



Strategic Review of Neonatal Level of Care Designations

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Executive Summary

Pursuant to Senate Bill 749, 86th Legislature, Regular Session, amending [Chapter 241, Health & Safety Code](#), the Department of State Health Services (DSHS), in consultation with the Perinatal Advisory Council (PAC), conducted a strategic review of the practical implementation of Hospital Level of Care Designations for Neonatal and Maternal Care. The strategic review should, at a minimum, identify:

- Barriers to a hospital obtaining its requested level of care designation
- Whether the barriers are appropriate to ensure and improve neonatal and maternal care
- Requirements for a level of care designation that relate to gestational age and
- Whether, in making a level of care designation for a hospital, the department or PAC should consider:
 - ▶ Geographic area in which the hospital is located, and
 - ▶ Regardless of the number of patients of a particular gestational age treated by the hospital, the hospital's capabilities in providing care to patients of a particular gestational age as determined by the hospital.

The report must summarize the Department's review of neonatal care and actions taken by the department based on the review and be submitted to the legislature not later than December 31, 2019.

DSHS performed a strategic review encompassing analysis of 152 hospital survey reports with 2,257 patient records reviews, pertinent sections of the Texas Administrative Code, geographical considerations, and level of care requirements in other states. Based on this review, DSHS identified two main areas that prevented hospitals from receiving their requested level of designation:

- Level III - not providing comprehensive care to infants of all gestational ages with mild to critical illnesses or requiring sustained life support.
- Level IV - not providing a comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists available to arrive onsite for face-to-face consultation and care, and the capability to perform major pediatric surgery including the surgical repair of complex conditions.

Additionally, other contributing themes to a hospital not meeting requirements for the requested level of care designation were:

- Lack of 24/7 physician and Neonatal Nurse Practitioner (NNP) coverage;
- Lack of trained direct-care staff;
- Health insurance directives requiring transfer of certain neonates to specified hospitals; and
- Absence of high-risk neonatal admissions.

DSHS analysis has identified common causes and barriers to hospitals receiving their requested level of designation and compared these factors to rules in other states. However, additional consultation with the PAC is necessary to determine whether the identified barriers are appropriate or whether the Neonatal Level of Care rules should be revised. DSHS will collaborate with the PAC to begin a formal review of the neonatal levels of care following the appointment of new PAC members in early 2020. This collaboration will include a review of the barriers identified in this report and analysis of whether changes required by SB 749 help mitigate barriers to obtaining a hospital's requested designation level. Based on recommendations from the PAC, DSHS will initiate the public rulemaking process to implement SB 749 changes and address other issues identified during the review process.

By December 31, 2020, DSHS will submit a follow-up report to the legislature outlining the PAC's determinations and any next steps for rulemaking.

1. Introduction

[Senate Bill 749, 86th Legislature, Regular Session, 2019](#), directs the Department of State Health Services (DSHS) to conduct a strategic review of the practical implementation of the adopted Hospital Neonatal Level of Care Designations rule that at a minimum identifies:

- Barriers to a hospital obtaining its requested level of care designation
- Whether the barriers are appropriate to ensure and improve neonatal and maternal care
- Requirements for a level of care designation that relate to gestational age and
- Whether, in making a level of care designation for a hospital, the department or PAC should consider:
 - ▶ Geographic area in which the hospital is located; and
 - ▶ Regardless of the number of patients of a particular gestational age treated by the hospital, the hospital's capabilities in providing care to patients of a particular gestational age as determined by the hospital.

The report must summarize the Department's review of neonatal care and actions taken by the Department based on the review and be submitted to the Legislature not later than December 31, 2019. DSHS will submit a second report by December 31, 2020, which will report on maternal levels of care and will further address whether barriers identified in this report are appropriate to ensure and improve neonatal and maternal care.

2. Background

Hospital designations are classifications that establish formal recognition of a hospital's level of care in a specific category, based on the hospital's compliance with established standard requirements. Designations help provide patients and families confidence that care provided by hospitals are substantially similar, regardless of geographical area or hospital size, when the hospitals have the same designation level.

Hospital designations advance care and create systems that, over time, improve health outcomes for patients. Designations do not dictate who a hospital may care for or what services a hospital may provide. Designations do not mandate patient transfers or limit a doctor's decision about patient care. Instead, designations recognize the highest functional level of care provided by a hospital inclusive of all lower level care provided. In Texas, hospitals may receive designations for the following care categories: trauma, stroke, neonatal, and maternal.

Creation of Neonatal and Maternal Levels of Care

The 83rd and 84th Legislatures directed the construct and functions of the Perinatal Advisory Council (PAC) to establish maternal and neonatal levels of care. Prior to these pieces of legislation, Texas hospitals self-designated their neonatal levels of care, and so there was a lack of uniformity in standards.

The Council, per statute, is composed of pertinent specialists and subspecialists in disciplines involved in the care of pregnant patients and newborns, as well as representatives from hospital administration. The Council served as the primary source of health care expertise for the Department's development of the formal administrative rules that define the neonatal and maternal levels of care designation requirements. The Legislature tasked the Council with:

- Developing and recommending criteria for designating neonatal and maternal levels of care;
- Developing and recommending a process for assignment of levels of care to a hospital;
- Recommending dividing the state into perinatal care regions; and

- Examining neonatal and maternal outcomes.¹

The Council conducted research and received extensive stakeholder feedback to frame the construction of the neonatal levels of care rules. Through this process, the PAC recommended, and Texas adopted, a set of neonatal level of care requirements consistent with the nationally recognized and accepted American Academy of Pediatrics guidelines.² More information on the process, stakeholder feedback, and PAC composition may be found in the September 2016 [Perinatal Advisory Council Report on Determinations and Recommendations](#).

The TAC rules established the following levels of care with corresponding standards for designation:

- **Level IV, Advanced Neonatal Intensive Care Unit.** The hospital provides care for the mothers and comprehensive care of their infants of all gestational ages with the most complex and critically ill neonates/infants with any medical problems, and/or requiring sustained life support.
- **Level III, Neonatal Intensive Care Unit.** The hospital provides care for mothers and comprehensive care of their infants of all gestational ages with mild to critical illnesses or requiring sustained life support.
- **Level II, Neonatal Special Care Nursery.** The hospital generally provides care for mothers and their infants of ≥ 32 weeks gestational age and birth weight ≥ 1500 grams with physiologic immaturity or problems that are expected to resolve rapidly and are not anticipated to require subspecialty services on an urgent basis.
- **Level I, Neonatal Well Nursery.** The hospital generally provides care for mothers and their infants of ≥ 35 weeks gestational age who have routine, transient perinatal problems.

Lower designation levels may, according to hospital discretion and medical decision-making, retain care of an infant at any gestational age with any medical problem. DSHS does not regulate the practice of medicine.

¹ [House Bill 15, 83rd Legislature, Regular Session, 2013](#), and [House Bill 3433, 84th Legislature, Regular Session, 2015](#)

² *Guidelines for Perinatal Care, 7th Edition*, American Academy of Pediatrics and American College of Obstetricians and Gynecologists (ed.), 2012.
<https://ebooks.aappublications.org/content/guidelines-for-perinatal-care-7th-edition>

Effective September 1, 2018, receiving a level of neonatal care designation is a requirement for Medicaid reimbursement for related services. Per statute, a hospital's specific designation level has no effect on the level or rate of reimbursement.

3. Neonatal Designation Process

Initial Designations

The Department of State Health Services (DSHS) awards neonatal level of care designations based on compliance with the Texas Administrative Code (TAC) requirements, which are intended to recognize the functional level of care demonstrated and maintained by an individual hospital.

Hospital compliance with the TAC is determined through evidence of Perinatal Care Region participation, survey findings and patient record reviews. The application review process seeks to verify documented evidence of a hospital's compliance with the TAC rules. The DSHS commissioner makes designation decisions based on that documented evidence. Further details on the application and survey process may be found in Appendix A, Survey Process.

The DSHS commissioner awarded 233 hospitals providing neonatal care designation prior to the September 1, 2018, deadline. Every designated hospital received a designation award letter and participated in a conference call with DSHS to discuss opportunities for program improvement, continued education on the rules, and the awarded level of care designation. For hospitals that did not receive their desired designation, DSHS also provided a written notice detailing the unmet requirements.

Below is a breakdown of the 233 facilities by awarded designation level. A map detailing the location of Texas designated hospitals by level may be found in Appendix B, Texas Maps of Neonatal Designated Facilities.

- Level IV, Advanced Neonatal Intensive Care Unit – 20
- Level III, Neonatal Intensive Care Unit – 57
- Level II, Neonatal Special Care Nursery – 75
- Level I, Neonatal Well Nursery – 81

Of the 233 designated hospitals, 18 percent (42 hospitals) were designated at a lower level than initially requested. DSHS instead designated them at the highest demonstrated level of care for which minimum requirements were met.:

- Designated Level II with a Level III application – 37 hospitals; and
- Designated Level III with a Level IV application – 5 hospitals.

The most common finding that prevented a hospital from obtaining the requested level of designation was the Level III requirement to provide care for mothers and comprehensive care of their infants of all gestational ages with mild to critical illnesses or requiring sustained life support. This was the single largest contributor to a hospital not receiving the level of designation requested, with 36 hospitals impacted. The six remaining hospitals demonstrated non-compliance with multiple requirements resulting in designation at a lower level than requested.

Appeals Process

As defined in the rule ([25 Tex. Admin. Code Section 133.184 \(g\)\(4\) \(2019\) \(Dept. of State Health Services, Designation Process\)](#)), if a hospital disagreed with the designation level awarded, they could take advantage of an appeal process that included two levels of appeal to dispute the findings of the original survey. The first level was to submit a written appeal within 60 days requesting a review by the EMS/Trauma Systems Director. If the first-level appeal review upheld the original determination and designation remained unchanged, a second-level written appeal requesting review by the Consumer Protection Division Associate Commissioner was available.

In response to stakeholder requests, DSHS developed and offered a follow-up survey option for the neonatal appeal process of initial neonatal level of care designations. This option was available to a hospital that had completed the first-level appeal review process but did not achieve the level of designation requested. The follow-up survey option allowed the hospital to have an additional onsite review by the same independent survey organization that conducted the initial survey.

During the follow-up survey, the survey team evaluated the specific areas that prevented designation at the requested level. The follow-up survey is abbreviated but the survey team makeup is defined in rule and so did not change. The survey included review of hospital documents, additional patient records, and corrective actions and programmatic changes implemented after the original survey date to the present, to verify hospital compliance with the rule requirements.

Ten of the 28 hospitals submitting an appeal received a designation at a higher level. Therefore, the final determinations resulted in 86 percent of hospitals receiving designation at the requested level.

4. Designation Implementation Evaluation

Designation serves the consumer by recognizing a standardized evaluation of the functional level of care provided and maintained by an individual hospital. A designation offers important insight for the consumer and promotes quality assurance and improvements in hospitals. Designation does not authorize or restrict medical care or medical decision-making, and the Department of State Health Services (DSHS) has no authority to regulate the practice of medicine. Hospitals may provide care that exceed their awarded designation level, and often do so with high quality of care for their patients.

DSHS analyzed neonatal applications to determine the evidence of services available, care provided, and patient disposition to determine a hospital's compliance with the Texas Administrative Code (TAC). Additionally, DSHS performed an in-depth retrospective analysis of every patient record review submitted with a Level II, III, or IV application to evaluate the demonstrated abilities of hospitals at each level.

Through DSHS review the overall results reflect that hospitals throughout the state provide comparable treatments at each designation level. Examples of similar hospital competencies by designation level include:

- For Level IV hospitals:
 - ▶ 90 percent commonly provide treatments of high frequency ventilation (HFV), inhaled Nitric Oxide (iNO), peripherally inserted central catheter (PICC) or central lines, and therapeutic hypothermia.
 - ▶ 100 percent provide surgical procedures.
 - ▶ 80 percent perform the most complex surgeries.
- For Level III hospitals:
 - ▶ 85 percent demonstrated HFV and ventilation greater than 24 hours.
 - ▶ Other treatments commonly used are iNO, PICC lines, and therapeutic hypothermia.

Details on this analysis may be found in Appendix C, Hospital Competencies by Neonatal Designation Level.

Gestational Age Requirements

Texas neonatal level of care requirements describe various populations of neonates, based on gestational age, birth weight, and the complexity and severity of their medical and/or surgical condition.

Table 1. Levels of Care Requirements Based on Certain Patient Population Descriptors.

Patient Population Descriptors	Level I Well Nursery	Level II Special Care Nursery	Level III Neonatal Intensive Care Unit	Level IV Advanced Neonatal Intensive Care Unit
Gestational Age	≥35 weeks (equal to or greater than)	≥32 weeks (equal to or greater than)	All gestational ages	All gestational ages
Birth Weight	None	≥1500 grams (equal to or greater than)	None	None

Patient Population Descriptors	Level I Well Nursery	Level II Special Care Nursery	Level III Neonatal Intensive Care Unit	Level IV Advanced Neonatal Intensive Care Unit
Severity of Condition	Routine, transient perinatal problems	Physiologic immaturity or problems expected to resolve rapidly and not anticipated to require subspecialty services on an urgent basis	Comprehensive care for mild to critical illnesses or requiring sustained life support	Comprehensive care for the most complex and critically ill neonates/infants and/or requiring sustained life support; Perform major pediatric surgery including the surgical repair of complex conditions

The Perinatal Advisory Council (PAC) recommended these requirements consistent with the *Guidelines for Perinatal Care, Seventh Edition*, which serves as the national resource on perinatal levels of care. For further context on whether the neonatal level of care requirements are appropriate to ensure and improve neonatal care, DSHS reviewed neonatal levels of care requirements for the eight other states that have implemented neonatal levels of care: Arkansas, California, Georgia, Illinois, Massachusetts, New York, Tennessee, and Washington. DSHS found that for gestational age, the eight other states have standards in place that are comparable to Texas standards.

Texas requirements are also in line with the updated *Guidelines for Perinatal Care, 8th Edition*, which states “evidence suggests that infants who are born at less than 32 weeks of gestation, or weigh less than 1500 grams at birth, or have complex medical or surgical conditions, regardless of gestational age, should be cared for at

a Level III facility. Designation of Level III care should be based on clinical experience, as demonstrated by large patient volume, increasing complexity of care, and availability of pediatric medical subspecialists and pediatric surgical specialists.”³

See Appendix D, Texas Level III Requirements Compared to Other States and National Standards.

Barriers to Requested Level of Designation

SB 749 instructs the Department of State Health Services (DSHS) to identify the most common barriers or causes to a facility not receiving its requested designation. Thirty-two of 233 hospitals did not receive their requested designation either through the initial or appeal process.

DSHS evaluated related survey reports and patient record reviews which identified barriers or causes in three categories: items overarching to all facility designation levels, items related to facilities seeking Level IV designation, and items related to facilities seeking Level III designation.

Overarching Items

DSHS found that hospitals, designated at all four levels of care, classified neonate severity of illness based on billing practices and coding instead of medical complexity of care required by the patient’s condition.⁴ This practice may have given hospitals a false sense of compliance with the level of care TAC requirements. DSHS will work through the PAC to provide hospitals clarity about the difference between the severity of illness in the TAC requirements versus billing codes.

At the same time, some hospitals conveyed difficulties meeting requirements that, in their judgement, did not provide adequate details. For example, some hospitals

³ *Guidelines for Perinatal Care, 8th Edition*, AAP Committee on Fetus and Newborn and ACOG Committee on Obstetric Practice, 2017. Sarah J. Kilpatrick, Lu-Ann Papile and George A. Macones (Ed.). <https://ebooks.aappublications.org/content/guidelines-for-perinatal-care-8th-edition>

⁴ Blue Cross Blue Shield. Neonatal Intensive Care Unit (NICU) Level of Care Authorization and Reimbursement Policy. Version 5.0. https://www.bcbstx.com/provider/pdf/ECPCP004_Neonatal_Intensive_Care_Unit_Level_of_Care_v5_06-08-17.pdf. Accessed October 17, 2019.

were concerned that the rules required anesthesiologists to directly provide anesthesia for all neonatal patients at their facility. To address this issue, DSHS developed and will maintain Neonatal FAQs to provide needed clarifications to the current TAC rules.⁵

Level IV Items

The number one cause of a hospital not achieving Level IV designation was not providing a comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists available to arrive on-site for face-to-face consultation and care, and the capability to perform major pediatric surgery including the surgical repair of complex conditions. These hospitals provide certain more complex services by transferring neonates for consultation and/or treatment to other hospitals, a practice reportedly driven by physician preference and contractual arrangements. This methodology did not meet the requirements for Level IV designation, since under the TAC rules, Level IV hospitals should be able to provide comprehensive care for the most critically ill and complex neonates.

Level III Items

The number one cause of a hospital not achieving Level III designation was not providing comprehensive care to infants of all gestational ages with mild to critical illnesses or requiring sustained life support. The underlying reasons varied by hospital. For example, certain hospitals limited the gestational age of the neonates who were cared for at the hospital. This was evident not only in hospital policy but in the hospital practice of immediately transferring neonates following delivery based on a gestational age cut-off. These hospitals described themselves as “self-limiting.”

Separately, some hospitals did not have deliveries or receive transfers of neonates of lower gestational ages. These hospitals could not demonstrate compliance with the Level III TAC requirements.

⁵Frequently Asked Questions from Neonatal (NICU) Designated Facilities, Department of State Health Services.
https://www.dshs.texas.gov/emstraumasystems/Perinatal/PDF/Neonatal_Designation_FAQs.pdf

Additionally, Level III hospitals have expressed some common themes that may have prevented them from demonstrating care for patient populations as defined in the rule, as follows:

- Immediately prior to the survey, added 24/7 coverage by physicians and Neonatal Nurse Practitioners, resulting in an inability to demonstrate delivery of the required level of care in medical record review;
- Lack of adequately trained nursing and/or respiratory therapy staff to provide care;
- Health insurance directives requiring transfer of certain neonates to specified hospitals; and
- Absence of the neonatal admissions that impacted the hospital's ability to demonstrate compliance with the level of care requirements.

The *Guidelines for Perinatal Care, 8th Edition*, states "evidence suggests that infants who are born at less than 32-weeks of gestation or weigh less than 1500 grams at birth or have complex medical or surgical conditions, regardless of gestational age, should be cared for at a Level III facility. Designation of Level III care should be based on clinical experience, as demonstrated by large patient volume, increasing complexity of care, and availability of pediatric medical subspecialists and pediatric surgical specialists." Evidence of demonstrated clinical care to support compliance at both Level III and Level IV was not found in the medical records of hospitals designated at a level lower than requested.

Six of the eight states that have adopted neonatal levels of care require Level III/Level IV hospitals to demonstrate clinical experience and competency through volume requirements related to gestational age, birth weight, and critical conditions including surgery. The *Guidelines for Perinatal Care* recommend patient volumes to maintain proficiency in the care of critically ill neonates to improve outcomes in mortality and morbidity. Individual states have adhered to the recommended guidelines by including volume requirements while Texas statute prohibits the consideration of volumes in Level I – III designations. See Appendix D, Texas Level III Requirements Compared to Other States and National Standards.

Geographic Considerations for Designation

Texas neonatal levels of care rules do not currently contain significant geographic considerations. During the DSHS rule development phase, some hospitals were concerned that the draft language limited their ability to provide care for neonates needing a level of care exceeding the TAC rule's general level of care description for

their designation level. To ensure clarity for these hospitals, DSHS added language to the Level II requirements specifically for hospitals located more than 75 miles away from a Level III or Level IV designated facility. This language requires the hospitals, when treating patients needing a higher level of care, to ensure the same level of care that a neonate would receive at a higher-level hospital if providing comprehensive care to infants less than 32-weeks gestational age and less than 1,500 grams. Additionally, the rules require hospitals to provide an in-depth critical review of the care provided through the neonatal Quality Assurance and Performance Improvement (QAPI) program.

In other states that have implemented neonatal levels of care, geographic considerations are present. Seven of the eight states have Certificate of Need requirements in place to establish a new hospital or health care service and so their programs are set against a different backdrop than the Texas health care system.

California and New York consider geographic location when determining neonatal levels of care hospitals in their states. California may deny a hospital approval of a neonatal level of care if a community need based on geographic considerations and a sufficient volume of critically ill neonates is not identified. The California Children's Services determines the community need in consultation with other state and federal agencies. New York's geographic consideration requires a maximum allowable surface travel time to reach a Level III hospital or Regional Perinatal Center equal to two hours or less under usual weather and road conditions to ensure access to the appropriate level of care. See Appendix D.

In Texas, 27 of 233 neonatal hospitals are 75 or more miles away from a Level III or Level IV designated hospital. Seven of the 27 hospitals are greater than 150 miles away from a Level III or Level IV hospital. Neonatal care at a Level III or IV hospital is within less than 150 miles for most Texas residents. See Appendix E, Geographical Considerations and Mileage.

In comparing the other state-adopted requirements for neonatal care, transferring an infant back to a lower-level hospital in the family's community for convalescing care post neonatal intensive care unit was essential. The PAC and stakeholders requested a "back-transfer" requirement for the rules but reimbursement is generally not approved. See Appendix D.

Improvement in Neonatal Care

Due to the short amount of time the neonatal levels of care rules have been effective, comprehensive metrics of improvement in neonatal outcomes cannot yet adequately be determined. However, DSHS has already identified many small evolutions in process and care through hospital applications and plans of correction, site visits, and discussions with hospital program staff. In this short amount of time, the Department has seen improvements in Quality Assurance and Performance Improvement (QAPI) programs, and hospital processes to improve patient care.

The QAPI program evaluates the provision of patient care and emphasizes a multidisciplinary approach to problem solving to improve neonatal outcomes. Implementation of a robust QAPI program is the greatest area of opportunity for improvement throughout the state. Of 2,257 case reviews from Level II, III, and IV hospital surveys, only 14 percent had evidence of patient case reviews in their QAPI process. However, QAPI alone was not the sole reason for any hospital not receiving their desired designation level.

Developing and implementing an effective and robust QAPI process takes time, commitment, and may be a fundamental change for many hospitals. The strength of any designation program is a robust QAPI process. Hospitals are working to develop and mature their QAPI by identifying opportunities for improvement based on care provided, developing improvement plans, implementing changes, and ensuring resolution for a robust QAPI process.

An additional opportunity for improvement is through the Perinatal Care Regions (PCRs). PCRs are geographically divided by counties aligned with and supported by the trauma Regional Advisory Councils, have established neonatal and/or perinatal committees. Designated hospitals come together in these regional committees to discuss issues affecting delivery of care, and to share best practices in a regional forum. This creates a hub and spoke model, where the higher designated hospitals (the hubs) provide outreach to the lower level designated hospitals (the spokes) for sharing best practices, education, and collaboration in community and neonatal care improvement.

The PCR committee chairs meet quarterly to focus on identifying quality improvement initiatives that can be implemented in all 22 PCRs. Many PCR chairs attend the Perinatal Advisory Council meeting in conjunction with the PCR meetings and may provide feedback on the quality improvement initiatives at the PAC

meeting. This will strengthen the collaboration between the Council, PCR, hospitals, and the regional systems of care.

Throughout this process, hospitals have increasingly collaborated with other hospitals within their respective PCRs, improved internal hospital policies, protocols, and resources because of the neonatal designation program. This indicates that the neonatal levels of care program has great potential to continuously improve hospital care and outcomes for mothers and their babies.

DSHS Actions and Next Steps

While this report addresses some considerations around the causes and barriers to facilities obtaining their desired designation level, more consultation with the PAC and with hospital stakeholders is necessary to identify the next steps for Texas.

The Department will collaborate with the PAC on a formalized rule review process of the neonatal level of care following the appointment of new PAC members in early 2020. This collaboration will include a review of the barriers identified in this report and analysis of whether changes required by SB 749 help mitigate barriers to obtaining a hospital's requested designation level. Based on recommendations from the PAC, DSHS will initiate the public rulemaking process to implement SB 749 changes and address other issues identified during the review process.

By December 31, 2020, DSHS will submit a follow-up report to the Legislature outlining the PAC's recommendations and any next steps for rulemaking.

5. Conclusion

The Texas neonatal level of care requirements are consistent with the nationally recognized and accepted American Academy of Pediatrics guidelines and are comparable to eight other states with similar programs. Awarded designations were appropriate based on compliance with the TAC rules.

Pursuant to Senate Bill 749, DSHS performed a strategic review encompassing analysis of 152 hospital survey reports with 2,257 patient records reviews, pertinent sections of the Texas Administrative Code, geographical considerations, and level of care requirements in other states. Based on this review, DSHS identified the following key areas that prevented hospitals from receiving their requested level of designation:

- Level III - not providing comprehensive care to infants of all gestational ages with mild to critical illnesses or requiring sustained life support.
- Level IV - not providing a comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists available to arrive onsite for face-to-face consultation and care, and the capability to perform major pediatric surgery including the surgical repair of complex conditions.

DSHS will collaborate with the PAC to begin a formal review of the neonatal levels of care following the appointment of new PAC members in early 2020. This will complete the SB 749 requirement about whether the barriers are appropriate to ensure and improve quality of neonatal and maternal care in Texas. Based on PAC recommendations, DSHS will initiate the public rulemaking process to implement SB 749 changes and address any other issues identified during the review process.

By December 31, 2020, DSHS will submit a follow-up report to the legislature outlining the PAC's recommendations and any next steps for rulemaking.

List of Acronyms

Acronym	Full Name
AAP	American Academy of Pediatrics
ACOG	American College of Obstetricians and Gynecologists
CPAP	Continuous Positive Airway Pressure
CT	Computed Tomography
DSHS	Department of State Health Services
ECMO	Extracorporeal Membrane Oxygenation
ELBW	Extremely Low Birth Weight
EMS	Emergency Medical Services
GA	Gestational Age
HFV	High Frequency Ventilation
iNO	Inhaled Nitric Oxide
IV	Intravenous
MRI	Magnetic Resonance Imaging
NICU	Neonatal Intensive Care Unit
PAC	Perinatal Advisory Council

Acronym	Full Name
PCR	Perinatal Care Region
PICC	Peripherally Inserted Central Catheter
QAPI	Quality Assessment and Performance Improvement
RE	Rural Exception
RN	Registered Nurse
ROP	Retinopathy of Prematurity
TAC	Texas Administrative Code
TETAF	Texas EMS Trauma and Acute Care Foundation
TPN	Total Parenteral Nutrition
VLBW	Very Low Birth Weight

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Appendix A. Survey Process

Hospital compliance with the Texas Administrative Code (TAC) is determined through evidence of Perinatal Care Region participation, survey findings and patient record reviews. The application includes the survey report and patient record reviews detailing the hospital's overall compliance with the requirements.

- Level I hospital applications require submission of a self-survey report with an administrative attestation to confirm compliance with the rules.
- Level II, III, and IV hospitals require submission of a survey report and patient record reviews documenting findings of compliance from an onsite review conducted by an independent survey organization prior to application.

For neonatal levels of care, the American Academy of Pediatrics and the Texas EMS Trauma and Acute Care Foundation conduct on-site peer review surveys to verify compliance with the TAC based on the level of designation being requested by the hospital. The individual organizations select surveyor candidates who participate in a neonatal hospital site surveyor course to gain essential knowledge and skills prior to conducting surveys.

Specific to the first round of neonatal designations, which included a new survey process, both organizations conducted pilot surveys at volunteering hospitals. To ensure consistency among surveys, DSHS staff attended 126 of the 149 neonatal surveys, including all pilot surveys, to provide guidance on the survey process and rule clarification to the surveyors.

Both survey organizations are responsible for credentialing each of the selected surveyor applicants as identified in the rules, [25 Tex. Admin. Code §133.190 \(2019\)\(Dept. of State Health Services, Survey Team\)](#). Every surveyor is a currently practicing professional with relevant experience and knowledge of neonatal care. The surveyors also meet the geographical distance restrictions defined in the rules and must have no conflicts of interest with the hospital they survey.

Both survey organizations implement their own survey process and methodology, as well as their own reports, to ensure compliance and/or noncompliance with requirements in the TAC. Survey teams consist of multidisciplinary professionals; team size and composition are based on requested level of designation. As an example, if the hospital applying for Level III designation provided optional

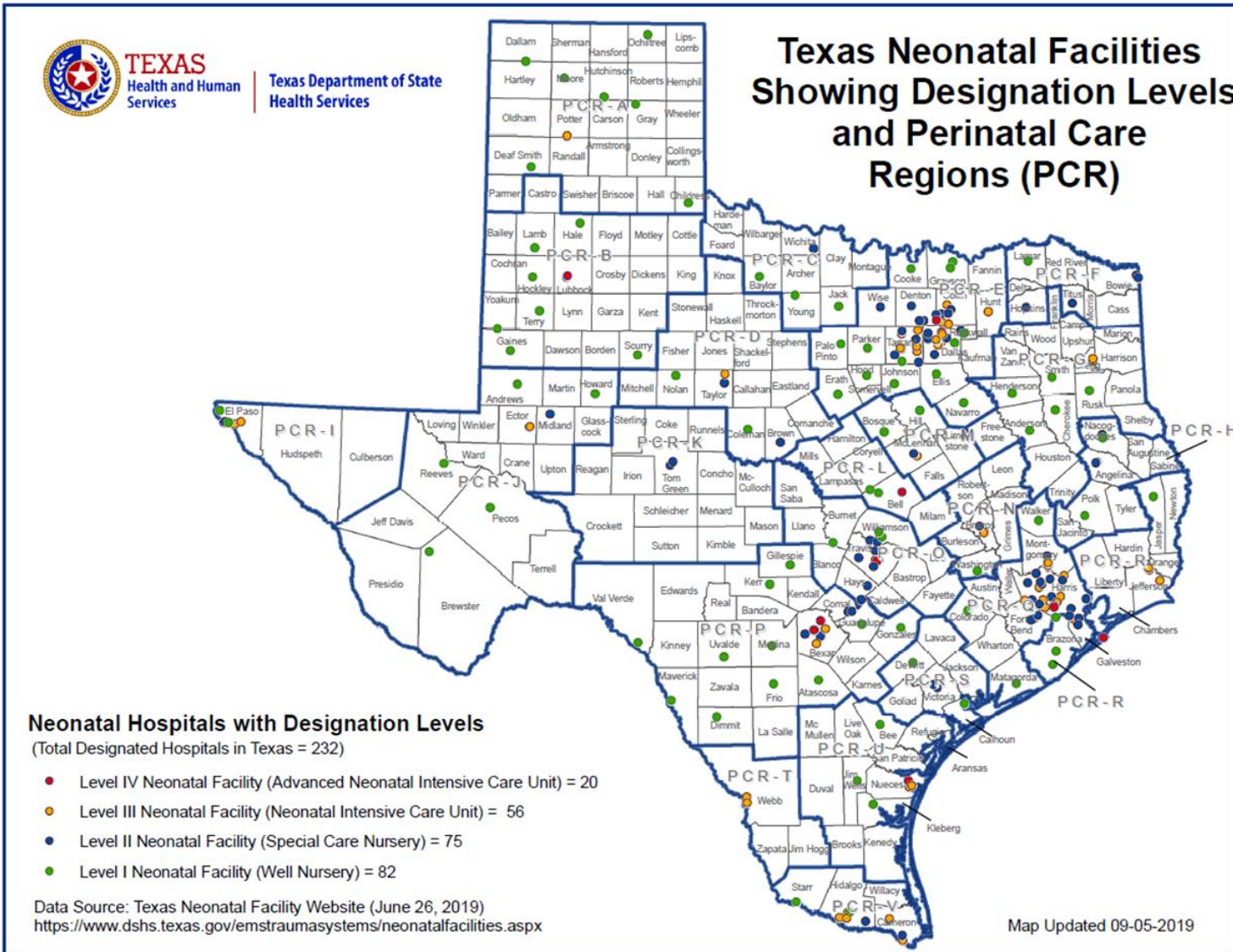
neonatal surgical services, then a pediatric surgeon would be part of the survey team.

Hospitals contract with the survey organization of their choice to arrange an on-site survey. Upon receiving a request for survey, the survey organization is responsible for identifying surveyors who meet the appropriate criteria for the level of designation being requested. Once the survey is completed, the survey organization must provide their findings to the hospital no later than 30 days following the date of survey. The hospital then completes a plan of correction for any identified potential deficiencies, completes their application packet and submits their application packet to DSHS within 120 days of the survey date.

Once DSHS receives an application from a hospital, a DSHS Perinatal Designation Coordinator, who is a Registered Nurse with perinatal experience, performs a desk review that includes an in-depth analysis of the survey report findings and patient record reviews submitted by the hospital. The purpose of this review is to verify documented evidence of compliance with the TAC rules. Designation is then recommended to the DSHS Commissioner based on compliance with the requirements.

Following completion of the initial designation period ending August 31, 2018, DSHS held a joint meeting with leadership of both surveying organizations and performed an in-depth quality review and evaluation of the survey processes for this initial designation period.

Appendix B. Texas Maps of Neonatal Designated Facilities

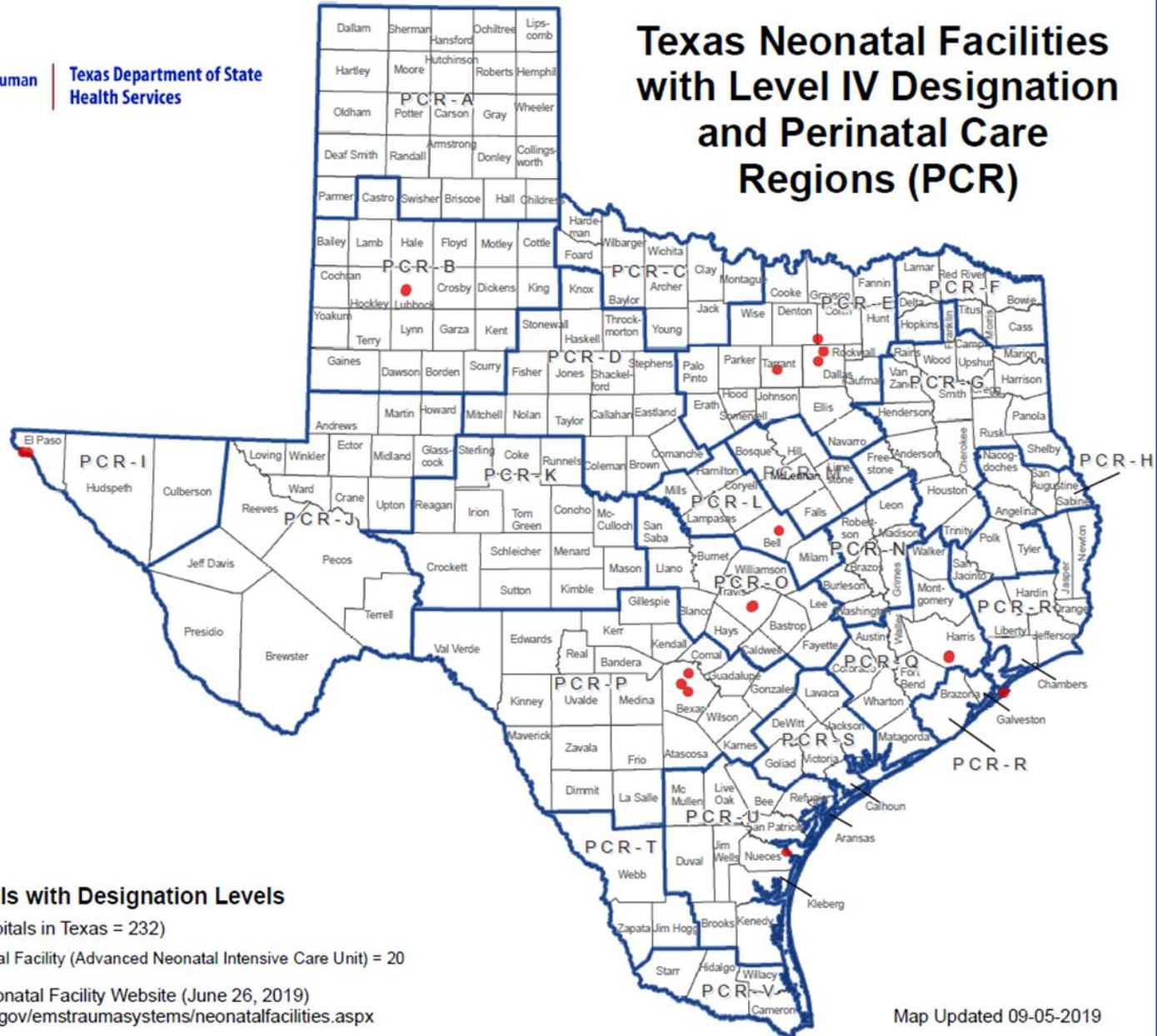




TEXAS
Health and Human
Services

Texas Department of State
Health Services

Texas Neonatal Facilities with Level IV Designation and Perinatal Care Regions (PCR)

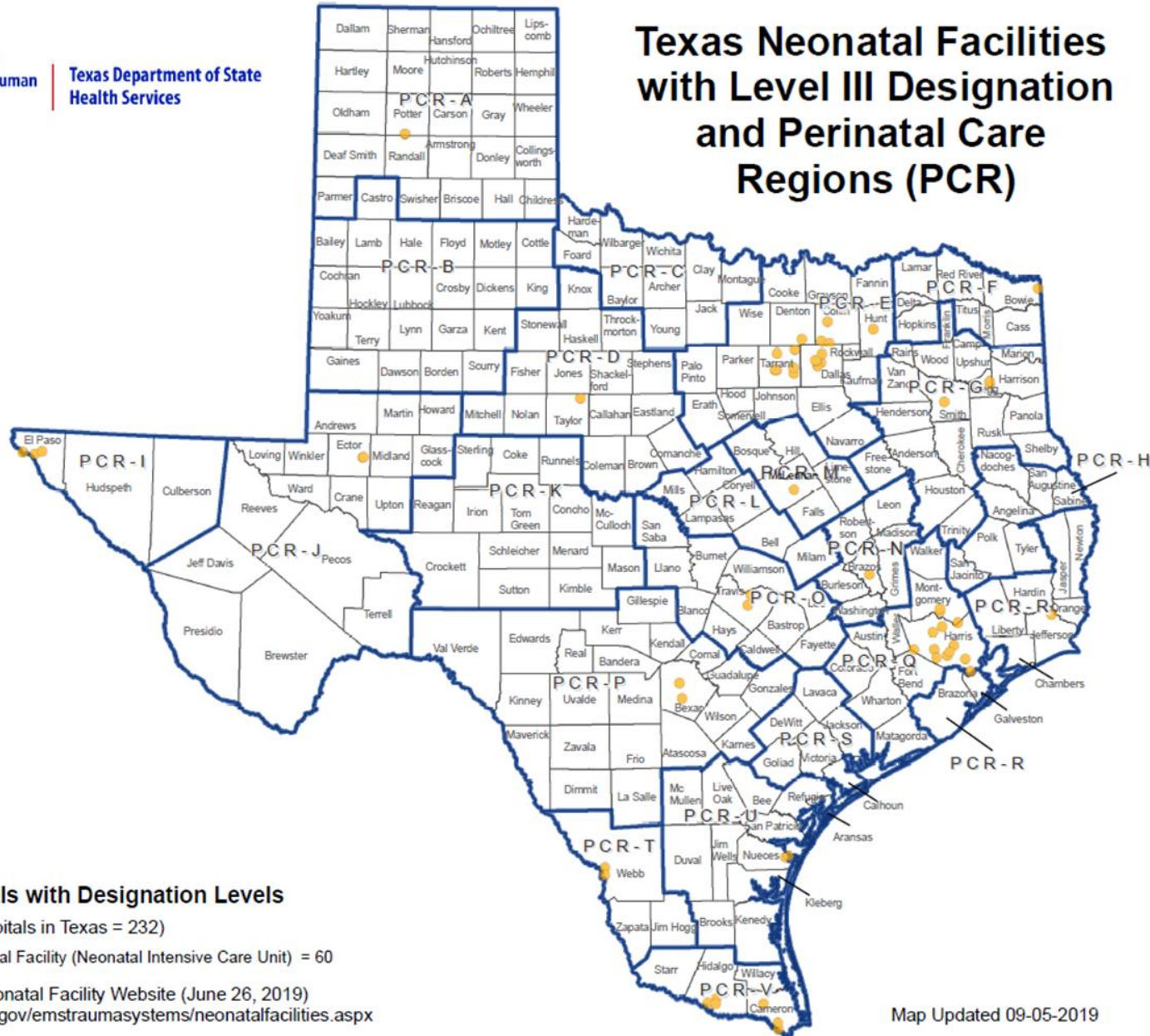




TEXAS
Health and Human
Services

Texas Department of State
Health Services

Texas Neonatal Facilities with Level III Designation and Perinatal Care Regions (PCR)

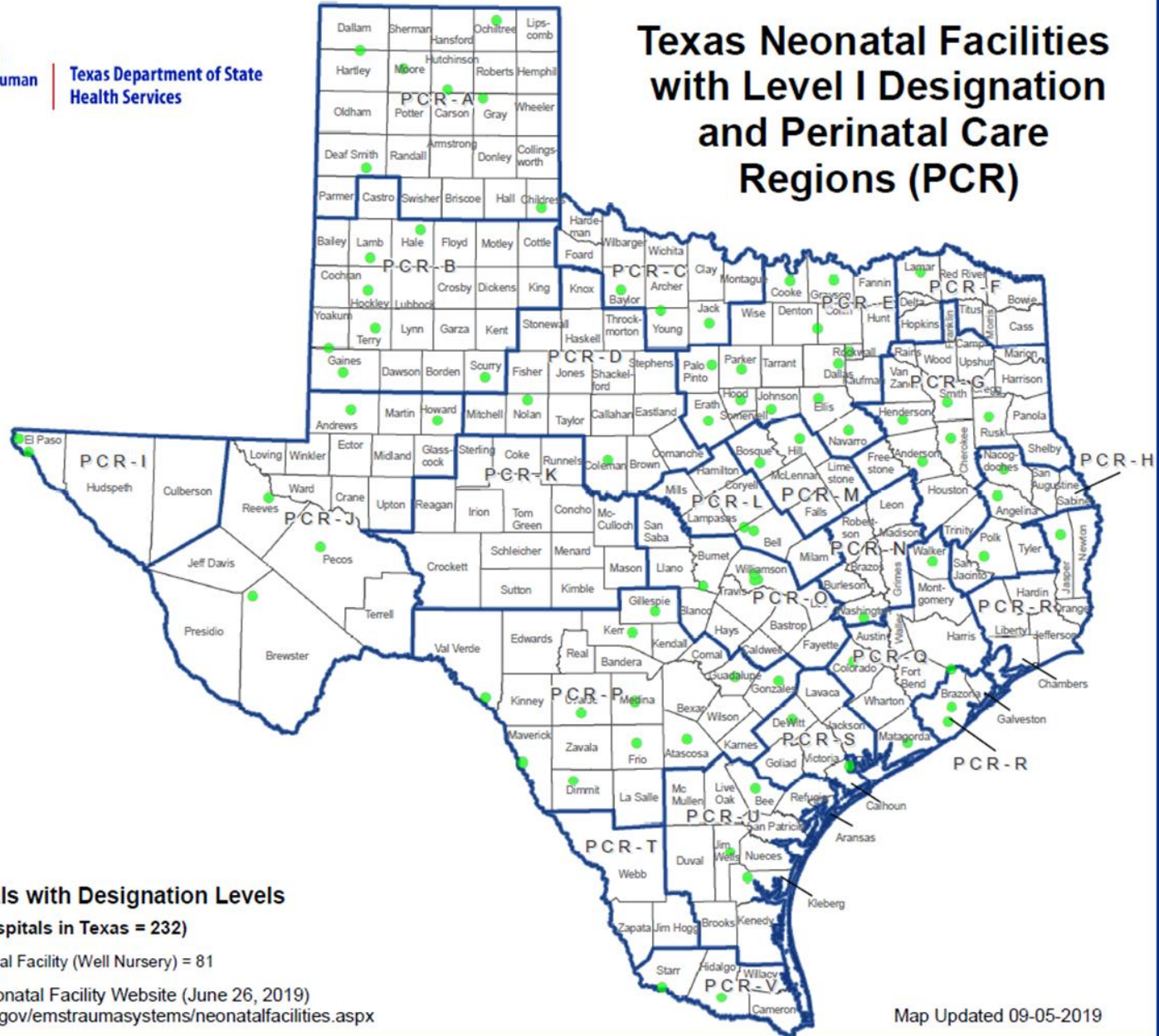




TEXAS
Health and Human
Services

Texas Department of State
Health Services

Texas Neonatal Facilities with Level I Designation and Perinatal Care Regions (PCR)



Neonatal Hospitals with Designation Levels
(Total Designated Hospitals in Texas = 232)

- Level I Neonatal Facility (Well Nursery) = 81

Data Source: Texas Neonatal Facility Website (June 26, 2019)
<https://www.dshs.texas.gov/emtraumasystems/neonatafacilities.aspx>

Map Updated 09-05-2019

Appendix C. Hospital Competencies by Neonatal Designation Level

Table 2. Percentage of Hospitals that Demonstrated the Following Modalities from Case Reviews

Neonatal Level of Care	HFV	iNO	PICC	Cooling	ECMO
LEVEL IV Hospital	100%	90%	90%	90%	35%
LEVEL III Hospital	85%	49%	66%	34%	0%
LEVEL II Hospital	7%	0%	27%	0%	0%

The services and treatments included:

- Ventilation abilities: conventional ventilation, synchronized intermittent mechanical ventilation, high frequency ventilation, inhaled nitric oxide, continuous positive airway pressure (including bubble and nasal), high flow nasal cannula, and ventilation greater than 24 hours;
- Vascular access abilities: umbilical venous catheter, umbilical arterial catheter, Broviac or central line, peripheral arterial line, peripheral inserted central catheter, peripheral IV, total parenteral nutrition administration;
- Special populations: therapeutic hypothermia, extracorporeal membrane oxygenation, surgeries, and complex surgeries;
- Disposition: discharges, transfers, deaths; and
- Multidisciplinary service involvement: lactation consultant, speech therapy, occupational therapy, physical therapy, respiratory therapy, social services, pastoral care, dietitian or nutritionist.

The Texas Administrative Code Section 133.182 defines low birth weight neonates, regardless of gestational age, as those whose weight at birth is less than 2,500 grams. Low birth weight is further subdivided as, very low birth weight (less than 1500 grams) and extremely low birth weight (less than 1000 grams). According to

the *Dartmouth Atlas Project*, this group also includes infants born small for gestational age. These smallest and typically most premature newborns are at the greatest risk for complications and need the highest level of care (Goodman et al., 2019).

The extremely low birth weight and very low birth weight neonates require an intricate plan of care, equipment, and well-trained staff for: coordination of ventilation, vascular access, testing for intraventricular hemorrhage and retinopathy of prematurity, as well as a multidisciplinary development team including lactation, physical therapy, occupational therapy, speech therapy, and social services. A thorough follow up for these neonates for specialists and early childhood intervention is essential for maintaining positive outcomes. This combination of specialized clinicians and services improves outcomes for these tiny patients, as shown in a recent research paper demonstrating improved outcomes in very low birth weight (VLBW) newborns delivered in hospitals with Level III/IV Neonatal Intensive Care Units (NICU) (Lasswell, Barfield, Rochart, & Blackmon, 2010).

Appendix D. Texas Level III Requirements Compared to Other States and National Standards

Level III Requirements	Current TAC	The Guidelines for Perinatal Care, 8 th Edition	Arkansas, California, Georgia, Illinois, Massachusetts, New York, Tennessee, Washington Comparison
<p>Gestational Age (GA)</p>	<p>All gestational ages</p> <p><i>Note: SB 749 changes will have DSHS consider a hospital's capabilities of care for any gestational age regardless of how many patients treated when determining requirements for a level of care designation.</i></p>	<p>All gestational ages including less than 32 weeks</p>	<p>State requirements consistent with AAP and Texas: California, Georgia, Massachusetts, New York, Tennessee, and Washington</p> <p>Arkansas: Level IIIA and IIIB. Level IIIA is greater than 26 weeks GA and 750 grams.</p> <p>Level IIIB is less than 26 weeks GA or 750 grams, or severe or complex illnesses.</p> <p>Illinois: Level IIE (Extended Capabilities) Greater than or equal to 30 weeks GA and 1250 grams.</p> <p>Level III all ages and weights with complex healthcare issues.</p>

Level III Requirements	Current TAC	The Guidelines for Perinatal Care, 8 th Edition	Arkansas, California, Georgia, Illinois, Massachusetts, New York, Tennessee, Washington Comparison
Birth Weight	Not stated	All birth weights including less than 1500 grams	See above
Severity of Condition	Stable physiologically up to and including mild to critical illnesses	Stable physiologically up to and including critical illnesses	All states include comprehensive care for infants with critical, severe or complex illnesses or requiring a high level of specialized care
Volume Six states have volume requirements for Level III Neonatal Hospitals	None <i>Note: SB 749 changes require DSHS to consider a hospital's capabilities of care for any gestational age regardless of how many patients treated when determining requirements for a level of care designation.</i>	Large patient volume	Arkansas: Level IIIA – 25 patients (Minimum # of Very Low Birth Weight (VLBW) or infants less than 32 weeks gestational age (GA) per year.) Level IIIB – 75 patients (Minimum # of VLBW or infants less than 32 weeks GA per year.) California: Sufficient caseload that is necessary to maintain proficiency in the care of critically ill neonates. Perform neonatal surgery including the performance of patent ductus arteriosus ligation.

Level III Requirements	Current TAC	The Guidelines for Perinatal Care, 8 th Edition	Arkansas, California, Georgia, Illinois, Massachusetts, New York, Tennessee, Washington Comparison
			<p>Massachusetts: Level III – Minimum of 2000 births per year in any one of the past three years. Demonstrates that the percent of Low Birth Weight infants (less than 2500 grams) delivered is not less than 10% of the annual births.</p> <p>New York: No fewer than 2000 high-risk newborn patient days annually.</p> <p>Washington: Average daily census of at least 10 Level II/Level III patients.</p> <p>Georgia: Funding based on volume and case mix.</p> <p>Illinois and Tennessee: No volume requirements.</p>

Level III Requirements	Current TAC	The Guidelines for Perinatal Care, 8 th Edition	Arkansas, California, Georgia, Illinois, Massachusetts, New York, Tennessee, Washington Comparison
Geographic Considerations	<p>None</p> <p><i>Note: SB 749 lays out a process for a hospital to waive a requirement after considering the expected impact on accessibility of care in the geographic area served. It also requires the PAC to consider the geographic and varied needs of citizens of this state when developing the criteria for the levels of neonatal and maternal care</i></p>	<p>None</p>	<p>Arkansas, Georgia, Illinois, Tennessee, and Washington: Not addressed.</p> <p>California: Approval held if there is not a community need based on geographic considerations and a lack of sufficient caseload necessary to maintain proficiency in the care of critically ill neonates.</p> <p>Massachusetts: Not Applicable.</p> <p>New York: maximum allowable surface travel time to reach a Level III or Regional Perinatal Center hospital shall be two hours under usual weather and road conditions, and the receiving hospital shall be accessible and convenient to the mother’s place of residence whenever possible.</p>

Level III Requirements	Current TAC	The Guidelines for Perinatal Care, 8 th Edition	Arkansas, California, Georgia, Illinois, Massachusetts, New York, Tennessee, Washington Comparison
<p>Back Transfers</p> <p>Infants are sent back to the community hospital to receive continuing care in a lower level hospital when their condition does not require neonatal intensive care.</p>	None	Consider return transport of recovering infants to lower-level hospitals when clinically indicated	<p>Arkansas: Patients whose condition has stabilized and no longer require specialized services should be considered for transporting back to the referring hospital. Requires written guidelines for back transfers.</p> <p>California: Ensure infants discharged from an Neonatal Intensive Care Unit to a facility closer to the home of the parent or primary caretaker are transferred to an approved hospital appropriate for those who no longer require NICU care but require continued hospitalization for their condition.</p> <p>Georgia: Assessment of the perinatal capabilities and determination of conditions necessitating return transfer.</p> <p>Illinois: Ensuring appropriate transport and back-transport is an</p>

Level III Requirements	Current TAC	The Guidelines for Perinatal Care, 8 th Edition	Arkansas, California, Georgia, Illinois, Massachusetts, New York, Tennessee, Washington Comparison
			<p>essential component of improving the perinatal system.</p> <p>Massachusetts: Transport capabilities to return patients to a hospital with a Level I or II service.</p> <p>New York: Shall return a newborn to the sending hospital when the condition has been stabilized and return is medically appropriate.</p> <p>Tennessee: Infants who are back transferred after their acute problems have been resolved.</p> <p>Washington: Return transport for discharge planning closer to patient's community.</p>

Appendix E. Geographic Considerations and Mileage

Women living in rural areas may have the greatest distances to travel for accessing higher-level neonatal care. Women travel longer distances to higher level of care hospitals as evidenced in the tables below. This distance may prevent them from delivering in the most appropriate hospital.

Forty of the 83 Level I hospitals are located greater than 50 miles from a Level III or IV hospital.

Table 3. Distance of Level I Hospitals from Level III or IV Hospitals

Nearest Level III or IV	Level I (83)
Greater than 150 miles	1
100 - 149 miles	8
75 - 99 miles	11
50 - 74 miles	20
25 - 49 miles	32
Less than 25 miles	11

Of the 40 Level I hospitals greater than 50 miles from a Level III or IV hospital, 22 are located greater than 50 miles from a Level II hospital.

Table 4. Distance of Level I Hospitals from Level II Hospitals

Nearest Level II	Level I (40)
Greater than 150 miles	6
100 - 149 miles	4
75 - 99 miles	5
50 - 74 miles	7
25 - 49 miles	15
Less than 25 miles	3

Over 75 percent of the Level II hospitals are less than 25 miles away from a Level III or IV hospital.

The single Level II hospital that is greater than 100 miles away from a Level III or IV hospital, applied for and is designated at a Level II.

Three of the seven Level II hospitals located greater than 75 miles from a Level III or Level IV hospital, applied for a Level III and were designated at a Level II.

Table 5. Distance of Level II Hospitals from Level III or Level IV Hospitals.

Nearest Level III or IV	Level II (72)
Greater than 100 Miles	1
75 - 99 miles	6
50 - 74 miles	3
25 - 49 miles	6
Less than 25 miles	56

Neonatal designations are determined by verifying evidence of compliance with the requirements in the rule. This consistency in care provided by designation assures the consumers that neonatal services do not significantly differ from one geographical area to another. Designation informs patients, their families, healthcare providers, and Emergency Medical Services organizations, about the hospital’s level of care provided when seeking care for specific conditions