An Update on the Strategic Review of Neonatal Level of Care Designations

As Required by

Senate Bill 749, 86th

Legislature, Regular Session,

2019

February 2022

TEXAS
Health and Human Services

Texas Department of State Health Services

Table of Contents

Executive Summary

The Department of State Health Services (DSHS), in consultation with the Perinatal Advisory Council (PAC), completed an update to the strategic review of the practical implementation of Hospital Level of Care Designations for Neonatal and Maternal Care pursuant to Senate Bill 749 (S.B. 749), 86th Legislature, Regular Session, 2019. The legislation requires that 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.

DSHS previously submitted the initial strategic review of the neonatal care designations in December 2019. In that report, DSHS outlined the need for additional collaboration with the PAC to comply with the statutory requirements, which was to be completed in 2020. Due to the disruption caused by the COVID-19 pandemic, DSHS completed additional research and PAC collaboration throughout 2020-2021 to provide the updates included in this report, while continuing the second cycle of neonatal levels of care designation applications.

In 2020-2021, there were fewer applications submitted because facilities discontinued or relocated maternal and neonatal service lines. All applicant facilities received the specific level of care requested. The 2019 cohort designated at a lower level of care than requested, in most cases, maintained their requested level of designation following a successful appeal, maintained the level of designation ultimately awarded, or achieved a higher level of designation. No appeals occurred since the last report.

The PAC formally conveyed the need for more data before making recommendations related to geographic area considerations and gestational age as required under S.B. 749. Specifically, the PAC made the following recommendation:

> *"We have heard much testimony from our stakeholders and had robust discussions on this issue at each meeting. However, we have also discussed the need for data to assess the impact of the current rules on neonatal and maternal morbidity and mortality prior to making any rule revisions. We do not know the current impact of the rules without this information. Rather than revising the rules on gestational age, the PAC recommends developing a statewide database with granular de-identified patient-based information, as data is needed in order to reach an evidence-based consensus on gestational age." (See Appendix B)*

Following PAC discussions and recommendations, DSHS incorporated the following changes to the draft neonatal rules update:

- Adopting telemedicine medical services for Levels I, II, and III that are in accordance with the standard applicable to the provision of the same service or procedure for an in-person setting.
- Allowing a hospital to appeal a level of care designation to a three-person panel consisting of a representative of the department, a representative of the commission, and an independent person who does not have a conflict of interest with the hospital, department, or commission.
- Establishing conditional designation or a waiver from a level of care designation requirement.
- Utilizing professional practice standards for the timeliness of neonatal echocardiography performance and interpretation.
- Clarifying that anesthesiologists direct and evaluate neonatal anesthesia care provided at Level III and Level IV facilities.

The neonatal rules incorporating the PAC's proposed changes are in the formal Health and Human Services (HHS) rulemaking process. The proposed rules will be considered by HHS Executive Council prior to appearing in the *Texas Register* as proposed rules for formal comment.

1. Introduction

The Department of State Health Services (DSHS) previously completed a strategic review of the practical implementation of the adopted Hospital Neonatal Level of Care Designations rule as required by Senate Bill 749 (S.B. 749), 86th Legislature, Regular Session, 2019.

DSHS submitted its report to the legislature in 2019. This included an overview of identified barriers and observations following the initial cycle of neonatal level of care designations in which 42 of 233 hospitals received a designation less than requested. Ten of the 42 hospitals eventually received their requested designation following an appeal process.

This report is an update to the strategic review completed in 2019. This report outlines activities by the Perinatal Advisory Council (PAC) and DSHS to fulfill the remaining statutory requirements of S.B. 749 and provides updates on the most recent neonatal designation application and review process.

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 a level of confidence to patients and families that care provided by hospitals is 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.

In Texas, formal neonatal levels of care have been in place since 2016. Prior to this, Texas hospitals self-designated their neonatal levels of care, and there was a lack of uniformity in standards.

The Perinatal Advisory Council (PAC) established by Chapter 241, Health and Safety Code, Section 241.187, serves as the primary source of health care expertise for DSHS' development of the formal administrative rules that define neonatal and maternal levels of care designation requirements. In consultation with the PAC, Texas has in place a set of neonatal level of care requirements consistent with the nationally recognized and accepted American Academy of Pediatrics guidelines.[1] The Texas Administrative Code (TAC) rules establish the following levels of care with corresponding standards for designation:[2]

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[1] *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

[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

- **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.

3. Neonatal Designation Process

The process to receive a designation is based on compliance with Texas Administrative Code requirements, which are intended to recognize the functional level of care demonstrated and maintained by an individual hospital. A complete overview of the designation process is in the 2019 report, Appendix A, Survey Process.

As of December 31, 2021, the re-designation cycle of neonatal designations is in progress with 177 of the 227 facilities completed. The total number of neonatal designated facilities decreased. Two rural facilities ceased perinatal services due to a decrease in the annual volume of deliveries and four other facilities moved their perinatal service lines to other system hospitals. All applicant facilities received the level of designation requested in the re-designation cycle to date.

The table below outlines the number of facility designations by level and overall totals in November 2019 and December 2021.

Table 1. Neonatal Level of Care Designations – November 2019 designations and December 2021 current designations.

Neonatal Level of Care	November 2019	December 2021
Level IV	20	22
Level III	57	66
Level II	75	57
Level I	81	82
Total	**233**	**227**

In 2021, all facilities that renewed their designations received the designation level requested. No appeals were filed in the re-designation cycle.

4. Designation Implementation Evaluation

S.B. 749 directed DSHS, in consultation with the PAC, to conduct a strategic review of the practical implementation of neonatal designations to 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.

Barriers to Requested Level of Designation

The initial cycle of designations completed in 2019 resulted in 42 of 233 hospitals not receiving their requested level of designation either through the initial designation. Ten of the facilities achieved a higher level designation after making an appeal.

As of February 2022, the renewal cycle of neonatal designation applications resulted in no denials or appeals. Applicant facilities received the level of care requested. Refer to the 2019 report for other barriers specific to Level IV and Level III designation applications.

DSHS evaluated related survey reports and patient record reviews to identify barriers to the requested level of designation.

For the 2019 report, 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.[3] 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.

For the 2019 report, some hospitals conveyed difficulties meeting requirements that, in their judgement, did not provide adequate details. For example, some hospitals 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 maintained Neonatal frequently asked questions (FAQs) to provide needed clarifications to the current TAC rules.[4]

In addition to the Neonatal FAQ document, DSHS will propose revisions to the neonatal Level III §133.188(d)(5) and Level IV §133.189(d)(5) rule language to further clarify the Level III and IV anesthesiologist requirements to "direct and evaluate" anesthesia care provided to neonates, instead of "directly provide" anesthesia care.

Renewal Cycle of Designations – Improvements from 2019 Determinations

The renewal cycle of neonatal designations initiated in 2020 resulted in all facilities receiving their requested designation to date. For the 2019 cohort that received less than their requested designation, most hospitals maintained their post-appeal designation or in some cases achieved a higher level of designation.

The 42 hospitals initially designated at a lower level in 2019 are currently designated as follows:

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[3] 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 January 2022.

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

- Designation Status for a Hospital Initially Designated Level II with a Level III Application in 2019 (37 hospitals):
  - Awarded a Level III after a successful appeal during the facility's initial cycle and are currently Level III's - 10;
  - Operated at a Level II during the facility's initial cycle and achieved Level III with the re-designation - 10;
  - Operated at a Level II during the facility's initial cycle and renewed at a Level II on re-designation - 12;
  - Operated at a Level II during the facility's initial cycle until a change of ownership occurred and is currently a Level I - 2; and
  - Operated at a Level II during the facility's initial cycle until the perinatal services were consolidated into other hospitals within their healthcare system - 3.
- 2021 Designation Status for a Hospital Initially Designated Level III with a Level IV application in 2019 (5 hospitals):
  - Awarded a Level IV after a successful appeal during the facility's initial cycle and is currently a Level IV - 1;
  - Operated at a Level III during the facility's initial cycle and renewed at a Level III on re-designation and has access to a Level IV facility ranging from 100 feet to 38 miles – 4;

Improvement in Neonatal Care

The neonatal designated hospitals continue to expand and mature their neonatal programs to ensure quality care is delivered to the neonates to improve outcomes. DSHS documented some improvements between the initial and renewal cycle of designation applications. All 227 hospitals that applied or re-applied for designation were awarded their requested level of designation.

DSHS will continue to work with the PAC to fulfill its duties in developing and recommending criteria for designating levels of neonatal care. The PAC recommended and DSHS incorporated the following changes to the rules that are currently in the formal rulemaking process:

- Adopting telemedicine medical services for Levels I, II, and III that are in accordance with the standard applicable to the provision of the same service or procedure for an in-person setting.
- Allowing of a hospital to appeal a level of care designation to a three-person panel consisting of a representative of DSHS, a representative of the

commission, and an independent person who does not have a conflict of interest with the hospital, DSHS, or commission.
- Establishing conditional designation or a waiver from a level of care designation requirement.
- Utilizing professional practice standards for the timeliness of neonatal echocardiography performance and interpretation.
- Clarifying that anesthesiologists direct and evaluate neonatal anesthesia care provided at Level III and Level IV facilities.

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 2. Levels of Care Requirements Based on Certain Patient Population Descriptors.

Patient Population Descriptors	Level I Well Nursery	Level II Special Care Nursery	Level II 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
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 PAC heard testimony from stakeholders and allowed robust discussions regarding the Level III requirement of providing comprehensive care to infants of all gestational ages with mild to critical illnesses or requiring sustained life support during council meetings held in February, March, June, September, and November of 2020.

On December 25, 2020, the PAC submitted recommendations to DSHS for rule revision (see Appendix B for the PAC recommendation letter). The recommendations for rule revision included utilization of telemedicine, facility waivers for designation requirements, a three-person panel to review facility appeals, and timeliness of neonatal echocardiography performance and

interpretation. The PAC emphasized the need for outcomes data prior to making decisions on the Level III requirement of providing comprehensive care to infants of all gestational ages with mild to critical illnesses or requiring sustained life support. The PAC stated the following:

> *"We have heard much testimony from our stakeholders and had robust discussions on this issue at each meeting. However, we have also discussed the need for data to assess the impact of the current rules on neonatal and maternal morbidity and mortality prior to making any rule revisions. We do not know the current impact of the rules without this information. Rather than revising the rules on gestational age, the PAC recommends developing a statewide database with granular de-identified patient-based information, as data is needed in order to reach an evidence-based consensus on gestational age."*

DSHS and PAC members received a multitude of comments and witnessed extensive discussions from stakeholders regarding the gestational age for Level II and Level III designation requirements. The PAC determined data were necessary to assess the impact of the current rules on neonatal outcomes prior to supporting a recommendation to revise the rules. Accordingly, no changes were made to the Level III requirement of providing comprehensive care to infants of all gestational ages with mild to critical illnesses or requiring sustained life support, and the current rule language of "all gestational ages" will remain until the PAC is able to review outcome-based data to identify best practices. The rule language was not revised, in line with the PAC's recommendation; however, DSHS will convene an internal working group to assess existing data sources to assist the PAC in its review.

Geographic Considerations for Designation

The PAC and DSHS evaluated geographic resources and opportunities with an emphasis on providing and maintaining quality care. The PAC has recommended that geographic needs be looked at in the application and determination of waivers. See Appendix B for additional information.

A common difficulty for families is the distance they must travel to remain involved in their infant's care when they are transferred from rural facilities to more urban facilities with a higher designation. DSHS and the PAC continue to remind facilities that back transfer of infants to their home-based facilities, when clinically appropriate, eases burdens on the families. While some hospitals point to a

reluctance to do so because of stated resistance from insurance providers and managed care organizations, several facilities successfully complete back transfers. Current rules do not discourage or prevent this practice.

As of December 2021, a total of 227 neonatal facilities remain designated. Two rural hospitals discontinued providing maternal and neonatal services due to low patient volumes and financial feasibility. This highlights the challenges currently experienced by the rural facilities related to increased staffing demands and the increased cost of maintaining specialty services. The closure of these services causes maternal patients to travel outside of their communities to receive care and deliver their infants. Another factor affecting a decrease in facilities included reallocation of resources for maternal and neonatal services to other hospitals within their system located in the same urban area. These changes had minimal effects on patient access to care.

DSHS Actions and Next Steps

DSHS continues to collaborate with the PAC in adopting rules in line with the appeals, waiver, and telemedicine provisions in S.B. 749. The rules are currently in the Health and Human Services (HHS) rulemaking process and will be reviewed by the HHS Executive Council prior to being published as proposed rules in the *Texas Register*.

The COVID-19 pandemic significantly impacted hospitals in their ability to prepare for and undergo the designation process in 2020 and 2021. In response to the delays and changing environment, DSHS developed "virtual" survey guidelines that allowed survey organizations to continue conducting designation surveys and extension guidelines to allow hospitals to receive an extension to their designation expiration date. The designation expiration date extension for neonatal designated hospitals ensured eligibility for Medicaid reimbursement to continue until a survey could be performed for renewal of designation.

During the PAC meetings, stakeholders requested clarification of the expectations of evidence needed for compliance in the Quality Assessment and Performance Improvement (QAPI) requirements. DSHS initiated virtual meetings with perinatal stakeholders across the state to provide an open forum for hospitals to ask questions and discuss issues impacting the maternal and neonatal designation programs along with sharing best practices with other hospitals of similar

designation levels. Separate meetings were scheduled for the Level I and II perinatal hospitals and the Level III and IV perinatal hospitals.

In the 2021 meetings, DSHS provided education for completing designation applications, preparing for surveys, and building an effective QAPI Plan. A QAPI education series was developed for designated hospitals. The EMS/Trauma Systems Section Director will begin presenting the series during February 2022 perinatal meetings. DSHS will continue to conduct virtual stakeholder meetings to receive stakeholder questions and feedback. A compliance document for the revised neonatal rules and a tool kit with resources and documents to implement the QAPI Plan are currently in development by DSHS. Upon adoption of the neonatal rules, education on the rule amendments will be presented during the virtual meetings. The chair and vice-chair of the PAC are invited to attend and participate in both stakeholder meetings.

Level I neonatal hospitals perform a self-assessment survey for designation and therefore do not receive recommendations to improve their programs from surveyors. DSHS conducted onsite and virtual reviews with several Level I hospitals to evaluate their neonatal program, identify opportunities for improvement, and provide additional education and resources to the program managers to improve compliance with the designation requirements. The department will continue to schedule visits with the Level I designated hospitals to support advancing their neonatal programs.

DSHS is developing a new surveyor training course for all perinatal surveyors to address the rule revisions and the elements of a compliant neonatal QAPI Plan and process. DSHS continues to collaborate with the survey organizations to ensure the survey process is consistent among organizations and for survey performance improvement.

5. Conclusion

The Texas neonatal level of care requirements remain consistent with the nationally recognized and accepted American Academy of Pediatrics guidelines.

The renewal of neonatal designations began in late 2020 and continues through 2022. Currently, 177 facilities have applied for neonatal re-designation and have been awarded the level of care requested.

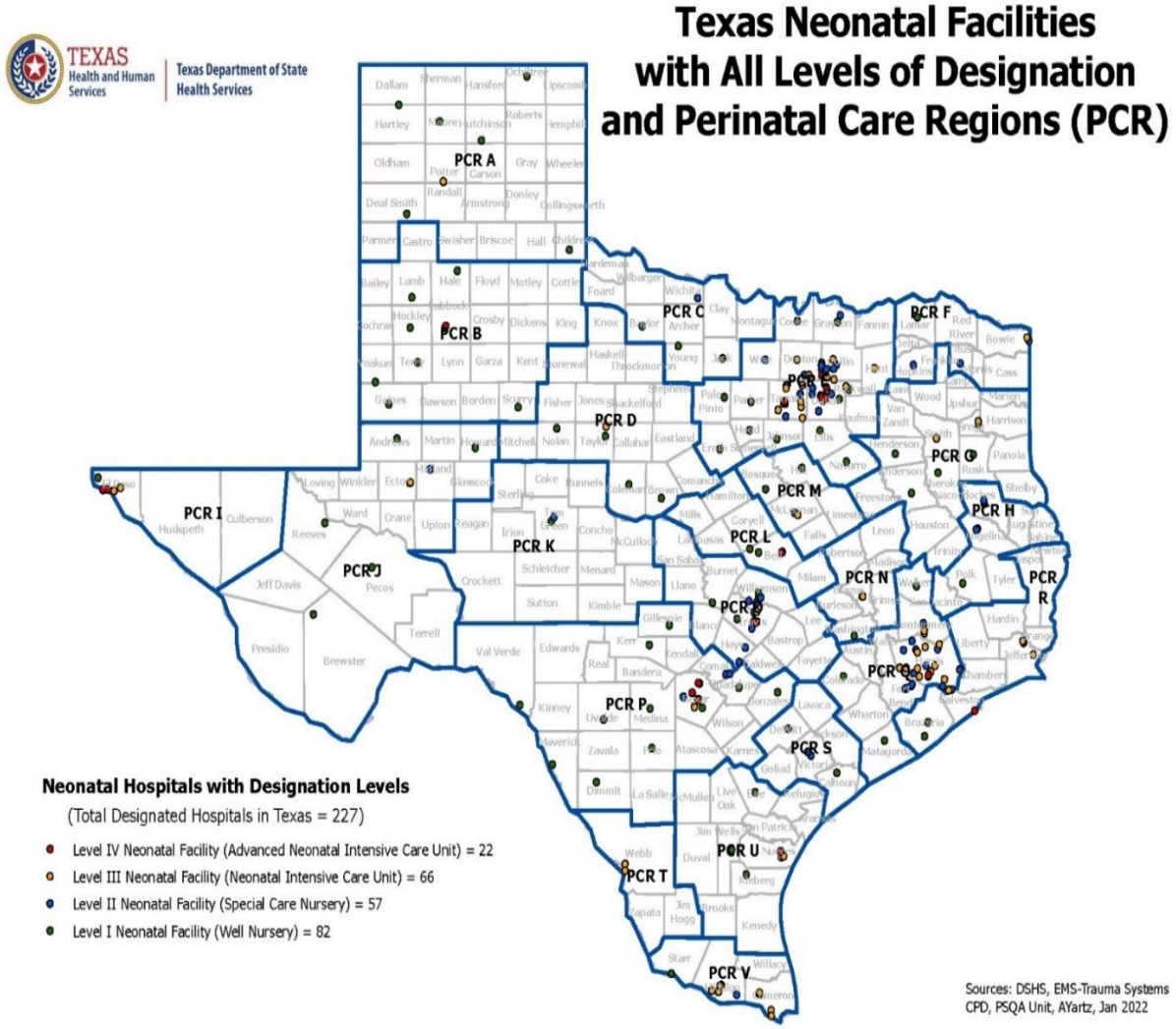
DSHS continues to make strides in implementing the neonatal designation process and supporting the PAC in making its recommendations for rules in line with S.B. 749. The rules are currently in the HHS rulemaking process and will be considered by the HHS Executive Council prior to being published as proposed rules in the *Texas Register*.

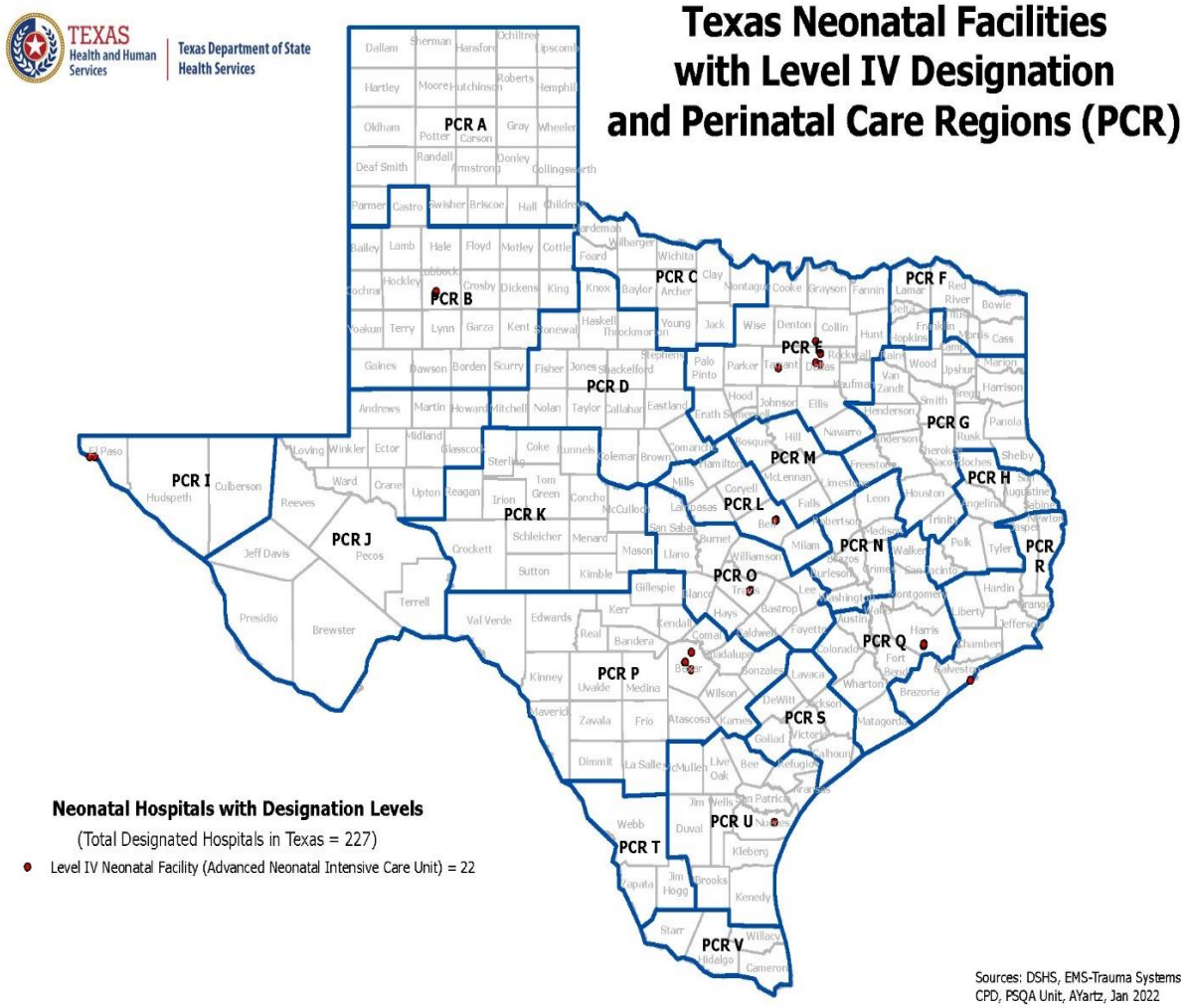
Facilities improved upon their performance in the renewal cycle of neonatal level of care designations. DSHS will continue to support and collaborate with the PAC as it continues to evaluate whether changes are needed to the rules to address identified designation barriers, as well as to reflect additional geographical considerations and more flexible gestational age requirements.

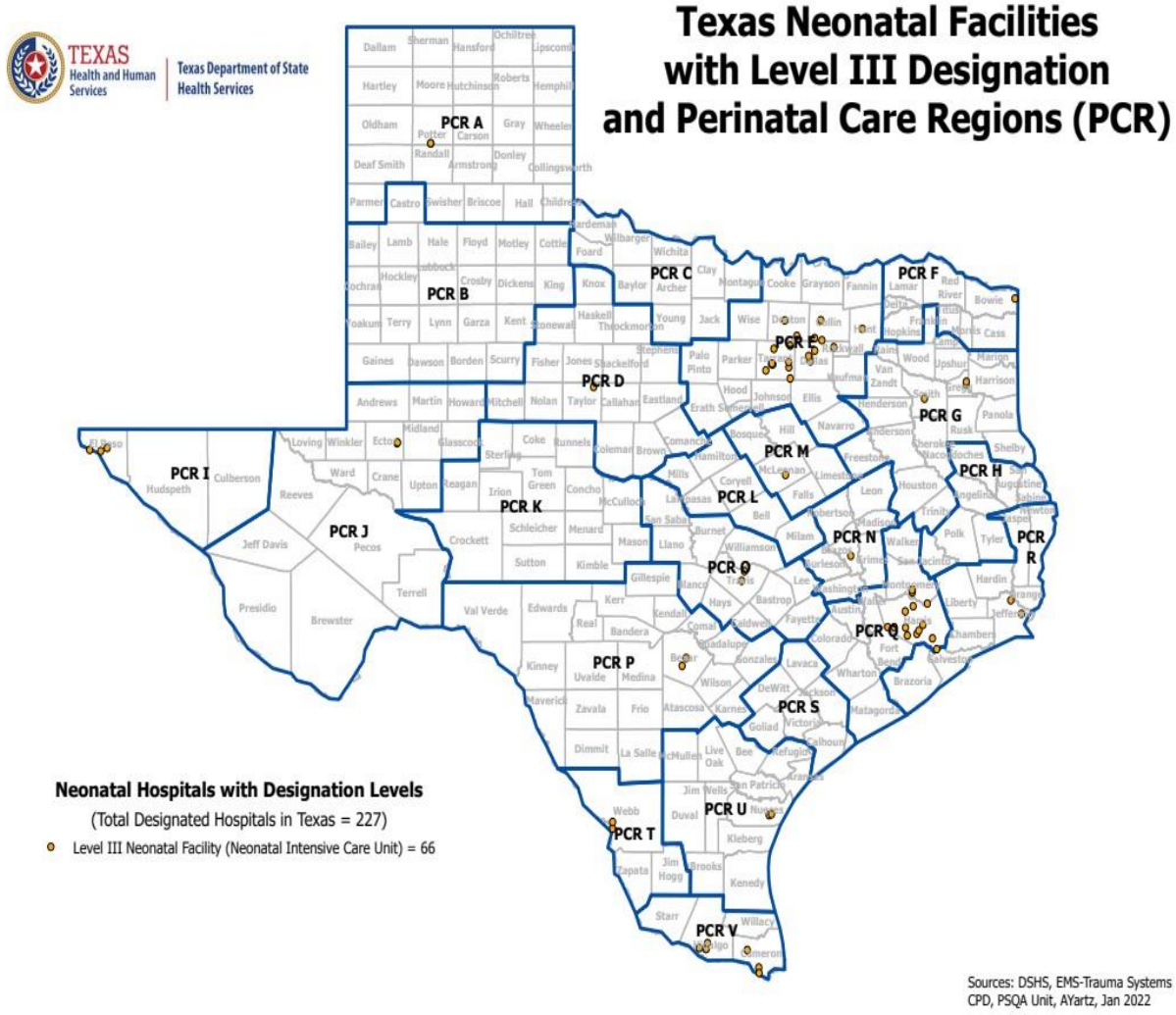
List of Acronyms

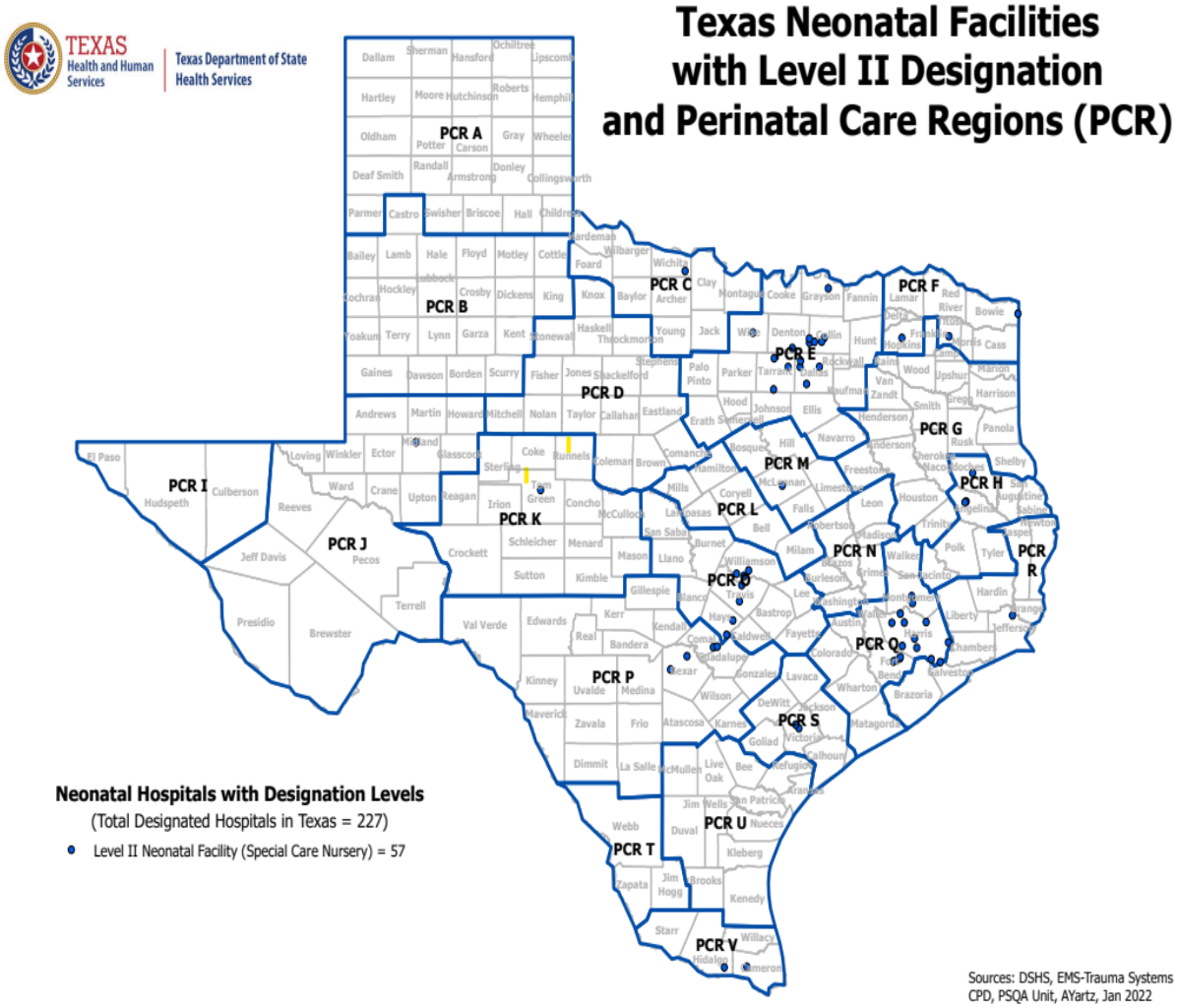
Acronym	Full Name
DSHS	Department of State Health Services
EMS	Emergency Medical Services
FAQ	Frequently Asked Questions
HHS	Health and Human Services
PAC	Perinatal Advisory Council
QAPI	Quality Assessment and Performance Improvement
SB	Senate Bill
TAC	Texas Administrative Code

Appendix A. Texas Map 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)
PCR A
PCR B
PCR C
PCR D
PCR E
PCR F
PCR G
PCR H
PCR I
PCR J
PCR K
PCR L
PCR M
PCR N
PCR O
PCR P
PCR Q
PCR R
PCR S
PCR T
PCR U
PCR V
Neonatal Hospitals with Designation Levels
(Total Designated Hospitals in Texas = 227)
Level IV Neonatal Facility (Advanced Neonatal Intensive Care Unit) = 22
Sources: DSHS, EMS-Trauma Systems
CPD, PSQA Unit, AYartz, Jan 2022


TEXAS
Health and Human Services
Texas Department of State Health Services
Texas Neonatal Facilities with Level III Designation and Perinatal Care Regions (PCR)
PCR A
PCR B
PCR C
PCR D
PCR E
PCR F
PCR G
PCR H
PCR I
PCR J
PCR K
PCR L
PCR M
PCR N
PCR O
PCR P
PCR Q
PCR R
PCR S
PCR T
PCR U
PCR V
Neonatal Hospitals with Designation Levels
(Total Designated Hospitals in Texas = 227)
Level III Neonatal Facility (Neonatal Intensive Care Unit) = 66
Sources: DSHS, EMS-Trauma Systems
CPD, PSQA Unit, AYartz, Jan 2022


TEXAS
Health and Human Services
Texas Department of State Health Services
Texas Neonatal Facilities with Level II Designation and Perinatal Care Regions (PCR)
PCR A
PCR B
PCR C
PCR D
PCR E
PCR F
PCR G
PCR H
PCR I
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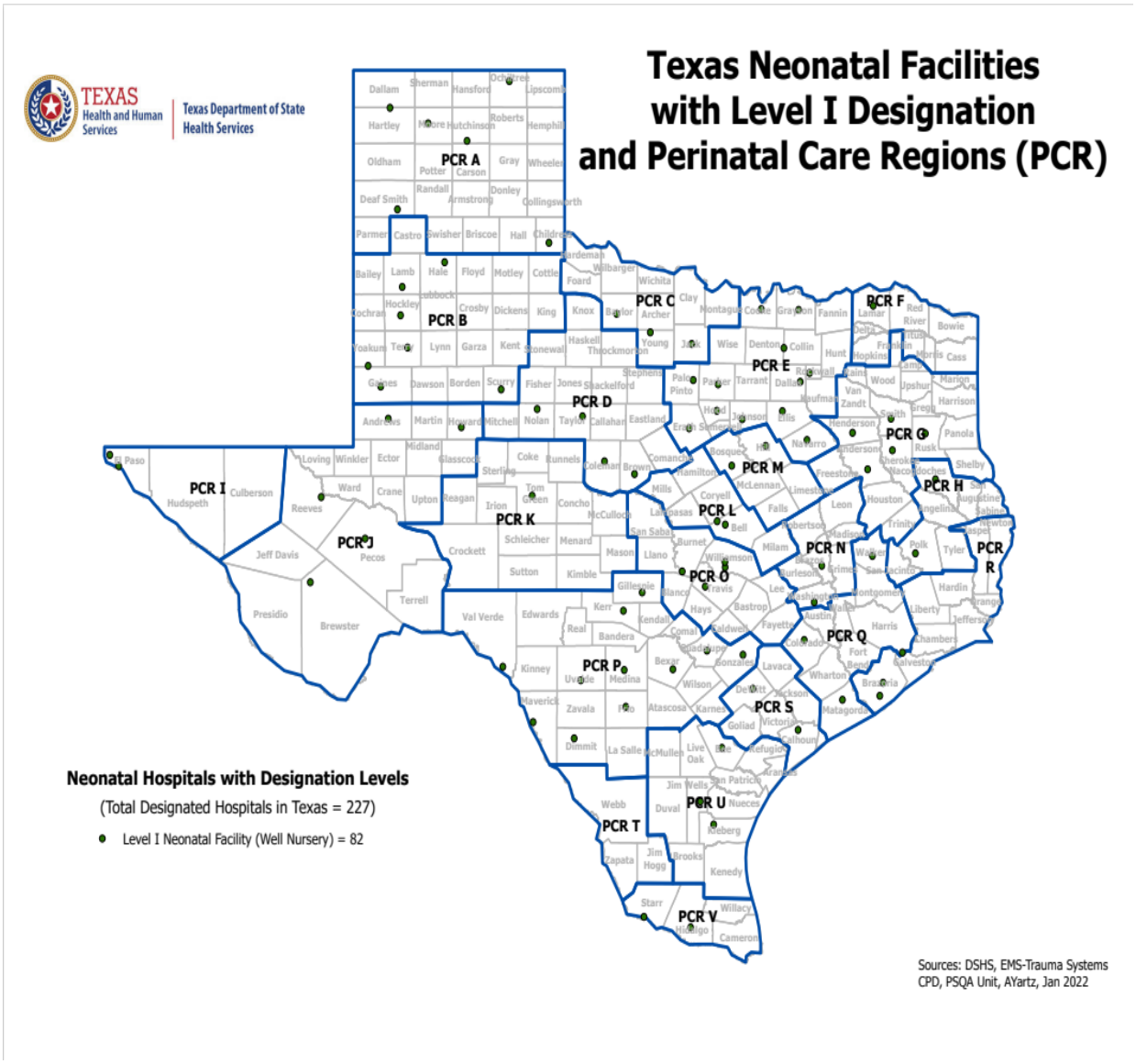
PCR V
Neonatal Hospitals with Designation Levels
(Total Designated Hospitals in Texas = 227)
Level II Neonatal Facility (Special Care Nursery) = 57
Sources: DSHS, EMS-Trauma Systems CPD, PSQA Unit, AYartz, Jan 2022


TEXAS
Health and Human Services
Texas Department of State Health Services
Texas Neonatal Facilities with Level I Designation and Perinatal Care Regions (PCR)
PCR A
PCR B
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PCR F
PCR G
PCR H
PCR I
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PCR K
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PCR N
PCR O
PCR P
PCR Q
PCR R
PCR S
PCR T
PCR U
PCR V
Neonatal Hospitals with Designation Levels
(Total Designated Hospitals in Texas = 227)
Level I Neonatal Facility (Well Nursery) = 82
Sources: DSHS, EMS-Trauma Systems
CPD, PSQA Unit, AYartz, Jan 2022

Appendix B. PAC Recommendation Letter sent to DSHS Commissioner on December 26, 2020

John Hellerstedt, MD
Executive Commissioner,
Texas Department of State Health Services
Austin, Texas

RE: Perinatal Advisory Council recommendations on SB 749, 86th legislative session

Dear Dr. Hellerstedt,

Thank you for your dedication and leadership over our state health services. We appreciate the opportunity to share our perspective on many issues, including those discussed in Senate Bill 749 as well as others repeatedly voiced during our meetings. For many years our Perinatal Advisory Council has actively worked to improve the care available to our Texas mothers and babies through providing guidance to the state on maternal and neonatal levels of care for hospital designation.

In this letter we will address telemedicine, gestational age recommendations, waivers, the appeals process, neonatal echocardiography, resuscitation, and board certification.

Senate Bill 749 requests that the Perinatal Advisory Council (PAC) provide guidance to the state on the subject of telemedicine. In our meetings, we discussed the need to determine which complex maternal or neonatal issues would necessitate consultation on site versus when telemedicine would be appropriate. The PAC membership discussed ACOG and AAP recommendations for telemedicine and how to modify the rules of designation in order to make telemedicine appropriate for Texas needs. We also discussed some of the intricacies of how facilities would meet these needs, including that MFM physicians should be involved in local drills to maintain the teamwork approach, among other details. In some of the stakeholder testimony, we received recommendations from the Texas District of ACOG on wording revisions for the rules of Level III maternal designation for MFM physicians as follows:

RULE §133.208 Maternal Designation Level III (d) (5):
(5) Maternal Fetal Medicine physician with inpatient privileges shall be available at all times for consultation and arrive at the patient bedside within 30 minutes of an urgent request to co-manage patients.

(a) If telemedicine is utilized for maternal fetal medicine co-management, the facility shall have:
(i) a written plan for the appropriate use of telemedicine in the hospital that is compliant with the Telehealth and Telemedicine as per the Texas Medical Board and Texas Occupations Code
(ii) A process for informed consent and agreement from the patient for this modality
(iii) the maternal fetal medicine physician has in-patient privileges at the facility, regularly participates in the on-site care of patients at the facility, has access to the patient's medical records, and participates in the QAPI process of the facility's maternal program
(iv) a process that monitors the processes and outcomes of the maternal telemedicine encounters

After further discussion, the Perinatal Advisory Council has recommendations specific to each maternal designation level regarding MFM consultation via telemedicine. We encourage the use of telemedicine when needed at Level I maternal designated facilities, a change from the current designation rules. Level II maternal designated facilities should continue to have MFM readily available at all times for consultation on site, by phone or by telemedicine, as needed. We recommend adopting the rules revisions from Texas ACOG as referenced above for Level III facilities. The PAC has no changes to recommend for telemedicine allowances at Level IV maternal designated facilities.

Additionally, we recognize areas medically underserved and in 'digital deserts' have limited availability of medical specialties. In *Obstetrics & Gynecology* from Aug 2020 (136:317-22), deploying audio-only virtual prenatal visits in two-thirds of the Parkland Hospital prenatal population increased access to care, satisfied patients, and did not result in an increase in adverse perinatal outcomes in more than 6,000 pregnant women delivered during the COVID-19 pandemic in 2020 (PubMed ID (PMID): 32544144). Audio-only virtual options are acceptable as a supplement to in-person visits and should not be viewed as in lieu of in-person visits. Having reviewed limited studies looking to identify worsened outcomes for audio-only consultation over the use of video virtual visits, the PAC was unable to find an issue and recommends employing audio-only virtual visits as a viable virtual option.

The PAC reviewed the guidelines for telemedicine for neonatal designated facilities. The neonatal designation rules currently have no verbiage regarding telemedicine for Level I and II facilities. The PAC

agrees that prearranged consultative agreements can be performed by using telemedicine technology and/or telephone consultation, for example from a distant location. Although there is no mention of telemedicine for Level I and II neonatal designated facilities in AAP guidelines or the current rules, we would encourage the use of telemedicine to provide additional support services at Level I and II neonatal designated facilities through prearranged consultative agreements, and recognize the need for QAPI to review services and outcomes to ensure high quality care continues being provided. Level III and IV neonatal designated facilities should continue to follow current AAP guidelines, requiring no neonatal rules revisions in regards to telemedicine.

Senate Bill 749 also requests that the PAC provide guidance to the state on the subject of gestational age at certain levels of neonatal care. We have heard much testimony from our stakeholders and have had robust discussions on this issue at each meeting. However, we have also discussed the need for data to assess the impact of the current rules on neonatal and maternal morbidity and mortality prior to making any rule revisions. We do not know the current impact of the rules without this information. Rather than revising the rules on gestational age, the PAC recommends developing a statewide database with granular de-identified patient-based information, as data is needed in order to reach an evidence-based consensus on gestational age. We recommend considering cost-savings as an approach to funding of this statewide database.

On the subject of waivers to the rules of designation, Senate Bill 749 requests the perspective of the PAC. This process involves a consideration of waivers for facilities who did not obtain the level of care designation for which they applied, or for facilities in a geographic area of need. **We must maintain quality in the care of our Texas mothers and babies, while allowing for appropriate access to high quality care.** In the state's deliberations on the appropriateness of a requested waiver, the PAC recommends taking into account this consideration prior to granting any waiver.

Regarding any appeals, for fairness of the process and efficiency of completion, Senate Bill 749 mandates a 3-person panel to review each hospital's appeal. The membership of this panel is already documented in the rules, stating there will be a member of the department, a member of the commission, and an independent member with expertise in the specialty who is not a state employee and has no conflict of interest with the hospital, department, or commission.

However, the determination of the independent member is not delineated. The PAC recommends that DSHS defines this process and allows for transparency of the process by including this detail posted on their website.

The PAC has also discussed the wording of the rules regarding timeliness of echocardiography performance and interpretation at neonatal facilities. Concerns were raised that the current wording in the rules requests pediatric cardiology consultation and interpretation of echocardiography within one hour of an urgent request. Rather than stating a time that has no known foundation in evidence-based medicine, we recommend the wording be revised to reflect that pediatric echocardiography with pediatric cardiology interpretation and consultation be completed within a time period consistent with current standards of professional practice (mirrors the wording in other sections of the rules).

Another topic of discussion at our last two meetings centers around resuscitation courses. We discussed revising the rules language regarding Advanced Cardiovascular Life Support to include the resuscitation course offered by the American Red Cross in addition to the one offered by the American Heart Association. The PAC recommends revising this rule to allow for any adult resuscitation course provided by a nationally accredited organization (neonatal rules would not be revised).

Finally, we received written testimony and verbal testimony from the Texas ACOG and PAC members regarding the need to have improved consistency regarding board certification of members of the maternal care team. We heard testimony for Level II and Level III Maternal Designation to be modified to include MFMs who are board eligible. (Board eligible in this section is defined as an obstetrics and gynecology physician who has completed an obstetrics and gynecology residency and is eligible for board certification according to the applicable board.) We also heard testimony for Level III and Level IV Maternal Designation (**RULE §133.209 Maternal Designation Level IV (d) (13) (C)**) to be modified to include anesthesiologists with board eligible status; and Level IV Maternal Designation (**RULE §133.209 Maternal Designation Level IV (d) (3)**) to be modified to include OB/Gyns with board eligible status. The PAC recommends the following changes to the rules document.

For Level II maternal designated facility, a board certified or board eligible maternal fetal medicine physician shall be available at all times for consultation. For Level III maternal designated facility, a board

certified or board eligible Maternal Fetal Medicine physician with inpatient privileges shall be available at all times for consultation and arrive at the patient bedside within 30 minutes of an urgent request to co-manage patients. For Level IV maternal designated facilities, a board certified or board eligible obstetrics and gynecology physician with maternal privileges shall be on-site at all times and available for urgent situations.

For Level III and Level IV maternal designated facilities, a board certified or board eligible anesthesiologist with training and/or experience in obstetric anesthesia, including critically ill obstetric patients, must be available for consultation at all times, and arrive at the patient bedside within 30 minutes for urgent requests. However, for Level IV maternal designated facilities we recommend to be a board certified anesthesiologist with training and/or experience in obstetric anesthesia to be in charge of obstetric anesthesia services.

Thank you again for the opportunity to share our perspective on these issues. We are hopeful that you will receive this feedback in the constructive manner in which it is intended.

Respectfully,

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