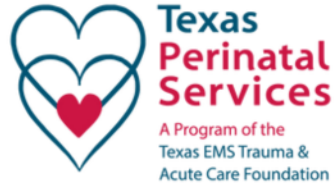

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February 28, 2022

Jorie Klein, RN
EMS/Trauma Systems Director
Texas Department of State Health Services
1100 West 49th Street
Austin, TX 78756-3199

Dear Ms. Klein:

Texas EMS, Trauma & Acute Care Foundation (TETAF) and Texas Perinatal Services (TPS) appreciates the opportunity to submit public comment on the Texas Department of State Health Services' (DSHS) draft of the Neonatal Rule Revisions Update. Texas Perinatal Services completed neonatal surveys in 80% of hospitals providing care to neonates across Texas. Providing neonatal survey services for Level II, III, and IV hospitals in Texas has given our organization a comprehensive knowledge of the processes in hospitals that are providing care to our newest and most fragile Texans.

With consideration based on Texas Perinatal Services' established role in the verification of neonatal centers in Texas, TETAF/TPS provides the following comments regarding the Neonatal Rule Revisions Update:

- Line 25: Does this addition indicate that the staff must be on-site?

25 (3) Available--Relating to staff who can be contacted for consultation at all times
26 without delay.

- Line 181: This language within the requirements for a Level III neonatal facility has led to unintended consequences for infants of lower gestational ages that were retained at Level III facilities due to the rule requirement. Management of a neonate should be individualized and decisions regarding transfer should be dictated by the needs of each unique patient. When facilities feel compelled to retain infants of lower gestation ages to ensure their designation status is not impacted, the potential for harm is increased. A change in this verbiage to, "Provide care for mothers and comprehensive care of their infants with mild to critical illness or requiring sustained life support of generally greater than or equal to 27 weeks," is suggested. A requirement to review cases of infants of gestational ages < 27 weeks within the Quality Assurance and Performance Improvement (QAPI) program to ensure appropriate care is provided should accompany this change.

181 (A) provide [~~care for mothers and~~] comprehensive care for [~~of their~~] infants
182 of all gestational ages with mild to critical illnesses or requiring sustained life
183 support;

- Line 225 & 1466: The directive for out-of-state surveyors in Level IV neonatal facilities has the potential to hamper the dissemination and sharing of best practices among Texas facilities and limit the ability of Texas facilities to learn from each other as part of the survey process. It will also be challenging to ensure consistency among the out-of-state surveyors in regard to their level of experience, as there are differences between regions. An out-of-state surveyor will also have less familiarity with the Texas Administrative Code (TAC), as they are not working under these requirements. We understand the importance of addressing potential conflicts of interest, but we do not believe this change will reliably and consistently exclude conflicts of interest. The enhanced guidance provided to determine potential conflicts of interest is appreciated.

218 (4) will not accept surveyors with any conflict of interest. If a conflict of interest
219 is present, the facility must decline the assigned surveyor through the surveying
220 organization. A conflict of interest exists when the surveyor has a current or past
221 relationship with the facility or key facility staff members. The conflict of interest
222 may include a previous working relationship, residency training, or participation in a
223 consultation program, or designation survey for the facility within the past five
224 years. Surveyors cannot be from the same Perinatal Care Region or TSA region or a
225 contiguous region of the facility's location. Level IV facilities should have surveyors
226 who currently practice outside of the state of Texas. If the survey occurs with a
227 surveyor who has a defined conflict of interest, the neonatal designation site survey
228 summary will not be accepted by the department; and

1466 (2) Level IV neonatal facilities should have surveyors who currently practice
1467 outside of the state of Texas.

- Line 284: The requirement to demonstrate implementation of the Plan of Correction (POC) with data demonstrating improvement within 60 days of the survey date has the potential to be extremely difficult for many facilities. The survey report is provided to the facility within 30 days of the date of the survey, potentially providing only a very brief time frame for development, implementation, and evaluation of an action plan. Additionally, the report provided to the facility provides only potential deficiencies, as your department makes the final determination on deficiencies.

284 (vi) documented evidence that the plan of correction is implemented with
285 data that demonstrates improvement within 60 days of the designation survey;

- Line 415: How will potential conflicts of interest be identified and addressed in the establishment of the appeal panel? Due to the sensitive nature of this process, it would seem prudent to establish rigorous standards to address the potential for conflicts of interest. We have reviewed the details in Senate Bill (SB) 749 but believe that additional clarification regarding how this will be addressed would be beneficial, particularly considering the enhanced guidance regarding assessing for conflicts of interest within the survey team.

415 (1) The EMS/Trauma Systems Section will establish a three-person appeal panel
416 following the approved appeal panel guidelines to assess the facility's designation
417 appeal as referenced in Texas Health and Safety Code 241.1836.

- Line 517: Many facilities are operating as a Level II neonatal facility and utilize the term "neonatal intensive care unit" or similar language. This addition would require them to discontinue use of this language and may be misleading to families, as many of these facilities are caring for infants with increasingly complex conditions within the capabilities of their facility.

517 (u) A facility will not use the terms "neonatal facility," "neonatal hospital," "neonatal
518 center," "advanced neonatal intensive care unit or hospital," "neonatal intensive
519 care unit or hospital," "neonatal special care hospital," neonatal well care hospital,"
520 or similar terminology in its signs or advertisements or in the printed materials and
521 information it provides to the public, unless the facility is currently designated at
522 that level of neonatal care.

- Line 604: The requirement to stand up a separate neonatal peer review committee is likely unnecessary and may be prohibitive for some facilities, dependent on their available resources. A requirement for specialized neonatal representation on a hospital peer review committee would be sufficient.

604 (iv) Level III and IV neonatal facilities must have a defined neonatal peer
605 review committee with a defined and documented structure with required
606 attendance as an element of their QAPI Plan. The neonatal medical director will
607 identify cases for discussion at this committee and lead or co-lead the meeting.

- Line 665: The section below is listed under responsibilities of the neonatal medical director. Is this indicating a directive to all facilities to review all transfers (inbound and outbound) through their QAPI plans, or is this only in reference to the oversight provided by facilities with a neonatal transport program?

> 665 (D) oversight of the inter-facility neonatal transport and utilization of
> 666 telehealth/telemedicine, if used;

- Line 697: The Neonatal Resuscitation Course (NRP) developed by AHA/AAP is the only version of NRP that is noted in the rule (line 63-65). The section of the rule shown below states that a "department-approved equivalent course" is acceptable, but there is no mention of other specific courses that are considered acceptable. Will a list of alternative courses be outlined in the rule?

> 697 (2) maintains a current status of successful completion of [~~have successfully~~
> 698 ~~completed and is current in~~] the Neonatal Resuscitation Program (NRP) or a
> 699 department-approved [~~an office-approved~~] equivalent course;[~~÷~~]

- Line 741: A physician specializing in obstetrics and gynecology is unlikely to have the level of experience in the care of neonates/infants that would be needed to serve as the neonatal medical director.

> 741 (1) is a currently practicing pediatrician, family medicine physician, or physician
> 742 specializing in obstetrics and gynecology with experience in the care of
> 743 neonates/infants;

- Line 1059 & 1240: The language noted below is only included for Level III and Level IV facilities. All facilities typically facilitate transports either by sending or accepting patients. Due to this language only being included in the Level III and Level IV sections, it is unclear if this is referring to the facilitation of transports by an in-house neonatal transport team and therefore would only apply if the facility had their own transport team.

> 1059 (4) facilitate neonatal transports; and
> 1240 (4) facilitate neonatal transports; and

- Line 1165: This language lacks clarity. Does the 30-minute timeframe refer to an interval related to the performance of the test, or is it referring to the availability of the radiologist with pediatric expertise?

> 1165 (D) [~~(B)~~] Neonatal diagnostic imaging studies available at all times with
> 1166 interpretation [~~of neonatal and perinatal diagnostic imaging studies~~] by radiologists
> 1167 with pediatric expertise available at all times and within 30 minutes of an urgent
> 1168 request; and

- Line 1348: Does this section of the rule require that a respiratory therapist meeting the criteria listed below should remain in the neonatal intensive care unit at all times?

1348 (13) A respiratory therapist, with experience and specialized training in the
1349 respiratory support of neonates/infants, whose credentials have been reviewed and
1350 approved by the Neonatal Medical Director, shall be on-site and immediately
1351 available.

- Line 1401: As the levels of neonatal care have evolved, it may be prudent to consider instituting a site survey requirement for the Level I facilities. There are QAPI requirements for these facilities when caring for neonates < 35 weeks gestational age. This requirement could be more effectively monitored via the expertise of a knowledgeable individual during a site survey. All levels of trauma centers are required to undergo a survey with an office-approved organization. As the requirements for neonatal care have evolved over the first two cycles, lower-level facilities would certainly benefit from the feedback and knowledge sharing that are part of a site survey.

1401 (1) Level I facilities neonatal program staff shall conduct a self-survey,
1402 documenting the findings on the approved department [~~office~~] survey form. The
1403 department [~~office~~] may periodically require validation of the survey findings, by an
1404 on-site review conducted by department staff.

TETAF and TPS respectfully provide these comments and recommendations in an effort to further evolve and support neonatal care across Texas. It is our hope that these joint efforts by DSHS and neonatal care stakeholders will positively enhance neonatal designation requirements and result in greater quality care for neonatal patients in Texas.

Please feel free to contact me with any questions or concerns.

Regards,

Dinah Welsh
President/CEO
TETAF/Texas Perinatal Services

TETAF
TEXAS EMS TRAUMA & ACUTE CARE FOUNDATION

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