



Perinatal Advisory Council Report on Determinations and Recommendations

**As Required By
H.B. 15, 83rd Legislature (Regular Session, 2013) and
H.B. 3433, 84th Legislature (Regular Session, 2015)**

**Health and Human Services Commission
September 2016**

Table of Contents

| | |
|----------------------------------------|-----|
| 1. Executive Summary | 1 |
| 2. Introduction | 3 |
| <i>Additional Council Task</i> | 5 |
| 3. Background..... | 5 |
| <i>Future Council Activities</i> | 6 |
| 4. Conclusion | 7 |
| Appendix A | A-1 |
| Appendix B:..... | B-1 |
| Appendix C:..... | C-1 |
| Appendix D:..... | D-1 |
| Appendix E:..... | E-1 |

Appendices

Appendix A: Formal correspondence regarding proposed Neonatal Rules

Appendix B: Formal correspondence regarding proposed Neonatal Rules

Appendix C: Annual Report from NICU Council

Appendix D: References

Appendix E: Highlights of Perinatal Advisory Council Meetings (2014 to 2016)

1. Executive Summary

Pursuant to House Bill (H.B.) 15, 83rd Legislature, Regular Session, 2013, the Texas Health and Human Services Commission (HHSC) established the seventeen-member Perinatal Advisory Council. The council develops and recommends criteria for designating neonatal and maternity levels of care, develops and recommends a process for assignment of levels of care to a hospital, recommends dividing the state into perinatal care regions, examines neonatal and maternal care utilization trends, and makes recommendations related to improving neonatal and maternal outcomes.

H.B. 3433, 84th Legislature, Regular Session, 2015, added two rural representatives to the council, bringing the total number of members to 19. H.B. 3433 also extended the deadlines for the neonatal designation by one year to September 1, 2018, and maternity designation by one year to September 1, 2020.

The council expires on September 1, 2025.

The council consists of 17 individuals representing neonatal and obstetric healthcare providers, and hospital representatives, who were appointed in the winter of 2013, and two rural members, who were added to the council in the winter of 2015 as directed by H.B. 3433. Additionally, two subcommittees were formed to enhance rural and private practice obstetrics input for maternity levels of care.

The Perinatal Advisory Council met 16 times in Austin from January 2014 to June 2016. The council received an abundance of stakeholder input from throughout the state, reviewed many publications, and had numerous presentations. Based on this rigorous process, the council made recommendations to the Department of State Health Services (DSHS) for neonatal levels of care standards in June 2014. Based on these recommendations, DSHS provided a draft of neonatal designation rules in July 2014. DSHS scheduled stakeholder meetings for input, and the council meetings also sought feedback from stakeholders over the following months. In response to these stakeholders meetings and feedback received, DSHS further refined the proposed rule language and published those proposed rules in the November 20, 2015, issue of the *Texas Register*.

The council made recommendations for the neonatal proposed rules in two letters:

- Texas HHSC Perinatal Advisory Council Comments on Proposed Neonatal Designation Rules (Level I facilities), dated December 19, 2015; (Appendix A) and
- Texas HHSC Perinatal Advisory Council Comments to Proposed Neonatal Designation Rules, submitted December 14, 2015, (Appendix B:).

The new rule, Hospital Level of Care Designations for Neonatal Care was adopted and published in the June 3, 2016, edition of the *Texas Register*. These rules can be found in [Texas Administrative Code \(TAC\) Title 25, Part 1, Chapter 133, Subchapter J](#). The rule became effective June 9, 2016.

The council began work on the maternity levels of care draft standards during its last two meetings in 2015. The council anticipates that it will make recommendations for maternity levels of care designation standards by December 2016. Similar to the inclusive and collaborative process used for the neonatal care recommendations, the council strongly recommends a process of receiving abundant input from stakeholders throughout the state, and particularly from rural areas. The council's future activities include the following:

- Finalize the recommendations for maternity levels of care standards,
- Provide continued support related to the neonatal designation process;
- Promote best practices;
- Identify potential unintended consequences from neonatal designation rules; and
- Make recommendations for outcome parameters.

The council will also provide a forum for discussion and make recommendations for the designation of Centers of Excellence of Fetal Diagnosis and Therapy Designation (H.B. 2131 84th Legislature, Regular Session, 2015). Ten individuals representing maternal fetal medicine, pediatric surgery, nursing, neonatology, and ethics were appointed to the subcommittee in June 2016.

2. Introduction

In 2013, H.B. 15 established a Perinatal Advisory Council, which is tasked to develop and recommend criteria for designating neonatal and maternity levels of care, develop and recommend a process for assignment of levels of care to a hospital, recommend dividing the state into perinatal care regions, examine neonatal and maternal care utilization trends, and make recommendations related to improving neonatal and maternal outcomes.

During the following legislative session, H.B. 3433 added two rural representatives to the council. It also extended the deadlines for the neonatal designation by one year to September 1, 2018, and maternity designation by one year to September 2, 2020.

H.B. 2131, 84th Legislature, Regular Session, 2015, established a Centers of Excellence for Fetal Diagnosis and Therapy subcommittee, to advise the council in the development of rules to establish the criteria that a health care entity or program in Texas must meet to receive designation as a Center of Excellence for Fetal Diagnosis and Therapy.

These activities are designed to ensure that maternal and newborn care is provided commensurate with the needs of the mother and baby and care is provided in a more rational and coordinated manner. The end result of these efforts will be improved birth outcomes in the state.

A report by the council is due to DSHS and the HHSC Executive Commissioner, by Sept 1, 2016. The council expires on September 1, 2025.

Formation of the Council and Council Makeup

H.B. 15 required the Executive Commissioner to create and appoint the members to the council and designate a chairperson. Per H.B. 15, council membership includes the following:

- Four neonatologists, at least two of whom must practice in a Level IIIC neonatal intensive care unit;
- One general pediatrician;
- Two general obstetrician-gynecologists;
- Two maternal fetal medicine specialists;
- One family medicine physician who provides obstetrical care and practices in a rural community;
- One representative from a children's hospital;
- One representative from a hospital with a Level II neonatal intensive care unit; and
- One representative from a rural hospital.

The council includes health-care providers who serve pregnant women and newborns, with a focus on newborn needs in the neonatal intensive care unit (NICU), including pediatricians, obstetrician-gynecologists, maternal fetal medicine specialists, neonatologists, children's hospital representatives, and rural providers.

Former Executive Commissioner Kyle Janek, MD appointed the following individuals to the Perinatal Advisory Council in the winter of 2013:

- Dr. Eugene Toy, Chair – Obstetrician /Gynecologist;
- Dr. Emily Briggs, Vice Chair – Family medicine physician delivering in a rural area;
- Dr. Frank Cho – Neonatologist /Level IIIC NICU;
- Ms. Barbara Greer, RN, MSN, NE-BC – Children’s hospital representative;
- Dr. Lisa Hollier – Maternal-Fetal Medicine;
- Dr. Dynio Honrubia – Neonatologist;
- Dr. Sanjay Patel – Neonatologist;
- Dr. George Saade – Maternal Fetal Medicine;
- Dr. Michael Speer – Neonatologist;
- Dr. Michael Stanley – Pediatrician/Neonatologist;
- Mr. Steve Woerner – Children’s hospital representative;
- Annette Perez, RN –General hospital representative;
- Dr. John Harvey – Neonatologist;
- Dr. Charleta Guillory – Pediatrician; and
- Mr. Allen Harrison – representative from a hospital with Level II NICU.

Since inception, various council members resigned their position because they moved away from Texas or their clinical demands became too great. These included:

- Dr. Michael Cardwell, who resigned his position in 2014 when moving out of state, and was replaced with Dr. Elly Xenakis;
- Dr. Dynio Honrubia, who resigned his position in 2015 and was replaced by Dr. Cynthia Blanco;
- Ms. Iris Torvik, who resigned her position in 2015, and was replaced by Cristina Stelly, RN; and
- Ms. Chrisine Stelly, who resigned her position in 2016 when moving out of state.

Staff is in the process of recommending a replacement for Ms Stelly's position.

As directed by H.B. 3433, 84th Legislature, Regular Session, 2015, two additional rural members were added to the council in winter 2015. These included:

- Dr. Alyssa Molina, family medicine physician in a rural area, Eagle Lake; and
- Ms. Sandra Rivers, RN, rural hospital representative, Sweetwater.

Thus, as of July 2016, the current make-up of the Perinatal Advisory Council consists of:

- Dr. Eugene Toy, Chair – Obstetrics-gynecology, Houston;
- Dr. Emily Briggs – family medicine physician who provides obstetrical care in a rural community, New Braunfels;
- Dr. Elly Xenakis – maternal fetal medicine, San Antonio; and
- Dr. Frank Cho – neonatologist in Level III or IV NICU, Austin.

- Dr. Sanjay Patel – Rural Hospital Representative, Odessa
- Ms. Barbara Greer, RN – nurse with expertise in perinatal health, Benbrook
- Dr. Charleta Guillory – pediatrician, Houston
- Mr. Allen Harrison – representative from a hospital with Level II NICU, Austin
- Dr. John Harvey – neonatologist from rural area, Amarillo
- Dr. Lisa Hollier – obstetrics-gynecology, Houston
- Dr. Cynthia Blanco – neonatologist in Level III or IV NICU, San Antonio
- Ms. Annette Perez, RN – general hospital representative, El Paso
- Dr. George Saade – maternal fetal medicine, Galveston
- Dr. Michael Stanley – neonatologist, Richardson
- Mr. Steve Woerner – children’s hospital representative, Corpus Christi
- Dr. Michael Speer – Ex-officio, Houston
- Ms. Sandra Rivers, RN – Rural Hospital Representative, Sweetwater
- Dr. Alyssa Molina – family medicine physician who provides obstetrical care in a rural community, Eagle Lake

Additional Council Task

Based on H.B. 2131, the DSHS with consultation from the Perinatal Advisory Council is to designate one or more facilities or programs as Centers of Excellence for Fetal Diagnosis and Therapy in Texas. The HHSC Executive Commissioner, in consultation with DSHS and the council, shall adopt rules for such designation. DSHS in consultation with the council is to appoint a subcommittee to make recommendations on the rules for the designation. H.B. 2131 specified that the rules be adopted by March 1, 2017. The HHSC Executive Commissioner appointed the following members to this subcommittee in June 2016:

- Dr. Michael A. Belfort, Maternal Fetal Medicine, Houston;
- Dr. Jorge D. Blanco, Maternal Fetal Medicine, Midland;
- Dr. Frank Cho, Ex-Officio Chair, Austin;
- Ms. Lisa Mason, RN, Dallas;
- Dr. Laurence McCullough, Ethicist, Houston;
- Ms. Yvette A. McDonald, RN, Round Rock;
- Dr. Kenneth J. Moise, Jr. Maternal Fetal Medicine, Houston;
- Dr. Jonathan NedreLOW, Neonatologist, Ft. Worth;
- Dr. Oluyinka Olutoye, Pediatric Surgeon, Sugar Land and
- Dr. KouJen Tsao, Pediatric Surgeon, Houston.

3. Background

H. B. 2636, 81st Legislature, Regular Session, 2011, created the Neonatal Intensive Care Unit (NICU) Council, which was the precursor to the Perinatal Advisory Council. The NICU Council submitted a report detailing the background information on perinatal issues in Texas, including definition of terms. Appendix C: includes the final report.

In deliberating over the complicated issues of neonatal standards of care and best practices, the Perinatal Advisory Council met in Austin eight times in 2014, five times in 2015, and three times from January to June 2016 (with three additional dates scheduled in July-December 2016). The council reviewed many publications and had numerous presentations. Appendix D: and Appendix E: include references and summary information from these meetings.

Using the last draft of the neonatal levels of care from the previous NICU Council, the Perinatal Advisory Council continued work on refining the recommendations. Based on the many documents reviewed, presentations provided, and extensive discussions among experts in the field, the council made recommendations of levels of care and provided those recommendations to DSHS in June 2014. DSHS drafted rule language and published those proposed rules in the November 20, 2015, edition of the *Texas Register*.

The Perinatal Advisory Council provided feedback to DSHS in the form of two correspondences: one included the rules in general, and the second addressed level I facilities. These correspondences are found in Appendix A and Appendix B:.

The council began work on the maternity levels of care draft standards in late 2015.

Formal Council Recommendations

The council made recommendations for the neonatal levels of care and provided these to DSHS in June 2014. These recommendations resulted in DSHS posting the first draft of proposed Hospital Level of Care Designations for Neonatal Care in August 2014.

After DSHS held several stockholder meetings on the proposed rule, the council made recommendations for the neonatal proposed rules in two letters:

- Texas HHSC Perinatal Advisory Council Comments on Proposed Neonatal Designation Rules (Level I facilities), dated December 19, 2015, (Appendix A); and
- Texas HHSC Perinatal Advisory Council Comments to Proposed Neonatal Designation Rules, submitted December 14, 2015, (Appendix B:).

The council anticipates making recommendations for maternity levels of care designation standards by December 2016.

The council strongly recommends continuing the process of seeking input from stakeholders throughout the state and particularly from rural areas.

Future Council Activities

1. **Maternity Levels of Care.** During the remainder of calendar year 2016, the council plans to primarily work on finishing its maternity designation levels of care standards and deliver those recommendations to DSHS. The council wants to be inclusive in this process, including getting input from rural hospitals, community hospitals, and outlying areas.

2. **Supporting Neonatal Designation Process.** Members of the council will participate in the webinars held by DSHS to help support the designation process. Perinatal Advisory Council meetings will continue to be venues for education from DSHS and opportunities to provide clarification and education. The council is well aware DSHS handles designation and makes decisions regarding compliance.
3. **Promote Best Practices.** The council will continue to identify and develop best practices in both neonatal care and maternity care. These practices should promote the highest level of healthcare for our Texas mothers and infants and also encourage wise use of limited resources, for cost-effective care.
4. **Identify Potential Unintended Consequences from Neonatal Designation Rules.** Despite lengthy and numerous discussions, stakeholders meetings, and input from many different individuals and institutions, there may be unintended consequences with any regulation, particularly a set of rules as comprehensive and complex as the Neonatal Levels of Care Designation Rules. The council will continue to review the Neonatal Designation Rules and provide a forum for input.
5. **Recommend Outcome Parameters.** A large part of assuring improved healthcare quality is that each individual facility have a robust quality improvement process, and track key outcome parameters. The council will discuss and make recommendations of key outcome parameters for hospitals at each level to consider tracking. These should be clearly defined, easily tracked, and demonstrate evidence-based links to quality, morbidity, or mortality.
6. **Provide a Forum for Discussion for Centers of Excellence of Fetal Diagnosis and Therapy Designation.** H.B. 2131 authorized a subcommittee to make recommendations for a process of designation for Centers of Excellence of Fetal Diagnosis and Therapy. The council will hear periodic reports of progress from this subcommittee, offer input, and allow for public discussion on this topic. When the subcommittee has provided its final recommendations, the council will review and discuss those recommendations, seek stakeholder input, and make formal recommendations to DSHS.
7. **Other Tasks as requested by Executive Commissioner.** The council will perform other tasks consistent with its purpose if requested by DSHS or the Executive Commissioner.

4. Conclusion

The Perinatal Advisory Council was established to continue the work of the NICU Council. The activities of the NICU Council and Perinatal Advisory Council are designed to ensure that maternal and newborn care is provided commensurate with the needs of the mother and baby, and care is provided in a more rational and coordinated manner. Eventually, Medicaid reimbursement for deliveries and newborn stays will be contingent on hospitals having DSHS designation. The end result of these efforts are improved birth outcomes.

The council's deliberations led to recommendations to DSHS which resulted in the adoption of new Hospital Level of Care Designations for Neonatal Care published in the June 3, 2016, edition of the *Texas Register*. The rule became effective June 9, 2016.

During the remainder of calendar year 2016, the council plans to primarily work on finishing its maternity designation levels of care standards, and deliver those recommendations to the Department by December 2016.

H.B. 2131 authorized a subcommittee to make recommendations for a process of designation for Centers of Excellence of Fetal Diagnosis and Therapy. The council will hear periodic reports of progress from this subcommittee, offer input, and allow for public discussion on this topic. When the subcommittee has provided its final recommendations, the council will review and discuss those recommendations, seek stakeholder input, and make formal recommendations to DSHS.

Appendix A

December 19, 2015

Jane Guerrero, Office of EMS/Trauma Systems Coordination
Health Care and Quality Section, Division of Regulatory Services
Department of State Health Services
Mail Code 1876, P.O. Box 149347
Austin, Texas 78714-9347

Sent via email: Jane.Guerrero@dshs.state.tx.us

RE: Proposed Rules Establishing Chapter 133. Hospital Licensing. Subchapter J. Hospital Level of Care Designations for Neonatal and Maternal Care (Level I facilities)

Dear Ms. Guerrero:

It has come to our attention that some level I facilities, especially in rural communities, are asking for the gestational age cut-off for level I facilities be "relaxed" because a strict 35 week and higher gestational age cut-off would cause undue burden on their families and patients, and increase healthcare and family personal cost. There also seems to be a misconception that the rules as currently written would require a transfer even if a transport would be deemed unsafe (such as weather-related issues). We would like to respond to these concerns.

1. The national guidelines, based on a large amount of scientific and medical evidence (Guidelines for Perinatal Care for many editions including current 7th ed, as well as the American Academy of Pediatrics national standards including Oct 2012), clearly indicate that the scope of level I facilities should be limited to uncomplicated and healthy infants at or greater than 35 weeks' gestation. One publication in the AAP Journal Pediatrics outlines the high incidence of complications, morbidity and mortality of these infants, some of the medical and nursing issues, and establishes the basis of this long-standing recommendation (Engle WA, Tamashek KM, Wallman CM, and the Committee on Fetus and Newborn. "Late-preterm" infants: a population at risk. Pediatrics 2007;120(6):1390-1401) - attached.

(a) Late preterm infants, as defined as between 34w+0d and 35w+6d gestational age, often have a weight similar to term infants and may be treated by parents, care-givers, and healthcare professionals as though they are developmentally mature and at low risk for morbidity. This may include being cared for at a level I nursery or with their mother after birth; these practices were common previously, but today, we recognize the hazards. For example, even subtle hypoglycemia can affect the infant's brain and cognitive development. Thus, today, we are more careful in monitoring these infants.

(b) In reality, when compared to term infants, late preterm infants are physiologically and metabolically immature, and have a higher risk of morbidity and mortality, and

readmission rate. Some of the complications are subtle and experienced personnel are better in detection and timely intervention. For instance, there can be long-lasting developmental deficits if hypothermia or hypoglycemia is unrecognized and untreated.

(c) In fact, physiologically a 34 week infant behaves more like a 32 week neonate than a 36 week infant. For these reasons, the standard of care in most hospitals is for an infant that is born at less than 35 weeks gestation to be admitted to the NICU for monitoring and assessment for complications for at least 24 hours, and the majority stay in the NICU for addressing respiratory issues, feeding issues, or hyperbilirubinemia.

(d) As compared to term infants, multiple studies and pooled data show late preterm infants have a 3-fold increased risk of sepsis, 3-9x higher likelihood to require mechanical ventilation, 12x more likely to have apnea, more likely to be admitted to NICU (one large study showed 88% at 34 weeks and 54% at 35 weeks), 4.6x increased risk of neonatal death, and 2-3x increased risk of readmission and post-discharge morbidity especially if discharged early [< 2 days]. Also are also often feeding difficulties, jaundice, and hypoglycemia.

(e) Recent advances in our understanding of apnea of prematurity have led to a current standard of care of cardiorespiratory monitoring of all infants less than 35 weeks for apnea due to 20 percent incidence of apnea in a 34 week gestation infant. A level I facility would generally not have staff, personnel or equipment for this monitoring.

2. The clinical standard of care regarding level I facilities caring for infants of 35 weeks or greater gestational age is based on our current understanding of what is appropriate and best for our patients. For more than 20 years, that standard, consistent with the national standard, is that infants even uncomplicated that are below 35 weeks gestation should be cared for at a level II or higher facility for the safety of the infant. This is because the physicians and nurses at level II or higher facilities are accustomed to detecting complications at an earlier stage and more likely to initiate timely intervention to address these issues. These hospitals have the appropriate support staff, equipment, and expertise to provide the requisite multi-faceted care, counseling and follow-up.

3. There are definite inconveniences and even issues of access for transfer/travel for patients and their families in rural level I hospitals (for instance, some are 75-100 miles away from the nearest level II or higher facility). We want to be sensitive to and support those hospitals and communities.

4. Throughout the deliberations and discussions during our Perinatal Advisory Council meetings, we have been deeply committed to finding solutions that provide flexibility in ways that do not jeopardize patient safety. We have continuously recognized the importance for our Texas hospitals and providers to be able provide care for the state's diverse communities. We value our rural hospitals.

5. Most importantly, our highest priority is the safe care for patients (infants).

Based on this information above (points 1-5), our council believes that the vast majority of infants below 35 weeks gestation should be cared for at a level II or higher facility. Based on the incidence of complications and readmissions in this population, we believe that it is both the best care and most cost-effective care. We recognize and appreciate the challenges faced by some rural hospitals/providers and their communities. We have been supportive of difficult situations faced by rural hospitals and have agreed to many changes to the proposed rules to accommodate their needs over the course of the past year.

We strongly recommend against changing the Neonatal Designation Rules that would universally allow **all** level I facilities to care for infants less than 35 weeks, because this would lower the Texas neonatal level of care **below** the national standard of care, and jeopardize the health and well-being of these infants. Level I facilities located in communities where there are no access issues to level II/III facilities, such as in urban or suburban centers, should care for uncomplicated infants equal to or exceeding 35 weeks.

We do not believe that issues of transport (such as weather hazards) require changing of the rule language. It is uniformly accepted that if the danger of transport is excessive, then a facility should exercise prudence and continue to care for the infant at their facility until transport is safe. This practice should not be viewed as violating any regulation.

We do not believe that level I facilities, even rural ones that are remote, should care for infants below 34 weeks gestation (even uncomplicated, because of the high complication rates in these infants), but stabilize and transport as expeditiously as safety allows.

In summary, our council would strongly prefer that level I facilities care for neonates at or above 35 weeks gestation for patient safety reasons. However, because of access issues such as those level I facilities being 75-100 miles away from the nearest higher level facility, if a rural level I hospital chooses to care for neonates between 34 to 35 weeks, then they should do so in a formal written fashion and demonstrate the expertise, personnel, and support staff that would be within the level of care that would be delivered at a higher level facility. This should include:

(a) A written program plan defining the scope of their neonatal service and how they will triage neonates less than 35 weeks gestation for transfer versus retention.

(b) Assure that their nurses, providers, and support staff have the expertise and current knowledge and skill, including maintaining and documenting competency, to care for late preterm infants to identify problems early, initiate appropriate intervention, and/or arrange for timely transfer if needed.

(c) Assure the appropriate counseling of the parents/guardians on the care and monitoring of these infants and arrange for appropriate follow-up.

(d) Document how they will ensure that the hospital care will optimize the infant's health and development, minimize morbidity, and minimize readmission.

(e) Conduct a 100 percent chart review of their preterm infants on a monthly basis, preferably together with a neonatologist or pediatrician with experience with preterm infants, and report that outcome data.

(f) Engage in a collaborative program with a higher level facility to ensure appropriate infrastructure, consultation, and quality assurance.

(g) For hospitals that have a large volume of neonatal care less than 35 weeks gestation, a self-attestation may not be sufficient, and a site visit may be required to assure the presence of sufficient care.

Our desire is for the best care for the newborns in Texas while being sensitive to the difficulties faced by rural hospitals. For instance, we understand the pain of a postpartum mother being separated from her newborn baby due to transfer, or the burden of a family needing to travel many miles away due to neonatal transfer. We would love to work collaboratively with any hospital that wishes to care for infants less than 35 weeks, and to provide any advice and recommendations on how to meet access challenges while ensuring patient safety. Our rural hospitals and care takers are crucially important to the neonatal care of the state.

If you have further questions, please contact me.

Sincerely,



Eugene Toy, MD
Chair, Perinatal Advisory Council

Eugene.c.toy@uth.tmc.edu

Appendix B:

Texas HHSC Perinatal Advisory Council Comments to PROPOSED NEONATAL DESIGNATION RULES

posted to the Texas Register (Vol 40, No 47) published Nov 20, 2015

Submitted to Jane Guerrero, Office of EMS/Trauma Systems Coordination, DSHS on Dec 14, 2015

| Heading | Section | Texas Register Page | Issue | Recommended change | Rationale |
|----------------------|------------------------------------------------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| General Requirements | § 133.183 General Requirements; Level IV (c) (4) (A) | 40 Tex Reg Page 8098 | A single facility cannot take care of any and all medical problems; we should keep with the national guidelines of a level IV facility | (A) Provide care for 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; | Delete “with any medical problems” to keep with national guidelines of the “most complex and critically ill” of a level IV facility |

| Heading | Section | Texas Register Page | Issue | Recommended change | Rationale |
|---------------------|-----------------------------------------------|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Designation Process | § 133.184 Designation Process (d) (4) (B) | 40 Tex Reg Page 8099 | Level II, III or IV facilities may not have had their site survey and will be designated a level I. Clarification of “level I designation” should be level I “until the site survey is completed” and not for the default 3 years | Add the phrase “until the survey is completed”; (B) Any facility that has not completed an on-site survey to verify compliance with the requirements for a Level II, III or IV designation at the time of application must provide a self-survey and attestation and will receive a Level I designation until the site survey is completed . The office at its sole discretion may recommend... | Specify the temporary level I designation pending site survey rather than imply that the facility is permanently at “Level I designation” for 3 years even after site survey is done. |
| Designation Process | § 133.184 Designation Process (e) and (e) (1) | 40 TexReg Page 8099; | Regions or Regional Advisory Councils should not be influencing a facility’s designation or the appeal process, but decisions should be made on the basis of whether requirements are met or not met. Add what may be | (e) If a facility disagrees with the level(s) determined by the office to be appropriate for initial designation or re-designation, it may make an appeal in writing not later than 60 days to the director of the office. The written appeal must include a signed letter from the facility's governing board with an explanation as to why the facility believes it | HB 15 has no certificate of need for designation. Also, during stakeholder meetings during legislative session, there was agreement from all involved that the regions and the RACs would not influence designation, so letter from PCR or RAC may |

| Heading | Section | Texas Register Page | Issue | Recommended change | Rationale |
|---------|---------|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | <p>included in written appeal: “as to why the facility believes it meets the requirements for the designation level.”</p> <p>Suggest deleting references about PCR, RACs or EMS.</p> | <p>meets the requirements for the designation level. the designation at the level determined by the office would not be in the best interest of the citizens of the affected PCR or the citizens of the State of Texas.</p> <p>(1) The written appeal may include a signed letter(s) from the executive board of its PCR or individual healthcare facilities and/or EMS providers within the affected PCR with an explanation as to why designati</p> | <p>seem to introduce potential for some hospitals to influence outcomes of designation (RAC leadership may be dominated by one hospital system for example)</p> |

| Heading | Section | Texas Register Page | Issue | Recommended change | Rationale |
|----------------------|------------------------------------------------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>on at the level determined by the office would not be in the best interest of the citizens of the affected PCR or the citizens of the State of Texas.</p> | |
| Program Requirements | § 133.185 Program Requirements (b) (2) (C) | 40 TexReg Page 8100; | Ensure appropriate follow-up for at risk infants born at any level (I-IV) by adding the language “and ensure appropriate follow-up for at risk infants” as a requirement. | Add “ensure appropriate follow-up for at risk infants” to (C) written triage, stabilization and transfer guidelines for neonates and/or pregnant/postpartum women that include consultation and transport services, and ensure appropriate follow-up for at risk infants. | At risk infants such as Down syndrome, cleft lip/palate can be born at any level facility and these infants need appropriate follow-up |
| Level I | § 133.186 Neonatal Medical Director Level I; (c) (4) | 40 TexReg Page 8101 | Neonatal providers “whose credentials have been reviewed by | (4) The primary physician, advanced practice nurse and/or physician assistant with special competence in the | NMD is usually not the one to approve privileges but can provide input and |

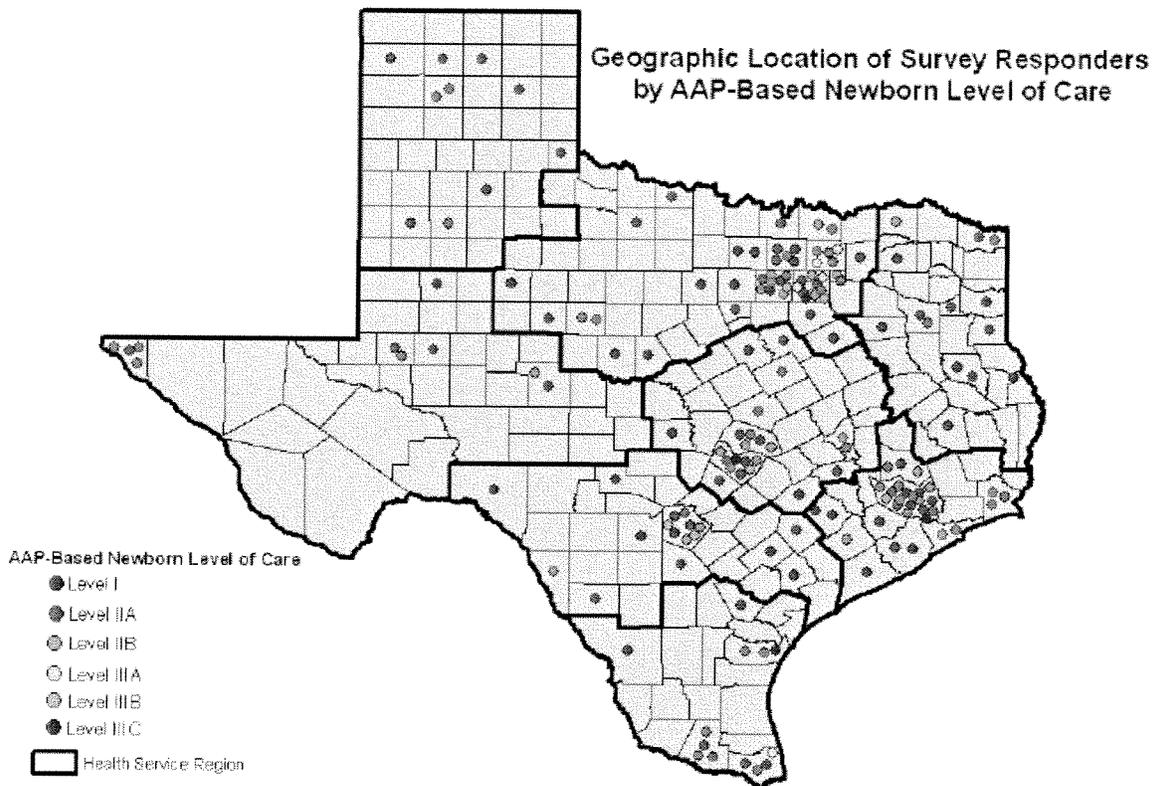
| Heading | Section | Texas Register Page | Issue | Recommended change | Rationale |
|----------|----------------------------------------------------------------------------|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | the NMD” rather than persons “who have been approved by the NMD”, since often in hospitals, the NMD doesn’t “approve privileges” but reviews the credentials. | care of neonates, whose credentials have been reviewed who has been approved by the NMD and is on call, and: | review credentials. This should also be changed in level II (page 8102 – (c) (4)), Level III (page 8103 – (d) (4)), and Level IV (Page 8104 – (d) (4)). |
| Level II | § 133.187 Neonatal Designation Level II; (b) (1) Neonatal Medical Director | 40 TexReg Page 8102 | A BC/BE pediatrician is typically not trained to be a medical director of a level II. Suggest delete “or board eligible/certified pediatrician” from the NMD criteria #1, and the pediatrician NMD is allowed via criteria #2 | (b) Neonatal Medical Director (NMD). The NMD shall be a physician who is: (1) a board eligible/certified neonatologist, or board eligible/certified pediatrician with experience in the care of neonates/infants and demonstrates a current status on successful completion of the Neonatal Resuscitation Program (NRP); or | A BC/BE pediatrician such as one just graduated from residency does not have sufficient training in NICU to be medical director of a level II facility. However the criteria in (b) (2) allows for pediatricians with 2 years of experience taking care of premature infants to be NMD |
| Level II | § 133.187 Neonatal Designation Level II; (c) (5) | 40 TexReg Page 8102 | Anesthesia services with pediatric experience is not needed at a level II since | Suggest clarifying that neonatal surgery or complicated invasive procedures should require level III or higher care. | This may be best placed in the Program Requirements rather than level II since it may |

| Heading | Section | Texas Register Page | Issue | Recommended change | Rationale |
|-----------|---------------------------------------------------|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Anesthesia services | | neonatal surgery and complicated invasive procedures should not be performed at level II facilities, and are performed at level III or higher facilities | (5) Neonatal surgery or complicated invasive procedures require the same level of care as a higher level facility including on-site continuous presence of neonatal provider, anesthesia services with pediatric experience, pediatric surgical and pediatric medical subspecialty care. | be confusing, and considered permissive for level II facilities to consider performing neonatal surgery. Anesthesia requirements should be same as level I |
| Level III | § 133.188 Neonatal Designation Level III; (a) (2) | 40 TexReg Page 8103 | Transfer for surgery should take into account geographic proximity via the issue of timeliness in transfer; the reason for “an appropriate level” and not “higher level” is because it may be transfer to another level III with surgical capability (same level). | (2) have access for consultation to a full range of pediatric medical subspecialists and pediatric surgical specialists, and the capability to perform major pediatric surgery on-site or through arrangement for appropriate timely transfer including accounting for transit time to a higher level-an appropriate designated facility; | While geography is not the only factor, it should be one factor considered; this is in the national guidelines “taking into account geographic proximity. The issue is timeliness (amount of time required in the process and potential transfer delays) which may impact on the neonate’s health. |

| Heading | Section | Texas Register Page | Issue | Recommended change | Rationale |
|-----------|---------------------------------------------------|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| Level III | § 133.188 Neonatal Designation Level III; (d) (4) | 40 TexReg Page 8103 | Neonatal provider needs to be on-site and ALSO AVAILABLE . As currently written, the availability is not stipulated; add “and available” | Add “and available”: (4) At least one of the following neonatal providers shall be on-site and available at all times, and includes pediatric hospitalists, neonatologists, and/or neonatal nurse practitioners, as appropriate, who have demonstrated competence in management of severely ill neonates/infants, whose credentials have been reviewed who has been approved by the NMD and is on call, and: | Just being on-site does not mean they are available, need to make it clear their primary responsibilities are to the NICU patients |
| Level III | § 133.188 Neonatal Designation Level III; (d) (5) | 40 TexReg page 8103 | Simple invasive procedures don’t need anesthesiologist; Add “complicated” to “invasive procedures” to read: “complicated invasive procedures” | (5) When neonatal surgery or complicated invasive procedures are required, anesthesiologists with pediatric expertise, shall directly provide the anesthesia care to the neonate, in compliance with the requirements found in §133.41(a) of this title (relating to Hospital Functions and Services). | Simple invasive procedures such as chest tube don’t need anesthesia, so we should specify “complicated invasive procedures” |

| Heading | Section | Texas Register Page | Issue | Recommended change | Rationale |
|-----------|--------------------------------------------------------|---------------------|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Level III | § 133.188 Neonatal Designation Level III; (d) (10) (A) | 40 TexReg Page 8104 | Personnel trained in imaging need to be available at all times but not onsite all times; suggest delete “on-site” | Delete “on site” (A) personnel appropriately trained in the use of x-ray equipment shall be onsite and available at all times; personnel appropriately trained in ultrasound, computed tomography, magnetic resonance imaging, and/or cranial ultrasound, echocardiography equipment on-site and available at all times; fluoroscopy shall be available; | Personnel who use x-rays should be onsite and available at all times, but other imaging personnel don’t need to be onsite 24/7, but they do need to be available at all times; Same change in level IV (page 8105, (d) (11) (A)) |
| Level III | § 133.188 Neonatal Designation Level III; (d) (11) | 40 TexReg Page 8104 | Option of “occupational or physical therapist” to alternative to speech pathologist | (12) Speech language pathologist and/or occupational or physical therapist with neonatal/infant experience shall be available to evaluate and manage feeding and/or swallowing disorders. | OT or PT with appropriate training/experience is acceptable for this role in feeding/swallowing issues |

Figure 8 Geographic Location of Hospitals by AAP-Based Level of Care



Source: OPDS Newborn Level of Care Survey 2012

Prepared by: Texas Department of State Health Services, Family and Community Health - Office of Program Decision Support - 09/06/2012

Appendix 3

HIGHLIGHTS OF NICU Council Meetings (2012)

- **March 27, 2012** – H.B. 2636 reviewed, introduction of members, introduction of HHSC and DSHS staff. Thorough review of the Quality of Care surveys by Dr. Rebecca Martin demonstrated the lack of standardization of NICU definitions in the state, and also some missing information from some hospitals. There was general consensus that neonatal care for those infants of Very Low Birthweight (VLBW, i.e., < 1500 g) infants were best cared for in a level III (highest level) NICU. A NICU Standards subcommittee was established. There was discussion that the new NICU levels of care would be released in fall 2012. Dr. Toy appointed Dr. Brenda Morris, neonatologist from Tyler, TX as Vice Chair of Council.
- **May 14, 2012** – Dr. Rebecca Martin continued the review of the Hospital Quality of Care surveys and identified 16 hospitals that did not meet minimal standards for level 1 care as defined by the American Academy of Pediatrics (AAP). There was discussion regarding the need to investigate the reasons these hospitals did not meet minimal standards. There was agreement that the AAP standards should be used to assess levels of care in Texas. The NICU Subcommittee discussed their beginning to construct a template for levels of care, discussion about the phrase “continuously available” referring to neonatologists, and need to be aware of 2012 four levels of care to be released in fall 2012. There was general consensus that the council would recommend standards based on evidence, on current national standards, and be based on the best interest for patients in Texas. The council unanimously agreed that standards for NICU’s were necessary for patient care, reimbursement standardization, and quality of care. The council also unanimously agreed that maternity levels of care should be established, since the appropriate maternal transfer leads to better neonatal outcomes compared to neonatal transfer. The council reviewed the *New England Journal of Medicine* article (Phibbs et al, 2007) which reported that neonatal mortality was lowest when VLBW infants were born in Level III (highest) NICUs which also had high volume (>100 admissions per year). An Obstetrical Standards Subcommittee was established to develop the maternal levels of care criteria.

After the obstetrical and neonatal survey results were administered by the DSHS, in May 2012, there were 24 hospitals which were identified as not meeting even minimal standards (level I). Dr. Toy telephoned each facility and spoke to the Chief Nursing Officer or Chief Medical Officer at each hospital to clarify the issues. Of the 24 hospitals, 6 had erroneously filled out the survey. For instance, one level I facility stated: “Did not take care of infants > 2500 g”. Upon written correction of this error, the hospital was removed from the non-compliant list. Of the 18 remaining hospitals, there were various issues such as not having neonatal or maternal transport protocols, not

having the ability to consult an anesthesiologist for complicated or emergency situations, or not having nursery trained nurses. Each hospital was advised of the importance of these requirements, and each provided written verification of remedy, such that by July 2012, all hospitals met at least minimal standards for neonatal or maternity care. Uniformly, each hospital was grateful to have the opportunity to correct deficiencies and acknowledged that their level and quality of care had improved through the process. This example is the microcosm of the anticipated increased quality of care when the formal neonatal and maternity levels of care will be implemented.

- **July 24, 2012** – The council reviewed the NICU Standards subcommittee report and entertained the possibility of telemedicine for subspecialty consultation in NICU's. The maternal levels of care subcommittee reviewed a template progressing from level I (lowest= basic care) to level IV (highest). The concept was level I = basic care encompassing deliveries of gestational ages >35 weeks, level II = gestational ages > 32 weeks gestational age, level III = all gestational ages and able to care for maternal critical illnesses, and level IV = Advanced NICU center that had special capabilities such as ECMO (Extra Corporeal Life Support) or caring for complex congenital heart disease. Level III or IV facilities may have the further responsibility of education and coordination of care of the region. The council unanimously agreed that a standard for being able to start a cesarean for every maternity hospital is 30 minutes. There was discussion about the need for reporting of data that is uniform, and also that a Quality Improvement process be in place for every perinatal hospital. Dr. Toy noted that he called several of the hospitals identified as not meeting the minimal standards based on the Hospital Survey, and all of the hospitals corrected their deficiencies; these included hospital transfer protocols, availability of anesthesiologist consultation in case of problems, and nursery trained nurses. These findings have already elevated the standard of care for these hospitals. Ms. Jane Guerrero, Director of EMS/Trauma at DSHS explained their regionalization system and the process. A best practice subcommittee was established. The concept was discussed that the standards recommended by the council could be used more universally than only relating to Medicaid patients.
- **September 10, 2012** – The new 2012 Neonatal Levels of Care policy statement published by the AAP was reviewed. There was ample discussion about the various definitions such as “continuously available”, availability of subspecialists, and question about whether advanced practice nurse practitioners could meet the definition of “continuously available”. There was acknowledgement that the article of NICU levels of care was a summary and would be expanded in the “Guidelines for Perinatal Guidelines, 7th edition” scheduled for release in Oct 2012. There was discussion that only 48.9% of Texas VLBW babies were born in a level III NICU, which ranked Texas in the bottom 5% states in the country. There was consensus about maternal and infant transfer protocols that needed to be in place, coordination among children's hospitals, obstetrical

hospitals and NICUs, and the need for back transfers from high levels of care back to home institution. Dr. Martin presented alarming statistics about the very high maternal mortality rates in Texas, which are 15 deaths/100,000 births, which is higher than the national average of 13/100,000. This rate is higher in African-American women and in urban centers. This racial difference is true for both maternal mortality and neonatal and infant mortality rates. The council worked on defining terms within the AAP Guidelines. There was general agreement that as much as feasible the council should use the AAP Guidelines, but since no national guidelines are “all encompassing”, there may need to be some flexibility in application since Texas is large and diverse in its geographic and healthcare composition. There was discussion about the need for cooperation and collaboration among hospitals in transfer relationships, and reimbursement from third party payers for back transfers.

- **October 16, 2012:** March of Dimes information was reviewed, including 400,000 infants born in Texas annually of which 13% require higher level of care. Currently there are no NICU standards so there is no clarity for care and reimbursement. The council agreed that the reporting of outcomes should be more regularly than annually. There was discussion regarding how to assure the correct requirements for each neonatal level of care and agreement that delivery volume, number of VLBW admissions, and average daily census may be used. The application of standards was discussed and it was agreed that for level III NICUs, an advanced neonatal nurse practitioner being in house with a neonatologist being readily available would be acceptable – provided that neonatologist is not “on call” for multiple institutions such that two simultaneous emergencies could not be sufficiently addressed. Discussions were held to develop processes allowing the use of telemedicine and prudent referrals so that there can be flexibility for smaller rural communities, but not allow abuse such as subpar “consultations” from remote locations that may satisfy the “rule” but not render quality care. There was agreement about the need for an in-house neonatologist in a level IV (highest level) facility. The importance of making induced hypothermia available in level III and IV NICUs with expertise was discussed, since there is good evidence that infants with ischemic brain injury have better outcomes with this treatment. Maternal levels of care were fine tuned and examples were given for each level of care. Best practice subcommittee continued to give examples of immunizations and therapeutic hypothermia as important. Ms. Kathy Perkins Director of Regulatory Services at DSHS gave a thorough presentation on the trauma and stroke designation and verification processes, and recommended that the NICU Council adopt this language. There are 22 regions for Trauma Care in Texas. Public comment was held. Various methods of verification were discussed with the recommendation being an outside reviewing body such Joint Commission for more advanced levels of care, with the site visit paid by the hospital. The concept of a Regional Advisory Council (RAC) looking out for the well being of the community was discussed.

- **November 12, 2012 Meeting:** Dr. Morris gave a presentation with a summary of NICU standards including clarification of some terminology that she reviewed with Dr. Lu-Ann Papile, Chair of the AAP Committee on the Fetus and the Newborn. She also reviewed an article authored by Dr. Paul Wise entitled “Neonatal Healthcare policy: promise and perils of reform.” The council then discussed ways of keeping with the national standards, but being somewhat flexible in the implementation of those standards. One example discussed was a level II nursery in a rural area that may serve the community with no other level II or higher hospital for hundreds of miles. If that rural hospital doesn’t have high enough volume, there may be ways of cross training, education, simulation, or other collaboration with other hospitals to maintain their skills. Meanwhile the outcomes would be monitored. Public comment revolved around clarification of next steps, recommendation to include hospitals in the implementation process, discussing that HHSC has already implemented decreased payment for NICU services by its new DRG payment system, and to consider flexibility in allowing family physicians to be medical co-directors of level II nurseries in rural areas. A timeline for implementation was described as 2 to 2 ½ years. A recommendation was made for the implementation and regionalization to be flexible enough to not disrupt existing referral patterns. A recommendation was made to reimburse for telemedicine since this technology would be essential in providing subspecialist care in rural areas. The regional advisory councils have not been formed yet and should be sufficiently small enough to understand and advocate for local and community needs. Each council member was also given the opportunity to describe his/her most pressing concern.

Appendix 4

References

Acolet D, Elbourne D, McIntosh N, et al. Confidential Enquiry Into Maternal and Child Health. Project 27/28: inquiry into quality of neonatal care and its effect on the survival of infants who were born at 27 and 28 weeks in England, Wales, and Northern Ireland. *Pediatrics*. 2005;116(6):1457–1465

Angrist JD, Imbens GW, Rubin DB. Identification of causal effects using instrumental variables. *J Am Stat Assoc*. 1996;91(434):444–455

American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. Guidelines for perinatal care. 7th ed. Elk Grove Village (IL): American Academy of Pediatrics and the American College of Obstetricians and Gynecologists; 2012

American Academy of Pediatrics. Section on Transport Medicine. Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients. 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012

Attar MA, Lang SW, Gates MR, Iatrow AM, Bratton SL. Back transport of neonates: effect on hospital length of stay. *J Perinatol*. 2005;25(11):731–736

Audibert F. Regionalization of perinatal care: did we forget congenital anomalies? *Ultrasound Obstet Gynecol*. 2007;29(3):247–248

Baiocchi M, Small DS, Lorch S, Rosenbaum PR. Building a stronger instrument in an observational study of perinatal care for premature infants. *J Am Stat Assoc*. 2010; 105(492):1285–1296

Berry MA, Shah PS, Brouillette RT, Hellmann J. Predictors of mortality and length of stay for neonates admitted to children's hospital neonatal intensive care units. *J Perinatol*. 2008;28(4):297–302

Blackmon LR, Barfield WD, Stark AR. Hospital neonatal services in the United States: variation in definitions, criteria, and regulatory status, 2008. *J Perinatol*. 2009;29(12):788–794

Blackmon L. The role of hospital of birth on survival of extremely low birth weight, extremely preterm infants. *NeoReviews*. 2003;4:e147–e157.

Bartels DB, Wypij D, Wenzlaff P, Dammann O, Poets CF. Hospital volume and neonatal mortality among very low birth weight infants. *Pediatrics*. 2006;117(6):2206–2214

- Bode MM, O'shea TM, Metzguer KR, Stiles AD. Perinatal regionalization and neonatal mortality in North Carolina, 1968-1994. *Am J Obstet Gynecol*. 2001;184(6):1302–1307
- Britton CV; American Academy of Pediatrics Committee on Pediatric Workforce. Ensuring culturally effective pediatric care: implications for education and health policy. *Pediatrics*. 2004;114(6):1677–1685
- Burstein DS, Jacobs JP, Li JS, et al. Care models and associated outcomes in congenital heart surgery. *Pediatrics*. 2011;127 (6). Available at: www.pediatrics.org/cgi/content/full/127/6/e1482
- Clement MS. Perinatal care in Arizona 1950–2002: a study of the positive impact of technology, regionalization and the Arizona perinatal trust. *J Perinatol*. 2005;25 (8):503–508
- Centers for Disease Control and Prevention (CDC). Neonatal intensive-care unit admission of infants with very low birth weight- 19 States, 2006. *MMWR Morb Mortal Wkly Rep*. 2010;59(44):1444–1447
- Clark SL, Belfort MA, Dildy GA, Herbst MA, Meyers JA, Hankins GD. Maternal death in the 21st century: causes, prevention, and relationship to cesarean delivery. *Am J Obstet Gynecol* 2008;199:36.e1–5.
- Chung JH, Phibbs CS, Boscardin WJ, Kominski GF, Ortega AN, Needleman J. The effect of neonatal intensive care level and hospital volume on mortality of very low birth weight infants. *Med Care*. 2010;48(7):635–644
- Cifuentes J, Bronstein J, Phibbs CS, Phibbs RH, Schmitt SK, Carlo WA. Mortality in low birth weight infants according to level of neonatal care at hospital of birth. *Pediatrics*. 2002;109(5):745–751
- Committee on fetus and newborn. Levels of neonatal care. *Pediatrics* 130(3):587-97, published online August 27, 2012.
- Committee on Perinatal Health. *Toward Improving the Outcome of Pregnancy: Recommendations for Regional Development of Maternal and Perinatal Health Services*. White Plains, NY: March of Dimes National Foundation; 1976.
- Committee on Fetus and Newborn/American Academy of Pediatrics. Levels of neonatal care. *Pediatrics*. 2006;114:1341–1347.
- Dobrez D, Gerber S, Budetti P. Trends in perinatal regionalization and the role of managed care. *Obstet Gynecol*. 2006;108(4):839–845
- Eichner JM, Johnson BH; Committee on Hospital Care. American Academy of Pediatrics. Family-centered care and the pediatrician's role. *Pediatrics*. 2003;112(3 pt 1):691–697

Fetus and Newborn Committee/Canadian Paediatric Society. Levels of neonatal care. *Paediatr Child Health*. 2006;11:303–306.

Gallagher J, Botsko C, Schwalberg R. Influencing Interventions to Promote Positive Pregnancy Outcomes and Reduce the Incidence of Low Birth Weight and Preterm Infants. Washington, DC: Prepared for March of Dimes by Health Systems Research, Inc; 2004.

Gould JB, Marks AR, Chavez G. Expansion of community-based perinatal care in California. *J Perinatol*. 2002;22(8):630–640

Gould JB, Sarnoff R, Liu H, Bell DR, Chavez G. Very low birth weight births at non-NICU hospitals: the role of sociodemographic, perinatal, and geographic factors. *J Perinatol*. 1999;19(3):197–205

Goodman DC, Fisher ES, Little GA, Stukel TA, Chang CH. Are neonatal intensive care resources located according to need? Regional variation in neonatologists, beds, and low birth weight newborns. *Pediatrics*. 2001;108(2):426–431

Hankins GD, Clark SL, Pacheco LD, O’Keefe D, D’altonD’Alton M, Saade G. Maternal mortality, near misses, and severe morbidity: lowering rates through designated levels of maternity care. *Obstet Gynecol* 2012; 120(4):929-34.

Heron M, Sutton PD, Xu J, Ventura SJ, Strobino DM, Guyer B. Annual summary of vital statistics: 2007. *Pediatrics*. 2010;125 (1):4–15

Howell EM, Richardson D, Ginsburg P, Foot B. Deregionalization of neonatal intensive care in urban areas. *Am J Public Health*. 2002;92(1):119–124

Howell EA, Holzman I, Kleinman LC, Wang J, Chassin MR. Surfactant use for premature infants with respiratory distress syndrome in three New York city hospitals: discordance of practice from a community clinician consensus standard. *J Perinatol*. 2010;30(9):590–595

Howell EA, Hebert P, Chatterjee S, Kleinman LC, Chassin MR. Black/white differences in very low birth weight neonatal mortality rates among New York City hospitals. *Pediatrics*. 2008;121(3). Available at: www.pediatrics.org/cgi/content/full/121/3/e407

Indiana Perinatal Network. Levels of hospital perinatal care in Indiana. Indianapolis (IN): 2008.

Institute of Medicine. Preterm Birth: Causes, Consequences, and Prevention. Washington, DC: National Academies Press; 2007

Johansson S, Montgomery SM, Ekblom A, et al. Preterm delivery, level of care, and infant death in Sweden: a population-based study. *Pediatrics*. 2004;113(5):1230–1235

Kattwinkel J, Cook LJ, Nowacek G, et al. Regionalized perinatal education. *Semin Neonatol* 2004;9(2):155–165

Kahn J, Linde-Zwirble W, Wunsch H, et al. Potential value of regionalized intensive care for mechanically ventilated medical patients. *Am J Respir Crit Care Med.* 2008;77:285–291.

Kaaja RJ, Greer IA. Manifestations of chronic disease during pregnancy. *JAMA.* 2005;294(21):2751–2757

Lasswell SM, Barfield WD, Rochat RW, Blackmon L. Perinatal regionalization for very low-birth-weight and very preterm infants: a meta-analysis. *JAMA.* 2010;304(9):992–1000

Lemons J, Lockwood C, eds. *Guidelines for Perinatal Care.* 6th ed. Elk Grove Village, IL: American Academy of Pediatrics and American College of Obstetrics and Gynecology; 2008.

Lessaris K, Annibale D, Southgate M, Hulseley T, Ohning B. Effects of changing health care financial policy on very low birth weight neonatal outcomes. *South Med J.* 2002;95:426–430.

Lorch SA, Baloochi M, Ahlberg CE, Small DS. The differential impact of delivery hospital on the outcomes of premature infants. *Pediatrics* 2012; 130:270-278.

Lorch SA, Myers S, Carr B. The regionalization of pediatric health care. *Pediatrics.* 2010;126(6):1182–1190

Lorch SA, Maheshwari P, Even-Shoshan O. The impact of certificate of need programs on neonatal intensive care units. *J Perinatol.* 2012;32(1):39–44

Lorch SA, Silber JH, Even-Shoshan O, Millman A Use of prolonged travel to improve pediatric risk-adjustment models. *Health Serv Res.* 2009;44(2 pt 1):519–541

March of Dimes. *Toward Improving the Outcome of Pregnancy III: Enhancing Perinatal Health Through Quality, Safety, and Performance Initiatives (TIOP3).* White Plains, NY: March of Dimes Foundation; 2010

March of Dimes Peristats. Rates of preterm birth by state, final 2010 and preliminary 2011. <http://www.marchofdimes.com/peristats/>. Accessed June 25, 2012.

Martin JA, Menacker F. Expanded health data from the new birth certificate, 2004. *Natl Vital Stat Rep.* 2007;55(12):1–22

Mayfield J, Rosenblatt R, Baldwin L, Chu J, Logerfo J. The relation in obstetrical volume and nursery level to perinatal mortality. *Am J Public Health,* 1990;80:819–823.

Meadow W, Kim M, Mendez D, et al. Which nurseries currently care for ventilated neonates in Illinois and Wisconsin? Implications for the next generation of perinatal regionalization. *Am J Perinatol.* 2002;19(4):197–203

Medical News Today. Health care spending in Canada to reach \$148 billion this year—infants and seniors account for highest spending per capita. <http://www.medicalnewstoday.com/articles/58214.php>. Published December 6, 2006. Accessed October 22, 2012.

Menard KM, Liu Q, Holgren E, Sappenfield W. Neonatal mortality for very low birth weight deliveries in South Carolina by level of hospital perinatal service. *Am J Obstet Gynecol*. 1998;179:1037–1046.

Menacker F, Martin JA. Expanded health data from the new birth certificate, 2005. *Natl Vital Stat Rep*. 2008;56(13):1–24

Morales LS, Staiger D, Horbar JD, et al. Mortality among very low-birthweight infants in hospitals serving minority populations. *Am J Public Health*. 2005;95(12):2206–2212

Neto MT. Perinatal care in Portugal: effects of 15 years of a regionalized system. *Acta Paediatr* 2006;95(11):1349–1352

Nowakowski L, Barfield WD, Kroelinger CD, et al. Assessment of state measures of risk appropriate care for very low birth weight infants and recommendations for enhancing regionalized state systems. *Matern Child Health J*. 2012;16(1):217–227

Ohlinger J, Katak A, Lavin JP Jr; et al. Evaluation and development of potentially better practices for perinatal and neonatal communication and collaboration. *Pediatrics*. 2006;118(suppl 2):S147–S152

Palmer KG, Kronsberg SS, Barton BA, Hobbs CA, Hall RW, Anand KJ. Effect of inborn versus outborn delivery on clinical outcomes in ventilated preterm neonates: secondary results from the NEOPAIN trial. *J Perinatol*. 2005;25(4):270–275

Phibbs CS, Baker LC, Caughey AB, Danielsen B, Schmitt SK, Phibbs RH. Level and volume of neonatal intensive care and mortality in very-low-birth-weight infants. *N Engl J Med*. 2007;356(21):2165–2175

Phibbs CS, Bronstein JM, Buxton E, Phibbs RH. The effects of patient volume and level of care at the hospital of birth on neonatal mortality. *JAMA*. 1996;276(13):1054–1059

Phibbs CS, Mark DH, Luft HS, et al. Choice of hospital for delivery: a comparison of high risk and low-risk women. *Health Serv Res*. 1993;28(2):201–222

Powell SL, Holt VL, Hickok DE, Easterling T, Connell FA. Recent changes in delivery site of low-birth-weight infants in Washington: impact on birth weight-specific mortality. *Am J Obstet Gynecol*. 1995;173(5):1585–1592

Robertson C, Sauve R, Christianson H. Province-based study of neurologic disability among survivors weighing 500 through 1249 grams at birth. *Pediatrics*. 1994;93:636–640.

Rautava L, Lehtonen L, Peltola M, et al; PERFECT Preterm Infant Study Group. The effect of birth in secondary- or tertiary level hospitals in Finland on mortality in very preterm infants: a birth-register study. *Pediatrics*. 2007;119(1). Available at: www.pediatrics.org/cgi/content/full/119/1/e257

Rautava L, Häkkinen U, Korvenranta E, et al; PERFECT Preterm Infant Study Group. Health and the use of health care services in 5-year-old very-low-birth-weight infants. *Acta Paediatr*. 2010;99(7):1073–1079

Richardson DK, Reed K, Cutler JC, et al. Perinatal regionalization versus hospital competition: the Hartford example. *Pediatrics*. 1995;96(3 pt 1):417–423

Rogowski JA, Horbar JD, Staiger DO, Kenny M, Carpenter J, Geppert J. Indirect vs direct hospital quality indicators for very low-birthweight infants. *JAMA*. 2004;291(2):202–209

Rogowski JA, Staiger DO, Horbar JD. Variations in the quality of care for very-low birthweight infants: implications for policy. *Health Aff (Millwood)*. 2004;23(5):88–97

Recommendations and guidelines for perinatal and freestanding neonatal care centers in Arizona. 3rd ed. Casa Grande (AZ): Arizona Perinatal Regional System, Inc.; 2012.

Schmitt SK, Sneed L, Phibbs CS. Costs of newborn care in California: a population-based study. *Pediatrics* 2006;117:154-160.

Shapiro-Mendoza CK, Tomashek KM, Kotelchuck M, et al. Effect of late-preterm birth and maternal medical conditions on newborn morbidity risk. *Pediatrics*. 2008;121(2). Available at: www.pediatrics.org/cgi/content/full/121/2/e223

Shlossman PA, Manley JS, Sciscione AC, Colmorgen GH. An analysis of neonatal morbidity and mortality in maternal (in utero) and neonatal transports at 24-34 weeks' gestation. *Am J Perinatol*. 1997;14 (8):449–456

Standards for Maternal and Neonatal Services in South Australia 2010. Adelaide (South Australia): Government of South Australia–SA Health; April 2010.

Staebler S. Regionalized systems of perinatal care. *Adv Neonatal Care* 2011;11(1):37-42.

Stoll BJ, Hansen NI, Bell EF, et al; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Neonatal outcomes of extremely preterm infants from the NICHD Neonatal Research Network. *Pediatrics*. 2010;126(3):443–456

Synnes AR, Macnab YC, Qiu Z, et al; Canadian Neonatal Network. Neonatal intensive care unit characteristics affect the incidence of severe intraventricular hemorrhage. *Med Care*. 2006;44(8):754–759

Texas Department of State Health Services. 2005 Natality report. <http://www.dshs.state.tx.us/CHS/VSTAT/latest/nnatal.shtm>. Published 2005. Accessed June 27, 2012.

Thompson LA, Goodman DC, Little GA. Is more neonatal intensive care always better? Insights from a cross-national comparison of reproductive care. *Pediatrics*.2002;109(6):1036–1043

Tonse N, Higgins R, Stark A, Leveno K. Optimizing care and outcomes for late preterm (near-term) infants: a summary of the workshop sponsored by the National Institute of Child Health and Human Development. *Pediatrics*.2006;118:1207–1214.

Toward improving the outcome of pregnancy III—enhancing perinatal health through quality, safety, and performance initiatives. White Plains (NY): March of Dimes Foundation; December 2010.

Tuncalp O, Hindin MJ, Souza JP, Chou D, Say L. The prevalence of maternal near miss: a systematic review. *BJOG* 2012;119:653–61.

US Department of Health and Human Services, Health Resources and Service Administration, Maternal and Child Health Bureau. National Performance Measure # 17. Available at: <https://perfddata.hrsa.gov/mchb/TVISReports/>. Accessed July 12, 2012

Van Mullem C, Conway A, Mounts K, Weber D, Browning C. Regionalization of perinatal care in Wisconsin: a changing health care environment. *Wis Med J*.2004;103(5):35–38.

Vieux R, Fresson J, Hascoet JM, et al; EPIPAGE Study Group. Improving perinatal regionalization by predicting neonatal intensive care requirements of preterm infants: an EPIPAGE-based cohort study. *Pediatrics*. 2006;118(1):84–90

Vieux R, Fresson J, Hascoet J, et al. Improving perinatal regionalization by predicting neonatal intensive care requirements of preterm infants: an EPIPAGE based cohort study. *Pediatrics*. 2005;118:84–90.

Walker DB, Vohr, BR, Oh W. Economic analysis of regionalized neonatal care for very low birth weight infants in the state of Rhode Island. *Pediatrics* 1985;76(1):69-74.

Wall SN, Handler AS, Park CG. Hospital factors and nontransfer of small babies: a marker of deregionalized perinatal care? *J Perinatol*. 2004;24(6):351–359

Warner B, Altimier L, Imhoff S. Clinical excellence for high-risk neonates:improved perinatal regionalization through coordinated maternal and neonatal transport. *Neonatal Intensive Care*. 2002;15(6):33–38.

Xian Y, Holloway RG, Chan PS, et al. Association between stroke center hospitalization for acute ischemic stroke and mortality. *JAMA*. 2011;305(4):373–380

Yeast JD, Poskin M, Stockbauer JW, Shaffer S. Changing patterns in regionalization of perinatal care and the impact on neonatal mortality. *Am J Obstet Gynecol.* 1998;178(1pt 1):131–135

Zeitlin J, Gwanfogbe CD, Delmas D, et al. Risk factors for not delivering in a level III unit before 32 weeks of gestation: results from a population-based study in Paris and surrounding districts in 2003. *Paediatr Perinat Epidemiol.* 2008;22(2):126–135.

Listing of Presentations

Martin Rebecca. Obstetrical levels of care report and survey for Texas, 2012. Presented during NICU Council Meeting, July 2012.

Martin Rebecca. Neonatal levels of care report and survey for Texas, 2012. Presented during NICU Council Meeting, May 2012.

Kathy Perkins, Director of DSHS Division of Regulatory Services. Presentation on Designation of services for Trauma and Stroke levels of care, Texas, presented Oct 16, 2012.

Sam Cooper, Director of Title V and Family Health, DSHS. Healthy Texas Babies Report, March, 2012.

Jane Guerrero, Director of EMS/Trauma System, Texas DSHS. Texas process of regionalized Trauma Care, July 2012.

Brenda Morris, MD, Vice Chair, NICU Council. Review and summary of American Academy of Pediatrics Policy Statement on Levels of Care 2012.

Brenda Morris, MD, Vice Chair, NICU Council. Literature Review of neonatal outcomes and NICU utilization, Oct 2012.

Brenda Morris, MD, Vice Chair, NICU Council. Literature Review of neonatal outcomes and NICU utilization, Nov 2012.

Appendix D:

References

Ahmad NN, Butsch WS, Aidarous S. Clinical management of obesity in women: addressing a lifestyle of risk. *Obstet Gynecol Clin North Am* 2016;43(2):201-30.

American College of Obstetricians and Gynecologists. Levels of Maternal Care. Obstetric care consensus. Washington, DC, Feb 2015.

Arizona Perinatal Regional System Inc. Recommendations and guidelines for perinatal and freestanding neonatal care centers in Arizona. 3rd ed. Casa Grande (AZ): APRS; 2012.

Berg CJ, Callaghan WM, Syverson C, Henderson Z. Pregnancy-related mortality in the United States, 1998 to 2005. *Obstet Gynecol* 2010;116:1302–9.

Burlingame J, Horiuchi B, Ohana P, Onaka A, Sauvage LM. The contribution of heart disease to pregnancy-related mortality according to the pregnancy mortality surveillance system. *J Perinatol* 2012;32:163–9.

Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstet Gynecol* 2012;120:1029–36.

Hankins GD, Clark SL, Pacheco LD, et al. Maternal mortality, near misses, and severe morbidity: lowering rates through designated levels of maternity care. *Obstet Gynecol* 2012;120:929-34.

Castellucci M. Pre-existing conditions contribute to rising US maternal mortality rates. *Mod Healthc* 2015;50:14-19.

Chou D, Tuncalp O, Firoz T, et al. Constructing maternal morbidity- towards a standard tool to measure and monitor maternal health beyond mortality. *BMC Pregnancy Childbirth* 2016;(16):45-50.

De Greve M, Van Mieghem T, Van Den Berghe G, Hanssens M. Obstetric admissions to the intensive care unit in a tertiary hospital. *Gynecol Obstet Invest* 2016;(11):103-7.

De la Rosa K, Mhyre J, Anderson FW. Maternal mortality from hemorrhage in Michigan 1998-2011. *Obstet Gynecol* 2016;127(1):544-9.

Drukker L, Hants Y, Farkash R, et al. Impact of surgeon annual volume on short-term maternal outcome in cesarean delivery. *Am J Obstet Gynecol* 2016;(16):1016-20.

Eller AG, Bennett MA, Sharshiner M, Masheter C, Soisson AP, Dodson M, et al. Maternal morbidity in cases of placenta accreta managed by a multidisciplinary care team compared with standard obstetric care. *Obstet Gynecol* 2011;117:331–7.

Guidelines for perinatal care, 7th ed, Elk Grove Village (IL): AAP; Washington DC: American College of Obstetricians and Gynecologists, 2012. Hankins GD, Clark SL, Pacheco LD, et al. Maternal mortality, near misses, and severe morbidity: lowering rates through designated levels of maternity care. *Obstet Gynecol* 2012;120:929-34.

- Howell EA, Egorova N, Balbierz A, et al. Black-white differences in severe maternal morbidity in New York City hospitals. *Am J Obstet Gynecol* 2016;16(302):202-10.
- Jeon HR, Kim SY, Cho YJ, Chon SJ. Hypertriglyceridemia-induced acute pancreatitis in pregnancy causing maternal death. *Obstet Gynecol Sci* 2016;59(2):148-51.
- Kassebaum NJ, Bertozzi-Villa A, Coggeshall MS, Shackelford KA, Steiner C, Heuton KR, et al. Global, regional, and national levels and causes of maternal mortality during 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2014;384:980-1004.
- Kilpatrick SJ, Abrero A, Gould J, et al. Confirmed severe maternal morbidity is associated with high rate of preterm delivery. *Am J Obstet Gynecol* 2016;16:216-21.
- Kozhimannil KB, Casey MM, Hung P, et al. Location of childbirth for rural women: implications for maternal levels of care. *Am J Obstet Gynecol* 2016;214(5):661-10.
- Kyser KL, Lu X, Santillan DA, Santillan MK, Hunter SK, Cahill AG, et al. The association between hospital obstetrical volume and maternal postpartum complications. *Am J Obstet Gynecol* 2012;207:42.e1–42.17.
- Main EK. Maternal mortality: new strategies for measurement and prevention. *Cur Opin Obstet Gynecol* 2010;22:511-6.
- Mariona FG. Does maternal obesity impact pregnancy related deaths? Michigan Experience. *J Matern Fetal Neonatal Med* 2016;9:1-13.
- Murki A, Dhope S, Kamineni V. Feto-maternal outcomes in obstetric patients with near miss morbidity: an audit of obstetric high dependency unit. *J Matern Fetal Neonatal Med* 2016;(10):1-3.
- Nair M, Kurinczuk JJ, Knight M. Establishing a national maternal morbidity outcome indicator in England: a population-based study using routine hospital data. *PLoS One*; 2016(11):10-13.
- Negggers YH. Trends in maternal mortality in the United States. *Reprod Toxicol* 2016;16(10):200-8.
- Olive EC, Roberts CL, Algert CS, Morris JM. Placenta praevia: maternal morbidity and place of birth. *Aust N Z J Obstet Gynaecol* 2005;45:499–504.
- Olvera L, Dutra D. Early recognition and management of maternal sepsis. *Nurs Womens Health* 2016;20(2):182-96.
- O'Malley EG, Popivanov P, Fergus A, et al. Maternal near miss: what lies beneath? *Eur J Obstet Gynecol Reprod Biol* 2016;199:1016-20.
- Patil V, Wong M, Wijayatilake DS. Clinical 'pearls' of maternal critical care: part 1. *Curr Opin Anaesthesiol* 2016;(3):304-16.
- Platner M, Loucks TL, Lindsay MK, Ellis JE. Pregnancy-associated deaths in rural, nonrural, and metropolitan areas of Georgia. *Obstet Gynecol* 2016; 245(6):441-6.
- Shields LE, Wiesner S, Klein C, et al. Use of maternal early warning trigger tool reduces maternal morbidity. *Am J Obstet Gynecol* 2016;(214):1-6.

Sullivan SA, Hill EG, Newman RB, Menard MK. Maternal fetal medicine specialist density is inversely associated with maternal mortality ratios. *Am J Obstet Gynecol* 2005;193:1083–8.

Tivedi D. Cochrane review summary: community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes. *Prim Health Care Res Dev* 2016;17(4):317-8.

Wright JD, Herzog TJ, Shah M, Bonanno C, Lewin SN, Cleary K, et al. Regionalization of care for obstetric hemorrhage and its effect on maternal mortality. *Obstet Gynecol* 2010;115:1194–200 .

Appendix E:

Appendix 4: Highlights of Perinatal Advisory Council Meetings (2014-2016)

| Meeting | Date | Summary |
|---------|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | 21 Jan 2014 | Welcome, Introductions, Review of Open Public Meetings Act, Review of Council Purpose and Legislative Charge, Synopsis of NICU Council Report, Report from HHSC Quality Team, Update of Neonatal Levels Standards, Public Comment was extensive re the draft neonatal standards |
| 2 | 25 Feb 2014 | Dr. Michael Cardwell resigned his seat since he had moved out of state; Dr. Elly Xenakis appointed. Draft of timeline introduced; Agreed upon approach to developing standards to start with national standards (Guidelines for Perinatal Care, 7 th ed) and then allow flexibility for Texas due to diverse geography; encourage best practices; encourage high quality and patient outcomes; Orientation of the Trauma system; orientation of the Rule making process; Neonatal Standards again reviewed and received a lot of stakeholder input |
| 3 | 16 Apr 2014 | Discussions about database for outcomes and the importance of the state building this database for quality; Discussions about how to divide the state into regions; Specific discussions about details of requirements at each neonatal level of care; Importance of funding back (home) transfers; Neonatal Standards again reviewed and received a lot of stakeholder input |
| 4 | 14 May 2014 | Discussion regarding neonatal requirements for various levels; two families from Tyler testified about the importance of a level III NICU in their community; Various criteria were discussed at each neonatal level with desire to elevate the quality of care and be consistent with national standards, and yet be flexible because of the diversity of the state and different ways that various hospitals deliver their care. Neonatal Standards again reviewed and received a lot of stakeholder input |
| 5 | 11 June 2014 | Further discussion and refining the neonatal standards; Importance of each individual hospital's quality improvement plan to elevating their care of patients; Importance of the Perinatal Program Plan to define the specific hospital's scope of care; Ms. Jane Guerrero presented a first draft of the neonatal rules based on the neonatal standards for discussion; Neonatal Standards again reviewed and received a lot of stakeholder input |
| 6 | 22 July 2014 | Perinatal Regional Advisory Councils discussed including their role of collaboration, coordination of resources, partnering with community, educating the community; different options re RACs were discussed and various ways of dividing the state; Neonatal Standards again reviewed and received a lot of stakeholder input |
| 7 | 7 Oct 2014 | American Academy of Pediatrics (AAP), which has applied to be a site visit organization, spoke at the meeting and discussed their approach to site visit would be consultative, peer review, using the state standards, and not biased toward academic institutions. Extensive discussion about specifics of level III and level IV, and the consensus was to use the Guidelines for Perinatal Care language where possible. Various issues such as rural facilities having a medical director not board |

| Meeting | Date | Summary |
|---------|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | certified raised and accommodations made in language allowing a physician with clinical experience and administrative skills acceptable. Neonatal Rules reviewed and received a lot of stakeholder input |
| 8 | 2 Dec 2014 | Review of the Nov 10, 2014 General Stakeholder meeting held by DSHS; some level II hospitals in smaller communities expressed concern about the gestational age cut-off of 1500g/32 weeks and thought they can handle up to 28 weeks and provide good care. Discussion about the specifics of the survey team and recommendations for sufficient clinical reviewers with experience at the same or higher level of the facility; There was very meticulous review of each neonatal level of care with extensive stakeholder input going line by line. All four levels were reviewed in detail. Accommodation was given when possible to ease burden of compliance for hospitals if it did not affect patient care and quality. Several hospital system, and numerous rural facilities were present and gave their input. |
| 9 | 11 Feb 2015 | <p>Discussion about neonatal levels and care and level II Rural Extended; various stakeholders gave their opinion, and will seek to recommend regulations that first serves the best interest of the patient, and also gives some flexibility for smaller hospitals to care for the patients in their community if it does not affect patient care, quality or outcome. Discussion also regarding concern about larger level III/IV units bullying smaller facilities into transfer due to third party payment etc. Consensus was reached that the patient's outcome and welfare is almost the most important factor. Much stakeholder input received including from facilities in Wichita Falls, Victoria, San Antonio, New Braunfels, Waco, and Tyler. The council recommended a level II RE category with care for the infants between 30-32 weeks to be the same as what would be received at a higher level facility.</p> <p>To address the concern of level II facilities that are a distance from a level III, the council recommended a level II Rural Extended designation in which a level II hospital at least 75 miles from the nearest level III/IV facility is able to provide care for neonates of 30 weeks, provided they provide the same care for that infant as a higher level (i.e., in-house 24/7 neonatal provider). This is based on the numerous published studies showing significantly improved outcomes of infants less than 32 weeks/1500g being born and cared for in the level III or higher facility. Presentation by Sam Vance and Dr. Kate Remick on the Emergency Medical Services EMS for Children State Partnership; The state explained that they decided to use the existing 22 Trauma RACs as the framework for the perinatal regional advisory councils (as stipulated in HB15) due to lack of funding for de novo RACs being formed, lack of infrastructure, and the tight timeline for implementation. There was extensive public comment throughout the meeting.</p> |
| 10 | 13 Apr 2015 | To ensure wider stakeholder input, two subcommittees were formed: Rural and Family Medicine Subcommittee, and General Ob/Gyn Physicians in Private Practice to provide greater input on the specific standards and especially the maternal levels of care. The logistics of |

| Meeting | Date | Summary |
|---------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | designation application including fee structure explained; The rationale for maternity levels of care explained since maternal mortality had increased 3-fold in Texas in the last 12 years, and also to get the sick babies to the right facility, we need to identify and appropriately triage pregnant women. |
| 11 | 1 June 2015 | Legislative update: HB3433 passed and provides one extra year for designation to received Medicaid funds (Sept 1, 2018 for neonatal, and Sept 1, 2020 for maternal designation), and also provides for 2 additional rural representatives to the PAC. HB2131 also passed which authorizes Centers of Excellence for Fetal Diagnosis and Therapy in Texas. Additionally the two additional subcommittees (Rural/Family Medicine, and also Gen Ob/Gyn) has altogether 12 additional members which has extensive and diverse geographic diversity. Ms. Guerrero presented the latest updated draft document of the Neonatal Rules Designation and received numerous comments and suggestions. The time frame for posting of the Neonatal Rules was discussed. |
| 12 | 22 Sept 2015 | Dr. Dynio Honrubia submitted his resignation to the council due to his increasing clinical demands; he was thanked for his sacrifice and service. Ms. Guerrero stated that the Draft Neonatal Designation Rules were reviewed and approved at the state Health Services Council meeting on Sept 10, 2015. An anticipated timeline for posting in the Texas Register was given: posting in the Register in about Nov 2015, 30 day public comment period, and adoption in about March or April 2016. When discussion regarding HB2131 was brought up, Dr. Toy recused himself since he stated that he was a full time professor at the University of Texas Medical School at Houston, which worked closely on this legislation. Dr. Briggs chaired this portion of the meeting. Multiple stakeholders gave testimony about the this concept of Centers of Excellence for Fetal Diagnosis and Therapy, and multiple council members expressed various concerns. The timeline for implementation of Sept 1, 2017 was discussed and thought to be very difficult to meet. The council appointed an ad hoc subcommittee to review the background of the issue and make recommendations for the process including qualifications for HB2131 subcommittee members. An overview of Maternity levels of care standards occurred. It was agreed to start with the national guidelines and used an evidence-based approach, but maintain flexibility to accommodate the diverse nature of the state. |
| 13 | 17 Nov 2015 | It was announced that Dr. Cynthia Blanco a neonatologist from San Antonio would be replacing Dr. Honrubia. Additionally, as per HB3433, Dr. Alyssa Molina from Eagle Lake and Ms. Sandra Rivers, RN from Sweetwater were introduced as new members as rural representatives to the council. The draft neonatal rules were reviewed and again recommendations were made for changes. Significant stakeholder input was given. During discussion about HB2131 subcommittee, Dr. Toy deferred to Dr. Briggs to chair. Dr. Frank Cho reported the ad hoc subcommittee consisted of himself, Ms. Stelly, Dr. Saade, Mr. Woerner, Dr. Patricia Santiago, Dr. Olynka Olutoye, and Dr. Ken Moise. Dr. Cho indicated that the subcommittee met three |

| Meeting | Date | Summary |
|---------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | <p>times for telephone conference call and reviewed 6 different journal articles. Dr. Cho recommended that the HB2131 subcommittee should consist of 15 members including MFM, Pediatric Surgeons, Neonatologists, ethicist, nurse, and a hospital representative. There was attempted balance of academic and community/private practice members. After ample discussion, it was decided to have a smaller number in the subcommittee in the range of 7-9. Dr. Goodman from Dartmouth Institute for Health Policy and Clinical Practice gave a presentation on improving newborn quality and care in Texas. Level I maternity level standards were discussed.</p> |
| 14 | 26 Jan 2016 | <p>Ms. Guerrero indicated that the proposed Neonatal Designation Rules were published in the Nov 20, 2015 issue of the Texas Register, and her office received numerous public comments including from 7 individuals, 1 state representative, 15 various facilities, and 13 organizations. She indicated that her office will study the comments, and then after finalizing the rules, send the rules to the Assistant Commission and General Counsel, and finally to the Executive Commissioner for final adoption. Two letters to the DSHS from the PAC were discussed: 1) <i>Texas HHSC Perinatal Advisory Council Comments to PROPOSED NEONATAL DESIGNATION RULES (submitted 12/14/2015)</i>; 2) <i>Texas HHSC Perinatal Advisory Council Comments on Proposed Neonatal Designation Rules (Level I facilities)</i>, addresses the flexibility requested by some Level 1 facilities, especially in rural areas, in the treatment of infants with a gestational age of less than 35 weeks. After careful consideration and review of the scientific literature, the council noted that because of issues that late preterm babies can face, and based on national guidelines, there is good reason to maintain the gestational age of 35 weeks and above for Level 1 facilities. The document also clarified recommendations for transportation of these infants. Dr. Ekta Escovar from Alpine Texas discussed the challenges they have in caring for their patients, and applauded the Perinatal Advisory Council and the state for the perinatal levels of care, and advocated for level I facilities caring only for infants of 35 weeks or greater. Discussion was held regarding the HB2131 subcommittee (chaired by Dr. Briggs) including a long list of concerns surrounding this issue; input was given from both council members and stakeholders. Maternity level 1 standards were discussed and received a multitude of stakeholder input.</p> |
| 15 | 29 Mar 2016 | <p>Guiding Principles were adopted, as per the new rules governing state committees. The PAC Report due Sept 1, 2016 was discussed in concept. Two best practices were discussed: 1) Rural neonatal practice by Dr. Escovar (presented on 1/26/2016), and 2) A postpartum hemorrhage best practice from LBJ Hospital in Houston which described a postpartum hemorrhage cart, medication availability system, and massive transfusion protocols. Regional Advisory Councils were discussed including information that each perinatal region should be contacting their regional Trauma RAC leadership. Level 1 and Level 2 maternity levels of care draft documents were reviewed and numerous suggestions and input from council members and stakeholders were heard. Ms. Guererro informed the council that</p> |

| Meeting | Date | Summary |
|---------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | <p>applications were received regarding the HB2131 subcommittee and that a review of the applications was in progress.</p> |
| 16 | 2 May 2016 | <p>Dr. Toy expressed appreciation to the members of the PAC for being faithful in attending the many meetings, for their expertise, and for their focus on improving perinatal care for Texas. Dr. Toy also acknowledged the many stakeholders such as hospital associations, rural associations, professional associations, healthcare providers, outside organizations, and many individuals. He thanked the various state staff such as David Williams, Matt Ferrera, Jane Guerrero and Elizabeth Stevenson for their contributions.</p> <p>Linda Robert from Tyler presented a best practice of standardization of documentation and interpretation of apnea, bradycardia, and desaturation events and how this allowed their hospital to better document and communicate.</p> <p>Dr. Speer presented a best practice from his hospital in TCH Pavillon for Women in Houston regarding the use of human breast milk and decrease in NEC.</p> <p>Ms. Stevenson gave an update on the HB2131 subcommittee, and said that the appointments would be forthcoming soon. She also stated that it was anticipated that the neonatal rules would be published in the Texas Register and become effective in June 2016.</p> <p>Dr. Toy showed an anonymous and voluntary survey that is planned to be sent to the 250+ hospitals in Texas that provide neonatal care regarding feedback on the process of neonatal levels of care. There was input and approval to proceed.</p> <p>Dr. Toy reviewed maternity levels 1, 2 and 3. There was ample discussion and much stakeholder input.</p> <p>Dr. Toy reviewed some of the key principles used in guiding the PAC:</p> <ul style="list-style-type: none"> • Government regulation should be using sparingly and only when needed • Each individual hospital should strive to become the level it desires • We should have an “even playing field” and not allow for big medical centers or large academic centers or large hospital systems to have unfair advantages • We put our patients and their health first in our deliberations and decisions • We recognize that Texas is a large and diverse state, and there is not a “one size, fits all” solution • We start with national guidelines and use evidence when available, but we need to be flexible because Texas is so large and diverse • We operate under transparency and openness • We use consensus in decision making as much as possible |

| Meeting | Date | Summary |
|---------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | <ul style="list-style-type: none"> • We strive to be open to input from everyone, and seek to understand their point of view • We try to have input during the “discussion phase” and not just “at the end of the day” • We strive to have open communication channels • We depend on individual hospitals to know their capabilities, serve their communities and improve their quality • We work collaboratively with our stakeholders • We respect the role of our partners (HHSC, DSHS, etc) • We promote best practices |