *uncomplicated cesarean delivery* • *preeclampsia without severe features at term*

Level II (Specialty Care)	
Definition	*Level I facility plus care of appropriate high-risk antepartum, intrapartum, or postpartum conditions, both directly admitted and transferred from another facility*
Capabilities	*Level I facility capabilities plus* • *Computed tomography scan and ideally magnetic resonance imaging with interpretation available.* • *Basic ultra-sonographic imaging services for maternal and fetal assessment.* • *Special equipment needed to accommodate the care and services needed for obese women.*
Types of health care providers	*Level I facility health care providers plus* • *continuous availability of adequate numbers of RNs with competence in level II care criteria and ability to stabilize and transfer high-risk women and newborns who exceed level II care criteria.* • *Nursing leadership and staff have formal training and experience in the provision of perinatal nursing care and should coordinate with respective neonatal care services.* • *Ob-gyn available at all times.* • *Director of obstetric service is a board-certified ob-gyn with special interest and experience in obstetric care.* • *MFM available for consultation onsite, by phone, or by telemedicine, as needed.* • *Anesthesia services available at all times to provide labor analgesia and surgical anesthesia.* • *Board-certified anesthesiologist with special training or experience in obstetric anesthesia available for consultation.* • *Medical and surgical consultants available to stabilize obstetric patients who have been admitted to the facility or transferred from other facilities.*
Examples of appropriate patients (not requirements)	*Any patient appropriate for level I care, plus higher-risk conditions such as* • *severe preeclampsia* • *placenta previa with no prior uterine surgery*

Level III (Subspecialty Care)	
Definition	Level II facility plus care of more complex maternal medical conditions, obstetric complications, and fetal conditions
Capabilities	Level II facility capabilities plus • Advanced imaging services available at all times. • Ability to assist level I and level II centers with quality improvement and safety programs. • Provide perinatal system leadership if acting as a regional center in areas where level IV facilities are not available (see level IV). • Medical and surgical ICUs accept pregnant women and have critical care provider's onsite to actively collaborate with MFMs at all times. • Appropriate equipment and personnel available onsite to ventilate and monitor women in labor and delivery until they can be safely transferred to the ICU.
Types of health care providers	Level II health care providers plus • continuous availability of adequate numbers of nursing leaders and RNs with competence in level III care criteria and ability to transfer and stabilize high-risk women and newborns who exceed level III care criteria, and with special training and experience in the management of women with complex maternal illnesses and obstetric complications. • Ob-gyn available onsite at all times. • MFM with inpatient privileges available at all times, either onsite, by phone, or by telemedicine. • Director of MFM service is a board-certified MFM. • Director of obstetric service is a board-certified ob-gyn with special interest and experience in obstetric care. • Anesthesia services available at all times onsite. • Board-certified anesthesiologist with special training or experience in obstetric anesthesia in charge of obstetric anesthesia services. • Full complement of subspecialists available for inpatient consultations.
Examples of appropriate patients (not requirements)	Any patient appropriate for level II care, plus higher-risk conditions such as • suspected placenta accreta or placenta previa with prior uterine surgery • suspected placenta percreta • adult respiratory syndrome • expectant management of early severe preeclampsia at less than 34 weeks of gestation

Level IV (Regional Perinatal Health Care Centers)	
Definition	Level III facility plus 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
Capabilities	Level III facility capabilities plus • on-site ICU care for obstetric patients. • On-site medical and surgical care of complex maternal conditions with the availability of critical care unit or ICU beds. • 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.
Types of health care providers	Level III health care providers plus • MFM care team with 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 comanagement of ICU-admitted obstetric patients. An MFM team member with full privileges is available at all times for on-site consultation and management. The team is led by a board-certified MFM with expertise in critical care obstetrics. • Physician and nursing leaders with expertise in maternal critical care. • Continuous availability of adequate numbers of RNs who have experience in the care of women with complex medical illnesses and obstetric complications; this includes competence in level IV care criteria. • Director of obstetric service is a board-certified MFM, or board-certified ob-gyn with expertise in critical care obstetrics. • Anesthesia services are available at all times onsite. • Board-certified anesthesiologist with special training or experience in obstetric anesthesia in charge of obstetric anesthesia services. • Adult medical and surgical specialty and subspecialty consultants' available onsite at all times to collaborate with MFM care team.
Examples of appropriate patients (not requirements)	Any patient appropriate for level III care, plus higher-risk conditions such as • severe maternal cardiac conditions • severe pulmonary hypertension or liver failure • pregnant women requiring neurosurgery or cardiac surgery • pregnant women in unstable condition and in need of an organ transplant

3. Two Step Recommendation (unless legislation to license is passed – then delete step 1).
    - Legislation to License Birth Centers
    - DHSR should update 10A NCAC 14C. 1401 to include a definition on birth centers, and the requirements and capabilities they need to have
        - Held to level of care?
        - ACOG Category
        - The North Carolina General Assembly should require birth centers to be licensed (work on wording).

b) DHSR should update 10A NCAC 14C. 1401 to include a definition on birth centers, and the requirements and capabilities they need to have
- ACOG birth center level
- AAP level I- won't work b/c of restrictions on birth centers; could do as similar to level 1 with these exceptions (work with birth center folks to specify); look at birth center regulations

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4. Hospitals that provide maternal and neonatal care should establish evaluation teams to review their maternal and neonatal care capabilities. Evaluation teams should include at a minimum an OB provider, Neonatal provider, OB manager, Neonatal Manager and data manager. Evaluation teams should use the CDC LOCATe tool to assess maternal and neonatal levels of care.

The North Carolina General Assembly should require external verification of the level (2-4 only?) and beds neonatal and maternal (need to work on how to write this). Add in something about quality improvement development/assessment of regional needs role of this process.
    - Level 1- verification by Perinatal and Neonatal Regional Coordinators
    - Level 2-4- external verification. External review should be conducted by a North Carolina group (who/where housed?) or an external organization such as the AAP.
    - Require every three years

>>Goal here to propose something akin to the Texas model

~~4.~~ Recommend each hospital be evaluated u~~nder~~ the CDC LOCATe tool
    - Report annually in the Hospital Renewal Licensure Application, unclear if required to report anywhere else
    - Do we need/want a verifying body? (aka Texas model) Who would this be?
    - Do we want to build as two step rec with volunteer moving to regulatory body over time
    - Steps? Start with self-designation and transition into an external recommendation process
    - Include PHAC/outreach program here to implement regular designation reviews?

Create LOCATe tool evaluation teams
    - **Example Email:**
        - Thank you for coordinating this meeting to complete the CDC LOCATe tool for UNC Johnston Clayton and Smithfield. The LOCATe tool was designed to implement a standardized method of assessing maternal and neonatal levels of care. The Perinatal Neonatal Outreach Team with UNC Center for Maternal and Infant Health is collaborating with the Department of Public Health's Women's branch to obtain this data. The information gathered during this meeting will help in assessing birthing facilities within Perinatal Region IV in North Carolina. Attached you will find copies of both the Levels of Maternal Care and Levels of Neonatal Care policy statements, as well as the LOCATe tool. A successful assessment meeting requires input from an interdisciplinary team comprised of an OB provider, Neonatal provider, OB managers, Neonatal

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Managers and data managers. Inviting an interdisciplinary team will help to ensure that we capture an accurate assessment of each facility. Please let us know if you have any questions prior to our meeting.

- Prior to our meeting please complete the following:
  - Please sign the letter of commitment attached. This document is used to demonstrate each facilities willingness to participate in the assessment and will be returned to DPH Women's Branch.
  - Please gather all data need to answer questions listed on page 12 of the LOCATe tool. The data can be collected using the last fiscal year for the time frame.

- **Suggested List:**
  - Obstetric MD representative
  - Pediatric MD representative
  - Labor & delivery Unit manager
  - Chief nursing officer

Commented [s1]: Everywhere have MD need MD/DO

Recommendations to be sorted:

5. Level IV neonatal and maternal care hospitals should serve as regional perinatal centers.
   - The Department of Public Health, Women's and Children's Services Division, should develop map all level 1-3 hospitals to at least 1 level 4 hospital in the state
   - The Department of Public Health, Women's and Children's Services Division, should create standards and duties expected of regional perinatal centers. These standards and duties should include:
     - The creation of a leadership team composed of, but not limited to, a physician, nurse, social worker who develop and provide education and best practice implementation support to referring hospitals, hospitals within their Medicaid region(i.e. mentorship to lower level hospitals, transport case review) and any other hospitals assigned to them by DPH
     - This team will also develop a tool to monitor outcomes from transports that will be utilized when providing training to their hospital and hospitals within the regional center's territory.
     - Regional Perinatal Leadership teams should meet quarterly to share information with other regional leadership teams, and to help shape health priorities
   -

Commented [s2]: Want to ensure there are linkages between levels 1-4 that ensure all hospitals are connected to a larger system that is working to improve outcomes for women and infants.
Want to ensure system works for families
Lots of various system maps that those providing services working within. Cannot solve but need to make sure working for families.

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~~5.~~6. Create regional centers?
   - Regional perinatal centers (question, do these know who they are and are they referred to as this) should foster strong relationships with referring hospitals by (support their needs how?)
     - What? Regional level III/IV that provide coordinating out outreach services;
     - Develop tool to monitor outcomes (of what? Who? Think this is about transport cases)
     - Have a leadership team composed of physician, nurse, social worker who use this tool to evaluate outcomes. Develop and provide education and best practice implementation support to referring hospitals (i.e. mentorship to lower level hospitals, transport case review)

        - Meet quarterly? With the leadership teams from other regional perinatal centers to share and shape health priorities
        - Who are the OB & Neo champions?
    - Regionalized systems of perinatal care are recommended to ensure that each newborn infant is delivered and cared for in a facility most appropriate for his or her health care needs, when possible, and to facilitate the achievement of optimal health outcomes. (AAP)
        - Because VLBW and/or very preterm infants are at increased risk of pre-discharge mortality when born outside of a level III center, they should be delivered at a level III facility unless this is precluded by the mother's medical condition or geographic constraints.
    - The NC Department of Public Health, Women's and Children's Services Division, should create and designate regional perinatal centers
        - By selecting Level 4 maternal and neonatal centers…..
        - By geography….
        - By Health System…..
    - The Department of Public Health, Women's and Children's Services Division, should create standards and duties expected of regional perinatal centers. These standards and duties should include:
        - The creation of a leadership team composed of, but not limited to, a physician, nurse, social worker who develop and provide education and best practice implementation support to referring hospitals (i.e. mentorship to lower level hospitals, transport case review)
        - This team will also develop a tool to monitor outcomes from transports that will be utilized when providing training to their hospital and hospitals within the regional center's territory.
        - Regional Perinatal Leadership teams should meet quarterly to share information with other regional leadership teams, and to help shape health priorities

~~6.~~7. DHHS Create Perinatal Advisory Committee
    - Hospital System Representative
    - Include nonhospital system representatives i.e. consumers, community based organizations.
        - Etc. – did one of the other states have a list of included people?
    - Include: purpose, type of members, who is financially responsible for it – Medicaid 50/50 match as a potential starting point? Mix of hospitals, Medicaid, etc.

8. Each regional perinatal center should have a perinatal and neonatal outreach coordinators.
9. Funding for regional perinatal and neonatal outreach coordinators should come from ???
~~7.~~10. XXX should provide funding for perinatal and neonatal outreach coordinat~~o~~rs in (Medicaid region/health system/something else) to …..
    - Develop and foster relationships between regional perinatal centers and all referring hospitals/providers.
    - Develop relationships with hospitals outside state borders that patients are frequently referred/transferred to
    - Something about safe and rehearsed transfer

- Convene quarterly? meetings of (who?) from each hospital in their region/network to review cases including all maternal and neonatal transports
- What else do we want them to do?
- Review the LOCATe levels
- Recommend GA develop funding for the outreach coordinators *because* of the existing responsibilities of RPC's
- Add neonatal & perinatal piece and outline the roles of each.
    i. See job descriptions attached

Recommendations to be worked on in the future:

~~8.~~11. Hospitals with labor and delivery units should educate patients about the capability of their labor and delivery unit and the process used when a higher level of care is needed.
- Are we recommending this be part of the delivery unit tour?
    - Hospital units should…. B) Providers should….
- Is this actually on OB/GYN to educate their patients?
- How do we communicate the recommendation that this conversation should happen?....
- Where does the education happen? Who does the educating? Text4Baby services→ prompting mothers to-be with what questions to ask
    - Online March of Dimes services maybe

~~9.~~12. Recommendation about patient rights/advocacy/engagement
- Consumer education
    - Families of babies that end up in the NICU

~~10.~~13. Recommendations around disparities and health equity perspective

~~11.~~14. Getting women to the place that they need to be born is key to addressing disparities

~~12.~~15. Geographic equity

~~13.~~16. Ask someone from the Divisions on how to best approach social determinants of health
- Talk to Medical Society Rep
- Does PHP's have a timeline they can share for what they will be able to offer & when
    - What does care management look like now? Are they planning on changing this in the future?