Frequently Asked Questions from Neonatal Designated Facilities

What is the purpose of neonatal levels of care?

The Texas Department of State Health Services (DSHS), along with many others, embrace the goal of improving the health outcomes of all Texans. In furtherance of that goal and pursuant to the direction of the Texas Legislature, the Neonatal Levels of Care (LOC) are assigned by DSHS. The designation is based upon the information provided to DSHS by the hospital seeking the designation, in conjunction with the results of a formal survey of each applicant conducted a third-party, either the American Academy of Pediatrics or the Texas EMS, Trauma and Acute Care Foundation.

Establishing and maintaining formal and highly effective systems of Quality Assurance/Performance Improvement (QAPI) form the essential foundation for achieving the goal of systematically improving the health outcomes of the infants who receive treatment in Texas' designated facilities. QAPI is a requirement of all Texas licensed hospitals to maintain on ongoing, data-driven program to evaluate and improve the provision of patient care. Therefore, every hospital applying for a Neonatal or Maternal designation must document that effective QAPI programs exist and are providing the clinical feedback necessary to systematically improve care to neonates.

All licensed hospitals in Texas are required to conduct QAPI. Hospitals applying for neonatal or maternal Level of Care designation should pay special attention to 25 Tex. Admin. Code §133.41(r), where the scope and impact required of QAPI programs are clearly specified. Given the centrality of effective QAPI to the intended purposes of neonatal and maternal LOC designations, all applicants must be able to document they conduct QAPI activities that satisfy the requirements found in rule.

What is designation and what does it mean?

Designation reflects a facility's documented capabilities and history of providing care to infants who generally conform to the descriptions that define the level of care. The levels describe various populations of infants, based on gestational age and the complexity and severity of their medical condition. A facility is assigned a specific LOC designation when it documents the capability and a history of providing quality care to the populations described in the LOC definitions. Facilities must demonstrate they meet all requirements established in rule in order to be designated at a particular level. A DSHS LOC designation does not mandate the care provided to any individual. The designated level does not mean that the facility is not capable of providing quality care to a broader range of infants. For instance, a Level II facility is not limited to providing care to only neonates that are 32-weeks gestation and older. Certain Level II facilities may be capable of providing appropriate care of lower gestational age neonates. However, in order to qualify for Level III designation, a facility must demonstrate the capability and history of providing care to all gestational ages with mild to critical illnesses or requiring sustained life support

Therefore, the LOC designations do not require and should not influence any physician or hospital administrator to forego providing services to patients that, in their professional judgment, the facility is capable of serving well. As with all medical decision-making, such determinations are based on the specific clinical circumstances of the case and must be made by the treating physician(s) in the best interest of that patient.

If our facility is a Level II, are we required to transfer any neonates less than 32 weeks to a higher level of care?

The designation level does not limit the gestational ages the facility may treat. The best interest of the patient must prevail over all other considerations. The physicians at the facility will continue to make medical decisions regarding care of the neonate.

The facility is required as part of the designation process to develop a written plan for the neonatal program that includes a detailed description of the scope of services available to all maternal and neonatal patients, defines the neonatal patient population evaluated and/or treated, transferred, or transported by the facility, that is consistent with prevailing professional

practice for neonatal and maternal care, and ensures the health and safety of patients.

What is required of the Level II facility if it keeps neonates less than 32 weeks?

Formal and highly effective systems of QAPI form the essential foundation for achieving the goal of systematically improving the health outcomes of the mothers and infants who receive treatment in Texas' designated facilities. When the facility admits neonates of lower gestational ages or birth weights than those listed in the Level II designation description, the facility shall provide care that meets the patient's needs in a manner that is comparable to that available in Level III or IV designated facilities for patients of comparable physiologic immaturity and clinical complexity. For all such patients, the designated facility shall document suitable clinical care reviews conducted by the Neonatal QAPI Committee.

Are pediatric anesthesiologists exclusively required to personally provide anesthesia care to all neonates in a Level IV facility?

No. The requirements specified for various LOC designations related to provision of anesthesia services are intended to contribute to the QAPI work of the facility. The requirements related to provision of anesthesia care do not supersede the regulatory requirements that pertain to the licensed medical professionals providing the care nor do they supersede the requirements of hospital licensure in Texas. The LOC requirements do not pertain to the provision of clinical services by such individual licensed healthcare professionals.

In a Level IV Neonatal facility, the rule requires that the facility implement policies designed to provide optimal and clinically appropriate care to all neonatal patients in the facility. Those policies shall specify that anesthesia care for the most complex and critically ill patients will be provided by a pediatric anesthesiologist, either in person or via their delegation. Naturally, designated facilities will, over time, care for neonates across a spectrum of criticality and complexity. The decision of how to provide optimal care to an individual patient is a matter of medical judgment and therefore beyond the scope of DSHS neonatal LOC designation requirements, *per se*. In that context, the designation requirements do not compel a pediatric anesthesiologist to personally provide care to every neonatal patient in a

Level IV facility. However, the neonatal LOC rule does require the designated facility to devise and implement policies and practices intended to optimize the health outcomes of every patient who receives care in that unit.

The facility is required as part of the designation process to develop a written plan for the neonatal program that includes a detailed description of the scope of services available to all maternal and neonatal patients, defines the neonatal patient population evaluated and/or treated, transferred, or transported by the facility, that is consistent with prevailing professional practice for neonatal and maternal care, and ensures the health and safety of patients.

What is the application process for facilities seeking Level II, III or IV neonatal designation?

To start the process, the facility will contract with a survey organization recognized by the department to perform a site visit and verify compliance with the requirements. The facility requests the neonatal level at which they want to be reviewed.

The survey organization provides the facility with a written report of the site review findings. The surveyor indicates compliance or non-compliance with the required elements as well as providing explanatory notes.

The facility then submits an application packet to the department, which includes the application form, application fee, survey report, patient care reviews, evidence of Perinatal Care Region (PCR) participation and a plan of correction, if needed.

If my facility is part of a multihospital system, may an individual from the system represent all hospitals at the Perinatal Care Regional (PCR) meetings?

No. Each designated facility is expected to participate in the regional meetings of the respective PCR. This is a condition of designation.

What is the process to determine designation?

The department reviews the survey report findings including the surveyor's notes, patient care reviews, facility PCR participation and the plan of

correction (if needed) to determine the facility's compliance with the requirements. Designation is awarded to a facility based on compliance with the requirements. When the department identifies a facility as non-compliant with the requirements, the facility will be recommended for the level of care at which the minimum requirements are met.

Since the surveys were conducted by two different organizations, were the process and the findings comparable?

Yes. Either the American Academy of Pediatrics or the Texas EMS, Trauma and Acute Care Foundation conducted the onsite surveys to verify compliance with the applicable sections of the Texas Administrative Code (TAC). The survey process for all organizations includes medical record reviews, review of facility documents, interviews of medical and facility staff, and a tour of the facility. Outcomes and findings of the surveys were similar.

How many years' worth of data will be required to show compliance or will program policy showing application of the new requirements be sufficient?

This is dependent on the types of patients seen by the facility. There is no defined minimum number of years; however, for QAPI purposes there must be sufficient data to demonstrate program effectiveness.

Every hospital applying for designation as a Neonatal or Maternal Level I, II, III or IV must document that effective QAPI programs exist and are providing the clinical feedback necessary to systematically improve care in that facility.

Can a facility have another survey that only looks at the areas previously cited as not meeting requirements?

Because this designation process is new, DSHS is offering a limited opportunity for facilities that did not achieve the requested designation level to obtain a follow-up survey in the areas where they did not meet requirements. A survey may include review: patient case reviews, guidelines or protocols, policies and procedures, physician and/or staff qualifications, QAPI program, staff interviews, and equipment and physical plant.

To ensure consistency with the original survey methodology, the same survey organization that conducted the original designation survey must be used. A facility is responsible for the cost of the follow-up survey. A facility that chooses to have a follow-up survey will not be charged additional DSHS fees.

Please note, the follow-up survey option described in this section is distinct from the standard appeals process, which is described below. In particular, programmatic changes or clinical care that took place after the date of the initial survey can be considered as part of the follow-up survey. The new information submitted must address those areas where the original application materials (including the survey findings) did not demonstrate the hospital meet all requirements for the requested LOC designation. Hospitals received written notification of those elements that did not meet requirements for the requested LOC.

Why was our facility designated at a lower level than requested on our application?

The department assigns each designation based on evidence of compliance with the requirements for each level. Designation at a lower level than requested by the facility occurs when compliance with the requirements is not in evidence. For example, if, as a matter of policy or routine practice, a facility transfers neonates based on gestational age, the facility would not meet the Level III requirements of caring for all gestational ages with mild to critical illnesses or requiring sustained life support.

Will Medicaid reimbursement be affected with a lower level designation?

No. Based on statute, a facility must have a neonatal designation to receive Medicaid reimbursement for neonatal care; however, the facility's rate of reimbursement for Medicaid services is not dependent on the level of designation, but is based on the services provided to the individual neonate. Health and Safety Code, Sec. 241.183(a)(7)

(a) The executive commissioner [of the Texas Health and Human Services Commission], in consultation with the department, shall adopt rules:

(7) requiring payment, other than quality or outcome-based funding, to be based on services provided by the facility, regardless of the facility's level of care designation.

Is there a process to appeal the designation decision at a lower level?

Yes. The appeal process provides an opportunity for the facility to submit additional information from the survey period that the facility feels shows why the designation level awarded was not correct and how they facility complied with requirements. The appeal does not provide the opportunity to submit new information regarding programmatic changes or clinical care that occurred after the date of the survey.

The appeal process is outlined in the Designation Process section of the rule, 25 Texas Administrative Code § 133.184.

If the facility disagrees with the level of designation awarded by the department, the facility may submit a written appeal to the Director of the Office of EMS/Trauma Systems. The written appeal must be submitted within 60 days from the date of the department’s letter notifying the facility of their designation. The facility must submit a signed letter from the governing board explaining how the facility meets the higher level requirements. The facility may include supporting information with the letter from the governing board. An appeal packet should address the designation requirements not met and include, as applicable to their situation, pertinent documentation of policies, processes, clinical information, and evaluation of care provided. For demonstrating continual evaluation of the care provided, quality improvement meeting minutes, patient care reviews and outcomes of those reviews can provide additional evidence of compliance.

The written appeal will be reviewed for compliance with the requirement(s) cited as deficiencies. The department will provide a written decision to the facility within 30 days from receipt of the complete written appeal.

- If the facility demonstrates compliance with the requirement(s) in the appeal, the department will recommend designation at a higher level.

- If the facility has not demonstrated compliance with the requirements, the Director of the Office of EMS/Trauma Systems will notify the facility of the decision to not change the original designation awarded.

- If the facility disagrees with the decision after the appeal review, it may submit a written request for further review within 30 days from the date of the letter sent by the department with the decision. This written appeal will be submitted to the Associate Commissioner of the DSHS Consumer Protection Division.

Is there a different process to appeal when a facility disagrees with a decision to deny, revoke or reduce designation?

Yes. When a facility repeatedly does not meet designation requirements, has a designation with a required corrective action plan to ensure compliance with the requirements, and fails to correct the deficiencies, the department may deny or revoke designation, or assign a lower level. If the facility disagrees with this decision, it may request a secondary review by a designation review committee.

A facility also has the option of requesting a hearing before the State Office of Administrative Hearings.